August 15, 2018

Acting Administrator Andrew Wheeler
& Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: Comments of 88 Environmental, Farmworker, Environmental Justice, Public Health, and Animal Protection Organizations on Proposed Regulations on "Transparency" in Regulatory Science, 83 Fed. Reg. 18,768 (April 30, 2018), Docket ID No. EPA-HQ-OA-2018-0259.

Earthjustice submits these Comments on behalf of the 88 undersigned environmental, farmworker, environmental justice, public health, and animal protection organizations that represent millions of people who live and work in this country. We breathe the air, drink the water, eat the food, and work in the factories, farms, and elsewhere. In every way, we depend on public health safeguards established by the U.S. Environmental Protection Agency ("EPA" or "Agency"). Our lives and our health depend on EPA's limiting pollution and toxic chemical exposure to amounts that will not cause harm. We strongly oppose the Proposed Rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018) ("Proposed Rule" or "Proposal") because of its clear intent and impact to weaken, or prevent the necessary strengthening of, these vital public health safeguards.

I. INTRODUCTION AND SUMMARY

Though EPA, former Administrator Scott Pruitt, and industry supporters of the Proposed Rule present it as one that will strengthen public confidence in science by insisting that the data underlying scientific studies are available to the public, as well as to industry itself, this superficial gloss conceals the pernicious purpose and impact of the Proposal. As demonstrated below, the true intent and effect of the Proposed Rule are not to strengthen science, but to exclude critical public health scientific studies – the very studies that have been instrumental in setting pollution limits that save hundreds of thousands of lives and prevent millions of diseases each year, and that protect against harmful and sometimes lethal exposure to toxic chemicals. Even EPA's own Scientific Advisory Board ("SAB") has expressed its concern with and opposition to this Proposal for this very reason. By excluding scientific studies that examine the health impacts of environmental contamination and toxic chemicals that meet all standards of scientific validity and rigor simply because they rely upon non-public data such as confidential medical information, EPA's Proposal would weaken, not improve, its decision-making. Analysis of the actual text, the preamble, and history of the Proposed Rule make clear that this exclusion of important sound public health science is indeed the intent of the Proposed Rule. It is not an incidental consequence of some other laudable goal, but rather is, in fact, the goal itself.

EPA did not arrive at this Proposal on science following careful analysis and discussion with scientific bodies. Rather, this Proposal follows numerous meetings between EPA staff and representatives of industries that sought to weaken rules and regulations necessary to protect public health. In fact, the text of the Proposed Rule comes not from any scientific source or career or expert staff within EPA, but rather from partisan bill language introduced years ago by members of Congress. *See infra* at Section II.C. And although the preamble to the Proposed Rule asserts that it was "informed" by the policies of major scientific journals, the policy is counter to sound scientific review policies and has been expressly repudiated by many of those journals. *See infra*, Section VI.B.1. Instead, the Proposal follows the tobacco industry playbook, using as a defense against limitations on harmful chemicals an attack on the science on process grounds. And, lest there be doubt about the true intent of the Proposed Rule, the fact that it does not act even-handedly but rather would favor inaction or removing protections over imposing or strengthening safeguards makes eminently clear the intent to protect polluters and not the public.

The problems with EPA's Proposal are put in stark relief when compared to basic principles of scientific and health-based decision-making. Indeed, if the restrictions EPA proposes here were applied to the Food and Drug Administration ("FDA") or the Centers for Disease Control and Prevention ("CDC"), it is unclear how many pharmaceuticals, vaccinations, or cures for diseases would ever have been approved or used as drug trial information, as underlying data frequently relies on epidemiological evidence and private medical information that cannot be released.[1] Even if EPA had authority to restrict the consideration of health-based information otherwise, it could have no scientific or rational basis to ignore health information that health professionals recognize is both relevant and often essential to consider when determining what health protections are needed.

Not only does the Proposed Rule threaten both public health and the integrity of decision-making, but it likewise is illegal, for many reasons.

- ***First***, EPA lacks the authority to issue the rule. EPA asserts authority under the Clean Air Act ("CAA"), Clean Water Act ("CWA"), Safe Drinking Water Act ("SDWA"), Comprehensive Environmental Response Compensation and Liability Act ("CERCLA"), Emergency Planning and Community Right to Know Act ("EPCRA"), Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), Toxic Substances Control Act ("TSCA"), and the Resource Conservation and Control Act ("RCRA"). Yet in virtually every case, EPA refers to sections that authorize or mandate the Agency to undertake research, not to impose unfounded limitations on the scientific information that informs public health decisions. EPA also cites provisions authorizing it to promulgate rules "necessary" to achieve the goals of the statute, but restricting sound science is neither

[1] *See, e.g.*, FDA, *Step 3: Clinical Research*, (last updated Jan. 4, 2018), https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm; Nat'l Institutes of Health, *Finding a Clinical Trial* (last updated on Mar. 13, 2017), https://www.nih.gov/health-information/nih-clinical-research-trials-you/finding-clinical-trial; CDC, *Clinical Trials* (last updated Nov. 29, 2017), https://www.cdc.gov/epilepsy/managing-epilepsy/clinical_trials.htm.

necessary nor consistent with the statutory goals – as EPA has previously determined – for moving the country toward clean air, water, workplaces, farms, and the environment.

- ***Second***, not only is the Proposed Rule not authorized by law, but it directly contravenes the specific mandate of numerous statutes, such as the SDWA and TSCA, that require EPA to use the "best available" science or all "reasonably available" science and information. It also undermines the public health objectives of the very statutes upon which EPA mistakenly relies as authority for the rule. A rule that deliberately excludes this best science cannot be reconciled with these firm Congressional mandates and public health purposes.

- ***Third***, EPA's process in proposing this rule, to date, violates procedural requirements of the Administrative Procedure Act ("APA"), as well as of the CAA, FIFRA, and TSCA. These requirements are designed to promote reasoned decision-making by ensuring the relevant documents underlying the decision are in the record and that the Proposal has sufficient specificity to permit a sound response. The Proposal does not meet those requirements. In addition, the Proposal also fails to comply with the procedures required by a number of Executive Orders, particularly the performance of an environmental justice analysis.

- ***Fourth***, EPA's Proposed Rule is arbitrary and capricious for a farrago of reasons. The Proposal is irrational and unsupported by facts, reason, history, scientific evidence, or even any reasoned explanation. EPA has failed to show that the purported benefits of the Proposed Rule – which are largely inflated or imagined – justify the burdens imposed on public health and the environment. The Proposal represents a significant change in a long-standing EPA policy without the requisite acknowledgment or justification for such a departure. Many definitions are vague and can easily be implemented in arbitrary or politically driven ways. And the Proposed Rule would allow the Administrator to make an exception for any of a wide variety of reasons, again, not cabining at all the exercise of discretion. Any one of these failures would render the rule fatally arbitrary and thus invalid; together they demonstrate that it would be extreme arrogance for EPA to continue this rulemaking to conclusion.

- ***Fifth***, in addition to its overall effect, many specific provisions of the Proposed Rule are independently illegal or improper. Among other things, as currently designed, the rule would likely apply in an uneven manner, for example, only to a decision to restrict the use of a pesticide, not to allow the use of such a chemical. It is a one-way street. Yet sound science must be followed wherever it leads. This rule puts a thumb on the scale toward regulation that ignores evidence of harm to human health. In addition, the Proposed Rule aims to undermine certain peer-reviewed science by injecting industry-manufactured uncertainty regarding science into the rulemaking process. The Proposal would cast doubt on science that has gone through independent peer-review by adding a second round of agency-required peer-review. And by injecting a mandate to "minimize

costs" into the rule, even where Congress has specifically forbidden consideration of costs in determining health standards, the Proposed Rule sows confusion, doubt, and delay, and weakens our public health.

- ***Finally***, EPA seeks comment on a number of ways it might make this rule even more destructive and deadly through possibilities like retroactive application or application in enforcement or permitting decisions. There is no reasoned or scientific basis for the Proposed Rule and certainly no such basis to extend it further.

EPA should end this rulemaking promptly, withdraw this Proposal, and base its decisions on the best science available. The lives and health of millions of people living in America depend on this and deserve nothing less.

TABLE OF CONTENTS

II. THE PROPOSED RULE WOULD EXCLUDE CRITICAL SCIENTIFIC STUDIES, HARMING THE PUBLIC SIMPLY TO FURTHER A POLITCAL AGENDA

A. The Proposed Rule Would Exclude Critical Scientific Studies.

Although the Proposed Rule is couched in terms of increasing transparency, its effect – and indeed its true purpose as made evident by emails, press statements, and other documents – would be to "preclude" EPA from using critical human health studies that rely on confidential medical information. 83 Fed. Reg. at 18,769, n.3. The rule would require that "the regulatory science underlying [a proposed EPA action] is publicly available in a manner sufficient for independent validation." *Id*. at 18,773 (proposed 40 C.F.R. § 30.1). Using terms that are vague, unsupported, and easily susceptible of manipulation, the Proposal would apply this public availability requirement to the "dose response data and models" underlying "pivotal regulatory science" used to justify "significant" "regulatory decisions." *Id*. (proposed 40 C.F.R. §§ 30.2, 30.3, 30.5).

In practice, the "data" underlying studies used to set quantitative limits and tolerances to protect public health and the environment often consists of confidential medical or other personal data gathered in epidemiological studies. Both the law and medical research ethics prohibit the disclosure of this data.[2] As EPA's own Science Advisory Board ("SAB") warned:

> For studies published many years ago, it may not be feasible to deliver public access to data and analytic methods. There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate.
>
> Furthermore, the rule could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts. The proposed rule does not acknowledge that the epidemiologic science community, for example, has been making significant efforts to make data available where possible and to develop studies based on publicly available data where appropriate.

See Memorandum from Alison Cullen, Chair, SAB Work Group, to Members of the Chartered SAB and SAB Liaisons, "Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)," 3 (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/W

[2] For example, as discussed *infra*, Section IV.E, under the Common Rule For Research Involving Human Subjects, 45 C.F.R. Part 46, in order to gain approval from an Institutional Research Board to conduct federally funded research, "when appropriate, there [must be] adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." 45 C.F.R. § 46.111(a)(7). This usually requires obtaining informed consent from the research subjects, including a description of how the researchers will preserve the confidentiality of identifiable records. *Id*. § 46.116(a)(5).

kGrp_memo_2080-AA14_final_05132018.pdf ("SAB Comment").[3] Thus, by imposing a requirement that certain data that cannot legally or ethically be made public be disclosed for the study to be used, EPA is effectively preventing the use of such studies.

In an effort to minimize the effect of the Proposed Rule, EPA asserts that "concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government." 83 Fed. Reg. at 18,770. As support for this assertion, EPA merely says, "[s]ee examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau." *Id*. n.16. But EPA ignores the fact that removing confidential information from the underlying data in such studies is impractical, ineffective, and unnecessary. For example, in the last ozone NAAQS review, EPA reviewed more than 4,000 studies and references, and cited more than 2,200 in the final Integrated Science Assessment. Anonymizing the confidential information in all of the data underlying over 2,000 studies would be overly burdensome in terms of effort and cost.[4]

[3] Given these potential impacts, at its May 31, 2018, meeting, the SAB voted to independently review this rule. *See* Doug Obey, "SAB Votes To Review EPA's Science, Emissions Rules In Sign Of 'Rebuke,'" *Inside EPA* (May 31, 2018), https://insideepa.com/daily-news/sab-votes-review-epas-science-emissions-rules-sign-rebuke. At this meeting, several members of the scientific and medical communities testified about the deleterious impact of the Proposed Rule. EPA, Meeting: Chartered Science Advisory Board (May 31 to June 1, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/7D239353BCECF85B852582600058B716?OpenDocument; Written Statement from Ms. Genna Reed, Union of Concerned Scientists, https://yosemite.epa.gov/sab/sabproduct.nsf/3B1AE8935A26E56C852582940075D516/$File/UCS+SAB+written+comment+5.31+v2.pdf; Written Statement from Dr. David McCabe, Clean Air Task Force, https://yosemite.epa.gov/sab/sabproduct.nsf/A4979E2FDC1153A7852582A600787981/$File/34697863.pdf; Written Statement from Lynn Goldman, The George Washington University, https://yosemite.epa.gov/sab/sabproduct.nsf/112CC313B0FB652D852582A6007BA0DA/$File/Goldman+Oral.pdf; Written Statement from Mary Rice, American Thoracic Society, https://yosemite.epa.gov/sab/sabproduct.nsf/6E8D2B56375A3FE5852582A600781D7E/$File/70258076.pdf; Written Statement from Liz Borkowski, Jacobs Institute of Women's Health, https://yosemite.epa.gov/sab/sabproduct.nsf/69E37E4047D5208A8525829E00601B26/$File/26246226.pdf; Written Statement from Dr. George Thurston, NYU School of Medicine, https://yosemite.epa.gov/sab/sabproduct.nsf/1A46C31B5E4BFFBF852582A60078E00A/$File/89488078.pdf.

[4] For example, in response to proposed legislation that would have required removal of all confidential information in all studies used by EPA, the Congressional Budget Office ("CBO") stated: "If the EPA continued to rely on as many scientific studies as it has used in recent years to support its covered actions, then CBO estimates that the agency would need to spend at least $100 million dollars per year to upgrade the format and availability of those studies' data to the level required by H.R. 1430." CBO, *Cost Estimate: H.R. 1430 Honest and Open New EPA Science Treatment (HONEST) Act of 2017* at 3 (Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.

Moreover, de-identifying personal information has thus far proven to be ineffective.[5] In 2000, the U.S. Department of Health and Human Services adopted Standards for the Privacy of Individually Identifiable Health Information (commonly known as the "Privacy Rule"), pursuant to its authority under HIPAA. *See* 45 C.F.R. Pts. 160 and 164. The Privacy Rule protects all individually identifiable health information held or transmitted by certain covered entities – that is, health plans, health care clearinghouses, or health care providers – and their business associates. *Id.* §§ 160.103, 164.502(a). Under the Privacy Rule, two methods have been used to de-identify individually identifiable health information so that the data may be disclosed. *First*, the entity may rely on the judgment of a qualified individual who determines, with documentation, "that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information." *Id.* § 164.514(b)(1). *Second*, the entity may remove multiple enumerated categories of information, including patient names, social security numbers, full face photographs, and biometric identifiers (such as fingerprints). *Id.* § 164.514(b)(2). An entity following this approach must generalize each patient's birth date to the relevant year and may include only the first three digits of a patient's zip code. *Id.* § 164.514(b)(2)(i)(B), (C). Despite these seemingly thorough requirements for de-identification, the Privacy Rule is significantly less protective than it appears. In the years since its adoption, publicly available personal information has proliferated, and new databases are created every day.[6] To "reidentify" de-identified data, an adversary need only discover an individual's "data fingerprint"—that is, the combination of values shared by nobody else in an anonymized data set.[7] The adversary can then link this fingerprint to publicly available, non-anonymized information to discover the individual's identity.[8]

---

[5] Even if it were effective – which it is not – as the Seventh Circuit has explained, people may have privacy interests in unidentifiable personal information: "Imagine if nude pictures of a woman, uploaded to the Internet without her consent though without identifying her by name, were downloaded in a foreign country by people who will never meet her. She would still feel her privacy had been invaded." *Nw. Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 929 (7th Cir. 2004). Indeed, according to a 1993 study, more than 60 percent of Americans want hospitals, pharmaceutical companies, and researchers to obtain patient consent before using medical information—even if that information has been de-identified. N. Nina Zivanovic, *Medical Information as a Hot Commodity: The Need for Stronger Protection of Patient Health Information*, 19 Intell. Prop. L. Bull. 183, 201 (2015).

[6] Zivanovic at 201; Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. Rev. 1701, 1724 (2010).

[7] Ohm at 1723. Indeed, 87 percent of the population can be identified based only on their 5-digit ZIP code, gender, and date of birth. Latanya Sweeney, *Simple Demographics Often Identify People Uniquely*, Carnegie Mellon University, Date Privacy Working Paper 3 at 2 (2000), https://dataprivacylab.org/projects/identifiability/paper1.pdf. More than half the population can be identified by their gender, data of birth, and city, town, or municipality, while nearly 20 percent can be identified by their gender, date of birth, and county. *Id.*

[8] Ohm at 1724. Of course, adversaries need not resort to such sophisticated methods. As the Seventh Circuit explained in the context of medical records relating to abortion, once a patients' de-identified records are made available, "persons of their acquaintance, or skillful 'Googlers,' sifting the information

Removing confidential information so that it can be publicly disclosed is also wholly unnecessary, as studies can be validated without demanding access to confidential data. As the SAB explained,

> The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies ***without public access to data and analytic methods***. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis.

SAB Comment at 4 (emphasis added). Yet these are some of the very studies EPA would exclude under the Proposed Rule. 83 Fed. Reg. at 18,769, n.3.

EPA then claims that the Proposal would not "compel[] the disclosure of any confidential or private information." *Id.* at 18,770–71. While technically, true, this is misleading, because the Proposal would force decision-makers to ignore important and relevant science precisely to avoid unnecessary and illegal disclosure.[9]

The exclusionary intent of the Proposed Rule is likewise demonstrated by proposed 40 C.F.R. § 30.8, which requires that the rule be implemented so as to "minimize costs." As the SAB explained, "[i]n addition, there are considerations associated with the cost and effort that would be involved in making large and complex existing datasets available within Institutional Review Board requirements, including the issue of who would be responsible for shouldering this burden." SAB Comment at 3. In other words, if EPA must minimize costs, the exclusion of science, rather than taking complicated and expensive steps to hide confidential medical data, is likely to be the approach followed.

B. EPA Inexcusably Ignores the Fact that by Excluding Critical Human Health Studies, the Proposed Rule Significantly Harms Public Health.

The harm this Proposed Rule is likely to cause cannot be overstated. Restricting science in the manner proposed by EPA would result in significant public health failures.

---

contained in the medical records concerning each patient's medical and sex history, will put two and two together, 'out' the . . . women, and thereby expose them to threats, humiliation, and obloquy." *Nw. Mem'l Hosp.* 362 F.3d. at 929.

[9] In his testimony before the House of Representatives Subcommittee on Environment, Committee on Energy and Commerce, former Administrator Pruitt expressly stated that EPA would only consider studies where the underlying data and methodology were made public. *See* U.S. House of Representatives, Transcript of Hearing: The Fiscal Year 2019 Environmental Protection Agency Budget (Apr. 26, 2018), https://docs.house.gov/meetings/IF/IF18/20180426/108218/HHRG-115-IF18-Transcript-20180426.pdf.

Epidemiological studies have been foundational to understanding critical connections between exposure to toxic chemicals and public health harms — connections that will be severed under EPA's Proposed Rule. For example, links between certain occupations and incidences of cancer were discovered through the precursors to epidemiological studies.[10] "Historically, much of what was known about the causes of cancer was derived from studies of workers," as the work environment offered critical characteristics allowing for the occurrence of cancer to be studied, namely "well-defined populations that are exposed, often at high levels, to agents that can be quantitatively characterized."[11] The methods used in these studies linking exposure to chemicals to the risk of disease "contributed importantly to the development of modern epidemiology."[12] Just as "[i[dentifying occupational carcinogens is an important research endeavor with broad relevance to science and public health," with "[k]nowledge of cancer hazards from occupational exposure support[ing] prevention and surveillance activities, as well as compensation of exposed workers,"[13] so too are epidemiological studies critical to protecting the public health from exposure to toxins in our air, water, and food. EPA's Proposal – which would remove most of these crucial studies from consideration when setting safety standards – poses a clear and present danger to our health and the environment.

Another example of toxic harm documented through epidemiological studies is airborne lead. General aviation aircraft emit the majority of airborne lead in the nation. Multiple studies have found an association between airborne lead exposure and elevated blood lead levels in children. But the Proposed Rule would, in effect, prohibit EPA from considering one of the key studies that directly links high childhood blood lead levels and living in proximity to general aviation airports. This study, M.L. Miranda et al., *A Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels*, Envtl. Health Persp. 119(10): 1513–1516 (Oct. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3230438/ ("Miranda Study"), a copy of which is submitted herewith, found a significant association between living in close proximity to a general aviation airport where non-commercial piston jets that use leaded aviation fuel (or "leaded avgas") are common, and elevated blood lead levels in children. The Miranda Study relies on state blood lead surveillance data for over 125,000 children between the ages of 9 months and 7 years in six North Carolina counties who had been tested for lead between 1995 and 2003, as well as GIS mapping of the locations of the children's homes relative to the locations of airports where aircraft use avgas, and estimates of lead emissions from aircraft. The data relied on by the Miranda Study would likely be characterized as "dose response data and models" under the Proposed Rule as the study links exposure to nearby emissions of lead with blood lead levels. Thus, EPA could refuse to rely on the Miranda Study in taking a significant regulatory action – such as regulating the use of leaded avgas – unless obvious personal identifiers of the 125,000 children whose blood lead levels were studied were made publicly available. Because North Carolina collected that data as part of a mandatory statewide registry

[10] Dana Loomis et al., *Identifying occupational carcinogens: an update from the IARC Monographs*, Occup. & Envtl. Med. (2018), http://oem.bmj.com/content/early/2018/05/16/oemed-2017-104944.
[11] *Id*.
[12] *Id*.
[13] *Id*.

of blood lead surveillance data – undoubtedly with assurances of strict confidentiality to the participants – it would be impossible for the Miranda Study authors to make these "dose response data and models" "publicly available in a manner sufficient for independent validation," as section 30.5 of the Proposed Rule would require as a condition for relying on the study. Moreover, the location data are fundamental to the analysis, and these data could not be redacted in a way that still permits reproduction of the results. The authors took special care when presenting their results to preserve the privacy of the child participants, as required by their institutional review board.

The Miranda Study found that living within 1,000 meters of an airport where avgas is used may have a significant effect on blood lead levels in children, and that the impacts of avgas are highest among those children living closest to the airport. Excluding the Miranda Study from consideration of the impact of the ongoing use of leaded avgas could lead EPA to underestimate the risks posed by leaded avgas by ignoring the association found in the Miranda Study between continued use of leaded avgas and children's exposure to lead. This could result in EPA's wrongly deciding that leaded avgas does not endanger public health, undercutting the basis for moving forward with a ban on leaded avgas despite the fact that leaded automobile gas was banned as a danger to public health decades ago.

EPA's exclusionary rule would also gravely limit EPA's ability to protect the public from the health hazards associated with perfluorooctanoic acid ("PFOA," also known as "C8") and perfluorooctane sulfonate ("PFOS"). As the result of a settlement of a lawsuit brought against a DuPont Washington Works facility near Parkersburg, West Virginia, related to contamination of drinking water, researchers conducted exposure and health epidemiological studies consisting of nearly 70,000 participants to examine the health impacts of exposure to these chemicals. These studies looked at "demographic data, medical diagnoses (both self-report and medical records review), clinical laboratory testing, and determination of serum concentrations of 10 perfluorocarbons (PFCs),"[14] information that is both sensitive and confidential. Through this work, the researchers identified probable links between exposure to these chemicals and six specific diseases: diagnosed high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer, and pregnancy-induced hypertension.[15] The results of these studies have been published in numerous articles in scientific journals. Yet, under EPA's Proposed Rule, this research would be excluded from consideration when determining health-based standards for PFOA under a number of environmental statutes, despite the clear evidence of harm these chemicals pose. Turning a blind eye to this data would have dramatic public health consequences, as it would preclude evaluation of valuable evidence of harm from exposure that could and should form the foundation of protections under the statutes EPA is charged with executing for the benefit of the public and the environment.

---

[14] Stephanie J. Frisbee et al., *The C8 Health Project: Design, Methods, and Participants*, Envtl. Health Persp 117:1873, 1873 (2009), https://ehp.niehs.nih.gov/wp-content/uploads/117/12/ehp.0800379.pdf.
[15] C8 Science Panel, *The Science Panel Website* (last updated Jan. 4, 2017), http://www.c8sciencepanel.org/index.html.

Many other studies would likewise be excluded from consideration under the Proposed Rule either because the data is confidential and not publicly available, or because the data is old and thus the results can no longer be replicated as required by the Proposed Rule. This includes, but is not limited to, the following:

- Early studies on the neurological effects of low-dose lead exposure on children's health have been foundational to setting lead levels for air and water, as well as for certain products such as paint.[16] The underlying data is confidential and not subject to public exposure. And it is likewise nearly 40 years old and thus likely no longer available.

- Studies demonstrating the link between exposure to arsenic and developing cancer depend upon confidential clinical examinations of the patients that served as research subjects,[17] and thus the sensitive health data underlying the studies cannot be publicly exposed.

- Studies on the impact of air pollution and mortality rates that have been used by EPA for decades to set air quality standards rely on confidential data that may not be lawfully disclosed.[18]

- EPA's toxicological reports in its Integrated Risk Information System ("IRIS") program, which create health reference values that the Agency uses under various statutes to assess health risks from different chemicals.[19]

---

[16] Herbert L. Needleman et al., *Deficits in Psychologic and Classroom Performance of Children with Elevated Dentine Lead Levels*, 300 New England J. Medicine 689 (1979); EPA, Air Quality Criteria for Lead 12-86 to 12-88, 12-95 (1986), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=32647; Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper, 56 Fed. Reg. 26,460, 26,468–69 (June 7, 1991); Lead; Identification of Dangerous Levels of Lead, 63 Fed. Reg. 30,302, 30,316–30,317 (June 3, 1998). The final rule was published at 66 Fed. Reg. 1206 (Jan. 5, 2001); National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66,964 (Nov. 12, 2008).

[17] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 65 Fed. Reg. 38,888, 38,902 (June 22, 2000).

[18] Douglas W. Dockery et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 New England J. Med. 1753 (1993).

[19] Industry has sought to stall and undermine these assessments using language strikingly similar to what is in the Proposed Rule. *See, e.g.*, Valerie Volcovici, "Pressured by industry, U.S. EPA slows formaldehyde study release: documents," *Reuters* (May 24, 2018), https://www.reuters.com/article/us-usa-epa-formaldehyde/pressured-by-industry-u-s-epa-slows-formaldehyde-study-release-documents-idUSKCN1IP3EX; *see also* Jennifer Sass, "Toxic Chemical Industry and House R's Attack on Science," NRDC (Sept. 27, 2017), https://www.nrdc.org/experts/jennifer-sass/toxic-chemical-industry-and-house-rs-attack-science; Written Testimony of Kenneth A. Mundt, Ramboll Environ, *The Iris Review Process: Chloroprene and the criticality of good science*, https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-115-SY18-WState-KMundt-20170906.pdf; Oral Presentation of James S. Bus, Exponent, Inc. (support provided by the

EPA's Proposal would exclude these pivotal epidemiological studies and IRIS assessments that rely on such studies, as well as other critical research merely because the underlying data cannot be made public.

Compounding this problem, many public health protections are predicated upon coincidental benefits – or "co-benefits" – defined as "favorable impact[s] of [a rule] . . . that [are] typically unrelated or secondary to the purpose of the action."[20] It has long been the practice of federal agencies to include co-benefits of regulatory action when studying a proposed rule.[21] For example, EPA includes PM2.5 reductions as a co-benefit for additional regulations, including, but not limited to, the National Emissions Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers and Process Heaters,[22] and the Petroleum Refinery NSPS.[23] In light of the interconnectedness of many of EPA's rules, a restriction on the science supporting one will have a domino effect, weakening support for all rules that rely on the undermined rule. By way of illustration, should the Proposed Rule's restriction on the science EPA can consider in its rulemaking processes impact the PM2.5 reductions, it will, in turn, severely undercut the support provided for all other environmental programs for which PM2.5 reductions serve as a co-benefit.[24]

American Chemistry Council), https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-115-SY18-WState-JBus-2070906.pdf; Am. Chemistry Council, https://www.americanchemistry.com/Policy/Regulatory-Reform/ACC-CEO-Makes-the-Case-for-Fixing-EPAs-IRIS-Program-Improved-Risk-Assessments.pdf. A repeated industry criticism of IRIS assessments focuses on "transparency," as a code to try to attack science (just as this Proposed Rule does) even though IRIS follows peer-reviewed, scientific protocols affirmed by the National Academies of Sciences. *See, e.g.*, "ACC: National Academies Missed a Critical Opportunity with IRIS Review," Am. Chemistry Council (Apr. 13, 2018), https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/National-Academies-Missed-Critical-Opportunity-With-IRIS-Review.html.

[20] OIRA, OMB, Exec. Office of the President, *Regulatory Impact Analysis: A Primer* at 7 (Aug. 15, 2011), https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf.

[21] *See, e.g., The Case for Co-Benefits: Regulatory Impact Analyses, Michigan v. EPA, and the Environmental Protection Agency's Mercury and Air Toxic Standards* (Feb. 2016), https://www-cdn.law.stanford.edu/wp-content/uploads/2016/09/The-Case-for-Co-Benefits-Regulatory-Impact-Analyses-Michigan-v.-EPA-and-the-Environmental-Protection-Agencys-Mercury-and-Air-Toxics-Standards.pdf.

[22] EPA, *Regulatory Impact Analysis: National Emissions Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers and Process Heaters* at 1-2 (Feb. 2011), https://www.regulations.gov/document?D=EPA-HQ-OAR-2002-0058-3290.

[23] EPA, *Regulatory Impact Analysis for the Petroleum Refineries NSPS* at 7-1, EPA-452/R-08-002, (Apr. 2008), https://www3.epa.gov/ttnecas1/docs/ria/refineries_ria_final-nsps_2008-04.pdf.

[24] Simultaneous with the Proposed Rule's attack on science, EPA issued an Advanced Notice of Proposed Rulemaking that aims to eliminate its ability to rely on co-benefits in the public health rulemaking process. *See* Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process, 83 Fed. Reg. 27,524 (June 13, 2018).

For all of these reasons, the Proposed Rule will have far-reaching and damaging consequences on public health protections. In a world in which EPA cannot consider critical studies demonstrating the deleterious impacts of toxic chemicals, pollutants, and pesticides when developing rules governing exposure levels, acceptable uses, and safety measures, there will be little to no available evidence to support the imposition of public health protections. Absent such evidence, EPA will be unable to implement rules that protect our air and water from harmful pollution, our farmworkers from toxic pesticides, and the public from overall exposure to chemicals, as EPA will have no science to point to as justification for such measures. Simply put, removal of this science from consideration in the rulemaking process will cause the very foundation upon which many of our public health standards depend to crumble.

C. The Proposed Rule Results Not from Any Scientific Principles or Justification but Rather from Industry Pressure to Weaken Public Health Protections and Follows the Tobacco Playbook.

While described as a measure to "better inform[] the public," "enhance[] the public's ability to understand and meaningfully participate in the regulatory process," and to ensure that "[t]he best available science must serve as the foundation of EPA's regulatory actions," 83 Fed. Reg. at 18,769, the Proposed Rule does nothing of the sort. Indeed, it was not intended to do so. Multiple documents indicate that the true purpose of this rule is to restrict EPA's ability to use relevant and credible – and frequently the best available – science that underlies strict and fully protective public health protections.

The genesis of the Proposed Rule is politically-driven legislation previously introduced by the House that would prohibit EPA from relying in its rulemaking on any science where the underlying research is not made publicly available.[25] Industry lobbied Congress in an effort to gut environmental and health laws by attacking the science upon which they are based. For example, both the Secret Science Reform Act of 2014 and the Secret Science Reform Act of 2015 provided that EPA may not take action "unless all scientific and technical information relied on to support such covered action is . . . ***publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of research results.***"[26] Two years later, after its prior unsuccessful attempts, the House passed the HONEST Act in March 2017, which again would have limited EPA's ability to perform any assessment or analysis based

[25] *See, e.g.*, Juliet Eilperin and Brady Dennis, "Pruitt unveils controversial 'transparency' rule limiting what research EPA can use," *Washington Post* (Apr. 24, 2018), https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/ (noting that, during a meeting between the then-EPA Administrator and Representative Lamar Smith, who introduced the House legislation, "Smith made 'his pitch that EPA internally implement the HONEST Act [so that] no regulation can go into effect unless the scientific data is publicly available for review.'").

[26] H.R. 4012, Secret Science Reform Act of 2014 (introduced Feb. 6, 2014), https://www.congress.gov/bill/113th-congress/house-bill/4012/text; H.R. 1030 - Secret Science Reform Act (introduced Feb. 24, 2015), https://www.congress.gov/bill/114th-congress/house-bill/1030/text.

on science if the public does not have complete access to the underlying data.[27] When these bills did not succeed, industry looked to a new audience to try put in place what Congress failed to enact: a ban on consideration of science when making regulatory decisions critical to public health and the environment if the underlying data is not made publicly available.

Industry pitched EPA hard, and found a willing ear, complaining that air pollution limits and toxin tolerances were being set at levels that were too stringent. Given that the strong Congressional mandate expressed in numerous statutes for strict health protections would require EPA to act if the science demonstrated a risk to public health, industry saw that their best bet was to knock out the science, this time through EPA itself.[28] Industry groups, including the National Association of Manufacturers and American Petroleum Institute, "pitched EPA a Proposal last spring that closely resembled what became Administrator Scott Pruitt's 'secret science' plan," according to EPA internal documents.[29] This plan closely tracks the longstanding attacks on EPA science from these groups.[30] EPA was responsive to the industry pitch and met with industry groups dozens of time, while repeatedly canceling the few scheduled meetings with public health advocates.[31]

Similarly, pesticide manufacturers, such as Dow Chemical Company, have long opposed the use of epidemiological studies that collect human health data that must be kept confidential. For example, they vigorously challenged EPA's proposal to revoke tolerances for chlorpyrifos, one of the country's most widely used pesticides, which in effect would have prohibited the use of chlorpyrifos on food crops. EPA had found that it could not conclude that exposure to this pesticide in food and drinking water was safe based on a risk assessment that included a safety factor mandated under the Food Quality Protection Act to protect the health of infants and children whose developing bodies are uniquely vulnerable to toxic pesticides. *See* 80 Fed. Reg. 69,079, 69,090 (Nov. 6, 2015); *see also* National Academy of Science ("NAS"), *Pesticides in the*

---

[27] *See also* H.R. 1430 - Honest and Open New EPA Science Treatment Act (introduced Mar. 8, 2017), https://www.congress.gov/bill/115th-congress/house-bill/1430/text; *see also,* Brian Resnick, "The House Just Passed Two Bills That Would Stifle Science at the EPA," *Vox* (Mar. 30, 2017), https://www.vox.com/science-and-health/2017/3/30/15112704/transparency-epa-bills-not. Also in March 2017, Republicans on the Senate Committee on Environmental and Public Works ("EPW") "made transparency, including data access, a priority" throughout the confirmation process for Gina McCarthy. *See* U.S. Senate Comm. on Env't and Pub. Works, *Minority Staff Rep., EPA's Playbook Unveiled: A Story of Fraud, Deceit, and Secret Science* at v, 48, 55 (2014) (*hereinafter* "Minority Staff Report"), https://www.epw.senate.gov/public/_cache/files/2d30f39e-2fde-4b37-8810-32fa21b6e6bd/epaplaybookunveiled.pdf (describing how the "EPW Republicans sought the Agency's secret science used to justify nearly all regulations issued under the Clean Air Act," and they "boycotted the Committee nomination vote of McCarthy" in protest of "the lack of transparency at" EPA).

[28] *See, e.g.*, Maxine Joselow, "Emails: EPA All Ears as Industry Pitched 'Secret Science,'" *E&E News* (May 17, 2018), https://www.eenews.net/stories/1060081997.

[29] *Id.*

[30] *See, e.g.*, Minority Staff Report.

[31] *See id.*; *see also* Sharon Lerner, "Scott Pruitt's Policy Director at EPA Met with Hundreds of Industry Representatives, Emails Show," *The Intercept* (May 16, 2018), https://theintercept.com/2018/05/16/scott-pruitt-epa-industry-lobbyists/.

Diets of Infants and Children (1993). EPA retained the safety factor over industry objections because epidemiologic studies indicate that prenatal exposure to chlorpyrifos can harm the developing nervous system. So the industry attacked those studies, claiming they needed to see the underlying medical information[32], even though the studies – conducted by highly reputable institutions including Columbia University, University of California-Berkeley, and Mt. Sinai School of Medicine – were all published peer-reviewed articles in scientific journals. While the Columbia scientists who authored the study have allowed EPA scientists to analyze the data in a secure setting on Columbia's campus, they have refused to make the raw data publicly available in order to protect the privacy of the mothers and children who participated in the research.[33] Not satisfied, the pesticide industry is pressing EPA to exclude the study so that it can continue to sell a pesticide known to cause severe harm to children. And EPA is playing along.

This attack on supposedly "secret science" is not new or unique to this EPA and cannot be viewed in a vacuum. Attacking the underlying science has been a key strategy for decades, most notably in the tobacco industry's effort to limit evidence of the enormous public health harms caused by tobacco. After EPA published its final Risk Assessment for Environmental Tobacco Smoke (secondhand smoke) in 1992, which concluded that secondhand smoke "is a human carcinogen, responsible for approximately 3,000 lung cancer deaths annually in U.S. nonsmokers,"[34] the tobacco industry went on the attack. The Risk Assessment had been based in part on a meta-analysis of "31 epidemiologic studies from 8 different countries" which showed a significant risk of harm.[35] Recognizing that "[v]igorous denial is not a satisfactory defensive strategy" and that "the most significant [secondhand smoke] problem facing the Industry is the result of epidemiological studies which indicate" a risk from exposure, the tobacco industry decided to attack epidemiological science.[36] Industry lawyers candidly noted that "there is virtually no chance of affecting change on this issue if the focus is" secondhand smoke so "our approach is one of addressing process as opposed to scientific substance, and global applicability

---

[32] CropLife, *Petition EPA to halt regulatory decisions that are highly influenced/determined by results of epidemiological studies that do not meet well-defined data quality standards, and that are not integrated into the health risk assessment in a transparent, well-defined manner* (Nov. 29, 2016), http://191hmt1pr08amfq62276etw2.wpengine.netdna-cdn.com/wp-content/uploads/2016/01/FINAL-CLA-Petition-Regulatory-Decision-Making-11-29-16.pdf; CropLife, Comments *Re: Chlorpyrifos; Tolerance Revocations; 80 FR 69080, November 6, 2015; Docket ID: EPA-HQ-OPP-2015-0653* (Jan. 25, 2015), https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0342.

[33] Letter from Linda P. Fried, Columbia University Medical Center, to Jack E. Housenger, EPA OPP Director, *Re: Columbia Center for Children's Environmental Health Epidemiology Study Data* (May 18, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0928.

[34] EPA, *Respiratory Health Effects of Passive Smoking (Also Known As Exposure to Secondhand Smoke or Environmental Tobacco Smoke – ETS)* – Overview (last updated Jan. 4, 2010), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2835.

[35] EPA, *Respiratory Health Effects of Passive Smoking (Also Known As Exposure to Secondhand Smoke or Environmental Tobacco Smoke – ETS)*, EPA/600/6-90/006F at 1-9, 2-8 (1992).

[36] Amended Final Opinion, *United States of America et al. v. Phillip Morris USA, Inc., et al*., Civ. Action No. 99-2496 at 185-86 (D.D.C. Aug. 17, 2006), http://www.publichealthlawcenter.org/sites/default/files/resources/doj-final-opinion.pdf.

to industry rather than focusing on any single industrial sector."[37] Shortly thereafter, one of RJ Reynolds' lobbying firms organized a "Secret Science" Work Group to "[f]ocus public attention on the importance of requiring disclosure of taxpayer-funded analytical data."[38]

This Proposed Rule follows suit. It is just another effort to hide evidence of the public health harm of toxic chemicals, given that there is no way to change the research results showing the deleterious effects.[39] And this time, the effort is much broader, as it is not hiding evidence related to just one industry or one product. Indeed, when describing the hearing on the Secret Science Reform Act of 2015 – a predecessor of the Proposed Rule – Representative Eddie Bernice Johnson noted that "[w]hen the Majority held a hearing on this legislation last Congress, every Majority witness at the hearing had significant ties to the tobacco industry. . .. Judging from the groups that have endorsed this bill, it might be more accurate to state that H.R. 1030 is the polluting industries' attempt to prevent EPA from using the best available science." *See* Minority Staff Report at 48. The same holds true for the Proposed Rule. EPA should not be permitted to "deliberately misle[a]d the public about the risks of" certain pollutants or other chemicals by hiding evidence of their harms.[40] As several courts have found, the best available ***politics*** does not equate to the "***best available science***,"[41] so while this Proposed Rule may serve EPA's political ends, it does not meet the mandates of sound science.

III. EPA LACKS LEGAL AUTHORITY TO ADOPT THE PROPOSED RULE, AND THEREFORE THE RULE IS UNLAWFUL

EPA has no authority to limit what scientific information may be considered in making regulatory decisions. No statute authorizes this rule, and EPA lacks any inherent authority to regulate absent a statutory basis. Thus, should EPA proceed to promulgate the Proposed Rule or otherwise limit what science can be considered in regulatory decisions, it will be acting in violation of the law. *See* 5 U.S.C. § 706(2)(C) (requiring a reviewing court to "hold unlawful and set aside agency action . . . found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.").

---

[37] Memorandum re Background and Proposed Program to Address Federal Agency Science from Christopher C. Horner, Bracewell & Patterson LLP, to Tim Hyde and Randy Johnson, RJ Reynolds Tobacco Company (Dec. 23, 1996), https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=jfww0019.

[38] Memorandum re Tasks to "Secret Science" Work Group from Leslie Gianelli, Powell Tate (April 10, 1998), https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=klyc0069.

[39] *See* Sharon Lerner, "Republicans Are Using Big Tobacco's Secret Science Playbook to Gut Health Rules," *The Intercept* (Feb. 5, 2017), https://theintercept.com/2017/02/05/republicans-want-to-make-the-epa-great-again-by-gutting-health-regulations/.

[40] *Id.*

[41] *Ecology Ctr., Inc. v. U.S. Forest Serv.*, 451 F.3d 1183, 1194 n.4 (10th Cir. 2006) (emphasis added).

A. The Stated Statutory Provisions Upon Which EPA Relies Do Not Provide Authority for the Proposed Rule.

EPA lists a number of statutes it administers as purported authority for this rule, including "provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions." *See* 83 Fed. Reg. 18,769. As discussed in detail below, none of the statutes cited by EPA authorizes this proposed action.[42] EPA thus lacks authority to promulgate this rule under any statutory regime administered by the Agency, rendering the rule invalid.

i. Clean Air Act ("CAA")

EPA cites two provisions of the Clean Air Act ("CAA") as authority for the Proposed Rule. As further detailed below, neither provision provides such authority.

First, EPA cites Clean Air Act § 103, 42 U.S.C. § 7403, as authority for the Proposed Rule. 83 Fed. Reg. at 18,769. However, this section provides no authority for such a rule. Instead, the section requires EPA to create a research and development program for prevention and control of air pollution and to conduct research on health effects, among other issues. Specifically:

- Section 7403(a) requires EPA to "establish a national research and development program for the prevention and control of air pollution," which includes funding or conducting studies, establishing technical advisory committees, and related activities.

- Section 7403(b) provides a list of specific "[a]uthorized activities" that EPA may take in establishing the "research and development program" under subsection (a), including, for example, collecting and making available information pertaining to the program, cooperating with other agencies, and making grants and contracts for research. *Id.* § 7403(b)(6).

- Section 7403(c) requires EPA to "conduct a program of research, testing, and development of methods for sampling, measurement, monitoring, analysis, and modeling of air pollutants."

- Section 7403(d) requires EPA to "conduct a research program on the short-term and long-term effects of air pollutants, including wood smoke, on human health."

- Section 7403(e) requires EPA to conduct ecosystem research.

[42] Even assuming any of the statutory provisions upon which EPA relies provided authority to restrict science – which they do not – at best, the provisions could authorize EPA's proposed policy only with respect to activities under the particular statute. The provisions could not authorize an across-the-board restriction on science for rulemakings under all statutes.

- Section 7403(f) requires EPA to oversee an "experimental and analytical research effort, with the experimental research to be carried out at the Liquefied Gaseous Fuels Spill Test Facility."

- Section 7403(g) requires that, in carrying out purpose of subsection (a), EPA shall "conduct a basic engineering research and technology program to develop, evaluate, and demonstrate nonregulatory strategies and technologies for air pollution prevention."

- Section 7403(h) authorizes certain research by the National Institute of Environmental Health Sciences.

- Section 7403(i) discusses coordination of research with "other Federal ecological and air pollution research efforts."

- Section 7403(j) discusses acid rain research.

- Section 7403(k) discusses air pollution conferences.

Notably absent from this long list of explicit requirements and responsibilities is rulemaking authority, much less authority to exclude scientific studies from consideration by EPA in any "regulatory decisions" for any reason, including whether or not the underlying data is, or can be made publicly available. *See* 83 Fed. Reg. at 18,773-74 (proposed 40 C.F.R. §§ 30.2, 30.3, 30.5) (indicating application of Proposed Rule only to use of studies and data in "significant regulatory decisions"). Indeed, the authorized activities included in Section 7403(b) are quite specific, including actions such as collecting and disseminating information, making grants and contracts, and even "construct[ing] facilities, provid[ing] equipment, and employ[ing] staff as necessary to carry out this chapter."

Congress knew how to authorize EPA rulemaking activities elsewhere in the Clean Air Act. That § 7403 does not include such authority, much less authority to restrict science in particular, shows a clear intent not to grant such authority. *Meghrig v. KFC W., Inc.*, 516 U.S. 479, 485 (1996). Rather, the purpose of § 7403 is plainly to promote research and to advance and increase the use and consideration of data, not to restrict it.[43]

Equally problematic, EPA's proposed action serves none of the goals and meets none of the requirements of § 7403. The Proposed Rule is not a "research and development program" and does not include the requisite components of such a program necessary for EPA to act pursuant to its authority under this provision. EPA is not proposing any grants or research fellowships, *see* § 7403(b), or any air pollutant monitoring, analysis, modeling, and inventory

[43] *See, e.g.*, § 7403(b), (c)(2), (d)(1)(A) ("collect and make available, through publications and other appropriate means . . . information . . . pertaining to [EPA's] research and other activities"; "collect and disseminate . . . basic data on chemical, physical, and biological effects of varying air quality . . ."; "establish[] a national network to monitor, collect, and compile data . . . of air emissions, deposition, air quality . . ."; "conduct studies, including epidemiological, clinical, and laboratory and field studies, as necessary to identify and evaluate exposure to and effects of air pollutants on human health").

research, *see* § 7403(c), or any "basic engineering research and technology program to develop, evaluate, and demonstrate nonregulatory strategies and technologies for air pollution prevention," *see* § 7403(g). Nor is EPA proposing to conduct any epidemiological studies on air pollution or to develop any methods or techniques for human health risk assessment, *see* § 7403(d).[44]

In addition, even if EPA could otherwise act pursuant to this provision, EPA may not develop health risk assessment methods and techniques applicable to air pollutants without including the following requisite statutory elements:

- The creation of an Interagency Task Force, *id*. § 7403(d)(2)(A);

- An evaluation of each of the listed hazardous air pollutants ("HAPs") under § 7412(b)(1) "based on reasonably anticipated toxicity to humans and exposure factors" listed therein, and which "shall be reviewed by the Interagency Task Force," *id*. § 7403(d)(2)(B);

- Preparation of environmental health assessments for each of the HAPs, with specific deadlines, that "shall be prepared in accordance with guidelines developed by the Administrator in consultation with the Interagency Task Force and the Science Advisory Board," including a specific list of scientific elements that includes "available toxicological and epidemiological information," "a determination of gaps in available information," and "where appropriate, an identification of additional activities . . . needed to identify the types or levels of exposure which may present significant risk of adverse health effects in humans." *Id*. § 7403(d)(2)(C).

EPA's Proposal does not include any, much less each, of these required components for an exercise of § 7403 authority. Thus, even if EPA otherwise had authority to act pursuant to this provision, the Proposed Rule is inconsistent with and contravenes the very provision which EPA itself cites.

For each and all of these reasons, § 7403 does not give EPA authority to regulate science or to exclude from EPA regulatory decisions the consideration of a subset of scientific studies.

Second, EPA cites section 301(a) of the Clean Air Act, 42 U.S.C. § 7601(a), as authority for the Proposed Rule. 83 Fed. Reg. at 18,769. This section of the Clean Air Act authorizes only "such regulations as are necessary to carry out [the Administrator's] functions under [the Clean Air Act]." 42 U.S.C. § 7601(a)(1). As discussed below, this provision does not authorize the Proposed Rule.

[44] Moreover, and as discussed in great detail *infra*, Section V, for EPA to perform any of these tasks, it would have to meet the procedural requirements constraining its research and development authority. For example, 42 U.S.C. § 7403(d) sets specific directions that ensure that EPA may not conduct a research program on the effects of air pollution on its own pursuant to this provision, but rather, for such "environmental health effects research," EPA must consult with the Secretary of Health and Human Services, generally. *Id.* § 7403(d)(1). EPA failed to follow these requisite procedures.

It is beyond cavil that general rulemaking provisions do not "'provide [EPA] Carte blanche authority to promulgate any rules, on any matter relating to the Clean Air Act, in any manner that the [EPA] wishes.'" *North Carolina v. EPA* 531 F.3d 896, 922 (D.C. Cir. 2008), *on reh'g in part*, 550 F.3d 1176 (D.C. Cir. 2008) (citing *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 873 (D.C. Cir. 1979)). Rather, such regulations must be "necessary" to carry out another statutory duty. *See, e.g., id.* ("EPA cannot claim retiring excess Title IV allowances is 'necessary' for EPA to ensure SIPs comply with section 110(a)(2)(D)(i)(I)."); 42 U.S.C. § 7601(a). And "'EPA cannot rely on its gap-filling authority to supplement the Clean Air Act's provisions when Congress has not left the agency a gap to fill'—i.e., 'when there is statutory language on point.'" *WildEarth Guardians v. EPA*, 830 F.3d 529, 539 (D.C. Cir. 2016) (citing *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063–64 (D.C. Cir. 2014)); *see also Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063–64 (D.C. Cir. 2014) ("[W]e have consistently held that EPA's authority to issue ancillary regulations is not open-ended, particularly when there is statutory language on point." (citing *Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1119 (D.C. Cir. 1995))).[45]

EPA has not argued, nor could it, that the Proposed Rule is "necessary" for fulfilling the agency's rulemaking duties under the CAA. Rather, as discussed *infra*, Section IV.A, EPA's proposed exclusion of scientific data that is not publicly available is antithetical to the purposes of the CAA. Moreover, EPA itself has repeatedly determined, and the D.C. Circuit has affirmed, that disclosure of the data underlying studies on which the agency relies is ***not*** necessary to fulfill the Agency's transparency and public comment obligations under the Clean Air Act, 42 U.S.C. § 7607(d).

For example, when EPA set the 1997 Particulate Matter National Ambient Air Quality Standards ("NAAQS"), "[s]everal commenters questioned EPA's ability to rely on studies demonstrating an association between PM and excess mortality without obtaining and disclosing the raw 'data' underlying these studies for public review and comment." 62 Fed. Reg. 38,652, 38,689 (July 18, 1997); *see also* EPA, *Responses to Comments on the 1996 Proposed Rule on the Nat'l Ambient Air Quality Standards for Particulate Matter* (July 1997), https://www3.epa.gov/ttn/naaqs/standards/pm/data/rtc_pm.pdf. EPA responded that "[i]t 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." 62 Fed. at 38,689. EPA made clear that disclosing such data was not its general practice, in part because EPA was not relying on the underlying data but rather on the study results themselves. *Id.* EPA recognized that "[i]f 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." *Id.* EPA explained:

[45] *See also Nat. Res. Def. Council v. Reilly*, 976 F.2d 36, 41 (D.C. Cir. 1992) (EPA cannot use its general rulemaking authority as justification for adding to a statutorily specified list); *Sierra Club v. EPA*, 719 F.2d 436, 453 (D.C. Cir.1983) (same); *see also Gonzales v. Oregon*, 546 U.S. 243, 264–65 (2006) ("It would go . . . against the plain language of the text to treat a delegation for the 'execution' of [the Attorney General's] functions as a further delegation to define other functions well beyond the statute's specific grants of authority.").

> [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.

Id. And when the 1997 PM NAAQS was challenged, the D.C. Circuit affirmed EPA's consideration of relevant scientific epidemiological evidence without disclosure of all of the raw data. *See Am. Trucking Ass'ns. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) (The court "agree[d] with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely 'would be ***impractical and unnecessary***.'" (quoting 62 Fed. Reg. at 38,689) (emphasis added)).

In *Coalition of Battery Recyclers Association v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010), petitioners again challenged EPA's failure to disclose underlying data for a study on the health effects of lead exposure, on which it relied to issue the 2008 Lead NAAQS. Specifically, the petitioners contended "the *Lanphear* study [on which EPA relied] contained such errors that EPA acted arbitrarily and capriciously in relying on results from the study without first obtaining and making public the underlying data for the study." *Battery Recyclers*, 604 F.3d at 622-23. EPA reiterated in its briefing that it would be "***impractical and unnecessary***" to disclose such data. *See* EPA Respondent Brief (Doc. No. 1230237) at 47 (Feb. 16, 2010) (citation and quotation marks omitted; emphasis added), *Battery Recyclers*, 604 F.3d at 623. The D.C. Circuit again agreed with and upheld EPA's determination that disclosure of underlying data is not necessary to consider the results of a health study to be relevant to a clean air rulemaking pursuant to 42 U.S.C. § 7607(d). The court applied its prior holding in *American Trucking*, that "'[t]he Clean Air Act imposes no such obligation' and that 'requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary.'" *Battery Recyclers*, 604 F.3d at 623 (quoting *American Trucking*, 283 F.3d at 372). Though petitioners "attempt[ed] to distinguish their request on the ground that in *American Trucking* the court was addressing requests for data underlying several studies, while they request only that EPA obtain and make public the data underlying the Lanphear study," *id.* at 623, the court found that argument unpersuasive, again "noting that raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants." *Id.* at 623 (citing *American Trucking*, 283 F.3d at 372).

EPA also cannot argue that excluding studies from the Agency's consideration when the underlying data cannot be publicly disclosed is "necessary" for ensuring the Agency relies on the best available science. As an initial matter, nowhere in the Proposed Rule does EPA find that particular studies, much less all studies that rely in part on the collection of confidential raw data (such as people's names and health records), are bad science, or even less reliable science. Nowhere does EPA show how health studies that rely in part on confidential personal information can never be relevant in any way to CAA rulemakings. Nor could it, as EPA has found such studies relevant and has relied on such studies for decades, and they are commonly accepted and valued as important scientific information of health effects within the scientific community. *See* Section IV.A. EPA cites no examples of situations where unsound, unlawful or

arbitrary decision-making resulted from an agency's reliance on studies that do not fit its newfound notions of "transparency" and "integrity." Rather, courts have repeatedly upheld actions that have relied on such studies, as cited above.

Moreover, EPA has not demonstrated that it is consistent with scientific principles to categorically ***exclude*** peer-reviewed scientific information from all consideration in a rulemaking, as EPA proposes to do. If EPA has any doubts or concerns regarding the merits of a particular study, it must address those doubts or concerns for that particular study in the context of a given rulemaking, where agency staff, internal scientific experts, scientific advisory committees, or commenters contend that study is relevant. EPA has provided no scientific justification for ignoring an entire class of health science simply because the underlying data has not been disclosed. Whether underlying data on which a study relies is made public or not simply has no bearing on whether a scientific study is good science, is accurate, is reliable, and is relevant to a scientific question (such as the health effects of air pollution). And to the extent EPA requires additional verification of a study, there are myriad ways it can do so without disclosing confidential data (for example, requesting an independent scientific body to conduct a confidential review). *See* Section IV.A, *infra*.

Furthermore, there is no statutory gap with respect to what studies EPA should consider (nor does EPA attempt to identify any). As further discussed below, sections of the Clean Air Act that govern air standards and rulemakings specify the applicable standards and generally require consideration of all available science. EPA has been adopting rules under most of these provisions for decades without finding any need for restrictions of the sort EPA proposes here. The Agency provides no explanation, and none exists, for suddenly finding "gaps" in these provisions.

Finally, EPA fails to acknowledge that it has had a longstanding policy of considering health studies without requiring disclosure of all underlying raw data. Indeed, it tries to minimize its prior position in a footnote, stating that: "Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use [of] non-public data in support of its regulatory actions." 83 Fed. Reg. at 18,769, n.3. It ignores the fact that EPA itself has ***consistently*** considered and used health studies dependent on non-public information for clean air rulemakings. Further, the Agency's longstanding policy has been that "EPA does not generally undertake evaluations of raw, unanalyzed scientific data as part of its public health standard setting process." 62 Fed. Reg. at 38,689. Only in "extreme cases – for example where there are credible allegations of fraud, abuse or misconduct – would a review of raw data be warranted." *Id*. That EPA now finds this data so important that it must be publicly disclosed before the Agency will even consider a study represents a monumental shift in course.

EPA is not working on a blank slate. Therefore, it must do more than just explain the change. Rather, EPA must provide "a more detailed justification," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41-42 (1983), because its new policy directly contradicts the Agency's prior findings that such studies are relevant to clean air rulemakings and provide evidence of health effects that the Agency can and must consider. EPA has not provided any reasoned explanation for its departure, much less an explanation with the requisite detail to justify its about-face.

ii. Clean Water Act ("CWA")

EPA cites sections 104 and 501 of the Clean Water Act, 33 U.S.C. §§ 1254, 1361, as statutory authority for its Proposed Rule. Upon examination, these sections do not provide the authority EPA suggests.

Section 104, 33 U.S.C. § 1254, entitled "Research, investigations, training, and information," addresses the Administrator's authority as it relates to the establishment of national programs, cooperation, investigations, water quality surveillance system, and reports. It requires the Administrator to, among other things: "conduct and promote the coordination and acceleration of, research, investigations, experiments, training, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, reduction, and elimination of pollution"; and to "initiate and promote the coordination and acceleration of research designed to develop the most effective practicable tools and techniques for measuring the social and economic costs and benefits of activities which are subject to regulation under this chapter." 33 U.S.C. § 1254(a)(1), (6).

Toward that end, the provision authorizes the Administrator to: "collect and make available, through publications and other appropriate means, the results of and other information, including appropriate recommendations by him in connection therewith, pertaining to such research and other activities referred to in" 1254(a)(1); and "cooperate with other Federal departments and agencies, State water pollution control agencies, interstate agencies, other public and private agencies, institutions, organizations, industries involved, and individuals, in the preparation and conduct of such research and other activities referred to in" 1254(a)(1). *Id.* § 1254(b)(1), (2). It also requires the Administrator to "conduct research on, and survey the results of other scientific studies on, the harmful effects on the health or welfare of persons caused by pollutants." *Id*. § 1254(c). And it requires the Administrator to conduct and update a variety of studies, including, but not limited to, studies on oil pollution controls, *id*. § 1254(i), effects and control of pesticides in water, *id.* § 1254(l), waste oil disposal, *id*. § 1254(m), effects of pollution on estuaries and estuarine zones, *id*. § 1254(n), pollution from agriculture, *id*. § 1254(p), and effects and methods of controlling thermal discharges, *id*. § 1254(t).

Thus, section 1254 discusses research and studies in great detail, but it does so by setting forth requirements for ***cooperation and promotion of research***. This section does not grant EPA any rulemaking authority at all, nor does it say anything about the Administrator's ability to screen or otherwise define the parameters for research that EPA can rely on for regulatory purposes. Instead, it describes the different areas for research and study and requires the Administrator to conduct research and studies in these areas.

The second CWA provision upon which EPA relies fares no better. EPA cites to section 501, 33 U.S.C. § 1361, as additional statutory authority for this rule. This is the provision generally authorizing the Administrator to "prescribe such regulations ***as are necessary to carry out his functions under this chapter***." 33 U.S.C. § 1361(a) (emphasis added). Such authority only exists if the regulation is, in fact, "necessary to carry out" the provisions under the CWA. *Mourning v. Family Publ'n Serv., Inc.*, 411 U.S. 356, 369 (1973) ("[w]here the

empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of [an] Act,' . . . the validity of a regulation promulgated thereunder will be sustained [only] so long as it is 'reasonably related to the purposes of the enabling legislation.'" (citation omitted)). The Proposed Rule is decidedly not necessary at all. As with the CAA discussed *supra*, the CWA regulatory authority enables the Agency to carry out its functions and fill any statutory gaps. The Proposed Rule is not needed to fill any "gaps" in the CWA, as Congress has already provided – in great detail – the Administrator's regulatory authority as it relates to research, emphasizing the need for the use and promotion of inclusive research. *See* § 1254. Moreover, a rule "devised pursuant to Congress' directive to issue regulations 'necessary to carry out' [an] Act . . . cannot stand if it is 'arbitrary, capricious, or manifestly contrary to the statute.'" *Ragsdale v. Wolverine World Wide, Inc*., 535 U.S. 81, 86 (2002) (citations omitted); *see also Am. Petroleum Inst.*, 52 F.3d at 1119 ("EPA cannot rely on its general authority to make rules necessary to carry out its functions when a specific statutory directive defines the relevant functions of EPA in a particular area."). As discussed below in Section IV.A and elsewhere herein, not only is the regulation unnecessary to carry out EPA's functions under the CWA or to fill any gaps, but it is arbitrary and antithetical to the objectives of the CWA. Thus, the Proposed Rule is not authorized under this general rulemaking provision.

iii. Safe Drinking Water Act ("SWDA")

Despite EPA's contrary contentions, the Safe Drinking Water Act ("SDWA"), 42 U.S.C. § 300f *et seq*., does not provide any authority for the adoption of a policy that would "preclude" EPA from considering all relevant scientific evidence in carrying out its duty to protect the quality of drinking water in the United States. *See* 83 Fed. Reg. at 18,769, n.3. In the Proposal, EPA points to two specific provisions of the SDWA as authorizing the rule, neither of which provides the necessary authority.

First, EPA points to 42 U.S.C. § 300j-1, but its reliance on this section is misplaced. Rather than authorizing the Administrator's selective exclusion of science and research, this section simply describes the Agency's responsibility to gather information—that is, "[to] conduct research, studies, and demonstrations relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments of man resulting directly or indirectly from contaminants in water, or to the provision of a dependably safe supply of drinking water." 42 U.S.C. § 300j-1(a)(1). This section also directs EPA to study certain serious threats to drinking water, including "polychlorinated biphenyl contamination," "disposal of waste (including residential waste)," "surface spills of contaminants," "virus contamination," "abandoned injection or extraction wells," "intensive application of pesticides and fertilizers in underground water recharge areas," "surface disposal of contaminants in underground water recharge areas," and "the nature, extent, sources of and means of control of contamination by chemicals or other substances suspected of being carcinogenic." *Id*. § 300j-1(a)(3)–(9). It therefore provides no legitimate basis for a rule that aims to limit the data that EPA can consider in executing the purposes of the SDWA.

Second, EPA cites the general grant of rulemaking authority in 42 U.S.C. § 300j-9(a)(1) as authorizing the Proposed Rule. However, this section likewise does not offer authorization. While this section empowers EPA "to prescribe such regulations as are necessary or appropriate to carry out [its] functions under this subchapter," the Proposed Rule is neither necessary nor appropriate to effectuate the SDWA.

The SDWA requires EPA to protect the public by limiting contaminants in public water systems. Specifically, the Act directs EPA to establish a "maximum contaminant level goal" for each contaminant "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 U.S.C. § 300g-1(b)(4)(A). EPA must then set an enforceable "maximum contaminant level" as close to this goal as is feasible. *Id*. § 300g-1(b)(4).

To accomplish these goals, in 1996, Congress amended the SDWA to ensure that EPA's regulatory decisions were scientifically sound and adequately protective of public health. As amended, the SDWA directs EPA to base its determination about whether to regulate any particular contaminant "on the ***best available public health information***." *Id*. § 300g-1(b)(1)(B)(ii)(II) (emphasis added). In addition, the amended SDWA expressly requires that, "to the degree that an Agency action is based on science, [EPA] shall use . . . ***the best available, peer-reviewed science and supporting studies*** conducted in accordance with sound and objective scientific practices[] 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)." *Id.* § 300g-1(b)(3)(A) (emphasis added). "Best available" means precisely what it says – the best of all that is available, not the best of some subset of what is available. The only qualifiers the SDWA places on what is "best available" are that the science be "peer-reviewed," and that the "supporting studies" be "conducted in accordance with sound and objective scientific practices." *Id*. Disclosure of confidential data underlying the studies plays no role in determining whether the science is the best available and is in no way required by the rule (but rather is expressly rejected by the scientific community, *see infra*). Any rule proposing to disregard reliable scientific information relevant to the regulation of drinking water contaminants directly conflicts with the SDWA's sound science mandate.

Given that the Proposed Rule is manifestly contrary to the SDWA, which expressly requires use of the best science available, it is not authorized by the general rulemaking authority in § 300j-9(a)(1). *Mourning*, 411 U.S. at 369; *Ragsdale*, 535 U.S. at 86. EPA is thus left without an appropriate authorizing provision under the SDWA.

iv. Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA")

EPA also cites to provisions under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") as authority for its Proposed Rule. However, upon examination, these provisions likewise provide no legal support for the Proposal.

The first provision upon which EPA relies – Section 115 – is inapposite. It merely sets out goal dates for EPA to begin assessment and remediation of facilities on the National

Priorities List, and is entirely irrelevant to the issues of the Proposed Rule. *See* 42 U.S.C. § 9616. While the second provision upon which EPA relies – Section 311 – is at least relevant to the issues of the Proposed Rule, it nonetheless conflicts with the proposition that the Proposed Rule espouses. It requires the Department of Health and Human Services, in consultation with EPA, to establish and support a research program consisting of:

> Basic research (including epidemiologic and ecologic studies) which may include each of the following:
>
> > (i) Advanced techniques for the detection, assessment, and evaluation of the effects on human health of hazardous substances.
> >
> > (ii) Methods to assess the risks to human health presented by hazardous substances.
> >
> > (iii) Methods and technologies to detect hazardous substances in the environment and basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances.

42 U.S.C. § 9660(a)(1)(A); *see also id.* § 9660(c) (authorizing EPA to conduct research on the "detection, assessment, and evaluation of the effects on and risks to human health of hazardous substances and detection of hazardous substances in the environment"). These provisions say nothing about authorizing EPA to adopt rules at all, much less rules limiting reliance on studies that do not meet the criteria of the Proposed Rule. Section 311(a) merely provides for the Department of Health and Human Services to establish and support certain research programs. It does not give EPA any authority at all, much less authority to limit the type of studies that can be relied upon for purposes of implementing CERCLA's operative provisions. Accordingly, CERCLA provides no support for EPA's actions here.

v. Emergency Planning and Community Right to Know Act ("EPCRA")

EPA likewise relies upon a provision in the Emergency Planning and Community Right to Know Act ("EPCRA") that in no way authorizes this Proposed Rule. Specifically, Section 328 of EPCRA – upon which EPA relies – merely authorizes EPA to "prescribe such regulations as may be necessary to carry out" the statute. 42 U.S.C. § 11048. But this provision does not "empower[] [EPA] to establish regulations which run far afield from the substance of the Act." *Kaw Valley, Inc. v. EPA* 844 F. Supp. 705, 708 (D. Kan. 1994) (citing *Central Forwarding, Inc. v. Interstate Commerce Comm'n*, 698 F.2d 1266, 1277 (5th Cir. 1983)). Given that the Proposed Rule is contrary to the purposes of EPCRA, *see infra*, Section IV.A, this general rulemaking provision cannot be considered "necessary," and thus does not do the work that EPA ascribes to it. *See Mourning*, 411 U.S. at 369; *Ragsdale*, 535 U.S. at 86.

vi. Federal Insecticide, Fungicide, Rodenticide Act ("FIFRA")

EPA also cites to two specific provisions in the Federal Insecticide, Fungicide, Rodenticide Act ("FIFRA") as statutory support for the Proposed Rule. Upon closer examination, these provisions do not provide the necessary authority for this Rule.

First, EPA points to Section 20(a), 7 U.S.C. § 136r(a), which provides:

> (a) Research
>
> The Administrator shall undertake research including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this subchapter, and the Administrator shall conduct research into integrated pest management in coordination with the Secretary of Agriculture. The Administrator shall also take care to ensure that such research does not duplicate research being undertaken by any other Federal agency.

By its plain language, this provision authorizes research, not the use of scientific studies in regulating pesticides. Thus, EPA's reliance on this provision as support for this rule is misplaced.

Second, the Proposed Rule cites Section 25(a)(1), 7 U.S.C. § 136w, which authorizes the EPA Administrator "to prescribe regulations to carry out the provisions of this subchapter." However, this broad authority is expressly limited to regulating "in accordance with the procedure[]" prescribed in FIFRA itself. *Id*. Yet, as discussed more fully in Section V, EPA failed to comply with these requisite procedures. Accordingly, this provision provides no authority for EPA's issuance of this rule.

vii. Toxic Substances Control Act ("TSCA")

EPA's reliance on the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2609, as authority for the Proposed Rule, fares no better. Indeed, much like many of the other statutory provisions upon which EPA relies, this provision governs EPA's authority to conduct and support research, and does not address EPA's authority to use scientific data or research in support of regulatory decisions.

Specifically, section 2609 grants EPA authority to "conduct such research, development, and monitoring as is necessary to carry out the purposes of this chapter. [EPA] may enter into contracts and may make grants for research, development, and monitoring under this subsection." 15 U.S.C. § 2609(a). Section 2609 grants EPA additional related authorities, including authority to:

- Create and operate information systems to store data relevant to chemical substances, *id*. § 2609(b);

- Develop "screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical[s]," *id*. § 2609(c);

- Establish a research program to develop chemical "monitoring techniques and instruments," *id*. § 2609(d);

- Conduct "basic research" on chemical screening and monitoring, *id*. § 2609(e), and train federal scientists on chemical screening and monitoring, *id*. § 2609(f); and

- Develop systems for information sharing among "Federal, state, and local authorities," *id*. § 2609(g).

Notably absent from the list of authorities under section 2609 is EPA's authority to determine what science it can consider when making regulatory decisions. Instead, the provision solely focuses on EPA's ability to conduct research or to fund research, independent of whether that research will or may be used by EPA to make regulatory decisions. Thus, section 2609 does not provide any basis for the authority claimed in the Proposed Rule.

Moreover, § 2625 of TSCA governs how EPA uses science when exercising its main regulatory powers under the statute, and establishes detailed criteria that EPA must use when "the Administrator makes a decision based on science" when carrying out its regulatory powers. 15 U.S.C. § 2625(h). Thus, this provision, and not those cited by EPA, would theoretically govern a rule related to the use of science. *See Bennett v. Islamic Republic of Iran*, 618 F.3d 19, 25 (D.C. Cir. 2010) ("'where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion.'" (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983))). However, and as discussed more fully *infra*, Section IV.A, the Proposed Rule contravenes the requirements of § 2625 that EPA consider all "reasonably available information" when making regulatory decisions, and thus is not authorized by this provision either.

viii. Resource Conservation and Recovery Act ("RCRA")

The Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6901 *et seq*., gives EPA the authority and responsibility to manage and control solid and hazardous waste, including the generation, transportation, treatment, storage, and disposal of the waste. EPA points to two provisions in RCRA for support of this Proposed Rule, neither of which authorizes this action.

The first provision of RCRA cited as authority for this rule, § 6912(a)(1), provides the Administrator with the general authority to "prescribe, in consultation with Federal, State, and regional authorities, such regulations as are necessary to carry out his functions under this chapter." 42 U.S.C. § 6912(a)(1). RCRA defines the functions of EPA in the area covered by RCRA, and therefore, EPA cannot rely upon the general authority to make rules provided by the statute. *Am. Petroleum Inst.*, 52 F.3d at 1119 ("EPA cannot rely on its general authority to make rules necessary to carry out its functions when a specific statutory directive defines the relevant

functions of EPA in a particular area."). Moreover, limiting the consideration of reliable health science when promulgating regulations that have significant health and environmental impacts is in no way "necessary" for the Administrator to carry out his functions under RCRA, and thus, for this reason too, the general rulemaking provision does not authorize this rule. *See Mourning*, 411 U.S. at 369.

The second provision of RCRA upon which EPA relies, § 6979, is inapposite. This provision pertains to labor standards related to wages for laborers and mechanics. 42 U.S.C. § 6979. This provision has no relevance to the Proposed Rule whatsoever and certainly does not provide the authority for it. Thus, nothing that EPA cites to in RCRA provides the requisite authority for this Proposed Rule.

ix. 5 U.S.C. § 301

In its notice extending the comment period and adding a public hearing, as an implicit admission that it has not cited sufficient authority for the Proposed Rule, EPA adds a new source of alleged authority, stating that "EPA is proposing this rule under authority of 5 U.S.C. 301, in addition to the authorities listed in the April 30th document." *See* 83 Fed. Reg. 24,255, 24,256 (May 25, 2018). Just like with the other statutory provisions upon which it relies, EPA is trying to fit a square peg in a round hole.

Section 301 of Title 5 provides "[t]he head of an Executive department or military department" authority to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." This provision governs internal organizational and bureaucratic steps required for operations. It allows all agencies to issue regulations to preserve and use their own papers and property. This section is plainly focused on allowing executive agencies to issue rules necessary to carry out the performance of their agencies' internal workings, not to allow EPA to regulate scientific material in rulemakings.

Indeed, the "purpose" of this section, "which originated in 1789 as a law 'to enable General Washington to get his administration underway by spelling out the authority of Government officers to set up offices and to file Government documents'. . . is to set up merely internal guidelines for a given governmental agency" to perform its job. *United States v. Lewis*, No. C-CR-89-114-01, 1990 WL 11111, *5 (W.D. N.C. Feb. 5, 1990) (citation omitted). That is why it is known as the "Housekeeping Statute," to literally allow the federal government to set up and keep house. *U.S. ex. Rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1254 (8th Cir. 1998) (citing H.R. Rep. No. 85-1461 (1958), *reprinted in* 1958 U.S.C.C.A.N. 3352). The Act was amended in 1966 as "codifying the general and permanent laws relating to the organization of the Government of the United States and to its civilian officers and employees." Pub. L. No. 89-554, 80 Stat. 378 (Sept. 6, 1966).

In *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979), the Supreme Court evaluated the Housekeeping Statute and held that it does not provide statutory authority for substantive regulations. After a brief historical analysis of the provision, the Court wrote:

> Given this long and relatively uncontroversial history, and the terms of the statute itself, it seems to be simply a grant of authority to the agency to regulate its own affairs. . . It is indeed a "housekeeping statute," authorizing what the APA terms "rules of agency organization procedure or practice" as opposed to "substantive rules."

Id. at 309–10. Multiple courts have agreed and limited rulemaking under this provision to non-substantive rules. *See, e.g., McDonnell Douglas Corp.*, 132 F.3d at 1256 (citing examples).[46]

Based on this long line of authority, EPA's reliance on this authority is sorely misplaced. EPA's attempt to "construe [this provision] as something more" is a "misuse" that "twist[s]" the statute beyond its intended purpose; EPA may not "twist this simple administrative statute into an authorization for the promulgation of substantive rules." *Id.* at 1255 (citing and quoting *Chrysler Corp.*, 441 U.S. at 310 n.41 (quoting H.R. Rep. No. 85–1461 at 7 (1958))).

The Proposed Rule does not relate to the organization of EPA or how it preserves its papers or keeps house. EPA's exclusion of critical health studies is such a far cry from being necessary to "set up offices" and to "file Government documents," that reliance on this provision hardly passes the laugh test. As discussed extensively in these Comments, the Proposed Rule is by no means necessary for EPA to perform its job but rather is antithetical to the very statutes it is responsible for effectuating. Accordingly, for the same reasons the general rulemaking authority provisions under all of the environmental statutes EPA cites do not authorize this rule, § 301 likewise does not permit EPA to issue a rule that undermines scientific integrity as well as all of the public health and environmental protections EPA is charged with enforcing.

B. EPA Has No Inherent Authority to Issue This Proposed Rule.

EPA's lack of statutory authority to propose this rule is fatal, as it has no inherent power to act. Indeed, it is well settled that a federal agency "literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *see also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."); *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) ("[I]t is 'axiomatic' that 'administrative agencies may act only pursuant to authority delegated to them by Congress'" (citation omitted)); *Ohio Dep't of Medicaid v. Price*, 864 F.3d 469, 476 (6th

[46] *See, e.g., In re Bankers Tr. Co.*, 61 F.3d 465, 470 (6th Cir. 1995) (Federal Reserve Board regulation requiring subpoenaed party to refuse production of confidential Federal Reserve Board information, contrary to Federal Rule of Civil Procedure 34, was not authorized by the Housekeeping Statute and "exceed[ed] the congressional delegation of authority"); *Exxon Shipping Co. v. U.S. Dep't of Interior*, 34 F.3d 774, 776–78 (9th Cir. 1994) (Housekeeping Statute did not authorize regulations allowing agency to withhold deposition testimony of federal employees); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 826–27 (S.D. Ohio 1995) (Housekeeping Statute did not authorize 1953 Defense Department directive on the use of human volunteers in experimental research); *McElya v. Sterling Med., Inc.*, 129 F.R.D. 510, 514 (W.D. Tenn. 1990) (Housekeeping Statute did not give Department of Navy authority to create general discovery privilege for persons under its jurisdiction).

Cir. 2017) ("Agencies, after all, are creatures of statutory authority." (citation and internal quotations omitted)). This is because, under the Constitution, Congress is the branch of government with lawmaking power. *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 317 (2013) (noting that an agency has no lawmaking power unless Congress delegates that power to it). "The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes." *Chrysler Corp.*, 441 U.S. at 302. Thus, EPA only has rulemaking power to the extent that Congress delegated it such power. *Lyng v. Payne*, 476 U.S. 926, 937 (1986) ("an agency's power is no greater than that delegated to it by Congress.").

Moreover, the fact that Congress has given EPA the authority to regulate in a certain area does not mean that it has general authority to make any rule within that area. This argument has been squarely rejected:

> The [agency's] position in this case amounts to the bare suggestion that it possesses *plenary* authority to act within a given area simply because Congress has endowed it with *some* authority to act in that area. We categorically reject that suggestion. Agencies owe their capacity to act to the delegation of authority from Congress.

Am. Library Ass'n. v. FCC, 406 F.3d 689, 708 (D.C. Cir. 2005) (quoting *Ry. Labor Executives' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 670 (D.C. Cir. 1994)) (internal quotations omitted; emphasis in original); *see also Liberty Mut. Ins. Co. v. Friedman*, 639 F.2d 164, 169 (4th Cir. 1981) ("a court must reasonably be able to conclude that the grant of authority contemplates the regulations issued." (citation and internal quotation marks omitted)). "[T]he power to issue regulations is not the power to issue any regulations." *Nat'l Mining Ass'n v. U.S. Dep't of the Interior*, 105 F.3d 691, 694 (D.C. Cir. 1997). In light of the statutory limitation on EPA's authority to restrict science in the way it proposes to do, *see infra*, Section IV, any general rulemaking authority on which it might otherwise try to rely does not authorize the Proposed Rule. *See, e.g., Nat. Res. Def. Council, Inc. v. Reilly*, 976 F.2d 36, 40-41 (D.C. Cir. 1992) (refusing to allow EPA to rely on general rulemaking authority to trump specific limitations on its authority because a vague "open-ended power" does not "trump the specific provisions of the [Clean Air] Act"; and "EPA's construction of the statute is condemned by the general rule that when a statute lists several specific exceptions to the general purpose, others should not be implied." (citation and internal quotation marks omitted)).

Accordingly, EPA has no general or inherent authority permitting it to lawfully adopt the Proposed Rule or otherwise limit what science may be considered in the rulemaking process. It, therefore, must be acting pursuant to some grant of authority by Congress for the Proposed Rule to be lawful. Yet none of the stated authorities upon which EPA relies provides the necessary

authority to promulgate this rule.[47] Given that EPA has no statutory authority to issue the Proposed Rule, its action is *ultra vires*. *See, e.g.*, *McDonnell Douglas Corp.*, 132 F.3d at 1257 ("An agency's promulgation of rules without valid statutory authority implicates core notions of the separation of powers, and we are required by Congress to set these regulations aside." (citing cases finding *ultra vires* agency action)). The Proposed Rule is therefore unlawful.

IV. THE PROPOSED RULE VIOLATES PROVISIONS OF THE LISTED AUTHORIZING STATUTES, AS WELL AS NUMEROUS OTHER STATUTES, POLICIES, AND EXECUTIVE ORDERS, AND IS THEREFORE UNLAWFUL.

A. The Proposed Rule Violates the Purported Authorizing Statutes.

Agency "regulations, in order to be valid, must be consistent with the statute under which they are promulgated." *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 609 (2013) (quoting *United States v. Larionoff*, 431 U.S. 864, 873 (1977)). As discussed below, the Proposed Rule violates a number of provisions in the statutes upon which EPA relies as statutory authority. For this reason, too, the Proposed Rule is invalid.

i. CAA

The Clean Air Act's specific rulemaking provisions do not allow EPA to create the restrictions on the consideration or use of health science that EPA proposes. Rather, these provisions govern each type of CAA rulemaking, and to the extent science can and must be considered under these provisions, EPA may not lawfully restrict the use of such science.[48] The Proposed Rule contravenes a number of CAA provisions and is thus unlawful.

First, sections 108 and 109 of the Clean Air Act do not allow EPA to restrict science as proposed and demonstrate that the Proposed Rule cannot lawfully be applied to any NAAQS rulemakings. These provisions specify that EPA's air quality criteria (on which the NAAQS are based) must "accurately reflect the latest scientific knowledge." 42 U.S.C. § 7408(a)(2); *id.* § 7409(b) (requiring those "criteria" be used to set NAAQS). This language unambiguously requires EPA to consider "all identifiable effects on public health," not just some. *Id.* § 7408(a)(2). The criteria "shall include information" on defined factors, "to the extent practicable." *Id.* This provision leaves no room for EPA to ignore or exclude studies because underlying data is not disclosed.

EPA cannot possibly ensure its air quality criteria "accurately reflect the latest scientific knowledge" if it refuses to even read certain studies based on an arbitrary public disclosure test. EPA's past practice illustrates this: for decades, the Agency's practice has been to review ***all*** available scientific studies, including those relying on non-public data. *See, e.g.*, *Battery Recyclers*, 604 F.3d at 616; *see also* EPA, *Integrated Science Assessment (ISA) for Particulate*

[47] EPA may not now add any new authority (if any exists) to try to save this action, as doing so would violate public notice-and-comment requirements under the statutes cited herein, as well as under the Administrative Procedure Act.

[48] Commenters do not concede that the Proposed Rule would necessarily apply to every action under these provisions.

Matter (Final Report, Dec 2009) (2009), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=216546; EPA, *Air Quality Criteria for Particulate Matter*, Vols. II-III (1996), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2832. The legislative history of § 108 confirms that Congress's intent was for EPA to "establish such national goals on the basis of ***the best information available***," not to sit idly by until industry representatives no longer dispute questions regarding health effects. S. Rep. No. 91-1196 (Sept. 17, 1970), CAA70 Leg. Hist. 19, 110 (emphasis added).

In addition, the Proposed Rule would direct EPA to violate the statutory procedures that must be followed when the Agency sets NAAQS. This includes EPA's appointment of an independent scientific review committee, including certain defined members, *see* 42 U.S.C. § 7409(d)(2)(A), and consideration of the recommendations of that committee when setting the NAAQS, *id.* § 7409(d)(2)(B)-(C); *see also, e.g.*, *Mississippi v. EPA*, 744 F.3d 1334, 1346 (D.C. Cir. 2013) (explaining NAAQS development process). That committee shall advise EPA regarding whether there are "areas in which additional knowledge is required." 42 U.S.C. § 7409(d)(2)(C). In promulgating NAAQS in the past, EPA has recognized that the CAA requires it to consider scientific advice and recommendations from such experts, including those that rely on health studies where underlying data is not disclosed.[49] Directing the Agency to ignore scientific studies presented by CASAC, just because the underlying data is not public, contravenes these statutory requirements.

Second, section 7409 of the Act requires EPA to adopt NAAQS based on the criteria, at levels requisite to protect public health with an adequate margin of safety. "[T]he Act requires [a] . . . preventative and precautionary" approach to setting NAAQS, whereby EPA must protect public health from "not just known adverse effects, but those of scientific uncertainty or that research has not yet uncovered." *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citation and quotation marks omitted). Congress "specifically directed" EPA "to protect against . . . effects whose medical significance is a matter of disagreement." *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980); *accord Nat. Res. Def. Council, Inc. v. EPA*, 824 F.2d 1146, 1152 (D.C. Cir. 1987) (en banc) (discussing legislative history). EPA's proposal would

[49] *See, e.g.*, EPA, *Integrated Science Assessment (ISA) of Ozone and Related Photochemical Oxidants (Final Report, Feb 2013)*, EPA/600/R-10/076F (2013), http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=247492; EPA, *Integrated Science Assessment (ISA) for Particulate Matter (Final Report, Dec 2009)*, EPA/600/R-08/139F (2009), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=216546; *see also* EPA, *Integrated Science Assessment (ISA) for Lead (Final Report, Jul 2013)* (July 2013), https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=255721; EPA, CASAC Review of the EPA's *Integrated Science Assessment for Lead (Third External Review Draft – November 2012)* (June 4, 2013), https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/39A3C8177D869EA085257B80006C7684/$File/EPA-CASAC-13-004+unsigned.pdf; *see also* EPA, EPA Clean Air Scientific Advisory Committee (CASAC) (last updated Aug. 3, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/WebProjectsbyTopicCASAC!OpenView (NAAQS assessments and criteria document).

flout these precedents by refusing to consider scientific studies – even those published in peer-reviewed journals by reputable scientists – based on an arbitrary data transparency policy.

To the extent the CAA allows EPA to weigh particular studies based on its expert judgment, this does not authorize EPA to categorically exclude an entire class of studies from being considered when performing a rulemaking to fulfill the Agency's statutory directive to protect public health and welfare. 42 U.S.C. § 7409(b)(1) (requiring primary NAAQS to be standards "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health"). EPA cannot rationally engage in its task of determining an appropriate level for the NAAQS if it entirely excludes relevant health studies from its consideration simply because underlying data has not been publicly released. Under the Proposed Rule, EPA would refuse to consider studies indicating that adverse health effects occur at a specific pollutant level—even where multiple studies reach the same results—where the studies fail to meet the agency's arbitrary disclosure tests. This would contradict the statutory requirement to assure public health protection by ignoring some of the most important health science relevant to that question and is the epitome of irrational agency action.

Third, the Proposed Rule violates section 7412 of the CAA, which includes myriad provisions that require EPA to evaluate health risks and effects of hazardous air pollutants ("HAPs" or "air toxics") and to set emission standards to reduce these risks and effects, based on certain science-based legal tests applicable to particular § 7412 rulemakings. *See, e.g.*, 42 U.S.C. § 7412(a), (b)(1)-(4), (f)(1)-(2). In no place does the statute limit EPA's consideration of scientific studies on health effects or risks to those studies where underlying data is publicly disclosed, nor does it authorize EPA to so limit its consideration of such scientific information. Instead, § 7412 includes language repeatedly indicating the requirement, embodying Congressional intent, for EPA to consider ***all*** relevant scientific information regarding health risks and effects, actual or potential, of hazardous air pollutants.

For example, § 7412(f) requires EPA to investigate and report, among other things, on "the actual health effects with respect to persons living in the vicinity of sources," and "***any available epidemiological or other health studies***" regarding the effects of HAPs, as part of the residual risk requirements. *Id.* § 7412(f)(1)(C) (emphasis added); *id.* § 7412(f)(1) (also providing other requirements for EPA's investigation and report to Congress). EPA submitted that report to Congress in 1999.[50] Section 7412(f) further provides that, in the absence of Congressional action on recommendations provided in EPA's Residual Risk Report to Congress, EPA "shall . . . promulgate standards for [each air toxics] category or subcategory if promulgation of such standards is required in order to provide an ample margin of safety to protect public health in accordance with this section (as in effect before November 15, 1990)." *Id.* § 7412(f)(2)(A). This provision also directs that:

> Emission standards promulgated under this subsection shall provide an ample margin of safety to protect public health in accordance with this section (as in effect before November 15,

[50] EPA, *Residual Risk Report to Congress*, EPA-453/R-99-001 (Mar. 1999), https://www.epa.gov/fera/residual-risk-report-congress-1999.

> 1990), unless the Administrator determines that a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. If standards promulgated pursuant to subsection (d) and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million, the Administrator shall promulgate standards under this subsection for such source category.

Id. § 7412(f)(2)(A). It would not be possible for EPA to fulfill its statutory directives under § 7412(f) to ensure that air toxics emissions standards "provide an ample margin of safety to protect public health," and to assess and remove any unacceptable health risks, unless EPA considered all relevant scientific studies in assessing such health risks. *Id.* § 7412(f)(2).

Further, § 7412(f)(2) also explicitly refers to EPA's Benzene Rule, which interpreted the prior version of this provision and which itself relied on certain studies and guidelines for which underlying data was not disclosed. *Id.* § 7412(f)(2)(B) (citing 54 Fed. Reg. 38,044 (Sept. 14, 1989)).[51] As EPA determined, and Congress, the D.C. Circuit, and EPA have affirmed through citation and reliance on that rule, § 7412(f) standards must be "based on the most current scientific knowledge," and on risk assessment guidelines and methods developed by EPA scientists and expert independent scientists. 54 Fed. Reg. at 38,062-63.[52] EPA has repeatedly recognized this reliance on an expansive array of scientific support that includes information that relies on epidemiological and other health studies for which the underlying data is not published in later § 7412(f) rulemakings as well.

Indeed, EPA itself has interpreted its legal responsibility pursuant to this provision as "incorporating into our assessments the best available science with respect to dose-response information."[53] To achieve that, EPA has followed scientific recommendations by the Office of

---

[51] In that rule, among other studies, "the Agency compiled and presented a 'Survey of Societal Risk' in its July 1988 proposal (53 FR 28512-28513)." 54 Fed. Reg. at 38,046. The underlying data for that survey was not disclosed, yet the Agency both considered and relied on it. *Id.*

[52] In that rule, EPA explained that risk assessments and § 7412(f) rules must be based on "the most current scientific knowledge and on sound scientific judgment"; EPA stated that it had based that rule on "an evaluation of the currently available information and on the regulatory mission of EPA to protect public health"; EPA also relied on the then-applicable Cancer Guidelines, and Guidelines for Exposure Assessment, explaining that "these guidelines were developed by scientists in EPA, and were extensively reviewed by the public and by expert scientists in industry, academia, environmental groups, and other governmental agencies." 54 Fed. Reg. at 38,062-63.

[53] *See, e.g.*, EPA, *Residual Risk Assessment for the Portland Cement Manufacturing Source Category in Support of the Sept. 2017 Risk and Technology Review Proposed Rule* at 23 (July 2017), https://www.regulations.gov/document?D=EPA-HQ-OAR-2016-0442-0153 (describing the Agency's current policy and scientific methodology for this type of health risk assessment); *see also e.g.*, EPA, *Residual Risk Assessment for Pulp Mill Combustion Sources in Support of the October, 2017 Risk and*

Air Quality Planning and Standards, and has prioritized certain sources of such dose-response information according, in part, to "level of peer review received."[54] These guidelines direct EPA to consult dose-response assessments such as a reference concentration (RfC, for inhalation), reference dose (RfD, for ingestion), and a unit risk estimate (URE, for cancer risk) and/or slope factor (SF, for cancer risk).[55] EPA's scientific method is to consult and rely on IRIS (an EPA database containing peer-reviewed scientific health assessment information) as a top priority source of such information, due in part to the high level of peer review. As EPA's guidelines explain: "IRIS is a critical resource for risk assessors because the database contains toxicity information that reflects a consensus among EPA program offices."[56] EPA also prioritizes dose-response information from the U.S. Agency for Toxic Substances and Disease Registry ("ATSDR"), and the California EPA Office of Environmental Health Hazard Assessment.[57]

Technology Review Final Rule at 6, 18-19 (July 2017), https://www.regulations.gov/document?D=EPA-HQ-OAR-2014-0741-0266 (same). In citing these examples, Commenters do not contend that EPA's approach is the most health-protective or that it fully incorporates the extent of current scientific knowledge, as they have repeatedly urged EPA to follow the more conservative and more scientifically up-to-date approach of the NAS Silver Book, as the Agency is well aware from submitted comments and from reviewing that report. *See, e.g.*, NAS, *Science & Decisions: Advancing Risk Assessment* (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment; Nat. Res. Def. Council, *Strengthening Toxic Chemical Risk Assessments to Protect Human Health* (Feb. 2012), https://www.nrdc.org/sites/default/files/strengthening-toxic-chemical-risk-assessments-report.pdf (describing ways EPA needs to strengthen, not weaken, risk assessments based on NAS recommendations). However, refusing to look at IRIS or other health reference values that rely in any way on non-public data as EPA proposes would represent a significant backward step by EPA, away from current science, as well as an about-face from its well-developed scientific policy and current methods which are based on years of evaluation and have gone through extensive peer review by the Science Advisory Board. *See, e.g.*, SAB, *Risk and Technology Review (RTR) Risk Assessment Methodologies* (May 2010) (supporting EPA's approach and urging EPA to take a more protective scientific approach on certain issues).

[54] EPA, *Cement Kilns Risk Assessment*, *supra* n.53, at 23 (citing EPA, 2014a. Table 1); EPA, Table 1: Prioritized Chronic Dose-Response Values for Screening Risk Assessments (June 18, 2018), https://www.epa.gov/sites/production/files/2014-05/documents/table1.pdf.

[55] EPA, *Cement Kilns Risk Assessment*, *supra* n.53, at 23 (The RfC is defined as an "estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The RfD is "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The URE is defined as "the upper-bound excess cancer risk estimated to result from continuous lifetime exposure to an agent at a concentration of 1 µg/m3 in air." The SF is "an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime exposure to an agent. This estimate, [is] usually expressed in units of proportion (of a population) affected per mg/kgday . . .").

[56] EPA, *Air Toxics Risk Assessment Reference Library*, Vol. 1 Tech. Res. Manual, EPA-453-K-04-001A at 3-9 (April 2004), https://www.epa.gov/sites/production/files/2013-08/documents/volume_1_reflibrary.pdf; *id.* at 12-25 ("Dose-response assessments that have achieved full intra-agency consensus are incorporated in the Integrated Risk Information System (IRIS), which is regularly updated and available on-line (www.epa.gov/iris).").

[57] EPA, *Cement Kilns Risk Assessment*, *supra* n.53, at 24.

Each of these recognizes the value of relevant scientific information without regard to whether full underlying data can be or has been publicly disclosed.[58]

Section 7412(a)(11) likewise illustrates the constraints the CAA imposes on limiting consideration of science when establishing cancer risk. This provision defines "carcinogenic effect" as having "the meaning provided by the Administrator under Guidelines for Carcinogenic Risk Assessment as of the date of enactment." 42 U.S.C. § 7412(a)(11). These Guidelines for Carcinogenic Risk Assessment ("Cancer Guidelines"), in turn, direct that EPA shall rely on "established scientific peer review processes," and state that "[t]he cancer guidelines incorporate basic principles and science policies based on evaluation of the currently available information."[59] The Cancer Guidelines also provide that EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens ("Supplemental Guidance") should be considered along with the Guidelines.[60] Both the Cancer Guidelines and Supplemental Guidance cite as relevant and in some instances important some of the very types of scientific studies that EPA's Proposed Rule would categorically exclude: epidemiological studies which rely on private or confidential medical information, or assessments such as IRIS, California Environmental Protection Agency's ("Cal. EPA") assessments, and other health reference concentration information that rely on such studies.[61] The Cancer Guidelines do not preclude the

---

[58] As IRIS values show, IRIS considers relevant and often essential epidemiological evidence for which underlying private confidential or medical information is not released. *See, e.g.*, EPA, *EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments, Vol. 1*, CAS No. 1746-01-06, EPA/600/R-10/038F, at 1-7 (Feb. 2012), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/supdocs/dioxinv1sup.pdf (discussing the use of two human epidemiological studies "as co-critical studies" to derive the reference dose in the IRIS assessment, and the SAB's agreement with EPA that these represent best available science); EPA, *Toxicological Review of Hexavalent Chromium* (Aug. 1998), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0144tr.pdf (relying on human epidemiologic studies); EPA, *Toxicological Review of Formaldehyde-Inhalation Assessment* (June 2010), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=497038 (relying on epidemiologic studies).

[59] EPA, *Guidelines for Carcinogen Risk Assessment* (*hereinafter* "Cancer Guidelines") at 1-2 (Mar. 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[60] EPA, *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, EPA/630/R-03/003F (Mar. 2005), https://www3.epa.gov/airtoxics/childrens_supplement_final.pdf.

[61] For example, the Supplemental Guidance states: "[The] critical data are either human epidemiological data on childhood exposures resulting in adult cancer or research studies with rodents involving early postnatal exposures. The major human data available are from radiation exposures . . . with very limited data available for humans exposed during childhood to chemicals." Suppl. Guidance at 13. The Cancer Guidelines and later EPA policy state that "***[a]ll studies that are considered to be of acceptable quality***, whether yielding positive or null results, or even suggesting protective carcinogenic effects, ***should be considered in assessing the totality of the human evidence***. Conclusions about the overall evidence for carcinogenicity ***from available studies in humans*** should be summarized along with a discussion of uncertainties and gaps in knowledge." Cancer Guidelines, *supra* n.59, at 2-4 (emphasis added). They further provide that "[h]uman data may come from epidemiologic studies or case reports . . . The most common sources of human data for cancer risk assessment are epidemiologic investigations . . .

consideration of any "one kind of data" as relevant, but instead "cover the assessment of available data," explaining that "[i]t is very important that all analyses consider the basic standards of quality, including objectivity, utility, and integrity."[62]

Thus, EPA's Proposal to ignore studies because underlying data is not disclosed is antithetical to the Guidelines upon which EPA relies when determining carcinogenic effects in § 7412(a)(11). The statute's text and incorporation of EPA's science guidelines on cancer risk are unambiguous and leave no gap to fill regarding what "carcinogenic" means. Thus, in regulating carcinogens EPA may not apply the Proposed Rule's exclusion of any relevant health science regarding carcinogens and carcinogenic risk from air pollutants in rulemakings.

Consistent with the reliance on all relevant health science to determine carcinogenic effects, for cancer and other health risks under § 7412(f), EPA has an existing policy of what it describes as using the "the best available science with respect to dose-response information. The recommendations are based on the following sources, in order of priority": (1) EPA IRIS values which have all gone through independent, external peer-review; (2) ATSDR values, which follow an approach similar to EPA's IRIS program; and (3) Cal. EPA values for which "[t]he process for developing these assessments is similar to that used by EPA to develop IRIS values and incorporates significant external scientific peer review."[63] Likewise, for non-cancer health risks from air pollution, EPA's guidelines do not exclude science that is relevant, even if underlying data is not disclosed.[64] Notably, the vast majority of health reference values that EPA uses in § 7412(f) come from EPA's IRIS program, which includes a scientific literature review of all available relevant studies, without excluding any due to a lack of disclosure of underlying data.[65]

Epidemiologic data are extremely valuable in risk assessment because they provide direct evidence on whether a substance is likely to produce cancer in humans, thereby avoiding issues such as: species-to-species inference, extrapolation to exposures relevant to people, effects of concomitant exposures due to lifestyles. Thus, epidemiologic studies typically evaluate agents under more relevant conditions. When human data of high quality and adequate statistical power are available, they are generally preferable over animal data and should be given greater weight in hazard characterization and dose-response assessment, although both can be used." *Id*. at 2-3.

[62] *Id.* at 1-5.

[63] *See, e.g.*, EPA, *Final Residual Risk Assessment for the Petroleum Refining Source Sector* at 15-16 (Sept., 2015), https://www.regulations.gov/document?D=EPA-HQ-OAR-2010-0682-0800.

[64] EPA, *Risk Assessment for Other Effects* (last updated Jan. 31, 2017), https://www.epa.gov/fera/risk-assessment-other-effects. *See also*, EPA, *Guidelines for Mutagenicity Risk Assessment* (1986), http://www2.epa.gov/risk/guidelines-mutagenicity-risk-assessment; EPA. *Guidelines for Developmental Toxicity Risk Assessment* (1991), http://www2.epa.gov/risk/guidelines-developmental-toxicity-risk-assessment; EPA, *Guidelines for Neurotoxicity Risk Assessment* (1998), http://www2.epa.gov/risk/guidelines-neurotoxicity-risk-assessment; EPA, *Guidelines for Reproductive Toxicity Risk Assessment* (1996), http://www2.epa.gov/risk/guidelines-reproductive-toxicity-risk-assessment; EPA et al., *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (1994), http://www2.epa.gov/risk/methods-derivation-inhalation-reference-concentrations-and-application-inhalation-dosimetry.

[65] EPA, IRIS Process for Developing Human Health Assessments (last updated March 7, 2018), https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process.

Fourth, the Proposed Rule is unlawful because EPA is considering costs and is relying on implementation costs as a basis for the Rule, in direct violation of § 7409, § 7412(f)(2), and other provisions of the Clean Air Act where cost is not a relevant or permissible factor in determining health and environmental impacts. *See, e.g.*, 83 Fed. Reg. at 18,768 (indicating that Proposed Rule would apply to "regulations for which the public is likely to bear the cost of compliance"); *see also id*. at 18,774 (proposed § 30.8) (requiring agency to implement the Proposed Rule "in a manner that minimizes costs"). Section 7412(f)(2) prohibits consideration of economic costs in assessing and determining whether the health risks that a major air toxics source causes are "unacceptable," as it requires a determination of what is required to provide an "ample margin of safety to protect the public health." *Nat. Res. Def. Council, Inc.*, 824 F.2d at 1164-65 (quotation marks omitted); Benzene Rule, 54 Fed. Reg. at 38,048-49 (citing Vinyl Chloride decision as prohibiting consideration of costs when determining a "safe" or "acceptable" emission level).[66] Similarly, as EPA explained in the Cancer Guidelines: "Risk assessments may be used to support decisions, but in order to maintain their integrity as decision-making tools, they are not influenced by consideration of the social or economic consequences of regulatory action." Cancer Guidelines, *supra* n.59, at 1-5 to 1-6. It is therefore both unlawful and arbitrary to use cost as a justification to ignore and exclude health science from residual risk air toxics assessments, and thus as part of the determination of whether risk is acceptable or unacceptable, pursuant to § 7412(f)(2).

Fifth, section 7412(n) directs EPA to "perform a study of the hazards to public health reasonably anticipated to occur as a result of emissions by electric utility steam generating units of pollutants listed under subsection (b) after imposition of the requirements of this chapter," and to list such sources "after considering the results of [this] study." 42 U.S.C. § 7412(n)(1). This provision includes no limitation on the data EPA can or must consider for this question, based on EPA's own interpretation. Thus, previously, in fulfilling its duty pursuant to this provision, EPA considered a wide array of scientific studies as relevant, regardless whether underlying data was disclosed.[67] Excluding consideration of relevant scientific material addressing such hazards

---

[66] *See also, e.g.*, NESHAP Proposed Rule, Pulp Mills, 81 Fed. Reg. 97,046, 97,064 (Dec. 30, 2016) (citing Benzene Rule and vinyl chloride decision) ("If risks are unacceptable, the EPA must determine the emissions standards necessary to bring risks to an acceptable level without considering costs."); NESHAP Proposed Rule, Friction Materials Mfg., 83 Fed. Reg. 19,499, 19,502 (May 3, 2018) (same); *see also Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468-71 (2001) (EPA is prohibited from considering costs in adopting national ambient air quality standards under the Clean Air Act rules).

[67] *See, e.g.*, EPA, Supplemental Finding That It Is Appropriate and Necessary To Regulate Hazardous Air Pollutants From Coal- and Oil-Fired Electric Utility Steam Generating Units; Final Rule, 81 Fed. Reg. 24,420, 24,421-23, 24,438, nn.1, 10, 11 (Apr. 25, 2016) (citing peer-reviewed risk assessments on human health effects and additional peer review of the Mercury Risk Assessment as well as evaluation of the non-mercury HAP risk assessment and co-benefits from reductions in PM2.5 and SO2 emissions in the MATS Regulatory Impact Analysis) (U.S. EPA. 2011. *Revised Technical Support Document: National-Scale Assessment of Mercury Risk to Populations with High Consumption of Self-caught Freshwater Fish In Support of the Appropriate and Necessary Finding for Coal- and Oil-Fired Electric Generating Units*. Office of Air Quality Planning and Standards. November. EPA– 452/R–11–009. Docket ID No. EPA-HQ–OAR–2009–0234–19913; U.S. EPA. 2011. *Supplement to Non-mercury Case Study Chronic Inhalation Risk Assessment for the Utility MACT Appropriate and Necessary Analysis*. Office of Air Quality Planning and Standards. November. Docket ID No. EPA–HQ–OAR–2009–0234–19912; U.S.

solely because underlying data is not available would arbitrarily lead to an incomplete assessment of relevant information and flout the statute's preventative and health-protective intent. EPA may not apply the Proposed Rule under this provision, as EPA has already recognized – for example, in acting pursuant to § 7412(n)(1) to reach the determination that it is "appropriate and necessary" to regulate power plants due to their health hazards[68] – but rather must consider the types of studies the Proposed Rule would ignore. EPA cannot depart from its decision to consider such studies relevant without meeting the *State Farm* and *Fox* tests, *see supra* at 23, which it unquestionably has not done here.

In addition, the listing and delisting provisions for HAPs and source categories, and the requirements for the urban air toxics program, require EPA to assess particular and potential health effects and risks from HAPs. *See, e.g.*, 42 U.S.C. § 7412(b)(2)-(3), (c)(9), (k). EPA's Proposal to ignore relevant scientific information due to the lack of public disclosure violates these requirements.

Sixth, CAA § 7429 requires EPA to evaluate health risks and does not allow the exclusion of relevant scientific information. For example:

- § 7429(a)(3) – standards must include new unit siting requirements that, on a site specific basis, minimize potential risks to public health or the environment;

- § 7429(e) requires permits to include site-specific provisions "if the Administrator or the State determines that emissions in the absence of such limitations or measures may reasonably be anticipated to endanger public health or the environment";

- § 7429 (h)(3) requires residual risk review under § 112(f), and § 129(b)(1) requires the inclusion of any residual risk standards in the guidelines for existing units.

Seventh, the Proposed Rule is antithetical to the very purpose of the Clean Air Act, which is "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." 42 U.S.C. § 7401(b)(1). A "primary goal" is "pollution prevention." *Id.* § 7401(c). Each of the above provisions must be read in a way that advances that goal; the Proposed Rule would do the contrary and is thus inconsistent with the statute and unlawful. EPA's Proposal runs directly counter to these goals and objectives by arbitrarily excluding consideration of science that discloses health impacts of air pollution. The Proposal is not neutral. It only excludes health-based science (dose-response studies, epidemiological studies) where underlying data is not disclosed, generally because it cannot or should not be disclosed to protect individual participants' privacy and confidentiality. EPA cannot exclude whole categories of scientific data untethered from a specific context or study, but rather must assess each health study on a case-by-case basis to determine whether or not it should be considered in a particular rulemaking, under EPA's long-standing scientific guidelines and policies and its regular approach in CAA rulemakings. Instead, this Proposed Rule excludes health studies from consideration as a class, up front, before EPA is even in the rulemaking stage

EPA. 2011. *Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards*. EPA–452/R–11–011. Docket ID No. EPA–HQ–OAR–2009–0234–20131.).

[68] 81 Fed. Reg. at 24,422-23.

under its authority. And it does so not for scientific reasons, but simply due to industry preferences – most notably because industry cannot pick them apart by replicating decades of air pollution health effects, or by contacting individuals who shared private medical information to replicate the collection of data.

While the CAA provides for protection of "public health and welfare," the Proposed Rule favors excluding science even if it is the most relevant and important evidence regarding how to protect public health. While the CAA aims for "pollution prevention" to protect public health, the Proposed Rule would prevent consideration of science relevant to these very goals. Therefore, EPA's Proposed Rule is unlawful and arbitrary. Thus, EPA cannot lawfully satisfy § 7429 for similar reasons as described above, unless it evaluates relevant information on risks.

Eighth, a number of **i**mportant CAA provisions require EPA to act based on a finding that air pollution is reasonably anticipated to endanger health or the environment. *See, e.g.*, 42 U.S.C. §§ 7415, 7422, 7521. The D.C. Circuit has ruled that such language "requires a precautionary, forward-looking scientific judgment about the risks of a particular air pollutant, consistent with the CAA's 'precautionary and preventative orientation.'" *Coal. for Responsible Regulation v. EPA*, 684 F.3d 102, 122 (D.C. Cir. 2012) (citation omitted). Such a precautionary approach does not require scientific certainty. "If a statute is 'precautionary in nature' and 'designed to protect public health,' and the relevant evidence is 'difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge,' EPA need not provide 'rigorous step-by-step proof of cause and effect' to support an endangerment finding." *Id*. at 121 (citation omitted). Thus, the court expressly rejected the notion that EPA can or should disregard uncertain or "difficult to come by" evidence under "endangerment" statutes. Indeed, the court rejected the notion that EPA could not rely on studies that synthesized the research of others:

> It makes no difference that much of the scientific evidence in large part consisted of "syntheses" of individual studies and research. Even individual studies and research papers often synthesize past work in an area and then build upon it. This is how science works. EPA is not required to re-prove the existence of the atom every time it approaches a scientific question.

Id. at 120. Thus, in making endangerment determinations, there is no lawful or rational basis for EPA to automatically exclude reliance on any studies that synthesize and evaluate research by others.

The Courts have also rejected EPA's attempts to avoid endangerment determinations based on considerations other than the specific endangerment criteria. In *Massachusetts v. EPA*, the Court held that the endangerment language in section 7521(a)(1) required EPA to assess whether motor vehicle emissions cause or contribute to air pollution which may reasonably be anticipated to endanger public health and welfare due to climate change, and to so determine exclusive of any other policy considerations. *Massachusetts v. EPA*, 549 U.S. 497, 532-34 (2007). Likewise, here, EPA cannot avoid its duty to make endangerment findings by arbitrarily rejecting scientific studies to serve vague and disingenuous policy interests such as allegedly fostering greater public trust and greater transparency in agency decisions.

The Proposed Rule also conflicts with specific language in § 7415 requiring an endangerment finding notification,

> [w]henever the Administrator, upon receipt of reports, surveys or studies from any duly constituted international agency has reason to believe that any air pollutant or pollutants emitted in the United States cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare in a foreign country or whenever the Secretary of State requests him to do so with respect to such pollution which the Secretary of State alleges is of such a nature, the Administrator shall give formal notification thereof to the Governor of the State in which such emissions originate.

42 U.S.C. § 7415(a). This provision does not allow EPA to ignore any such "reports, surveys or studies," if they show "reason to believe" that an air pollutant endangers public health. *Id.*

Similarly, § 7422 directs that EPA "shall review ***all available relevant information***," to determine whether to make an endangerment finding for certain radioactive pollutants (including source material, special nuclear material, and byproduct material), cadmium, arsenic and polycyclic organic matter. 42 U.S.C. § 7422(a) (emphasis added). This language expressly forecloses EPA's refusal to consider available studies based on an arbitrary transparency screen. *See also* 42 U.S.C.§ 7521(a)(1)-(a)(3)(B) (providing for EPA to promulgate revised standards for heavy duty trucks "[o]n the basis of information available to the Administrator concerning the effects of air pollutants emitted from heavy-duty vehicles or engines and from other sources of mobile source related pollutants on the public health and welfare, and taking costs into account").

Finally, the CAA's rulemaking provision for air standards and limitations does not allow EPA to ignore relevant scientific information, including information provided by Commenters, and likewise may not direct a court to ignore this data. Section 7607 of the CAA – which provides for judicial review of air rulemakings – prescribes more detailed rulemaking procedures than those provided by the Administrative Procedure Act for a designated list of air emission standards and rules. 42 U.S.C. § 7607(d)(1). These procedures protect the public's right to notice and comment, in part, by requiring EPA to place into the docket and to consider and respond to all such comments. *Id.* § 7607(d)(4)(B)(i) ("Promptly upon receipt by the agency, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period shall be placed in the docket."); *id.* § 7607(d)(5) ("In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions . . ."); *id.* § 7607(d)(6)(B) ("The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.").

EPA's Proposed Rule contravenes these requirements and is therefore unlawful because it allows EPA to decide, before even receiving comments, that it will not consider or respond through regulatory action to any comments that submit scientific material for which underlying information is not disclosed. Under § 7607(d), EPA may not lawfully decide to ignore an entire class of science; if submitted by commenters as relevant, EPA must consider and respond in the context of the statutory test that applies to its rulemaking. Failure to do so is unlawful and arbitrary. *Id.* § 7607(d)(9).[69]

Relatedly, for certain rules where recommendations are provided from scientific experts, § 7607 requires additional material to be placed into the docket, without EPA discretion. *Id.* § 7607(d)(3) (requiring a "statement" that "shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 7409(d) of this title and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences."). EPA's Proposed Rule unlawfully violates this provision because it would direct EPA to refuse to consider or discuss such information if based on studies for which underlying data were not disclosed.

More generally, EPA may not attempt to restrict, before a rulemaking has even begun, the type of information it will consider in that rulemaking. Doing so impinges on the federal courts' authority to determine what scientific evidence is relevant to application of CAA requirements in rulemakings. Pursuant to § 7607, the relevant court of appeals, and most frequently the D.C. Circuit, has jurisdiction to consider a petition for review of an EPA air rule. 42 U.S.C. § 7607(b). This grant of jurisdiction includes a grant allowing the court to decide what record material is relevant. *Id.*; *see also id.* § 7607(c). Notably, the court rules provide that the record on review of an agency order or regulation must include, *inter alia*, "the pleadings, evidence, and other parts of the proceedings before the agency." D.C. Cir. R. 16 ("If necessary, the court may direct that a supplemental record be prepared and filed."); *see also* Fed. R. App. P. 16. Similarly, the Federal Rules of Evidence require courts, not EPA or any other federal agency, to determine what evidence is "relevant" and "admissible." *See, e.g.*, Fed. R. Evid. 401-402 (allowing courts, and Congress by statute, but not federal agencies, to prescribe rules of evidence and determine admissibility of evidence and expert testimony).[70] Scientific information

[69] Ignoring an entire class of science is also unlawful under the APA – which applies to all EPA rulemaking – as the APA likewise requires notice and comment and requires EPA to respond to all submitted comments. *See* 5 U.S.C. § 553. EPA has also promulgated rules specific to certain statutes that likewise require notice and comment as well as consideration of and responses to those comments by EPA. *See, e.g.*, 40 C.F.R. § 25.3 (rulemaking under the CWA, SDWA, and RCRA require "public participation," including "providing access to the decision-making process, seeking input from and conducting dialogue with the public, assimilating public viewpoints and preferences, and demonstrating that those viewpoints and preferences have been considered by the decision-making official"). Thus, for the same reason the Proposed Rule violates the CAA's rulemaking provision, so too does it violate the APA and a number of other statutes that EPA is responsible for implementing.

[70] "Relevant evidence is admissible unless any of the following provides otherwise: the United States Constitution; a federal statute; these rules; or other rules prescribed by the Supreme Court." Fed. R. Evid. 402. "A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized

submitted by commenters undoubtedly qualifies as "evidence" that the court must consider, even if EPA refuses to do so.[71] EPA may not lawfully prevent submission of such evidence, or attempt to exclude it from a rulemaking record. *Id.*[72]

Where EPA previously attempted to restrict or change the statutory test and authority granted to courts to evaluate CAA cases, the D.C. Circuit rejected that as unlawful and outside of the bounds of EPA's authority. *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1062 (D.C. Cir. 2014) (vacating affirmative defense to civil penalties because it changed the standard set by statute for court's discretion in enforcement cases, and thus violated § 7604 and § 7413). For this reason, too, the Proposed Rule is invalid.

ii. CWA

The Proposed Rule violates the Clean Water Act in two ways: *first*, it runs afoul of its requirement to use all relevant science and the best technology available; and *second*, it undermines its mandate to protect public health. For each of these reasons, the rule cannot stand.

First, pursuant to Section 1251 of the Clean Water Act, the primary objective of the CWA is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a). Toward that end, a fundamental policy underlying the CWA is "to support and aid research relating to the prevention, reduction, and elimination of pollution." *Id*. § 1251(b). The CWA thus promotes the use of good science. The Proposed Rule handicaps EPA from accomplishing these broad goals and objectives by limiting the available science and research.

For example, section 1313(c) of the CWA governs the establishment and modification of water quality standards. Pursuant to this provision, these standards "shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of" the CWA. *Id*. § 1313(c)(2)(A). In setting these standards, EPA must "tak[e] into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation." *Id.* If EPA limits the type of science acceptable for these purposes, it is not fulfilling this obligation of the CWA as it is not using all means to accomplish this requirement.

---

knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *See also, Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

[71] Courts have repeatedly allowed the use of certain health studies as proof of harm from air pollution even though their underlying data are not publicly disclosed. *See, e.g.*, *Battery Recyclers*, 604 F.3d at 623.

[72] Not only does this apply to appeals of decisions under the Clean Air Act, but it also applies more generally to any agency rulemaking decision arising out of any statute under EPA's authority that is appealed to an appellate court where the Federal Rules of Appellate Procedure and Federal Rules of Evidence apply.

Similarly, section 1313(d) requires states to establish "the total maximum daily load" for certain identified pollutants, and it must do so "at a level necessary to implement the applicable water quality standards with seasonal variations and a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality." *Id.* § 1313(d)(1)(C). As with Section 1313(c), if EPA is required to do this without all available science, it is not fulfilling its obligations under this provision.

Not only do the limitations on science undermine the Agency's ability to most effectively fulfill the obligations of the Clean Water Act, but they likewise contradict provisions in the Act that require use of the best technology available. For example, section 1311(p)(1) requires that any modified requirements of effluent limitations in certain permits apply "the best available technology economically achievable." Failure to do so will render the effluent limitations invalid. *See, e.g.*, *Nat. Res. Def. Council v. EPA*, 808 F.3d 556, 564 (2d Cir. 2015). Several other provisions likewise require the use of the best technology to carry out the purpose of the Act. *See, e.g.*, 33 U.S.C. § 1314(b)(1) (regulations establishing or revising effluent limitations must apply "the best practicable control technology currently available" to identify "the degree of effluent reduction attainable"); *id*. § 1314(b)(2)(A) (regulations establishing or revising effluent limitations must apply "the best control measures and practices achievable" to identify "the degree of effluent reduction attainable . . . including treatment techniques, process and procedure innovations, operating methods, and other alternatives for classes and categories of point sources")); *id*. § 1314(b)(4)(A) (regulations establishing or revising effluent limitations must apply "the best conventional pollutant control technology" to identify "the degree of effluent reduction attainable . . . for classes and categories of point sources").

Second, the CWA also contains several additional provisions that demonstrate its overarching goal of protecting the public health. For example, one of the provisions in section 1254 – one of the two sections cited by EPA as authorizing this Proposed Rule – addresses the "collection and dissemination of scientific knowledge on the effects and control of pesticides in water." 33 U.S.C. § 1254(l). Pursuant to this provision, the Administrator is charged with developing and issuing to the States for the purpose of carrying out the CWA "the latest scientific knowledge available in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities," and updating that information "whenever necessary to reflect developing scientific knowledge." *Id*. There are no qualifications or other limiting factors in the type of scientific knowledge that must be considered. Rather, the provision contemplates inclusiveness to most effectively accomplish the CWA's objectives.

Several other provisions likewise address science and research as they relate to the public health goals of the CWA. For example, section 1254a requires the Administrator to "conduct research on the harmful effects on the health and welfare of persons caused by pollutants in water." A provision addressing protection of the Great Lakes states, in part, that "[t]he Administrator may not carry out a project under this paragraph for remediation of contaminated sediments located in an area of concern— (i) if an evaluation of remedial alternatives for the area of concern has not been conducted, including a review of the short-term and long-term effects of

the alternatives on human health and the environment." *See* 33 U.S.C. § 1268(c)(11)(D). Section 1311(g)(2), which addresses requirements for modifications to effluent limitations, requires that such modifications not result in "the discharge of pollutants in quantities which may reasonably be anticipated to pose an unacceptable risk to human health or the environment." And section 1314(a)(9) provides that the Administrator "shall publish new or revised water quality criteria for pathogens and pathogen indicators (including a revised list of testing methods, as appropriate), based on the results of the studies conducted under section 1254(v)," for the purpose of protecting human health in coastal recreation waters, and that at least once every five years, the Administrator must review and if necessary revise the water quality criteria. And EPA has long recognized that the NPDES (§ 402 permit) and fill discharges (§ 404 permit) programs require protection of public health. *See, e.g.*, 33 U.S.C. §§ 1342, 1344 (authorizing EPA to prohibit, withdraw, or veto a discharge that "will have an unacceptable adverse effect on municipal water supplies, shellfish beds and fishery areas . . . wildlife, or recreational areas") and implementing regulations, including Section 404(b)(1) Guidelines (40 C.F.R. Part 230).[73]

Taken together, these provisions demonstrate that the overall focus of the CWA is to promote and protect the public health and water quality in the most comprehensive way possible. Thus, any measure that could limit science or research supporting these objectives is antithetical to the Act. For these reasons, EPA's reliance on the CWA to support its restrictions on science is entirely misplaced.

iii. SDWA

EPA's proposal to exclude reliable, accessible, and relevant science is antithetical to the requirements of the SDWA and thus is unlawful. The SDWA was established to protect the quality of the drinking water in the United States. To accomplish this, the SDWA requires EPA to limit contaminants in public water systems. As discussed *supra*, it does this by establishing a "maximum contaminant level goal" for each contaminant "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 U.S.C. § 300g-1(b)(4)(A). And in deciding whether to regulate any particular contaminant to protect public health, EPA must rely on "the ***best available public health information***." *Id*. § 300g-1(b)(1)(B)(ii)(II) (emphasis added). And to the extent EPA relies on science, it must use "***the best available, peer-reviewed science and supporting studies***" available. *Id*. § 300g-1(b)(3)(A) (emphasis added). Thus, any decision to categorically ignore or otherwise fail to consider relevant scientific information when regulating drinking water would be unlawful under the SWDA.

[73] *See, e.g.*, 40 C.F.R. Part 122 (requiring permits to implement water quality standards and protect public health); 40 C.F.R. § 230.10(c)(1), § 230.11 (prohibiting discharge of dredged or fill material which will cause or contribute to significant degradation of the waters of the United States, which includes: "[s]ignificantly adverse effects of the discharge of pollutants on human health or welfare, including but not limited to effects on municipal water supplies, plankton, fish, shellfish, wildlife, and special aquatic sites."); *see also* § 230.50 (municipal and private water supplies).

iv. CERCLA

Under CERCLA, Congress created a hazardous substance research and classification regime based largely on studies that "determine relationships between exposure to toxic substances and illness"—the very dose response studies that the Proposed Rule would stifle. 42 U.S.C. § 9604(i)(1). The statute requires EPA and ATSDR to annually update a list of hazardous substances commonly found at facilities on the National Priorities List that the agencies determine "pos[e] the most significant potential threat to human health due to their known or suspected toxicity to humans and the potential for human exposure to such substances . . ." *Id.* § 9604(i)(2)(A), (B). EPA must also develop guidelines for ATSDR's toxicological profiles of each listed substance, which must include "available toxicological information and epidemiologic evaluations . . . to ascertain the levels of significant human exposure for the substance and the associated acute, subacute, and chronic health effects." *Id.* § 9604(i)(3)(A). For any substance for which adequate information is unavailable, EPA and ATSDR must create a program of toxicological and epidemiological research to develop that information. *Id.* § 9604(i)(5).

Congress specified that CERCLA health assessments include:

> preliminary assessments of the potential risk to human health posed by individual sites and facilities, based on such factors as the nature and extent of contamination, the existence of potential pathways of human exposure (including ground or surface water contamination, air emissions, and food chain contamination), the size and potential susceptibility of the community within the likely pathways of exposure, the comparison of expected human exposure levels to the short-term and long-term health effects associated with identified hazardous substances and any available recommended exposure or tolerance limits for such hazardous substances, and the comparison of existing morbidity and mortality data on diseases that may be associated with the observed levels of exposure.

42 U.S.C. § 9604(i)(6)(F). And when assessing alternate remedial actions under CERCLA, EPA must "at a minimum, take into account . . . the persistence, toxicity, mobility, and propensity to bioaccumulate of such hazardous substances and their constituents [and] short- and long-term potential for adverse health effects from human exposure." *Id.* § 9621(b)(1).

EPA's Proposed Rule would prevent the Agency from using the very types of health assessments that Congress mandates. It undermines both the letter and spirit of the statute, and is therefore unlawful.

v. EPCRA

The Proposed Rule also violates EPCRA. EPCRA requires EPA to make determinations about whether to list new chemicals in the statute's Toxic Release Inventory program "based on

generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to [EPA]." 42 U.S.C. § 11023(d)(2). Specifically, Congress instructs EPA to add a chemical to the Toxic Release Inventory list when:

> (A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.
>
> (B) The chemical is known to cause or can reasonably be anticipated to cause in humans—
>
> (i) cancer or teratogenic effects, or
>
> (ii) serious or irreversible—
>
> (I) reproductive dysfunctions,
>
> (II) neurological disorders,
>
> (III) heritable genetic mutations, or
>
> (IV) other chronic health effects.
>
> (C) The chemical is known to cause or can reasonably be anticipated to cause, because of—
>
> (i) its toxicity,
>
> (ii) its toxicity and persistence in the environment, or
>
> (iii) its toxicity and tendency to bioaccumulate in the environment,
>
> a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

Id. EPA thus has a mandate from Congress to consider the types of toxicological studies that EPA's Proposed Rule would prevent the Agency from considering. For this reason, the Proposed Rule cannot withstand scrutiny.

vi. FIFRA

Not only does FIFRA not provide authority for the Proposed Rule, but it likewise contains provisions directly at odds with the purpose and effect of the Rule.

Under FIFRA, EPA must register a pesticide (with rare exceptions) before it may be sold or used in the United States. 7 U.S.C. § 136a(a). To register or re-register a pesticide, EPA must

determine that its use "will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(D); *see id.* § 136(bb) (definition of "unreasonable adverse effects"). FIFRA defines "unreasonable adverse effects" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id*. § 136(bb).

EPA requires a company seeking establishment or retention of a pesticide registration to submit data and information to enable EPA to make its unreasonable adverse effects determination. In addition to a standard set of data, EPA can issue data call-in notices requiring additional testing and information. Often, EPA requires the registrant to conduct particular laboratory tests to assess the pesticide's toxicity. As Nancy Beck noted during the drafting of the rule, pesticide regulations require manufacturers to submit to EPA "a huge amount of data," and that the studies come to EPA as Confidential Business Information ("CBI"). *See* Maria Hegstad, "Absent ORD Chief, Trump's Toxics Pick Expands Reach Across EPA Science," *Inside EPA* (May 10, 2018), https://insideepa.com/weekly-focus/absent-ord-chief-trumps-toxics-pick-expands-reach-across-epa-science. The raw data underlying the industry laboratory studies is rarely made available to the public, and the registrants would almost certainly oppose such disclosure on CBI grounds. Nor are such studies typically peer reviewed.

In addition, after a pesticide has been registered, the registrant must provide EPA all factual information regarding the pesticide's unreasonable adverse effects. 7 U.S.C. § 136d(a)(2). Such information comes in a variety of forms – from academic studies, poisoning incident reports, or studies conducted for other regulatory authorities at the state, federal, or international level. Often, the raw data are unavailable.

The Proposed Rule thus conflicts with FIFRA's pesticide registration requirements as it eliminates from consideration important studies used to show the unreasonable adverse effects of the pesticide toxins. As Beck herself acknowledged of an early version of the rule, the directive would "'jeopardize our entire pesticide registration/re-registration process.'" Maria Hegstad, "Absent ORD Chief, Trump's Toxics Pick Expands Reach Across EPA Science," *Inside EPA* (May 10, 2018). Accordingly, the Proposed Rule cannot stand.

vii. TSCA

EPA's proposed refusal to consider or use science relevant to decisions that will affect public health directly contravenes the newly enacted revisions to TSCA. Numerous provisions of TSCA make clear that EPA may not prohibit the consideration of non-public data in regulatory decision-making under TSCA. Indeed, when viewed as a whole, TSCA establishes a comprehensive scheme for how EPA is to evaluate and use science in making regulatory decisions that forecloses the Proposed Rule.

First, TSCA requires EPA to consider all "***reasonably available information***" when making any regulatory decisions under sections 2603, 2604, and 2605. 15 U.S.C. § 2625(k) (emphasis added) (EPA "shall take into consideration information relating to a chemical . . . that

is reasonably available to [the Agency]"); *also id.* § 2605(c)(2)(A).[74] Thus, the statute mandates that if a study is reasonably available to EPA, EPA must consider it when making a significant regulatory decision under these provisions of the statute. Whether the data underlying a scientific study is publicly available has no bearing on whether the study itself is reasonably available to EPA. Because the Proposed Rule purports to apply to all significant regulatory decisions made by EPA under TSCA – including those made under these provisions – it is unlawful.

Second, when making any regulatory decision under sections 2603, 2604, and 2605, TSCA requires EPA to make an individualized evaluation of any information reasonably available to the Agency, and thus, prohibits the blanket ban erected in the Proposed Rule. Section 2625(h) establishes five statutory factors that EPA must consider when "mak[ing] a decision based on science." 15 U.S.C. § 2625(h)(1)-(5). One of these statutory factors expressly addresses situations in which non-public scientific data is before the Agency, and requires the Agency to "consider . . . the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models." *Id.* § 2625(h)(5). In addition, EPA must consider whether the methodologies used to collect the data are "reasonable," *id.* § 2625(h)(1), and the "degree of clarity and completeness" with which the methods used were documented, *id.* § 2625(h)(3). In sum, Section 2625(h) requires EPA to review each scientific study on a case-by-case basis to determine whether and how to use it. This case-by-case evaluation requires EPA to consider the public or non-public nature of the underlying data as one of many factors and prohibits EPA from implementing a blanket ban on the use of non-public data in significant regulatory decisions under TSCA.

Third, the Proposed Rule is at odds with the requirement that EPA act "***consistent with the best available science***." *Id.* § 2625(h) (emphasis added). Although Congress did not define the term in TSCA, it is clear from other statutes that an agency cannot lawfully act consistent with the best available science when it categorically bars consideration of any science based on non-public data. For example, the Endangered Species Act requires federal agencies to consider the "best scientific and commercial data available," *see* 16 U.S.C. § 1536(a)(2), and courts have held that this provision requires an agency to consider "***all*** relevant data . . . even when it is imperfect, weak, and not necessarily dispositive." *League of Wilderness Defenders/Blue Mountains Biodiversity Project v. Connaughton*, 752 F.3d 755, 763-64 (9th Cir. 2014) (emphasis added); *see also Bldg. Indus. Ass'n of Superior Cal. v. Norton*, 247 F.3d 1241, 1246 (D.C. Cir. 2001) (an agency "must utilize the 'best scientific . . . data ***available***,' not the best scientific data ***possible***") (emphasis in original). EPA itself acknowledged that this sort of restriction on

[74] "In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on ***reasonably available information*** with respect to—(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture; (ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture; (iii) the benefits of the chemical substance or mixture for various uses; and (iv) the reasonably ascertainable economic consequences of the rule . . ." 15 U.S.C. § 2605(c)(2)(A) (emphasis added).

science is contrary to the requirements of TSCA; when analyzing the same restrictions proposed in the HONEST Act, EPA recognized:

> Provisions under the newly amended Toxic Substance Control Act (TSCA) . . . would be significantly impacted by the HONEST Act. First, a number of provisions in section 26 could not be upheld under the HONEST Act. Section 26(h) requires the Agency to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with best available science." . . . ***[T]he HONEST Act would not allow EPA to use the best available science***. ***Section 26(i) requires the Agency to use the "weight of scientific evidence" in making decisions under TSCA, and EPA believes this would not be possible given that the provisions of the HONEST Act would prohibit the use of some data***. Finally, section 26(k) requires the Agency to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonable available." EPA would be in violation of the HONEST Act when upholding these provisions under TSCA, namely ***instead of using the best available science and all reasonable available data for chemical regulations, EPA would be restricted to selecting information based on availability***. This approach would introduce research bias that would compromise the quality of the Agency's work.

EPA, EPA Analysis of HONEST Act to CBO at 3-4 (2016), https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO (emphasis added).

Indeed, where Congress has sought to qualify a best available science requirement by implementing a total bar on particular types of science, it has done so expressly. For example, in the Consumer Productive Safety Improvement Act of 2008, Congress directed a panel studying phthalates to use "the most recent, best-available, ***peer-reviewed***, scientific studies." 15 U.S.C. § 2057c(b)(2)(B) (emphasis added). The absence of any such prohibition in TSCA is further proof that the Proposed Rule is prohibited by the statute's best-available-science requirement.

Fourth, the Proposed Rule is inconsistent with the TSCA requirement that EPA make regulatory decisions using a "weight of the scientific evidence" approach. *Id.* § 2625(i). As EPA has itself recognized, this approach requires the Agency to individually evaluate the strengths and weakness of any study reasonably available to the Agency. 40 C.F.R. § 702.33 (defining "weight of scientific evidence" as "comprehensively, objectively, transparently, and consistently, identify[ing] and evaluat[ing] ***each stream of evidence***, including strengths, limitations, and relevance of ***each study*** and [] integrat[ing] evidence as necessary and appropriate based upon strengths, limitations, and relevance" for purposes of risk evaluations under 15 U.S.C. § 2605 (emphasis added)). Thus, the Proposed Rule's outright ban on

consideration of scientific studies that rely on non-public data is prohibited by the weight of the scientific evidence approach required under TSCA.

In sum, these provisions – considered together and in light of other provisions of the statute – establish a comprehensive scheme for how EPA is to consider scientific data, and this scheme prohibits the Proposed Rule's ban on the consideration of non-public data. Together, they require EPA to: consider ***all*** reasonably available scientific information; evaluate each piece of information, including the methods by which it was acquired and analyzed; use each piece of information in a manner consistent with the best available science; and give each piece of information its due weight.

In addition, in deciding whether or not "there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings," EPA must consider "any . . . information available to the Administrator." 15 U.S.C. § 2603(f). And other provisions of TSCA expressly address certain types of non-public data and authorize EPA to consider it in making regulatory decisions. *See* 15 U.S.C. §§ 2604(b), 2613.

In light of the numerous provisions of TSCA addressing the consideration of scientific data, it is evident that if Congress had intended to allow EPA to bar the consideration of non-public data, it surely would have said so expressly. Given the comprehensiveness of these provisions providing otherwise, there is simply no room for a blanket ban on science that relies on non-public data. The Proposed Rule is therefore unlawful.

viii. RCRA

Not only do the provisions of RCRA upon which EPA relies not provide the requisite statutory authority, but other provisions of RCRA render the Proposed Rule unlawful. Specifically, section 8001 of RCRA provides that the Administrator shall conduct or otherwise assist in research, investigations, experiments, and other studies without limitation on what studies or data can be considered. 42 U.S.C. § 6981. The law mandates a broad and inclusionary role for science, requiring EPA to consider studies without limitation. The Proposed Rule's elimination from consideration of entire categories of scientific data conflicts with the requirements of this section of RCRA, and thus cannot stand. *See Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597 (2013).

B. The Limitations on Science Also Contradict Other Environmental Statutes.

Not only does the Proposed Rule contravene the statutes upon which EPA relies as statutory authority, but its limitations on science likewise conflict with core provisions of other environmental statutes. For example, the Food Quality Protection Act ("FQPA"), which regulates pesticide residue in conjunction with FIFRA, sets safety standards based on the consideration of ***all available data***. Limiting the data available to conduct studies necessary to evaluate the harmful effects of pesticides runs counter to this mandate.

Specifically, Congress overhauled our food safety laws when it unanimously passed the FQPA, amending both the Federal Food, Drug, and Cosmetics Act ("FFDCA")[75] and FIFRA. The overhaul responded to a seminal 1993 National Academy of Sciences ("NAS") report criticizing EPA for treating children like "little adults" by failing to address the unique susceptibility of children to pesticide exposures based on the foods they eat, their play, metabolism, and sensitive stages of their development. NAS, *Pesticides in the Diets of Infants and Children* (1993). The NAS recommended that EPA revamp and strengthen its pesticide regulations to account for children's vulnerabilities, consumption patterns, and exposures. Because it would take time to fill gaps in knowledge, safeguards and methodologies, the NAS recommended that additional protection be afforded in the form of "uncertainty" or "safety factors." The NAS first described how EPA has regularly used uncertainty factors and then proposed an additional uncertainty factor for fetal developmental toxicity and where data are incomplete: "In the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children. To validate this presumption, the sensitivity of mature and immature individuals should be studied systematically to expand the current limited data base on relative sensitivity." *Id*.

The FQPA strengthened the food safety standard in several ways. ***First***, under the FQPA, the EPA Administrator "may establish or leave in effect a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(i). In other words, the absence of sufficient information to find a pesticide safe means it cannot be allowed in or on our food.

Second, safe "means the Administrator has determined there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id*. § 346a(b)(2)(A)(ii). The FQPA, therefore, requires that EPA conduct an assessment based on aggregation of all exposures to a pesticide whether from eating foods, drinking water with residues of the pesticide, or uses of the pesticide in and around the home or other places where people can be exposed. 21 U.S.C. § 346a(b)(2)(A)(ii), (C)(i)(I) & (ii). The FQPA also requires EPA to assess and protect against unsafe risks posed by cumulative exposures to pesticides that share a "common mechanism of toxicity," as is the case with pesticides in the organophosphate, carbamate, and pyrethroid families. *See* 21 U.S.C. § 346a(b)(2)(C)-(D).

Third, EPA must make specific safety determinations for infants and children. *Id*. § 346a(b)(2)(C)(ii)(I) & (II). It must consider available information concerning "the special susceptibility of infants and children," including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." *Id*.

[75] Under the FFDCA, EPA must establish the maximum residue of a pesticide allowed on food, called a "tolerance," in order for a pesticide to be permitted on food that is imported or sold in interstate commerce. 21 U.S.C. § 346a(b) & (c). EPA may "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe." *Id*. § 346a(b)(2)(A)(i). If it finds a pesticide residue would not be safe, EPA must revoke a tolerance. *Id*.

§ 346a(b)(2)(C)(i)(II). EPA must also base its tolerance decisions on available information about food "consumption patterns among infants and children." *Id.* § 346a(b)(2)(C)(i)(I) & (III).

Fourth, EPA must account for children's sensitivities, scientific uncertainty, and gaps in available data. The statute requires that "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre -and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." *Id.* § 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.*; *see Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1046 (9th Cir. 2008) (reversing EPA's shrinkage of the safety factor in the absence of supporting data).

As an over-arching mandate, the FQPA directs EPA to make its tolerance determinations based on its assessment of the pesticide's risk. 21 U.S.C. § 346a(b)(2)(C)(i). And throughout its mandates to assess the full effects of a pesticide, the FQPA directs EPA to base its risk assessment on "available information" about consumption patterns, special susceptibility of infants and children, and cumulative effects. *Id.* The FQPA also expressly directs EPA to consider the validity, completeness, and reliability of the available data from studies, the nature of the toxic effect, available information about the relationship between study results and human risk, and available information about aggregate and cumulative effects. *Id.* § 346a(b)(2)(C)(ii).

The Proposed Rule upends these mandates by requiring EPA to put on blinders and ignore a huge and important subset of the available data. It collides squarely with the congressional direction to consider all available data and information in order to protect our food and children in particular. It also conflicts with the congressional mandate to afford greater protection to children and our food when gaps in data prevent a full quantitative assessment and establishment of a dose-response. It thus undermines EPA's ability to carry out its obligations under the FQPA.[76]

C. Administrative Statutes Prohibit the Proposed Prohibitions.

EPA's Proposed Rule likewise ignores requirements set forth in two administrative statutes that govern its rulemaking: the Regulatory Flexibility Act and the Data Quality Act. Under the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq.*, federal agencies must consider the impacts their regulations will have on small entities and must consider less burdensome alternatives. In developing a new regulation, an agency must take one of two actions: certify that a proposed rule will not have a significant economic impact on a substantial number of small

[76] The FQPA also amended FIFRA's "unreasonable adverse effects" definition to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FQPA] standard." 7 U.S.C. § 136(bb)(2). Accordingly, EPA can register or re-register a pesticide only if there is a reasonable certainty of no harm from aggregate and cumulative exposures to the pesticide under the FQPA standard. The FQPA's science standards therefore extend to EPA's FIFRA determinations. Accordingly, just as the Proposed Rule runs afoul of the FQPA's standards, so too does it violate FIFRA's mandates, as amended by the FQPA.

entities, or prepare an initial regulatory flexibility analysis. EPA must publish its initial regulatory flexibility analysis or a summary of it in the Federal Register along with the proposed rule. Here, EPA includes a certification with the Proposed Rule stating that it will not have a significant economic impact on a substantial number of small entities. However, it provides no support for this certification.

Pursuant to the Data Quality Act, also known as the Information Quality Act, Treasury and General Government Appropriation Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515 Appendix C, 114 Stat. 2763A-153 (2000), the Office of Management and Budget ("OMB") issued government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies. . . ." The OMB guidelines directed each federal agency to issue its own information quality guidelines to "ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency." 67 Fed. Reg. 8451, 8459 (Feb. 22, 2002). Following OMB's instructions, EPA issued its own guidelines that apply to information it disseminates to the public. EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, or Information Disseminated by the Environmental Protection Agency* (Oct. 2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf. According to these guidelines, EPA uses a "weight-of-evidence" approach that "considers ***all relevant information*** and its quality, consistent with the level of effort and complexity of detail appropriate to a particular risk assessment." EPA Guidelines 6.4 (emphasis added). The Proposed Rule contravenes these requirements, as it will prevent EPA from considering all relevant information by precluding consideration of certain data.

Moreover, pursuant to EPA's guidelines, EPA must ensure that the information it disseminates "is accurate, reliable and unbiased." EPA Guidelines 6.4(A). To do so, it uses:

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

Id. (emphasis added). Given that the Proposed Rule eliminates from consideration any scientific study where the underlying data cannot be made publicly available, it undoubtedly precludes the use of the best available science in certain situations. Thus, the Proposed Rule is inconsistent with EPA's implementation of the Data Quality Act.

D. The Proposed Rule is Entirely Inconsistent with the Executive Orders Upon Which EPA Relies for Support.

EPA also cites to a number of Executive Orders as support for the Proposed Rule. However, upon examination, it is eminently clear that these orders are wholly inconsistent with the intent and effect of the Proposed Rule. Regardless, Executive Orders cannot lawfully or

constitutionally substitute for statutorily granted authority or contradict statutory requirements; thus, the Executive Orders provide no support or authority for the Proposed Rule.

i. Exec. Order No. 13,777, 82 Fed. Reg. 12,285

EPA asserts that the Proposed Rule is consistent with Executive Order 13,777, 82 Fed. Reg. 12,285 (Mar. 1, 2017), titled "Enforcing the Regulatory Reform Agenda." It is not. This Executive Order establishes a task force to "evaluate existing regulations . . . and make recommendations to the agency head regarding their repeal, replacement, or modification." It thus seeks to ***reduce*** regulation, and in no way authorizes EPA to promulgate new rules.[77]

Additionally, the Proposed Rule is contrary to the stated purpose and policy of Executive Order 13,777, which is to "lower regulatory burdens on the American people by implementing and enforcing regulatory reform." The Proposed Rule will do just the opposite. It will preclude EPA from considering certain data regarding health and environmental impacts of pollutants, contaminants, and other substances in its rulemaking process. The overall impact of such limitations on rulemaking aimed at protecting public health and the environment will be increased burdens on the American people.

ii. Exec. Order No. 13,783, 82 Fed. Reg. 16,093

EPA also asserts that the Proposed Rule is consistent with Executive Order 13,783, 82 Fed. Reg. 16,093 (Mar. 31, 2017), titled "Promoting Energy Independence and Economic Growth." Yet again, EPA is wrong.

In an effort to show the Proposed Rule's consistency with this Executive Order, EPA quotes the following part of the Order: "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics." 83 Fed. Reg. at 18,769, n.5. However, as these Comments reveal, the Proposed Rule contravenes this policy in a number of ways: it fails to comply with a number of statutes and executive orders; the costs of the rule far outweigh the benefits; it will cause substantial and far-reaching harm to public health and the environment; and it has been developed through a process that lacks transparency. *See* Sections II, III, IV, V. Moreover, if implemented, the Proposed Rule will lead to future rulemakings that likewise will be inconsistent with this Executive Order, as it will preclude EPA from considering the best available peer-reviewed science and economics, which in turn will impact the cost-benefit analysis, and may violate notice-and-comment and judicial review procedures. *See* Section V.A. Thus, the Proposed Rule is entirely ***inconsistent*** with Executive Order 13,783.

[77] That EPA would say that the Proposed Rule is consistent with an Executive Order focused on deregulation is tantamount to an admission that the Rule's purpose and effect is to limit the development of rules that are critical to the protection of public health and the environment.

Executive Order 13,783 also provides that greenhouse gas impact estimates should be consistent with guidance in OMB Circular A-4 (Sept. 17, 2003), which specifically requires that this analysis be based on "the best reasonably obtainable scientific, technical, and economic information available." Though the Circular states that, where available, peer-reviewed, transparent, and reproducible studies should be used, it neither requires nor authorizes the preclusion of consideration of scientific studies based on data that cannot be made publically available. Instead, it recognizes that there will be circumstances "[w]here other compelling interests (such as privacy, intellectual property, trade secrets, etc.) prevent the public release of data or key elements of the analysis," and provides in those cases that, rather than precluding the data, the use of "especially rigorous robustness checks to analytic results" should be applied and documented. Accordingly, for this reason too, the Proposed Rule is inconsistent with Executive Order 13,783.

iii. Exec. Order No. 13,563, 76 Fed. Reg. 3821

Executive Order 13,563 states that "[o]ur regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. ***It must be based on the best available science***. . .." 76 Fed. Reg. 3821, 3821 (Jan. 18, 2011) (emphasis added). EPA's reliance on this Executive Order cannot be taken seriously.

While EPA states in the preamble that "[t]he best available science must serve as the foundation of EPA's regulatory actions," 83 Fed. Reg. at 18,769 & n.1, the Proposed Rule undermines this foundational requirement. It has the purpose and effect of precluding the use of some of the best available science, that is, all science based on non-public data, simply because the underlying data is not publicly available. Best available science means "all existing scientific evidence relevant to the decision," and agencies simply "cannot ignore existing data." *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 Serv.*, 380 F.3d 428, 436 (8th Cir. 2004)). Yet the Proposed Rule requires EPA to ignore existing data if it is not available for public release. Therefore, the Proposed Rule is inconsistent with Executive Order 13,563, as well as those statutes or principles that requires EPA to consider the best available science. *See* Section IV.

iv. No Executive Order Can Authorize or Contradict Enacted Statutory Restrictions on EPA's Authority.

EPA cannot lawfully or rationally rely on an executive order to authorize the Proposed Rule, and cannot allow any cited order to influence development of the final rule. As detailed in other parts of these comments, the Clean Air Act and other statutes provide specific requirements for rulemakings with which EPA's Proposal conflicts, and which do not authorize this Proposal.

An executive order cannot override a statute, limit the delegated authority and the legal responsibilities provided to the EPA Administrator by federal law, add factors that are impermissible under the statute, or delay statutorily required agency action. *See, e.g.*, *In re: United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 551 (D.C. Cir. 1999). In addition,

weakening or delaying public health protections based on an executive order would be unconstitutional, violating separation of powers and the requirement to follow duly enacted laws passed by Congress and signed by the President. It would likewise be unlawful, contrary to the public health obligations and rulemaking requirements of EPA's governing statutes. And EPA cannot consider or apply any other executive order in any way in this rulemaking without providing the requisite public notice and opportunity for comment that the Clean Air Act and APA require, as further discussed elsewhere in these comments.[78]

E. The Proposed Rule Violates Public Law 95-622 and the Common Rule for Research Involving Human Subjects.

EPA's Proposed Rule also conflicts with Public Law 95-622 and the interagency regulations on testing of human subjects required by that law. In 1978, Congress created a President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the "Commission") and directed the Commission to study the "protection of human subjects," defined to include the "health, safety, and ***privacy*** of individuals." 42 U.S.C. § 300v–1(b)(2), (f)(2) (emphasis added). This included a study of and issuance of recommendations concerning, among other subjects, procedures and mechanisms "to safeguard the ***privacy*** of human subjects of behavioral and biomedical research, [and] to ensure the ***confidentiality*** of individually identifiable patient records." *Id*. § 300v–1(a)(1)(E), (a)(4) (emphasis added).

In response to this charge, in 1981, the Commission recommended that all federal agencies adopt uniform regulations concerning the protection of human research subjects. *See* 47 Fed. Reg. 13,272 (March 29, 1982). Accordingly, in 1991, EPA and 13 other federal departments and agencies adopted uniform regulations on this issue (the "Common Rule"), *see* 56 Fed. Reg. 28,003 (June 18, 1991), requiring that all research involving human subjects that is "conducted, supported or otherwise subject to regulation by any Federal department or agency" be reviewed and approved by an institutional review board ("IRB"). 40 C.F.R. § 26.101(a). In order to approve research involving human subjects, an IRB must ensure that "there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." *Id*. § 26.111(a)(7).

In particular, the Common Rule prohibits EPA from relying on research that is "deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm . . . or impaired their informed consent." *Id*. §§ 26.1704(b)(2), 26.1705(b). It recognizes that the protection of private information of the subject is central to a subject's ability to provide informed consent. *See generally id*. § 26.116. And the protection of private information is central to the Common Rule more broadly – one of only two situations under which IRBs may waive the requirement to obtain written consent is if the release of the consent form risks linking the subject to the research. *Id*. § 26.117(c)(1).

EPA's Proposed Rule is thus antithetical to the confidentiality requirements of the Common Rule. It would ignore relevant health science absent publication of personal data that is

[78] *See, e.g.*, 42 U.S.C. § 7607(d)(3)-(7), (h).

required to be kept confidential under the Common Rule. To enable EPA to consider their studies in a relevant rulemaking, IRBs would have to make the underlying data publicly available, which would place them at risk of termination of federal funding, termination of ongoing studies, denial of approval for new studies, or disqualification of the IRB or its parent institution. 40 C.F.R. Part 26 subpart O & §§ 26.103, 26.123, 26.1123.

V. EPA FAILED TO FOLLOW PROPER PROCEDURES

A. EPA Failed to Follow the Administrative Procedure Act as Required for Meaningful Public Participation and Judicial Review.

The Administrative Procedure Act ("APA") establishes rulemaking procedures and judicial review requirements for agency rules that EPA has failed to follow here. 5 U.S.C. §§ 553, 706. These requirements – which EPA entirely and unlawfully ignores – are central both to ensure an opportunity for the affected public to comment, and to ensure an adequate record for judicial review. This includes:

- Providing a meaningful opportunity for notice-and-comment;
- Ensuring that the docket contains all documents on which EPA relies;
- Providing additional information regarding what the public is being asked to comment on, and adding details that are missing from the proposal, before taking further comment.

EPA has failed to comply with these mandates, rendering this rulemaking unlawful under the APA, for several reasons.

First, in issuing this Proposed Rule, EPA violated the APA by failing to place in the administrative record all of the documents on which it purports to rely. The preamble to the Proposed Rule cites more than thirty specific documents on which EPA purportedly relies. *See, e.g.*, 83 Fed. Reg. at 18,769-72 & nn.1-2, 4-24. Of the specifically cited and relied upon documents, only about 12 are included in the docket, available at www.regulations.gov, Docket ID: EPA-HQ-OA-2018-0259, as of the date of publication of the Proposed Rule. In addition, EPA provides no support for its proposed conclusion that "EPA believes the benefits of this proposed rule justify the costs." 83 Fed. Reg. at 18,772. Nothing in the record demonstrates what costs or benefits EPA considered to reach this determination, or whether it evaluated at all the harm to public health and to privacy that this Proposed Rule would cause.

Absent the ability to review such documents, the public is deprived of adequate notice or an ability to provide informed comments regarding the Proposal and EPA's rationale for issuing the Proposed Rule. EPA's failure to put the documents on which it relies into the record violates notice-and-comment under the APA and other statutes that supplement such notice requirements. *See, e.g.*, *Am. Radio Relay League v. FCC*, 524 F.3d 227 (D.C. Cir. 2008) (agency may not cherry-pick documents on which it relies for public review; it is a violation of public notice and comment to refuse to put the documents in full on which the agency relied into the record).

Second, failing to place all of the documents on which EPA relies into the record also violates the judicial review provision of the APA by making it impossible for commenters to provide adequate comments or a complete record for judicial review of any final action EPA takes. 5 U.S.C. § 706 ("In making the foregoing determinations, the court shall ***review the whole record*** or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error." (emphasis added)); *Am. Radio Relay League*, 524 F.3d at 242-43 (Tatel, J., concurring) (reiterating importance of the requirement for agency to place unredacted studies into the docket because not doing so "undermines this court's ability to perform the review function APA section 706 demands"); *see also Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971)) ("[R]eview is to be based on the ***full*** administrative record that was before the Secretary ***at the time*** he made his decision." (emphasis in original)).

Not only is EPA's failure to include in the regulatory docket all of the documents upon which it relies a violation of the APA, but it likewise contravenes procedural requirements in Title 28 of the U.S. Code that govern judicial review of agency action. *See, e.g.*, 28 U.S.C. § 2112(b) ("The record to be filed in the court of appeals . . . shall consist of the order sought to be reviewed or enforced, ***the findings or report upon which it is based***, and the pleadings***, evidence***, and proceedings before the agency . . . concerned." (emphasis added)); Fed. R. App. P. 16 ("The record on review or enforcement of an agency order consists of . . . ***any*** findings or report on which it is based." (emphasis added)); *see also* 28 U.S.C. §§ 2071-77 (providing federal courts with authority to establish binding rules of procedure and evidence). Thus, EPA's slipshod creation of the regulatory docket for the Proposed Rule cannot withstand scrutiny under either the APA or the judicial review provisions for Title 28.

Third, EPA has violated the APA (and all statutes that track its notice-and-comment requirements) by failing to provide sufficient specificity regarding the Proposed Rule. Under the APA, notice is only sufficient "'if it affords interested parties a reasonable opportunity to participate in the rulemaking process,' and if the parties have not been 'deprived of the opportunity to present relevant information by lack of notice that the issue was there.'" *WJG Tel. Co., Inc. v. FCC*, 675 F.2d 386, 389 (D.C. Cir. 1982) (citations omitted); *see Fla. Power & Light Co. v. Nuclear Regulatory Comm'n*, 846 F.2d 765, 771 (D.C. Cir. 1988). The Proposed Rule is plagued by a lack of detail as to how EPA will interpret the broad and vague terms it creates, how it will use the Rule in connection with particular rulemakings, and how it will implement the new "independent peer review" and "exemption" provisions, and these shortcomings undermine the sufficiency of the notice provided by the Proposal. For example:

- The new definitions of "dose response data and models," "pivotal regulatory science," "regulatory decisions," "regulatory science," and "research data," in § 30.2 are extremely broad and impermissibly vague. EPA provides no specific examples of what these terms mean or how they will actually be implemented under the long list of statutes implicated by this rule.

- Sections 30.1, 30.2, 30.3 – discussing the purpose of the Proposed Rule, the applicable definitions, and how the Proposed Rule will apply – provide broad requirements for EPA without giving any information regarding how or when EPA will implement them in connection with any given proposed or final rule.

- EPA states in § 30.5 that the Proposal will require EPA to "ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation . . ." Yet EPA provides no indication of what this means, how it will so "ensure," or what it will do if it is not possible to ensure this, among other shortcomings.

- Section 30.6 addresses the "additional requirements" related to the use of dose response data and models underlying "pivotal regulatory science," but it is devoid of details necessary to assure meaningful public review and comment on how, when, or in what way EPA will implement this. It also cites no specific science and gives no indication of how or why EPA is attempting to redefine scientific information on dose response differently than it has done in the past to allow for informed consideration of why EPA is even attempting to address this issue.

- Sections 30.7 and 30.9 describe the "role" of "independent peer review" in the Proposal and permissible "exemptions" under the Rule, yet these descriptions fail to provide the process that will be used to inform the public of when a given document or study impacted by this rule does or does not qualify for an exemption. There is no indication of whether EPA will provide notice or comment, or any steps allowing for public participation, when deciding whether or not to exclude a given study from consideration.

- The preamble to the Proposed Rule is replete with broad (and unsubstantiated) statements regarding limits on EPA's ability to consider and use science in rulemakings, as well as environmental issues EPA envisions being impacted by the Proposed Rule – for example, the NAAQs – but EPA fails to provide any specific information to inform public notice and comment on the purported impact of Proposed Rule. Commenters have done their best in view of this to provide comment on all of the likely harm that EPA's vague and general statements would cause if fully implemented in regulatory language, but they are severely prejudiced due to EPA's refusal to provide specific notice as required by the APA.

In sum, EPA has failed to satisfy the requirements for specific public notice that can assure meaningful comment, falling far short of the fundamental threshold requirements for notice and comment. This shortcoming is fatal to its ability to finalize this Proposed Rule.

In addition, it is especially problematic that EPA's Proposal states that EPA will apply the Proposed Rule to "regulatory decisions" which it defines as "final regulations determined to be 'significant regulatory actions' by [OMB]." 83 Fed. Reg. at 18,773 (proposed § 30.2). Under

this definition, EPA can exclude and ignore science in future rulemakings without specifying where or how it will do so and without providing any public notice or comment in a future rulemaking that would be impacted by this Rule. EPA's attempt to limit the rulemaking process for undefined other rules in this manner is a violation of the APA for all of the reasons described above.

Finally, EPA's APA violations would cause significant harm to Commenters and the public if the Rule were finalized without correcting these problems. The inability to review and attempt to understand the documents on which EPA relies and thus to comment meaningfully and receive effective judicial review cause severe prejudice to the affected public. *See* 5 U.S.C. § 706(2). Even if EPA were to add documents to the docket at a later date, that would not cure this fatal flaw. Given the sweeping scope of this Proposed Rule – which would restrict the consideration and use of important health science in rulemakings which, in turn, would likely lead to a weakening of air, water, waste, chemical, pesticide and other protections – the failure to publish the documents for review for an adequate time period has undermined the public's ability to comment meaningfully, and impermissibly prevented the affected public from being able to seek and receive effective judicial review based on the record.

B. EPA Failed to Follow Procedural Requirements Under FIFRA.

EPA likewise failed to follow the specific procedures required by the Federal Insecticide, Fungicide, and Insecticide Act ("FIFRA") when issuing the Proposed Rule. Specifically, section 25w of FIFRA requires, among other things, that EPA provide a copy of any proposed rule or regulation to the Secretary of Agriculture for review and comment 60 days before a proposed rule is published in the Federal Register. 7 U.S.C. § 136w(a)(2)(A). EPA must then provide the Secretary a copy of the rule EPA intends to publish as a final rule no later than 30 days before publication. *Id*. § 136w(a)(2)(B). EPA must also consult with its own Scientific Advisory Panel in an effort to receive comments from it regarding the impact the proposed rule will have on health and the environment. *Id*. § 136w(d).[79] Such consultation must occur under the same timelines sets forth for consulting with the Secretary of Agriculture. *Id*. § 136w(d)(1). Lastly, before a final rule can take effect, EPA is required to submit the rule to Congress and "the rule or

[79] Indeed, FIFRA sets forth a specific role for its Scientific Advisory Panel, yet EPA entirely ignored them in this process:

> [t]he Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this subchapter. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections.

7 U.S.C. § 136w(d)(1).

regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted." *Id.* § 136w(a)(4).

Thus, FIFRA sets forth a clear process in which EPA must consult with a number of entities, including both the U.S. Department of Agriculture and a Scientific Advisory Panel when issuing rules impacting pesticides. *See, e.g.*, *Nat'l Coal. Against the Misuse of Pesticides v. EPA*, 867 F.2d 636 (D.C. Cir. 1989) (noting that "FIFRA generally requires the Administrator [of EPA] to consult with the Secretary of Agriculture . . . and a seven member Scientific Advisory Panel (on environmental health questions) prior to making public any notice of intent to cancel," in context of pesticide registration cancellation). Yet it is indisputable that EPA utterly failed to take these necessary steps. For this reason, too, EPA's Proposal cannot stand.

C. EPA Failed to Follow the Procedural Requirements Under TSCA.

Pursuant to section 2609 of TSCA, prior to promulgating any rules, EPA must "consult[] and cooperate[] with the Secretary of Health and Human Services and with other heads of appropriate departments and agencies." 15 U.S.C. § 2609(a); *see also id.* § 2609(b)(2)(A), (c), (d), (e), (g). Therefore, to the extent EPA relies on TSCA as authority for the Proposed Rule, it must consult and cooperate with the Secretary of Health and Human Services. Yet nowhere in the Proposed Rule does EPA indicate that it has done so. Failure to comply with this requirement would render any final rule unlawful. *See* 5 U.S.C. § 706(2)(D) (a reviewing court "shall . . . hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law").

D. EPA Failed to Follow the Procedural Requirements Under the CAA.

EPA's Proposal is also deficient because it fails to follow particular procedural requirements under the CAA that are legally required for EPA to issue certain types of rules. Specifically, the CAA requires that the Clean Air Scientific Advisory Committee ("CASAC") complete a review of air quality criteria and the NAAQS every five years. 42 U.S.C. § 7409(d)(2)(B). Because the Proposed Rule aims to "preclude [the Agency] from using [non-public] data in future regulatory actions," it would impact the CASAC's review of air quality criteria. 83 Fed. Reg. at 18,769, n.3. Accordingly, EPA was required to follow the path prescribed by the CAA – including submission of the proposed rule to CASAC for review, allowing CASAC to provide recommendations to the Administrator, and then requiring the Administrator to include a statement regarding the recommendations made by CASAC in the Proposed Rule. 42 U.S.C. §§ 7409(d)(2)(B), 7607(d)(3); *see also* 42 U.S.C. § 7607(b), (d). Yet, there can be no dispute that none of these steps were taken before issuance of the Proposed Rule.

E. EPA Failed to Perform the Analysis Required by EO 12,898.

EPA's Proposed Rule also violates the environmental justice requirements of Executive Order 12,898, 59 Fed. Reg. 7629 (Feb. 16, 1994). By its own admission, EPA entirely ignored its obligation to assess the environmental justice impact of this rule prior to issuing the Proposal, dismissively stating – without any justification – that "this action is not subject to Executive Order 12,898 (59 Fed. Reg. 7629, February 16, 1994) because it does not establish an

environmental health or safety standard." 83 Fed. Reg. at 18,773. EPA's rationale is inconsistent with the Order, contrary to EPA's own environmental justice plan, inconsistent with EPA's prior positions and practices, and results in the very harms the Order is designed to protect against.

First, by its own terms, and despite EPA's mischaracterization, Executive Order 12,898 applies to more than just "standards." Indeed, the Order applies to all agency "programs, policies, and activities." *See, e.g.*, 59 Fed. Reg. at 7629 (agencies must make "achieving environmental justice part of its mission by identifying and addressing as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations"). Toward that end, when promulgating rules "that substantially affect human health or the environment" – which this Proposed Rule indisputably does – EPA must ensure that the rule does not have a disproportionate impact on minorities, and it must "provide minority populations and low-income populations the opportunity to comment on the development and design of research strategies undertaken pursuant to this order." *Id*. at 7631. EPA's novel and unsupported interpretation is wholly untethered from both the spirit and the text of the Order.

Second, EPA's limiting interpretation ignores EPA's own environmental justice plan – promulgated pursuant to Executive Order 12,898 – the ultimate vision of which is for EPA to "integrate[] environmental justice into everything" it does. EJ2020 Action Agenda at iii. To accomplish this vision, EPA sets forth eight different priority areas, the first of which is "rulemaking." *Id*. Specifically, EPA aims to "institutionalize environmental justice in rulemaking," including performance of "rigorous assessments of environmental justice analyses in rules," in order to "deepen environmental justice practice within EPA programs to improve the health and environment of overburdened communities." *Id*. Recognizing that "[r]ulemaking is an important function used by the EPA to protect human health and the environment for all communities," EPA devotes the second chapter of the plan to "Rulemaking," and through this chapter, aims to "ensure environmental justice is appropriately analyzed, considered, and addressed in EPA rules with potential environmental justice concerns, to the extent practicable and supported by relevant information and law." *Id*. at 13. Consistent with its environmental justice plan and with Executive Order 12,898, EPA issued its own *Guidance on Considering Environmental Justice During the Development of Regulatory Actions*, recognizing how "vital" it is "that Agency rule-writers identify and address potentially disproportionate environmental and public health impacts experienced by minority populations, low-income populations, and/or indigenous peoples," *Guidance* at 1 (May 2015), https://www.epa.gov/sites/production/files/2015-06/documents/considering-ej-in-rulemaking-guide-final.pdf, as well as a *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis*. *Technical Guidance* (June 2016), https://www.epa.gov/sites/production/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf. Thus, EPA has regularly and purposefully focused on the need for environmental justice assessments of its rulemakings. EPA's blithe claim that this Proposed Rule does not require an environmental justice assessment is clearly at odds with what the Agency itself recognizes it must do to comply both with Executive Order 12,898, as well as its own policies.

Third, EPA's failure to perform an environmental justice impact analysis is entirely inconsistent with EPA's regular practice. Indeed, EPA consistently performs this sort of assessment when acting under the CAA, CWA, and other statutes.[80] This information unquestionably has been relevant to public health rulemakings in the past. EPA's refusal to consider the environmental justice consequences of the Proposed Rule – consequences that are certainly "relevant" under *State Farm* – and its departure from its long-standing pattern and practice of considering such data without a reasoned explanation for changing course are therefore arbitrary and capricious.

Fourth, and as discussed more fully below, *see infra* Section VIII, EPA's Proposed Rule will result in the very kind of disproportionate impact on low-income and minority communities that the Executive Order was designed to protect against. As EPA itself recognizes, minority, low-income, and tribal communities "may face greater risks" to public health and the environment "because of proximity to a contaminated sites or because fewer resources are available to avoid exposure to pollution." *Envtl. Justice FY2017 Progress Report* at 8, https://www.epa.gov/sites/production/files/2018-04/documents/usepa_fy17_environmental_justice_progress_report.pdf. Examples include disproportionate exposure to lead, particulate matter, and other hazardous air pollutants. *See, e.g.*, *id.* at 8 ("reduction in lead exposure has not been realized equally across the United States and it remains a top childhood environmental health problem, disproportionately impacting minority and/or low-income populations"); *id.* at 9 ("[l]ow-income populations are among the populations that are most at-risk for adverse health effects from exposure to [particulate matter]"). Indeed, study after study has confirmed that communities of color and economically disadvantaged communities are disproportionately located near toxic waste and other sources of pollution, and that these communities disproportionately suffer adverse public health and environmental impacts.[81] It is also the case that these discrete communities are frequently the

---

[80] *See, e.g.*, 78 Fed. Reg. 3086, 3267 (2013) (describing the goal of Executive Order 12,898 and EPA's actions to comply with these goals, noting that it "conducted an outreach and information call with environmental justice organizations" and "identified potential disproportionately high and adverse effects on minority and/or low-income populations related to PM2.5 exposures," and "identified persons from lower socioeconomic strata as an at-risk population for PM-related health effects," and noting that "the EPA has carefully evaluated the potential impacts on low-income and minority populations. . . ."); *see also* EC/R Inc., *Risk and Technology Review - Final Analysis of Socio-Economic Factors for Populations Living Near Secondary Lead Smelting Facilities*, prepared by EC/R Inc. for EPA (Dec. 2011), http://earthjustice.org/sites/default/files/Leadsmeltersocioeconomicanalysis.pdf; EC/R Inc., *Risk and Technology Review - Analysis of Socio-Economic Factors for Populations Living Near Petroleum Refineries*, prepared by EC/R Inc. for EPA (Jan. 2014).

[81] These studies include, but are not limited to: Mohai, P. et al., *Racial and Socioeconomic Disparities in Residential Proximity to Polluting Industrial;* Zwickl, K. et al., *Regional Variation in Environmental Inequality: Industrial air toxics exposure in U.S. Cities*, Political Economy Research Institute Working Paper Series No. 342 at 20 (Feb. 2014); Cal. EPA, OEHHA, *Cumulative Impacts: Building a Scientific Foundation* at 5-17 (Dec. 2010), http://oehha.ca.gov/media/downloads/calenviroscreen/report/cireport123110.pdf (citing numerous research studies showing that exposure to pollution-emitting facilities, hazardous waste facilities and disposal, toxic releases, non-attainment air areas, high motor vehicle air pollution areas, and other types

subjects of epidemiological studies that measure the health impacts of environmental and public health programs. Indeed, EPA previously recognized the importance of "strengthen[ing] the foundational link between EPA science and the needs of underserved and overburdened communities, in areas of air, water, land, health disparities, and in tribal science grants." *2017 Progress Report* at 6. Yet now, with no explanation or need, EPA does an about-face and attempts to destroy this link. EPA's Proposal to eliminate reliance on epidemiological health studies will thus have the effect of excluding critical and available evidence of adverse harms particular to these discrete groups, thereby removing from consideration the very science that has historically led to much-needed protections for the most vulnerable communities.

In sum, EPA was required under Executive Order 12,898 – as well as its own environmental justice plan and guidance – to conduct an assessment of the environmental justice impact of the Proposed Rule, but admittedly failed to so do. Its blatant (and acknowledged) failure to comply with its obligations is yet another reason why the Proposed Rule cannot stand.

VI. THE PROPOSED RULE IS ARBITRARY

Not only is EPA's Proposed Rule unlawful both substantively and procedurally, but it is also impermissibly arbitrary. Indeed, the Proposed Rule is the epitome of arbitrary rulemaking: in crafting the rule, EPA

> relie[s] on factors which Congress has not intended it to consider, entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

State Farm, 463 U.S. at 43 (defining "arbitrary and capricious" agency action). EPA wholly fails to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). To the contrary, as described below, EPA has mischaracterized its prior policy, relied on authorities that undermine its reasoning and conclusions, failed to adequately account for the Proposed Rule's costs and benefits, granted itself unfettered discretion to decide whether and how the Rule will apply, and created an unjustified inequity between what science can be used to support a decision *not* to

---

of pollution is more likely to be concentrated in communities with higher minority and lower income populations); Boyce, J.K. et al., *Measuring environmental inequality*, Political Economy Research Institute Working Paper Series No. 409 at 14-16 (Dec. 2015); Hicken, M.T. et al., *A novel look at racial health disparities: the interaction between social disadvantage and environmental health*, 102:12 Am. J. of Pub. Health 2344, 2346-47 (Dec. 2012); Vipputuri, S. et al., *Blood lead level is associated with elevated blood pressure in blacks*, 41:3 Hypertension 463, 464-65 (Mar. 2003); deFur, P.L. et al., *Vulnerability as a Function of Individual and Group Resources in Cumulative Risk Assessment*, 115:5 Envtl. Health Persp. 817, 820-21 (2007).

regulate dangerous chemicals as compared to what can be used to support a decision to regulate. For all of these reasons, the Proposed Rule cannot stand.

A. The Proposed Rule Conflicts with Existing Government Policies and EPA's Prior Positions, and EPA Has Not Adequately Explained this Inconsistency.

Although each new administration has some authority to change course, changes "cannot be solely a matter of political winds and currents." *N.C. Growers Ass'n v. United Farm Workers*, 702 F.3d 755, 772 (4th Cir. 2012) (Wilkinson, J. concurring). Instead, an agency must at least "display awareness that it ***is*** changing position" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. at 515. If the new policy "rests upon factual findings that contradict those which underlay its prior policy[] or when [the] prior policy has engendered serious reliance interests that must be taken into account," the agency must provide "a reasoned explanation . . . for disregarding those facts and circumstances." *Id.* at 516; *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) ("An unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." (internal quotation marks omitted) (quoting *Nat'l Cable & Tele. Commc'ns Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005))). Without "some fidelity to law and legal process, . . . government becomes a matter of the whim and caprice of the bureaucracy." *N.C. Growers Ass'n*, 702 F.3d at 772.

In stark contrast to these principles, EPA has done an about-face here, proposing a rule contrary to prior policy and based entirely on partisan politics and bureaucratic impulse. Though EPA asserts that the Rule "builds upon prior EPA actions in response to government wide data access and sharing policies," and corrects the Agency's failure to "consistently follow[] previous EPA policy (*e.g.*, EPA's Scientific Integrity Guidance . . .) that encouraged the use of non-proprietary data and models," 83 Fed. Reg. at 18,770, n.13, this is entirely untrue. Rather, as the prior policies and actions identified in the Proposed Rule demonstrate – and as summarized above (*see, e.g.*, Section IV.A (CAA)) – EPA has long been committed to sound science, including reliance on the best available science regardless of the nonpublic nature of the underlying data. For example, EPA's Scientific Integrity Policy states that the dissemination of scientific information should be "uncompromised by political and other interference" and expressly "[p]rohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions." EPA, *U.S. Environmental Protection Agency Scientific Integrity Policy* at 4–5 (Feb. 2012), https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf. The Proposed Rule clearly contravenes this policy.

The Proposed Rule is also inconsistent with EPA's Plan to Increase Access to Results of EPA-Funded Scientific Research. This Plan acknowledges that "[f]ederal agencies have a responsibility to protect confidentiality and personal privacy" and cautions that "some research data cannot be made fully available to the public but instead may need to be made available in more limited ways, e.g., establishing data use agreements with researchers that respect necessary

protections." EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* at 4 (Nov. 29, 2016), https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research. The Plan expressly concludes 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.***" *Id.* at 4–5 (emphasis added); *see also* OMB, 67 Fed. Reg., 8452, 8456 (Feb. 22, 2002) (explaining that "the reproducibility standard does not apply to all original and supporting data disseminated by agencies" and, in any case, "[e]ven in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard"). EPA's Proposal to exclude reliable science based solely on consideration of whether the underlying data is fully available to the public is a complete reversal in position from its own prior Plan, with no legitimate explanation for the change.

Equally problematic, the Proposed Rule is entirely inconsistent with prior positions EPA has taken on this very issue. Most notably, in March 2017 – just one year before issuance of this Proposed Rule – EPA responded to questions from Congress on the proposed HONEST Act of 2017, and took a position that is squarely at odds with the Proposed Rule. *See* EPA, *CBO Questions for EPA Regarding H.R. xxxx, The HONEST Act of 2017* at 1 (2017), https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO ("HONEST Act Q&A"). For example, in noting its opposition to the HONEST Act, EPA stated:

> EPA supports access to data and is already on a path to make data public and transparent. EPA will do this at no additional cost to the taxpayer. EPA will do this while protecting [Personally Identifiable Information] and CBI. EPA will do this while preserving its ability to use the best available science. And EPA will do this while retaining its ability to respond quickly to emergency events. EPA strongly opposes the HONEST Act because it does none of these things and ***will significantly impede EPA's ability to protect the health and the environment of Americans***.

Id. at 4 (emphasis added). The Agency further explained that:

> The HONEST Act would not protect [Personally Identifiable Information] and CBI, and this would strongly discourage industry and academia from working with EPA. Many scientists, including those from the private sector, would not be willing to provide their data because EPA could not guarantee to protect their information, such as their trade secrets, intellectual property, or their study participants' medical records. Scientific research is a competitive field, and it is likely that not all investigators from the private sector, or academia, will be willing to make their underlying data available – at least not immediately. ***In some instances, EPA might be***

> ***precluded from using the best available science if the underlying data is not made available or is embargoed for a period of time***. Therefore, in accordance with the HONEST Act, EPA could not use these studies to help protect health and the environment. ***This would impede EPA's ability to use the best available science, because it is presumptively not the best available science if you cannot access all the science.***

Id. at 2-3 (emphasis added). It further explained that limiting science in the way proposed by the HONEST Act – and thus as proposed in the Proposed Rule –

> would mean that ***EPA would be unable to develop policies, guidance or regulations using the best available science***. Instead of using the best-available research for their assessments, EPA would be restricted to selecting studies based on their data availability. This approach would introduce potential research bias that could compromise the quality of the agency's work.

Id. at 4-5 (emphasis added). EPA recognized that the HONEST Act would restrict the use of reliable science, noting that the proposed legislation

> ***would certainly limit access to the majority of studies currently in the peer reviewed literature***. It's not just the number of studies but the type of studies and the integration of the results of these different types of studies with that inform the underlying scientific basis of EPA's decisions. The most informative studies include large comprehensive datasets, such as epidemiology studies, and animal toxicology studies from the open scientific literature, generally do not have all necessary information available on publication. With no new resources, the number of studies that EPA would be able to draw from would be greatly reduced **– *EPA roughly estimates it could be reduced by approximately 95% given the stated data-availability requirements and processes in this bill.*** And for industry-sponsored data submitted for pesticide registration, little to no data may be publicly available prior to a new registration . . ..
>
> Few peer-reviewed studies published in scientific journals meet the requirements described in this bill. Therefore, EPA roughly estimates that less than perhaps 5% would have all of the information publicly available to independently confirm the study details as required under this bill.

Id. at 6 (emphasis added).

EPA's current stance on the category of health studies it now seeks to ban is likewise an about-face from the position it took in 2011 in response to a request by CropLife America for

EPA to establish "firm criteria for quality assessment of epidemiological studies to be used in risk assessment." In response to CropLife America's effort – which, like EPA's Proposed Rule, was allegedly aimed at increasing transparency in the rulemaking process – EPA emphasized its view that mandating requirements around science would stifle scientific development and would be antithetical to the need to weigh various considerations when resolving science questions.[82] Specifically, EPA stated:

> EPA's general practice is to address issues through non-binding guidance documents rather than by mandatory regulations. There are several reasons for this approach. First, and probably most important, ***science questions usually cannot be reduced to a rigid decisional framework; rather science questions invariably involve the weighing of multiple considerations and the use of scientific judgment.*** As the SAP report on EPA's Draft Framework noted in its recommendations on criteria to be used in EPA decision-making: "Inevitably, it will be necessary to exercise some degree of scientific judgment in this assessment." Second, encasing science decision-making in a rigid rule structure is inconsistent with the fluid and developing nature of science. Thus, ***EPA is concerned that writing science decision-making rules will stultify or freeze the science underlying the rule making scientific advances less likely***. Finally, the nature of science issues is not easily compatible with the timeframes associated with formal rulemaking. Given the extended time often required to promulgate or amend a rule, the science underlying science-based criteria may well have significantly advanced between the time of the proposal and the time of the final rule. EPA may then be forced into restarting the rulemaking process or may end up being locked into outdated science decision-making until a rule can be amended. There are numerous examples of EPA appropriately addressing important science questions through guidance, not rules, at both the Agency and the program-specific (pesticide) level.
>
> [CropLife America] has offered no compelling reason to follow a different course with regard to epidemiological data. Epidemiological data are no more "important" to pesticide risk assessments than many other data or inputs or science-related issues. . . . [T]here are many ways to insure a transparent process for science decision-making guidelines other than through rulemaking. Finally, ***there is nothing unique about***

[82] Letter from Steven P. Bradbury, Director, Office of Pesticide Programs, EPA, to Dr. Wendelyn Jones, CropLife America, *re: Petition for Rulemaking To Establish Criteria For Acceptance Of Epidemiological Evidence Into the Pesticide Risk Assessment Process for Human Health Effects* at 2 (April 15, 2011) (attached).

> ***epidemiological data that would indicate that EPA could not craft non-binding guidelines for incorporating epidemiological data in risk assessments***, including non-binding guidance on specific criteria to be considered in weighing the value of particular epidemiological data.
>
> EPA agrees that transparency is a critical part of its science decision making. Our decisions on important policies and guidance documents always follow a transparent process with numerous opportunities for public comment.[83]

And as discussed *supra*, Section IV.A, EPA's position contradicts the stance it took when setting the Particulate Matter NAAQS in 1997, where it noted that "[i]t 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." 62 Fed. Reg. 38,652, 38,689 (July 18, 1997). EPA now ignores what it acknowledged before, namely that "[i]f 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***." *Id*. (emphasis added).

In the current rulemaking, EPA seems to have conveniently forgotten these prior inconsistent positions. Instead, EPA implausibly characterizes the Proposed Rule as a mere extension of existing policies, ignores its prior positions on landmark scientific studies, and contradicts its approach to considering science in the rulemaking process. EPA fails to demonstrate any awareness that it is dramatically changing course with respect to the use and consideration of scientific information, and fails to provide an adequate reason for the change. The Proposed Rule is arbitrary and capricious as a result.

B. The Proposed Rule is Based on Irrational, Unsupported Conclusions.

Not only is the Proposed Rule a drastic departure from EPA's prior policies, positions, and procedures, but it likewise is predicated on irrational and unsupported conclusions. Indeed, a close examination of generally applicable data access policies and guidelines – including policies and recommendations of third party organizations and major scientific journals upon which EPA allegedly relies – reveals that EPA's Proposed Rule is not based on a reasoned explanation and has no rational connection to facts in the record, but rather is entirely baseless.

1. EPA's Proposal is inconsistent with generally applicable data access policies and guidelines.

According to EPA, "[t]he proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science" and "the policies recently adopted by some major scientific journals, spurred in some part by the 'replication crisis.'" 83 Fed. Reg. at 18,770. However, a review of the websites of these organizations and

[83] *Id*. at 2-3 (emphasis added).

journals, and statements made by journal editors regarding the Proposed Rule, indicate that the policies and guidelines on which EPA allegedly relies do not provide any support. Instead, they are wholly inconsistent with what EPA is attempting to do with this Rule.

i. EPA's Proposal is inconsistent with policies and recommendations of third party organizations upon which it relies.

Though EPA cites "the policies or recommendations of third party organizations who advocated for open science" as support for the Proposed Rule, 83 Fed. Reg. at 18,770, many of the policies and recommendations do nothing of the sort. Instead, they acknowledge that: there are numerous barriers to the disclosure of data, such as requirements to protect personal privacy; disclosure of data necessarily varies among scientific fields based on these barriers; flexibility in data access policies and guidelines is essential; and the best available science is inclusive and not exclusive in nature. EPA's Proposal to exclude studies solely because the studies include nonpublic data contradicts these principles.

For example, the Administrative Conference of the United States ("ACUS") Science in the Administrative Process Project, which EPA listed, recommends that agencies take a flexible approach to data disclosure: "To the extent practicable and in compliance with applicable legal restrictions, privileges, protections, and authorities, agencies should seek to provide disclosure of data underlying scientific research[.]" 78 Fed. Reg. 41,352, 41,358 (July 10, 2013). This recommendation thus states only that agencies should "seek to provide disclosure" of data "to the extent practicable" and acknowledges that many legitimate barriers to disclosure of data may exist. *Id*. Furthermore, ACUS contemplates scenarios where "data are not subject to legal or other protections" but where "the data's owners nonetheless will not provide such access." *Id*. In these cases, ACUS does not recommend that agencies deprive themselves of data. Rather, ACUS writes, "agencies should note [that the data's owner did not provide access] and explain why they used the results if they chose to do so." *Id*. Thus, the ACUS's policy in no way supports exclusion of studies simply because the underlying data is not publicly available.

The Bipartisan Policy Center's ("BPC") Science for Policy Project, another organization upon which EPA relies, emphasizes similar flexibility. Rather than rejecting science when the underlying data have not been made public, the BPC encourages online publication of methods and data but notes that "[t]he extent to which data and methods should be made public will vary by field[.]"[84] In fact, in its comments requesting an extension of the deadline for filing comments in this rulemaking, BPC expressly states that it

> never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available. Indeed, the panel's overarching recommendation for assembling the "best available science" reads: "Agencies and their scientific advisory committees should ***cast a wide net*** (emphasis added) in reviewing studies relevant to regulatory policy, and

[84] BPC, *Improving the Use of Science in Regulatory Policy* at 46 (2009), http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf.

> should make their methods for filtering and evaluating those studies more transparent."[85]

Its policies in no way support the exclusion of relevant science.

The Center for Open Science likewise does not advocate for excluding science merely because the underlying data is not public, but rather counsels flexibility in determining what level of transparency is appropriate for a given study. Its Transparency and Openness Promotion ("TOP") Guidelines for journals[86] "recognize[] that not all of the standards are applicable to all journals or all disciplines. Therefore, rather than advocating for a single set of guidelines, the TOP Committee defined three levels for each standard."[87] These levels "provide flexibility for adoption depending on disciplinary variation."[88] The Center for Open Science has invited journals to "suggest revisions that improve the guidelines or make them more flexible or adaptable for the needs of particular subdisciplines."[89] Like the other organizations upon which EPA relies, it too has adopted a flexible approach to transparency and thus provides no support for EPA's rigid exclusion.

EPA also cites "policies and recommendations from . . . members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology[.]" 83 Fed. Reg. at 18,770, n.10. In reality, these "policies and recommendations" are merely responses to an online questionnaire by a limited number of members of the three societies.[90] A report on the questionnaire's methodology and results acknowledged extremely low response rates ranging from 23 to 27 percent across the three groups surveyed.[91] Furthermore, the report stated that nearly two-thirds of people who responded to the survey worked in industry or were consultants who may perform work for industry clients.[92] No more than 13 percent of respondents were based in academia.[93] If the survey attempted to ascertain any potential conflicts of interest among industry and consultant respondents, such results were not included in the report. EPA should not rely on a limited set of responses to an online poll, especially when the Agency does not possess information about conflicts of interest among respondents.

---

[85] BPC, *Bipartisan Policy Center comments on "Strengthening Transparency in Regulatory Science"*, Docket ID No. EPA-HQ-OA-2018-0259-0670 (May 22, 2018), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0670.

[86] Center for Open Science, TOP Guidelines, https://cos.io/our-services/top-guidelines (accessed July 2, 2018).

[87] Nosek B.A. et al., *Promoting an open research culture*, Science, 348, 1422-1425, 1423-1424 (2015).

[88] Center for Open Science, TOP Guidelines, https://cos.io/our-services/top-guidelines (accessed July 2, 2018).

[89] Nosek B.A. et al., *Promoting an open research culture*, Science, 348, 1422-1425, 1423-1424 (2015).

[90] *See* Center for Media and Public Affairs and Center for Health and Risk Communication at George Mason University, *Expert Opinion on Regulatory Risk Assessment* (Dec. 6, 2013), http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf.

[91] *Id*. at 5.

[92] *Id*. at 6.

[93] The report states that "13 percent [were] based in academia or non-profit organizations." *Id*.

ii. EPA's Proposal is inconsistent with policies adopted by major scientific journals.

As additional support for its ill-advised rule, EPA claims that "policies recently adopted by some major academic journals" informed the data access guidelines and policies that EPA allegedly considered as it developed the Proposed Rule. 83 Fed. Reg. at 18,770. In particular, it cites "related policies from the *Proceedings of the National Academy of Sciences*, *PLOS ONE*, *Science*, and *Nature*." *Id.* But EPA provides no information as to how these journals' policies supposedly informed the data access guidelines and policies. Despite this lack of transparency by EPA, one thing is clear: the Proposed Rule is decidedly inconsistent with the policies these journals have adopted, as stated by the journals themselves.

Indeed, a joint statement by the editors of *Proceedings of the National Academy of Sciences* (*PNAS*), *PLOS*, *Science*, *Nature*, and *Cell* indicates that their journals follow the TOP Guidelines and provide necessary flexibility in how data are shared. The editors write that the TOP Guidelines "recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; ***in not every case can all data be fully shared***."[94] The editors cite "data sets featuring personal identifiers" as an important example of "data that cannot be shared openly with all."[95] Ultimately, the editors conclude that the Proposed Rule would jeopardize the development of science-based policies:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. ***Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes***.[96]

EPA's reliance on these journals' policies is thus sorely misplaced.

iii. EPA has not shown the existence of a replication crisis or its potential relevance to dose-response data and models.

EPA also premises the Proposed Rule on a so-called "replication crisis." It claims – with no support – that the policies of major scientific journals that purportedly informed the development of the Proposed Rule were "spurred in some part by the 'replication crisis.'" 83 Fed. Reg. at 18,770. This alleged crisis is a complete fabrication. The term "replication crisis" does not occur in any of the sources cited by EPA in support of this clause. *Id*. at 18,770, n.12.

---

[94] Jeremy Berg et al., "Joint statement on EPA proposed rule and public availability of data," *Science* (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116 (emphasis added).
[95] *Id*.
[96] *Id.* (emphasis added).

Indeed, the word "crisis" only appears in one of the sources, which refers to a "reproducibility crisis" and then notes that it is "debatable" whether this term is appropriate.[97]

Nonetheless, EPA asserts without support that such a crisis exists and implies that its existence supports imposing the rigid requirements of the Proposed Rule. This is untrue. While there are discussions within certain scientific fields, such as clinical psychology, about inconsistent results that have been obtained when experiments conducted in those fields are repeated,[98] EPA has not explained why these discussions should cast doubt on the dose-response data or models used by the Agency. In support of the "replication crisis" clause, EPA provides web addresses to three commentaries authored by Dr. John Ioannidis of Stanford University,[99] an editorial in the journal *Science*,[100] and an editorial by *The Economist* newspaper.[101] 83 Fed. Reg. at 18,770, n.12. EPA does not explain why any of the observations made in these commentaries or editorials are relevant to dose-response data and models. Perhaps that is because they are not.

In fact, the authors cited by EPA have sharply criticized the Proposed Rule. Dr. Ioannidis wrote, "If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim."[102] *Science* editorialized, "Here, a push for transparency appears actually to be a mechanism for suppressing important scientific evidence in policy-making, thereby threatening the public's well-being."[103] *The Economist* has described the proposal as part of "a campaign to stifle science at the EPA."[104] As they put it, "[a]ir-quality rules and pesticide limits rely on analyses of confidential medical records—which Mr Pruitt may now label suspect and try to undo."[105] Once again, EPA's cited support undermine, rather than support, the Proposed Rule.

2. <u>There is no evidence that the benefits justify the costs much less a rational finding of that; instead, available evidence shows the opposite.</u>

In the preamble to the Proposed Rule, EPA states – with no evidence or justification – that "the benefits of this proposed rule justify the costs." 83 Fed. Reg. at 18,772. This conclusory statement is the very definition of arbitrary and capricious. *State Farm*, 463 U.S. at 42-43. EPA provides no evidence of what it considered to reach this statement, much less why

---

[97] Munafò M.R. et al., *A manifesto for reproducible science*, Nature Human Behavior 1, 1 (2017).
[98] *See, e.g.*, Open Science Collaboration, *Estimating the reproducibility of psychological science*, Science, 349, aac4716 (2015).
[99] Munafò M.R. et al., *A manifesto for reproducible science*, Nature Human Behavior 1, 1 (2017); Goodman S.N. et al., *What does research reproducibility mean?*, Science Translational Medicine 8, 1-6 (2016); Ioannidis J.P.A., *Why Most Published Research Findings Are False*, PLoS Medicine 2, e124 (2005).
[100] McNutt M., *Reproducibility*, Science 490, 229 (2012).
[101] "How science goes wrong," *The Economist* (2013).
[102] Ioannidis J.P.A., *All science should inform policy and regulation*, PLOS Medicine 15 at 2 (2018).
[103] Berg J., *Obfuscating with transparency*, Science 360, 133 (2018).
[104] "Scott Pruitt embarks on a campaign to stifle science at the EPA," *The Economist* (Apr. 26 2018), https://www.economist.com/united-states/2018/04/26/scott-pruitt-embarks-on-a-campaign-to-stifle-science-at-the-epa.
[105] *Id*.

its conclusion is rational. Indeed, EPA provides no information at all about what the "benefits" or "costs" of the Proposed Rule are, or what it evaluated to reach its conclusion. There is simply nothing in the record to support EPA's conclusory statement.

Despite the lack of evidence in the regulatory docket, as these and other comments make clear, the costs of this Proposed Rule are far-reaching and substantial, while EPA has failed to identify any alleged benefits at all, other than vague and unsupported references to improved transparency. EPA's Proposal to undermine, exclude, and ignore important and relevant health science in rulemaking proceedings will have serious implications on public health, privacy, the environment, and the judicial review process, and thus the costs will be significant. EPA cannot ignore these harms in its cost-benefit analysis,[106] even if the costs are not readily quantifiable. *See, e.g.*, *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (costs include "harms that regulation might do to human health or the environment"); Executive Order 12,866, 58 Fed. Reg. 51,735, 51,735 (Oct. 4, 1993) (it is "essential to consider" the "qualitative measures of costs and benefits that are difficult to quantify"); *see also* Food Labeling: Nutrition Labeling of Standard Menu Items in restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. 20,825, 20,828 (May 4, 2017) (acknowledging that delaying a nutrition labeling requirement would lead to millions of dollars in lost health benefits). Yet there is no evidence that EPA evaluated any of these adverse impacts, quantitatively or qualitatively.[107] Moreover, EPA itself estimated that the economic cost of this type of restriction on science would cost "considerably more" than $250 million.[108]

In addition, in performing certain CAA and other rulemakings, EPA may not consider the economic implications of considering or excluding certain science ***at all***. *See* Section IV.A. Yet

---

[106] Not only does EPA provide no support for its claim that the benefits justify the costs for this Proposed Rule, but it likewise failed to follow the procedures ordinarily used to obtain confirmation of its cost-benefit analysis. In fact, EPA entirely sidestepped the procedures set forth in Executive Order 12,866 pursuant to which the Office of Information and Regulatory Affairs reviews regulatory actions to ensure the Agency's analysis of costs and benefits is accurate, to provide time for interagency review and stakeholder meetings, and to provide the agency with any necessary changes to the proposed rule. For this Proposed Rule, OIRA completed its review ***only four days after receiving it***. And these four days fell over the weekend, meaning that OIRA spent roughly two working days reviewing a rule that will have significant and far-reaching consequences across multiple statutes.

[107] Indeed, in a recent report on rulemakings related to health – the very type of rulemakings most impacted by the Proposed Rule – EPA and OMB quantified some of the benefits of various regulations that would be dramatically weakened under the new rule. *See, e.g.*, OMB, *2017 Draft Report to Congress on the Benefits and Costs of Federal Regulations*, https://www.whitehouse.gov/wp-content/uploads/2017/12/draft_2017_cost_benefit_report.pdf; EPA, *Benefits & Costs of the Clean Air Act from 1990 to 2020, the Second Prospective Study* (Apr. 2011), https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act-1990-2020-second-prospective-study, https://www.epa.gov/sites/production/files/2015-07/documents/fullreport_rev_a.pdf. These recent studies show health rulemakings, particularly air rulemakings, create significant benefits (including health and protection of life, reductions in the need for health care and health care costs, as well as job creation, and other economic values in avoiding days lost at work and school) that are quantitatively larger and more qualitatively valuable than the costs of pollution controls or other economic costs of the regulations.

[108] EPA, *CBO Questions for EPA Regarding H.R. xxxx, the HONEST Act of 2017* at 1, 2, 8, 10 (2017), https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO.

EPA's failure to provide any lawful or rational justification for its costs/benefits statement for the Proposed Rule suggests that economic cost may have impermissibly played a role in its analysis. Had EPA focused on health rather than cost, EPA could not possibly find that the benefits of ignoring health science outweigh the costs for public health rulemakings.

C. Section 30.9 Allows Standardless and Arbitrary Application of the Rule.

The Proposed Rule is arbitrary and capricious because its standardless provisions give EPA unfettered discretion in deciding whether and how the Rule applies. It has long been held that regulations must contain "narrow, objective, and definite standards to guide the [decisionmaking] authority,' . . . thereby to guard against the danger of arbitrary action." *United States v. Abney*, 534 F.2d 984, 986 (D.C. Cir. 1976) (quoting *Shuttlesworth v. City of Birmingham, Ala.*, 394 U.S. 147, 149 (1969)). "When administrators provide a framework for principled decision-making" by "articulat[ing] the standards and principles that govern their discretionary decisions in as much detail as possible," "the result will be to . . . enhanc[e] the integrity of the administrative process." *Envtl. Def. Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 598 (D.C. Cir. 1971). But where a regulation is "wholly silent as to what factors the agency is to consider in granting exceptions . . . [a]gency discretion is unfettered," and the regulation is "arbitrary, capricious and contrary to law." *Nat. Res. Def. Council, Inc. v. EPA*, 863 F.2d 1420, 1432 (9th Cir. 1988).

EPA's Proposed Rule lacks the requisite standards and principles that are the hallmark of lawful agency decision-making. The vague definitions proposed in 40 C.F.R. § 30.2 invite limitless agency discretion to decide when the Rule's requirements apply. For example, the Proposed Rule defines "regulatory science" as "scientific information . . . that provide the basis for EPA final significant regulatory decisions." 83 Fed. Reg. at 18,773. But this definition lacks any discernible meaning. There is no standard or definition for determining when scientific information does or does not "provide the basis" for a regulatory decision, nor are there any standards or definitions for what subset of "regulatory decisions" should be deemed "significant." Likewise, the Proposed Rule defines "pivotal regulatory science" as studies that "drive the requirements and/or quantitative analysis" of EPA's action, *id.*, but this too lacks any understandable meaning. There is no standard governing what science does or does not "drive" the regulatory action. The lack of regulatory standards here means that EPA staff will impermissibly determine applicability of the rule "based upon their own unwritten personal standards." *White v. Roughton*, 530 F.2d 750, 754 (7th Cir. 1976).

In contrast to the definitions of proposed section 30.2 – which lack any meaning or standards at all – proposed section 30.9 provides a veritable grab bag of reasons the Administrator may use in his discretion to decide when not to apply the Rule. It allows the Administrator to grant a case-by-case exemption to the Rule's requirements if the Administrator determines it is not "feasible" to ensure that data may be made publicly available "in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." 83 Fed. Reg. at 18,774. It also authorizes the Administrator to exempt application of the Rule if it is not "feasible" to conduct peer review for the multiple reasons outlined in OMB

guidance. *Id*. Here, the many vague and discretionary "exception[s] . . . threaten[] to swallow the rule," *Nat. Res. Def. Council, Inc.*, 863 F.2d at 1432, empowering the Administrator to pick and choose the preferred scientific studies he wants considered or excluded from consideration in any given rulemaking procedure with no clear standards or principles to keep this discretion in check.

Proposed sections 30.2 and 30.9 thus give EPA unfettered discretion to be a case-by-case arbiter of scientific information, without notice-and-comment, any oversight, or any stated standards or principles limiting this discretion. These provisions allow for arbitrary application of the Rule, rendering the Proposed Rule arbitrary and thus unlawful.

D. The Proposed Rule Impermissibly Favors So-Called "Secret Science" That Supports a Decision *Not* to Regulate a Chemical While Disfavoring Public Health Research that Supports a Decision to Regulate a Chemical.

Under the terms of the Proposed Rule, EPA must ensure that underlying data is publicly available only "[w]hen promulgating significant regulatory actions." 83 Fed. Reg. at 18,773 (proposed to be codified as 40 C.F.R. § 30.5). But as defined in the Proposed Rule, a significant regulatory action refers only to the ***promulgatio****n* of a new rule or regulation.[109] Accordingly, as written, the Proposed Rule arguably allows EPA to utilize non-public studies or studies that rely on non-public data to justify a decision not to regulate at all. This creates a lopsided and inequitable playing field whereby EPA can rely upon studies that it prohibits others to use when it decides not to issue a new regulation.

An example highlights the dangerousness of this inequity. Under TSCA, many provisions involve go/no-go decisions about whether to promulgate regulations at all. Thus, upon consideration of whether to regulate a chemical, EPA could arguably utilize non-public studies or studies that rely on non-public data to justify a decision not to regulate. For example, EPA could use non-public data to justify a finding that a chemical does not pose an unreasonable risk to health or the environment under Section 2605 and thus does not require regulation. Pursuant to the definitions in the Proposed Rule, such a decision does not qualify as a significant regulatory action, because a finding of no unreasonable risk does not trigger any new rule or regulation. By contrast, EPA would not be able to rely on non-public studies or studies that rely on non-public data to justify a decision to regulate a chemical.

The Proposed Rule thus creates a regulatory regime in which EPA ***can*** consider science based on non-public data if it shows that a chemical is not harmful (or minimizes the harmful

[109] In the Proposed Rule, a significant regulatory action means "final regulations determined to be 'significant regulatory actions' by the Office of Management and Budget pursuant to Executive Order 12866." 83 Fed. Reg. at 18,773 (proposed to be codified as 40 C.F.R. § 30.2). In turn, Executive Order 12,866 defines a significant regulatory action, in relevant part, as "any regulatory action that is ***likely to result in a rule*** that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency . . ." Exec. Order 12,866, 58 Fed. Reg. 51,735 (emphasis added).

effects of a chemical) and supports not regulating the chemical, but ***cannot*** consider science that shows that a chemical has harmful effects if it is similarly based on non-public data but supports a decision to regulate the chemical. EPA has not, and indeed cannot, provide any explanation or basis for this differential treatment. For this reason, too, the Proposed Rule is arbitrary and capricious and cannot stand.

Equally problematic, the Proposed Rule could lead to absurd results. For example, when determining whether a chemical poses an unreasonable risk of harm under TSCA, EPA has to consider all relevant scientific studies. If EPA finds that a chemical poses an unreasonable risk and that it must issue a regulation on that basis, the Proposed Rule mandates exclusion of studies based on non-public data from consideration, even if those same studies provide the basis for the unreasonable risk finding. Absent these particular studies, the remaining research may show no unreasonable risk of harm, obviating the need for regulation, and in turn, eliminating the Proposed Rule's requirement that EPA not consider the excluded studies. Instead, when determining no unreasonable risk of harm, EPA ***must*** consider the excluded studies because such a finding does not result in a significant regulatory action and thus the Proposed Rule's ban on non-public data would not apply. But because the excluded study demonstrates that the chemical ***is*** unreasonably risky, EPA could not go forward with an unreasonable-risk determination. This could create an endless cycle of review and re-review with certain studies included, then excluded, and then included again, ***ad infinitum***. In such situations, application of the Proposed Rule creates a catch-22 in which EPA cannot make ***any*** determination that complies with both the APA's requirement of reasoned decision-making and the requirements of the Proposed Rule.

These flaws would plague any decision made under any provision of the statute in which EPA is required to choose between issuing or not issuing a regulation and, therefore, renders the Proposed Rule arbitrary and capricious. *See e.g.* 15 U.S.C. § 2603(a) (EPA must require testing if it finds that a chemical "may present an unreasonable risk").

E. EPA Has Failed to Show Any Need or Reasoned Basis for the Proposed Rule.

EPA's stated justifications for the Proposed Rule consist of vague platitudes such as a purported desire to strengthen the transparency and integrity of EPA regulatory science and to enhance the public's ability to understand and meaningfully participate in the regulatory process. 83 Fed. Reg. at 18,769. Yet the Proposal does not show how or why EPA's existing practices fail to adequately achieve these purposes, or how the proposed new procedures would do a better job. In reality, EPA's historic practices in adopting health and welfare standards are extraordinarily transparent, public, and accessible to interested persons.

By way of example, EPA's NAAQS process begins with preparation of an Integrated Science Assessment ("ISA"), an extensive review of available science relevant to the development of NAAQS. *See* EPA, *Integrated Science Assessment for Ozone and Related Photochemical Oxidants*, EPA 600/R-10/076F, at 1i-1ii (Feb. 2013). Preparation of the ISA is preceded by a public workshop and call for information. *Id.* EPA collects and screens studies (with a heavy focus on studies that have been peer reviewed), prepares an initial characterization of evidence, and then provides a peer review process of the initial draft materials for scientific

quality of "building blocks" from scientists from both outside and within EPA. *Id*. at 1vii. There is then preparation of draft syntheses of the studies and draft conclusions and causal determinations, followed by CASAC input and an opportunity for public comment before preparation of the final ISA. After that, EPA staff prepares a Policy Assessment ("PA") based on integration and interpretation of the findings of the ISA and a separate risk and exposure assessment ("REA"). Both the PA and REA are themselves subject to separate rounds of public comment. And there is yet another round of public comment after EPA proposes its action on the NAAQS. *Id*.

All of the foregoing comprises one of the most open, publicly accessible processes ever devised for the development of health standards. There are multiple layers of peer review and more than ample opportunity for the public to raise questions about the adequacy and accuracy of the studies and models presented. EPA does not and cannot rationally explain why this system requires yet another layer of complexity to provide adequate transparency, integrity, and public understanding of the process.

EPA's process for revising ambient water criteria for the protection of human health provides another example of the transparency afforded to its rulemaking, as it provides open access to information for interested persons. In 1998, EPA "improved" this process "to provide expanded opportunities for public input, and to make the process more efficient." 63 Fed. Reg. 68,354, 68,355 (Dec. 10, 1998). To revise its ambient water criteria, EPA must follow a multi-step process. *First*, EPA must "undertake a comprehensive review of available data and information" before developing draft criteria. *Id*. *Second*, EPA must "publish a notice in the Federal Register and on the Internet announcing its assessment . . . of the pollutant" which "describe[s] the data available to the Agency," and solicits "scientific views as to the application of the relevant Agency methodology." *Id*. *Third*, EPA must "utilize information obtained from both the Agency's literature review and [from] the public [comments] to develop draft recommended water quality criteria." *Id*. *Fourth*, and concurrent with the development of the draft criteria, EPA must publish in the Federal Register a notice soliciting the public's "scientific views on the draft criteria," and must "initiate . . . a documented critical review by qualified independent experts." *Id*. *Fifth*, EPA must then evaluate and respond on the record to all "[m]ajor scientific issues" (if any) raised during the peer review or public comment period. *Id.* *Finally*, EPA must "revise the draft criteria as necessary, and announce the availability of the final water quality criteria in the Federal Register and on the Internet." *Id*. Like the NAAQS process, this process too is fully open and transparent.

Moreover, it would be irrational and impracticable to require EPA to seek out the underlying data for, and demand separate peer review of, all data and models the Agency uses for purposes of characterizing the quantitative relationship between dose or exposure and magnitude of a predicted health or environmental impact. For instance, in the last ozone NAAQS review, EPA reviewed more than 4,000 studies and references for the ISA, and cited more than 2,200 in the final ISA. *See* EPA, Health and Environmental Research Online, ISA-Ozone (2013) (last updated July 2, 2018), https://hero.epa.gov/hero/index.cfm/project/page/project_id/1628. It is neither practicable nor

necessary for EPA to demand production of underlying data from thousands or even hundreds of studies, and to require new peer reviews of each. EPA cannot construe the statute in a way that would render it impossible to complete the review and revision of the NAAQS that Congress mandated.

EPA further tries to justify the Proposed Rule as a way to ensure the Agency is not arbitrary and capricious in its conclusions. But as previously noted, the D.C. Circuit has twice rejected the notion that EPA must obtain and disclose data underlying the studies it relies on in NAAQS development.

VII. OTHER PROVISIONS OF THE RULE ARE UNLAWFUL

A. EPA's Requirement in Proposed 30.6 to Give Explicit Consideration to Studies that Explore Threshold Models Is Arbitrary.

EPA's Proposed Rule requires the Agency to "give explicit consideration to high quality studies that explore . . . various threshold models across the dose or exposure range[.]" 83 Fed. Reg. at 18,774 (proposed 40 CFR § 30.6). A "threshold" is a dose or exposure "below which effects do not occur or are extremely unlikely."[110] A "threshold model" – a type of "non-linear" model[111] – is a dose-response model in which there is no response below the threshold dose or exposure.[112] EPA's proposed prioritization of threshold models is arbitrary, for at least three reasons.

First, EPA provides no evidence to justify the proposed requirement that it consider threshold models in dose-response assessments. EPA baldly asserts that "there is growing empirical evidence of non-linearity [*i.e.*, a threshold[113]] in the concentration-response function for specific pollutants and health effects[,]" but provides not a single example or citation for this unsubstantiated claim.[114] *Id*. at 18,770. By contrast, EPA has found strong empirical evidence of no-threshold concentration-response functions for lead and reduced IQ, and particulate matter and increased mortality, following extensive reviews of the relevant literature to inform the

[110] National Research Council, *Science and Decisions: Advancing Risk Assessment* at 128 (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.
[111] EPA uses the terms "threshold" and "nonlinear" repeatedly but does not define them in the Proposed Rule. According to EPA Risk Assessment Guidelines, "the term 'nonlinear' refers to threshold models (which show no response over a range of low doses that include zero) and some nonthreshold models[.]" EPA, *Guidelines for Carcinogen Risk Assessment* at 1-11, n.3 (2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.
[112] A threshold model "show[s] no response over a range of low doses that include zero[.]" *Id*.
[113] EPA appears to use the terms "non-linearity" and "threshold" interchangeably. If so, then EPA has asserted that there is growing evidence of thresholds in unspecified concentration-response functions but has failed to provide a supporting example or citation. If not, then EPA has not even asserted that there is growing evidence of such thresholds and has failed to state, let alone support, any scientific rationale for the proposed requirement to give explicit consideration to studies that explore threshold models.
[114] A "concentration-response function" is a dose-response model in which the "dose" is the concentration of an air pollutant.

Agency's national ambient air quality standards.[115] EPA's failure to provide any support for its claim is telling.

Second, the proposed requirement to consider threshold models ignores essential science, namely the approach to dose-response assessment recommended by the NAS in *Science and Decisions: Advancing Risk Assessment*. Historically, researchers applied no-threshold dose-response models to carcinogens and threshold models to non-carcinogens.[116] But in *Science and Decisions*, NAS determined that, due to the variability in susceptibility and exposures to other chemicals (background exposures) within populations, the effects of non-carcinogens may lack thresholds in ***populations*** even when these effects have thresholds in certain ***individuals*** who are less susceptible and/or have lower background exposures.[117] In other words, thresholds vary by individual; for some, effects have high thresholds, while for others, effects have practically no threshold due to increased susceptibility or background exposures,[118] and this latter group may develop disease when a population is exposed, even at very low levels.[119] Based on these findings, NAS concluded that no-threshold models should be applied to ***both*** carcinogens and non-carcinogens unless reliable data affirmatively support a threshold model based on detailed assessments of mode of action (how a chemical causes disease), susceptibility, and background exposures.[120] EPA's Proposed Rule entirely ignores *Science and Decisions*, its recommended approach to dose-response assessment, and the need for a detailed assessment before concluding that a threshold model is appropriate.

The "explicit consideration" of "studies that explore . . . various threshold models" required under the Proposed Rule does not qualify as a "detailed assessment" of the type recommended by NAS. While NAS recommends consideration of the available data on mode of action, susceptibility, and background exposure ***before*** deciding whether dose-response models are appropriate,[121] the Proposed Rule requires consideration of threshold models regardless of this data. EPA provides no justification for ignoring NAS' researched approach to dose-response data.

Third, EPA's proposed requirement also disregards the Agency's own Guidelines for Carcinogen Risk Assessment, which expressly state that, in cancer risk assessments, no threshold should be assumed unless the mode of action is known and the chemical does not cause cancer

---

[115] EPA, *Integrated Science Assessment for Lead* at lxxxviii (2013), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=518908 ("[T]here is no evidence of a threshold below which there are no harmful effects on cognition from [lead] exposure."). EPA, *Integrated Science Assessment for Particulate Matter* at 2-25 (Dec. 2009), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=494959 ("Overall, the studies evaluated further support the use of a no-threshold log-linear model[.]").

[116] NAS, *Science and Decisions*, *supra* n.110, at 127-128.

[117] *Id*. at 131.

[118] *See id*.

[119] *See id*.

[120] *See id*. at 148.

[121] *Id*. The sequence of steps recommended by NAS, including the assessment of mode of action, susceptibility of vulnerable populations, and background exposure *before* model selection is depicted by Figure 5-8. *Id*. at 144.

by inducing DNA mutations that initiate tumor development.[122] Like *Science and Decisions*, the Cancer Guidelines state that it is necessary to assess mode of action to determine whether a threshold or no-threshold model is appropriate.[123] EPA has historically followed this approach to ensure that its cancer risk assessments are adequately health-protective.[124] The Proposed Rule breaks from this prior practice and instead disregards science that the Cancer Guidelines say should be considered. EPA's reversal of longstanding policy is unjustified and arbitrary, and should not be permitted.

B. The Requirement in Proposed 30.7 that EPA Independently Peer-Review All Pivotal Regulatory Science Used to Make Regulatory Decisions is Arbitrary.

As part of the Proposed Rule, EPA injects a new requirement – without justification – that EPA "conduct independent peer review on all ***pivotal regulatory science*** used to justify ***regulatory decisions*** consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein." 83 Fed. Reg. at 18,774. Once again, a review of the support upon which EPA relies demonstrates that this peer review obligation is contrary to current policy. It is also unnecessary, costly, and unrealistic. It seems the only things this new peer review process would accomplish is the exclusion of reliable science, increased cost and time for effective reviews, and delay of regulatory decisions that impact public health.

1. Independent Peer Review by EPA Is Unnecessary.

There is no dispute that independent peer review plays a pivotal role in the regulatory development process, subjecting original research methods and outcomes to a panel of experts in the same field.[125] Independent peer review "is a process for enhancing a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis".[126] Peer reviewers are individuals with technical expertise in the area of the work or product under review. Independent peer review processes eliminate issues arising due to conflicts of interest between the reviewer and the developers of the product/scientific work.[127] When conducted properly, independent peer review provides validation for original research and ensures that basic scientific integrity practices are employed to aid decision makers

---

[122] Specifically, the Guidelines say that a linear model is used as a default approach unless these conditions apply. *See* EPA, *Guidelines for Carcinogen Risk Assessment*, *supra* n.111, at 3-21. A linear model, known more fully as a low-dose-linear model, is a model "whose slope is greater than zero at a dose of zero[,]" which implies no threshold. *Id*. at 1-11, n.3.

[123] *Id* at 3-21.

[124] *Id*.

[125] *See, e.g.*, Bruce P. Dancik, *Importance of Peer Review*, The Serials Librarian 19:3-4, 91-94 (1991), https://www.tandfonline.com/doi/pdf/10.1300/J123v19n03_11; Frank Gannon, *The essential role of peer review*, EMBO Rep. 2(9): 743 (Sept. 2001), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1084042/; *see also* NAS, *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices* (2000), http://www.nap.edu/catalog/9882.html.

[126] *Id.*

[127] EPA, *EPA Science Policy Council HANDBOOK – Peer Review – 2nd Edition*.

in making sound policy decisions. OMB's Final Information Quality Bulletin for Peer Review ("OMB Bulletin") confirms these principles: "Peer review can increase the quality and credibility of the scientific information generated across the federal government."[128] Overall, it is well understood that peer review is an essential element of the regulatory process.

While it is certainly a best practice to consider only science that has been independently peer reviewed when making regulatory decisions, that does not necessitate independent peer review ***by EPA***. Rather, most scientific bodies – including *Nature, Science*, the Bipartisan Policy Center, and *Proceedings of the National Academies of Sciences* – employ some of the most robust peer review practices that they already apply to the types of studies for which the Proposed Rule will require EPA review. Thus, as the OMB Bulletin recognizes, "[p]ublication in a refereed scientific journal may mean that adequate peer review has been performed."[129] Thus, additional review by EPA is duplicative and wholly unnecessary.

More importantly, EPA's Proposal is antithetical to the science communities' policies. Rather than strengthening science, the independent peer review process would serve to exclude reliable and tested science that has been foundational to protecting public health and the environment. Indeed, despite EPA's reliance on the policies of several major scientific journals, the Editors-in-Chief of *Science, Nature, Proceedings of the National Academy of Sciences*, and several other highly revered scientific journals and members of the scientific community released a joint statement in response to the Proposed Rule, making clear that the Rule itself "does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which concludes ever more rigorous features, inform the landscape of decision making."[130] The joint statement concludes: "[e]xcluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."[131]

2. <u>EPA's Independent Peer Review Requirement Will Lead to Unnecessary Delay and Increased Costs.</u>

Not only is independent peer review by EPA unnecessary, but it is also impractical and irrational for EPA to conduct its own independent peer review of the underlying data for studies that already have undergone a rigorous scientific review process, which is the case for those studies published in scientific journals or independently evaluated by a scientific body. It would also lead to undue delay. The standard time taken to review scientific manuscripts in the fields of medicine, public health, and natural sciences is, on average, 12-14 weeks.[132] If EPA were to follow a comparably rigorous independent peer review on all pivotal science utilized in the regulatory decision making process, such an action would result in untimely delays in

---

[128] OMB, *Final Information Quality Bulletin for Peer Review* at 1 (Dec. 16, 2004), http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf.
[129] *Id* at 22.
[130] Jeremy Berg et al., "Joint statement on EPA proposed rule and public availability of data," *Science* (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.
[131] *Id.*
[132] Janine Huisman & Jeroen Smits, *Duration and quality of the peer review process: the author's perspective*, Scientometrics 113:633 (2017), https://doi.org/10.1007/s11192-017-2310-5.

implementation of public health protections. For example, the NAAQS Integrated Science Assessment and Risk and Exposure Assessments regularly include the review of thousands of scientific studies. It would be enormously inefficient and costly (if even possible) for EPA to re-review all of these studies.

Moreover, as clearly outlined in the OMB Bulletin, the independent peer review guidelines "do[] not cover time-sensitive health and safety disseminations, for example, a dissemination based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began. For this purpose, 'health' includes public health, or plant or animal infectious diseases".[133] This encompasses most of the studies that EPA intends to review, including but not limited to, the Integrated Risk Information System ("IRIS") assessments, TSCA risk evaluations, and National Emissions Standards for Hazardous Air Pollutants risk assessments.[134] In each case, EPA utilizes scientific data to make safety determinations for chemical pollutants and impacts on human health and the environment, and thus, timely review is tantamount to protecting public health. The Proposal to add another layer of review – one that is wholly unnecessary and duplicative – is antithetical to the time sensitive nature of these reviews.

Furthermore, the Bulletin makes clear that agencies should "ensure peer review does not unduly delay the release of urgent findings."[135] Thus, if EPA wants to independently peer review all pivotal science, then it must clearly outline how it will ensure the process will not lead to undue delay. It has failed to do so. For example, there is nothing in the Proposed Rule outlining how EPA will conduct an independent review of the studies underlying the NAAQS standard, which will require review of hundreds if not thousands of science documents, within the NAAQS review cycle. The standard review period in the independent peer review process (*i.e.*, from submission of a manuscript to final review) is time intensive. If it can take months to review one manuscript,[136] it is difficult to envisage how EPA could subject every piece of pivotal regulatory science to the same standard of review and still complete scientific assessments in a timely manner.

Equally problematic, the proposed independent EPA review will lead to undue costs in terms of the time and resources required to review the relevant data. In *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer Review Practice* ("NAS Review"), the National Academy of Sciences states that "[t]he cost of a peer review

---

[133] *Id.*

[134] EPA, Basic Information about the Integrated Risk Information System (last updated March 7, 2018), https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system; EPA, Risk Evaluations for Existing Chemicals under TSCA (last updated June 11, 2018), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca; EPA, Risk and Technology Review (last updated June 22, 2018), https://www3.epa.gov/airtoxics/rrisk/rtrpg.html.

[135] OMB, *Final Information Quality Bulletin for Peer Review* at 1 (Dec. 16, 2004), http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf.

[136] Janine Huisman & Jeroen Smits, *Duration and quality of the peer review process: the author's perspective*, Scientometrics 113:633 (2017), https://doi.org/10.1007/s11192-017-2310-5.

effort should be carefully considered in terms of in-house staff time and resources, as well as the limited time and energy of busy experts who must take time from other worthwhile endeavors."[137] EPA ignores this aspect in its cost-benefit analysis of the Proposed Rule, rendering the resulting rule arbitrary.

C. Section 30.8's Requirement to Consider and Minimize Costs is Unlawful.

Proposed Section 30.8, which would require EPA to implement the provisions of the Rule "in a manner that minimizes cost," is unlawful and arbitrary, for several reasons.

First, because EPA has only the authority conferred to it by statute, the Agency must identify the statutory authority upon which it bases its regulatory decisions about what data and models to consider on the minimization of cost. *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (quoting *Verizon v. FCC*, 740 F.3d 623, 632 (D.C. Cir. 2014) ("It is 'axiomatic' that 'administrative agencies may act only pursuant to authority delegated to them by Congress.'") (alteration and citations omitted)). The Agency has failed to do so here.

Second, EPA's proposal to base these decisions on cost is inconsistent with statutory mandates requiring the Agency to base regulatory decisions on the best available science. *See, e.g.*, 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II) (directing EPA to base its determination about whether to regulate any particular contaminant "on the best available public health information"); 15 U.S.C. § 2625(h) (requiring EPA to act "consistent with the best available science"). Plain meaning and common usage confirm that "best available science" does not refer to whatever science is least costly. *See also supra*, Section IV.A.

Third, EPA's proposal to base its data quality decisions on cost is inconsistent with applicable statutory mandates requiring EPA to make regulatory decisions based on considerations of public health. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 469 (2001) (cost "is ***both*** so indirectly related to public health ***and*** so full of potential for canceling the conclusions drawn from direct health effects that it would surely have been expressly mentioned . . . had Congress meant it to be considered." (emphasis in original)).[138]

Fourth, section 30.8 is also unlawfully vague. As the Supreme Court has explained, "'cost' includes more than the expense of complying with regulations; any disadvantage could be termed a cost." *Michigan v. EPA*, 135 S. Ct. at 2707. Yet the provision does not specify to what types of costs it refers. And despite the fact that various types of costs would necessarily need to be weighed against one another when applying this provision, the Proposed Rule is notably silent as to how that will be done. As proposed, it appears to confer nearly limitless discretion on EPA

---

[137] NAS, *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices* (2000), http://www.nap.edu/catalog/9882.html.

[138] If anything, EPA's proposal to base decisions on consideration of cost here is even more irrational than it was in *Whitman*, because in this case, decision-making about the science used to inform EPA's regulatory decisions will result in a proliferation of costs and benefits that resist quantification, monetization, and comparison. These include substantial and important non-market values, including privacy, transparency, health and environmental considerations, and even the value of scientific knowledge itself.

to decline to collect and utilize relevant science on grounds of cost, in contravention of applicable statutory mandates and reasoned decision-making. *See U.S. Sugar v. EPA*, 830 F.3d 579, 644 (D.C. Cir. 2016) ("in light of the unambiguous statutory command [to regulate toxic pollution sources] . . . [t]he Agency was obligated to collect the data it needed").

Finally, even if EPA had authority to base its data quality decisions on cost, it would be irrational and arbitrary for EPA to ignore all the costs and benefits to the public – including public health and environmental costs and benefits and privacy-related costs and benefits –that may flow from its decisions. EPA must treat costs and benefits alike, and may not "put a thumb on the scale by undervaluing the benefits and overvaluing the costs of more stringent standards." *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008). And it may not ignore the public health, environmental, and privacy-related costs of its action or inaction of its decision just because they are not quantified. *See, e.g.*, Exec. Order No. 13,563 § 1, 76 Fed. Reg. at 3821; Exec. Order No. 12,866 § 1, 58 Fed. Reg. at 51,735 (it is "essential to consider" the "qualitative measures of costs and benefits that are difficult to quantify"). OMB Circular A-4 cautions agencies against ignoring the potential magnitude of unquantified benefits, because the approach with the "largest quantified and monetized . . . estimate" is not necessarily the most cost-justified. Under all of these authorities, a "full accounting" of the costs and benefits of a rule requires that indirect benefits be counted "equivalently" with other costs and benefits.[139]

For all of these reasons, section 30.8 is arbitrary and capricious and thus invalid.

VIII. EPA'S PROPOSAL WOULD DISPROPORTIONATELY HARM LOW-INCOME COMMUNITIES AND MINORITY COMMUNITIES

Not only is EPA's elimination of its use of critical human health research and studies that serve to protect and promote public health and the environment unlawful, but it is also discriminatory. The Proposed Rule has a disproportionately deleterious impact on low-income communities and minority communities – the overburdened populations that benefit most from the epidemiological studies used to set limits on air and water pollutants and to set safe exposure levels for pesticides and other toxics. By removing this critical category of studies from consideration when setting limits on pollutant and toxic exposure as well as standards for safe air and water, EPA is turning a blind eye to accessible and illuminating evidence that provides much-needed safeguards to the vulnerable communities most impacted by the laws EPA is charged with enforcing. These communities will disproportionately suffer as a result.

Since the 1987 landmark report *Toxic Wastes and Race in the United States*,[140] studies have confirmed again and again that communities of color and also economically disadvantaged

[139] Cass R. Sunstein, *The Real World of Cost-Benefit Analysis: Thirty-Six Questions (and Almost as Many Answers)*, 114 Colum. L. Rev. 167, 190 (2014).
[140] Dr. Benjamin F. Chavis, Jr. & Charles Lee, *Toxic Wastes and Race in the United States*, Commission for Racial Justice, United Church of Christ (1987),

populations are disproportionately located near toxic waste sites and other sources of pollution. And research has also found that overall air pollution exposure is more strongly concentrated in communities of color.[141] Pesticide exposure likewise disproportionately impacts low-income and minority communities: farmworkers tend to be poor,[142] and the vast majority are of Latin American origin,[143] and they have a higher incidence of pesticide poisoning than other workers.[144] For example, in California, the counties with the greatest use of the highly toxic pesticide chlorpyrifos are the counties with the highest poverty levels and largest Latino populations.[145] In April 2014, the California Department of Public Health issued a report showing that thousands of children, disproportionately people of color, attend school in close proximity to pesticide use.[146] Overall, the disproportionate burden of environmental exposure among these low-income communities and communities of color cannot be disputed.[147]

Fundamental to the research revealing the disproportionate impact of environmental harms on low-income and minority communities and the need to set appropriate standards is epidemiological data. Indeed, this category of science that EPA wants to eliminate has been foundational to establishing disparate harms from a variety of toxics in air, water, pesticides, and other environmental sources. For example:

- Epidemiological studies have shown that there is a persistent disparity in the blood lead levels measured in children of color compared to white children. These studies revealed that in 2011-2012, the mean level was almost 40 percent higher in black children 1-5 years old than in white children of the same age.[148]

---

https://www.csu.edu/cerc/researchreports/documents/ToxicWasteandRace-TOXICWASTESANDRACE.pdf.

[141] Zwickl, *Regional Variation in Environmental Inequality* at 9-10; Ash, M. et al., *Is environmental justice good for white folks? Industrial air toxics exposure in Urban America*, 94:3 Soc. Sci. Q. 616, 616 (2013); Morello-Frosch, R. et al., *Separate and unequal: residential segregation and estimated cancer risks associated with ambient air toxics in U.S. metropolitan areas*, 114:3 Envtl. Health Persp. 386, 390-92 (2006).

[142] U.S. Department of Labor, *National Agricultural Workers Survey* (2011-2012), http://www.doleta.gov/agworker/naws.cfm (on average, a farmworker family earns an annual income ranging from $17,500-$19,999).

[143] *Id*.

[144] Geoffrey M. Calvert et al., *Acute Pesticide Poisoning Among Agricultural Workers in the United States, 1998-2005*, 51 Am. J. Indus. Med. 883, 890 (2008).

[145] Letter from Environmental Justice Organizations to Cal. EPA Assistant Secretary for Environmental Justice and Tribal Affairs Arsenio Mataka at 2-3 (Aug. 26, 2014).

[146] Cal. Dep't of Public Health, *California Environmental Health Tracking Program: Agriculture Pesticide Use Near Public Schools in California* (April 2014), http://cehtp.org/file/pesticides_schools_report_april2014_pdf.

[147] Mohai, P. et al., *Racial and Socioeconomic Disparities in Residential Proximity to Polluting Industrial*; Zwickl, K. et al., *Regional Variation in Environmental Inequality* at 20.

[148] Jain R.B., *Trends and Variability in Blood Lead Concentrations Among US Children and Adolescents*, Envtl. Science and Pollution Research, 23, 7880-7889 at 7884 (2016).

- While studies have shown that the mean blood lead level in black children is much lower than it was several decades ago, epidemiological studies have shown that even low levels of lead in the blood are harmful.[149]

- A 2011 peer-reviewed epidemiological study found that urine samples of children ages 6 to 24 months were more likely to have six organophosphate metabolites the closer the child lived to a pesticide application site.[150]

- Longitudinal cohort epidemiologic studies have shown that even low levels of exposure to the highly toxic pesticide chlorpyrifos can disrupt brain development in prenatally exposed children, leading to developmental delays, lower IQ, learning disabilities, and ADHD-like behaviors.[151]

- Epidemiological studies demonstrate that farmworkers have a higher rate of pesticide poisoning than any other workers[152]

Thus, it is clear that epidemiological studies have provided a consistent source of reliable data that has been critical to demonstrating disproportionate exposure to toxic chemicals. These studies in turn have been pivotal to setting air, water, and pesticide standards necessary to protect low-income and minority populations from harmful levels of exposure.

EPA's proposal to eliminate use of epidemiological studies will have a disparate impact on the most overburdened and vulnerable communities, eliminating the very source of data relied upon to provide protections crucial to their health and wellbeing. This Proposed Rule will perpetuate the environmental injustices that low-income and minority communities already face, as it will remove the primary tool used to study and address the inequitable environmental harms suffered by these populations.

IX. ADDITIONAL TOPICS FOR COMMENTS

A. Retroactive Application of the Law Would Be Unlawful.

EPA also requested "comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently

---

[149] Lanphear B.P. et al., *Low-Level Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, Envtl. Health Persp. 113, 894-899 at 898 (2005).
[150] Asa Bradman et al., *Determinants of Organophosphorus Pesticide Urinary Metabolite Levels in Young Children Living in an Agricultural Community*, 8 Int. J. Envtl. Res. Public Health 1061 (2011).
[151] Rauh V.A., Garfinkel R., Perera F.P. et al., *Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children*, Pediatrics 118(6):e1845-59 (2006); Bouchard M.F., Chevrier J., Harley K.G. et al., *Prenatal Exposure to Organophosphate Pesticides and IQ in 7-Year Old Children*, Envtl. Health Persp. 21003185 (Apr. 2011); Rauh V.A. et al., *Prenatal exposure to the organophosphate pesticide chlorpyrifos and childhood tremor*, Neurotoxicology 51:80-86 (2015).
[152] Geoffrey M. Calvert et al., *Acute Pesticide Poisoning Among Agricultural Workers in the United States, 1998-2005*, 51 Am. J. Indus. Med. 883, 890 (2008).

introduce bias regarding the timeliness and quality of the scientific information available." 83 Fed. Reg. at 18,772. Like much of the rest of the Proposal, it is unclear what exactly EPA is asking or suggesting. Certainly, to the extent EPA uses the Proposed Rule to exclude important, valid scientific information, it will bias the quality of the scientific information available.

To the extent EPA suggests the Rule may be applied retroactively, there is simply no basis for doing so. It is well-established that an agency cannot apply a rule retroactively absent clear congressional intention for such application. *E.g.*, *Sierra Club v. Whitman*, 285 F.3d 63, 68 (D.C. Cir. 2002) (referring to "unusual ability to implement rules retroactively"); *Bowen v. Georgetown Univ. Hospital*, 488 U.S. 204, 208 (1988) ("Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result. By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." (citations omitted)). EPA has not identified any such congressional intention in any of the statutes at issue, and thus retroactive application of the Rule would be unlawful.

Nor would the statutes upon which EPA relies support such an application. For example, as explained above, the Clean Air Act does not allow—and, as the D.C. Circuit has held, certainly does not require, *e.g.*, *American Trucking*, 283 F.3d at 372—applying the so-called transparency provisions of the Proposed Rule at all in rules subject to the procedural requirements of Clean Air Act § 307(d). Such rules include NAAQS. Further, far from suggesting that EPA could lawfully reopen long-settled NAAQS to apply a new and novel standard of review, the Clean Air Act requires EPA to review and revise air quality criteria and NAAQS at least every five years and to "promulgate such ***new*** standards as may be appropriate." 42 U.S.C. § 7409(d)(1) (emphasis added). This carefully chosen language confirms that Congress did not intend for EPA to apply rules like the Proposed Rule to undo existing NAAQS, but instead intended for regular reviews of scientific information to result in new NAAQS.

Even if EPA had statutory authority to apply the Proposed Rule retroactively, it could not do so rationally. *See Sierra Club*, 285 F.3d at 68 (if EPA had authority to implement a rule retroactively, "retroactivity must be 'reasonable,'"). Indeed, retroactive application of the Proposed Rule would undo well-settled rules in a tremendously unfair and irrational way, and would lead to widespread confusion about countless environmental and public health policies and protections.

B. Application of the Proposed Rule to Enforcement Actions, Individual Party Adjudications, or Permit Proceedings Would Be Unlawful.

EPA also seeks comment on whether provisions of the Proposed Rule should apply to enforcement activities, individual party adjudications, or permit proceedings. It should not. Application of the proposed provisions to such matters would be illegal and arbitrary for all the reasons set forth above, as well as for the following additional reasons.

First, with respect to enforcement actions, EPA has no authority to bar the courts or administrative adjudicators from considering relevant evidence merely because that evidence

hasn't passed an arbitrary test for transparency and peer review. The Clean Air Act, for example, vests authority over judicial enforcement actions to the courts, not EPA, and EPA has no authority to dictate to the courts what evidence they can and can't consider, or what weight to give such evidence. *See Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063-64 (D.C. Cir. 2014). Indeed, courts and administrative law judges are equipped with tools to separate out credible and non-credible scientific evidence, *see, e.g.*, Fed. R. Evid. 702; *Daubert*, 509 U.S. 579. Relatedly, whether a scientific study is sufficiently transparent or has been peer reviewed provides no bearing on administrative enforcement of these statutes, which provide enforcement authority over whether there has been a violation of specified requirements and prohibitions, *see, e.g.*, 42 U.S.C. § 7413(a)(1)-(5). It also is wholly irrelevant to determining administrative civil penalties. *See, e.g.*, *id.* § 7413(e). Though the Clean Air Act does allow consideration of "such other factors as justice may require" in setting civil penalties, EPA does not and cannot explain how its transparency and peer review tests could possibly be relevant to whether "justice" requires a different penalty for violation of a prohibition or requirement. If a defendant feels that a standard is unjust because of a lack of data transparency or peer review in supporting studies, the sole remedy is to seek review in the Court of Appeals within 60 days of the standard's publication. The validity of standards cannot be questioned in an enforcement proceeding. *See, e.g.*, 42 U.S.C. § 7607(b)(2).

Second, EPA does not explain how or where its Proposed Rule could be relevant in individual party adjudications. Though the administrative penalty provisions of the Clean Air Act provide for individual party adjudications, *see, e.g.*, 42 U.S.C. § 7413(d)(3)-(4), EPA's proposed procedures bear no relevance or applicability to such adjudications.

Third, the proposed procedures cannot lawfully or rationally be required in the context of EPA decisions to abate "imminent and substantial endangerments" ("ISEs") to human health and the environment. *See, e.g.*, 42 U.S.C. §§ 300(i)(a) (SDWA § 1431(a)), 6973(a) (RCRA § 7003(a)), 7603 (CAA § 303), and 9606(a) (CERCLA § 106(a)). None of these provisions set or authorize limitations on the studies that can be relied upon in identifying ISEs. To the contrary, both courts and the EPA have interpreted these statutes as precautionary in nature, allowing abatement action where there is only a risk of harm. *See, e.g.*, EPA, *Guidance On the Use of Section 303 of the Clean Air Act*, EPA-R08-OAR-2013-0556-0015, at 2-4 (1991) ("Section 303 Guidance"); *see also United States v. Vertac Chemical Corp.*, 453 F.3d 1031, 1045 (8th Cir. 2006) (describing § 9606(a)'s ISE standard as "cautionary" in sanctioning EPA's decision to issue a unilateral administrative order requiring cleanup of former manufacturing site). ISE authorities are so precautionary in nature that they may be used even when the risk of harm is uncertain. *See United States v. Conservation Chem. Co.*, 619 F. Supp. 162, 194 (W.D. Mo. 1985) ("Both the courts and Congress have recognized that the evaluation of a risk of harm involves medical and scientific conclusions that clearly lie on the frontiers of scientific knowledge, such that proof with certainty is impossible."). EPA guidelines state that "[i]f the Agency can show a 'reasonable medical concern' created by the suspect emissions, it will have met the 'imminent and substantial endangerment' test of Section 303." Section 303 Guidance at 4.

EPA may be required to make an endangerment finding despite "some residual uncertainty." *Massachusetts v. EPA*, 549 U.S. at 534 (holding that EPA could not avoid its statutory obligation to regulate greenhouse gases by noting the uncertainty surrounding climate change unless the scientific uncertainty was so profound as to preclude EPA from making a reasoned judgment about the risk of harm); *see also Coal. for Responsible Regulation v. EPA*, 684 F.3d 102, 121 (D.C. Cir. 2012) ("existence of some uncertainty does not, without more, warrant invalidation of an endangerment finding. If a statute is 'precautionary in nature' and 'designed to protect the public health,' and the relevant evidence is 'difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge,' EPA need not provide 'rigorous step-by-step proof of cause and effect' to support an endangerment finding." (quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976), a case regarding endangerment findings under § 211(c)(1)(A) of the Clean Air Act). For all the foregoing reasons, the language and purpose of the endangerment provisions would be flouted by a requirement that EPA be barred from (or forced to delay) relying on available peer reviewed studies to decide whether and how to remedy a hazardous substance release, contamination of drinking water, or other immediate threat.

Finally, to the extent EPA decides to apply this Proposed Rule in the context of enforcement, adjudicatory, and permit actions – which it should not – it must first issue a proposal setting out its basis for such a rule and provide opportunity for comment under the Administrative Procedure Act and Clean Air Act § 307(d). EPA cannot rely on the comment opportunity provided by its April 30, 2018 Proposal, as the Proposal provides no notice whatsoever of the substance of what EPA might or might not include in a rule applying to enforcement and other actions excluded from the regulatory text of the proposal. *See* 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. § 30.3).

On Behalf Of:

Alaska Community Action on Toxics	Little River Waterkeeper
Alianza Naciondal de Campesinas, Inc.	Living Rivers & Colorado Riverkeeper
Altamaha Riverkeeper	Lower Susquehanna Riverkeeper Association
Animas Riverkeeper	Matanzas Riverkeeper
Appalachian Mountain Advocates	Miami Waterkeeper
Atchafalaya Basinkeeper	Milwaukee Riverkeeper
Bayou City Waterkeeper	Missouri Coalition for the Environment
Boulder Waterkeeper	Missouri Confluence Waterkeeper
Breast Cancer Prevention Partners	Mountain Watershed Association
Buffalo River Watershed Alliance	MountainTrue
Cahaba Riverkeeper	National Black Justice Coalition

California Communities Against Toxics
California Safe Schools
CATA - The Farmworker Support Committee
Center for Food Safety
Central Maryland Beekeepers Association
Clean Air Council
Clean Air Task Force
Community Alliance for Global Justice
Coosa Riverkeeper
CRLA Foundation
Defenders of Wildlife
Downwinders at Risk
Earthjustice
Environmental Health Strategy Center
Environmental Integrity Project
Environmental Stewardship
Family Farm Defenders
Farms Not Arms
Farmworker Association of Florida
Farmworker Justice
Food & Water Watch
Friends of the Earth
Government Accountability Project
Green Riverkeeper
Greenpeace USA
Hip Hop Caucus
Humane Society of the United States
Humboldt Baykeeper
Huron Environmental Activist League
International Society for Children's Health and the Environment
National Family Farm Coalition
Neighbors for Clean Air
OVEC-Ohio Valley Environmental Coalition
Partnership for Policy Integrity
PCUN
Peace Roots Alliance
Pesticide Action Network North America
Physicians for Social Responsibility
Pollinate Minnesota
Potomac Riverkeeper Network
Rural Empowerment Association for Community Help
Santa Barbara Channelkeeper
Save The Poudre: Poudre Waterkeeper
Save The River, Upper St Lawrence Riverkeeper
Save The Sound - Long Island Soundkeeper
Secular Coalition for America
Sierra Club
Snake River Waterkeeper
Suncoast Waterkeeper
Tennessee Riverkeeper
Tri-Valley CAREs (Communities Against a Radioactive Environment)
UFW Foundation
Union of Concerned Scientists
United Farm Workers
Upper Missouri Waterkeeper
Waterkeeper Alliance
Waterkeepers Chesapeake
Wayne Action for Racial Equality

Iowa Citizens for Community Improvement
Johns Hopkins Center for a Livable Future
Kids To The Country
Kootenai Environmental Alliance
Winyah Rivers Foundation, Inc.
Women's Environment and Development Organization (WEDO)
Worker Justice Center of NY
Yadkin Riverkeeper