UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF ILLINOIS, STATE OF MAINE, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, PEOPLE OF THE STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NORTH CAROLINA, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF VERMONT, STATE OF WASHINGTON, STATE OF WISCONSIN, KING COUNTY WASHINGTON, CITY OF CHICAGO, CITY OF LOS ANGELES, and CITY OF NEW YORK,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and ANDREW R. WHEELER as Administrator of the UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Defendants.

COMPLAINT FOR DECLARATORY RELIEF AND VACATUR

INTRODUCTION

1. Plaintiff States, Counties, and Cities ("Plaintiffs") bring this action against the Environmental Protection Agency ("EPA" or "the Agency") and Administrator Andrew R. Wheeler to challenge the final rule entitled "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information," 86 Fed. Reg. 469 (Jan. 6, 2021) ("Final Rule"). The Final Rule directs EPA to give less weight to scientific studies,

models, or other information in its regulatory decision-making on the sole basis that the underlying dose-response data are not publicly available for independent validation. The Final Rule will not "strengthen" the validity of the scientific information relied upon by EPA; instead, it will subvert well-established Agency practices for developing science-based regulations, significantly undermining the Agency's core responsibilities to implement substantive environmental statutes through use of the "latest," "generally accepted," and "best available" science. A rule that deliberately and arbitrarily requires EPA to give less weight to relevant, peer-reviewed, and probative science based on a non-scientific criterion—the public availability of underlying data—is contrary to clear congressional mandates to use the best available science to protect public health and the environment.

2. To develop quantitative limits and standards to protect public health and the environment under numerous substantive statutes, EPA relies on dose-response data and models gathered in epidemiological studies. The underlying data in these studies necessarily include confidential medical and personally identifiable information that cannot be publicly disclosed under privacy laws and medical research ethics. For decades, these foundational studies have served as the scientific underpinnings of EPA's most important regulations to protect the public from environmental and public health threats including air and water pollution, toxic chemicals, and pesticides. By restricting the use of this fundamental science, the Final Rule poses a threat to the credibility of regulatory science, in direct conflict with EPA's core mission of protecting human health and the environment.

3. Since first proposing the rule nearly three years ago, *see* Proposal to Limit Use of Scientific Evidence in Rulemaking, 83 Fed. Reg. 18,768 (Apr. 30, 2018) ("Initial Proposal"), EPA has received significant criticism from the scientific community—including from EPA's own Science Advisory Board ("SAB") and the National Academies of Sciences, Engineering, and Medicine ("NAS")—which EPA has largely ignored. Scientists have made clear that existing, well-established peer-review mechanisms already ensure that underlying research data are scientifically sound, and that the public availability of such data has no bearing on the validity of scientific studies. The Final Rule's emphasis on data availability rather than data accuracy will weaken the body of scientific evidence available to the Agency and arbitrarily reduce the weight given to valid, probative studies in EPA's development of regulations and science-based policies and decisions.

4. Moreover, EPA did not and cannot identify a valid statutory basis for promulgating the Final Rule. Rather, EPA cites to the Federal Housekeeping Statute, 5 U.S.C. § 301, a statute that governs internal agency practices and procedures, not the development of substantive rules. By its very terms, the Federal Housekeeping Statute does not apply to EPA—and even assuming EPA has some inherent housekeeping authority, EPA cannot rely on a general grant of authority to promulgate regulations or develop policies that are inconsistent with the Agency's specific statutory directives to use the "latest," "generally accepted," and "best available" science as the foundation of its regulatory decision-making. Nor does the Final Rule constitute "housekeeping" at all, given the broad substantive

impact it will have on EPA's development of health-based standards and other scientific information.

5. Because the Final Rule is unlawful and harms the Plaintiffs and our residents, Plaintiffs seek a ruling from this Court declaring the Final Rule in excess of EPA's statutory authority, not in accordance with law, and arbitrary and capricious; and vacating the Final Rule on those grounds.

JURISDICTION AND VENUE

6. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 2201(a). Jurisdiction is also proper under the judicial review provisions of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702 and 704.

7. Venue is proper within this federal district, pursuant to 28 U.S.C. § 1391(e), because plaintiff State of New York resides within the district.

THE PARTIES

8. Plaintiff State of New York is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of itself and as trustee, guardian, and representative of all residents, citizens, and political subdivisions of New York State.

9. Plaintiff State of California is a sovereign state in the United States of America. The State of California brings this action by and through Attorney General Xavier Becerra, the Office of the Secretary of the California Environmental Protection Agency, the California Air Resources Board, the California Department of Pesticide Regulation, the California Department of Toxic Substances Control, the

California Office of Environmental Health Hazard Assessment, and the California State Water Resources Control Board. The Attorney General is the chief law officer of California, Cal. Const., art. V, § 13, and is authorized to file civil suits directly involving the state's rights and interests or deemed necessary by the Attorney General to protect public rights and interests, including the State's environment and natural resources. *See* Cal. Gov't Code §§ 12511, 12600–12; *Pierce v. Superior Ct.*, 1 Cal.2d 759, 761–62 (1934).

10. Plaintiff City of Chicago is a municipal corporation and home rule unit organized and existing under the constitution and laws of the State of Illinois. Chicago is the third largest city in the United States by population.

11. Plaintiff Connecticut is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of itself and as trustee, guardian, and representative of all residents, citizens, and political subdivisions of Connecticut.

12. Plaintiff State of Delaware is a sovereign state of the United States of America. This action is brought on behalf of the State of Delaware by Attorney General Kathleen Jennings, as the chief law officer of the State, who is empowered to exercise all such constitutional, statutory, and common law power and authority as the public interest may require. *See Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941); Del. Code Ann., tit. 29, § 2504.

13. Plaintiff State of Illinois brings this action by and through Attorney General Kwame Raoul. The Attorney General is the chief legal officer of the State of

Illinois (Ill. Const., art. V, § 15) and "has the prerogative of conducting legal affairs for the State." *Envt'l Prot. Agency v. Pollution Control Bd.*, 372 N.E.2d 50, 51 (Ill. Sup. Ct. 1977). He has common law authority to represent the People of the State of Illinois and "an obligation to represent the interests of the People so as to ensure a healthful environment for all the citizens of the State." *People v. NL Indus.*, 604 N.E.2d 349, 358 (Ill. Sup. Ct. 1992).

14. Plaintiff King County, Washington is a political subdivision of the State of Washington and brings this action on behalf of itself.

15. Plaintiff the City of Los Angeles is a municipal corporation located within the State of California and brings this action on behalf of itself.

16. Plaintiff Maine, represented by and through its Attorney General, is a sovereign state of the United States of America. The Attorney General of Maine is a constitutional officer with the authority to represent the State of Maine in all matters and serves as its chief legal officer with general charge, supervision, and direction of the State's legal business. Me. Const. art. IX, § 11; 5 M.R.S. §§ 191–205. The Attorney General's powers and duties include acting on behalf of the State and the people of Maine in the federal courts on matters of public interest. The Attorney General has the authority to file suit to challenge action by the federal government that threatens the public interest and welfare of Maine residents as a matter of constitutional, statutory, and common law authority.

17. Plaintiff Maryland is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of itself and

as trustee, guardian, and representative of all residents, citizens, and political subdivisions of Maryland.

18. Plaintiff Massachusetts is a sovereign Commonwealth of the United States of America. The Commonwealth of Massachusetts brings this action by and through Attorney General Maura Healey, the chief legal officer of the Commonwealth, on behalf of itself and its residents to protect the Commonwealth's sovereign and proprietary interests in the conservation and protection of its natural resources, public health, and the environment. *See* Mass. Const. Am. Art. 97; Mass. Gen. Laws, ch. 12, §§ 3 and 11D.

19. Plaintiff People of the State of Michigan brings this action by and through Attorney General Dana Nessel, who is authorized by statute and under common law to initiate litigation in the public interest on behalf of the People of the State of Michigan.

20. Plaintiff Minnesota is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of itself and as trustee, guardian, and representative of all residents, citizens, and political subdivisions of Minnesota. The Minnesota Attorney General "shall appear for the state in all causes in the supreme and federal courts wherein the state is directly interested." Minn. Stat. § 8.01.

21. Plaintiff New Jersey is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of

itself and as trustee, guardian, and representative of all residents, citizens, and political subdivisions of New Jersey.

22. Plaintiff City of New York is a municipal corporation and political subdivision of the State of New York.

23. Plaintiff State of New Mexico joins in this action by and through Attorney General Hector Balderas. The Attorney General of New Mexico is authorized to prosecute in any court or tribunal all actions and proceedings, civil or criminal, when, in his judgment, the interest of the state requires such action. N.M. Stat. Ann. § 8-5-2.

24. Plaintiff State of North Carolina brings this action by and through Attorney General Joshua H. Stein. The North Carolina Attorney General is the chief legal officer of the State of North Carolina. The Attorney General is empowered to appear for the State of North Carolina "in any cause or matter . . . in which the state may be a party or interested." N.C. Gen. Stat. § 114-2(1). Moreover, the Attorney General is authorized to bring actions on behalf of the citizens of the state in "all matters affecting the public interest." *Id.* § 114-2(8)(a).

25. Plaintiff State of Oregon brings this suit by and through Attorney General Ellen F. Rosenblum. The Oregon Attorney General is the chief legal officer of the State of Oregon. The Attorney General's duties include acting in federal court on matters of public concern and upon request by any state officer when, in the discretion of the Attorney General, the action may be necessary or advisable to protect the Oregon's interests. Or. Rev. Stat. § 180.060(1).

26. Plaintiff Commonwealth of Pennsylvania is a sovereign state in the United States of America. The Commonwealth of Pennsylvania brings this action by and through Attorney General Joshua Shapiro. The Attorney General is the chief law officer of Pennsylvania, Pa. Const. art. IV, § 4, and is authorized to file civil suits on behalf of the Commonwealth. 71 P.S. § 732-204.

27. Plaintiff State of Vermont is a sovereign state of the United States of America. It brings this action through Attorney General Thomas J. Donovan, Jr. The Attorney General is authorized to represent the State in civil suits involving the State's interests when, in his judgment, the interests of the State so require.

28. Plaintiff State of Washington is a sovereign entity and brings this action to protect its own sovereign and proprietary rights. The Attorney General is the chief legal adviser to the State of Washington. The Attorney General's powers and duties include acting in federal court on matters of public concern. This challenge is brought pursuant to the Attorney General's independent constitutional, statutory, and common law authority to bring suit and obtain relief on behalf of the State of Washington.

29. Plaintiff State of Wisconsin is a sovereign state of the United States of America and brings this action by and through its Attorney General, Joshua L. Kaul, who is the chief legal officer of the State of Wisconsin and has the authority to file civil actions to protect Wisconsin's rights and interests. See Wis. Stat. § 165.25(1m). The Attorney General's powers and duties include appearing for and representing the State, on the governor's request, "in any court or before any officer,

any cause or matter, civil or criminal, in which the state or the people of this state may be interested." *Id*.

30. Defendant EPA is an agency of the United States government.

31. Defendant Andrew R. Wheeler is the Administrator of EPA and the highest-ranking official in the EPA. He is sued in his official capacity.

STATUTORY FRAMEWORK

The Administrative Procedure Act

32. Under the APA, a reviewing court "shall . . . hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id*. § 706(2)(C).

33. An agency action is arbitrary and capricious for purposes of the APA "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered 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." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983). The agency "must 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*.

34. Final agency actions are subject to judicial review under the APA. 5 U.S.C. § 704.

Federal Environmental Statutes

35. As the federal agency tasked with protecting public health and the environment, EPA administers numerous environmental statutes that require use of the "latest," "generally accepted," and "best available" science as the foundation of the Agency's standard setting and other regulatory decision-making.

The Clean Air Act

36. The Clean Air Act ("CAA"), 42 U.S.C. §§ 7401–7671q, requires EPA to establish science-based standards to control air pollution to protect public health and welfare.

37. Sections 108 and 109 of the CAA specify that EPA's air quality criteria must "accurately reflect the latest scientific knowledge." *Id.* § 7408(a)(2). In establishing air quality criteria, EPA must consider "all identifiable effects [of air pollutants] on public health and welfare" and "include information" on certain science-based factors "to the extent practicable." *Id.* EPA must use these criteria to adopt National Ambient Air Quality Standards ("NAAQS") at levels requisite to protect public health with an adequate margin of safety. *Id.* § 7409(b).

38. Similarly, section 112 of the CAA requires EPA to evaluate health risks and effects of hazardous air pollutants ("HAPs") and to set emission standards to reduce such risks using science-based considerations. *See id.* § 7412. For instance, section 112(f) of the CAA requires EPA to investigate and report 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).

The Safe Drinking Water Act

39. Congress passed the Safe Drinking Water Act ("SDWA"), 42 U.S.C. §§ 300f–300j-26, to protect the quality of drinking water in the United States. To accomplish this goal, the SDWA requires EPA to limit contaminants in public water systems 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." *Id.* § 300g-1(b)(4)(A).

40. In determining whether to regulate a contaminant, EPA must rely "on the best available public health information," *id.* § 300g-1(b)(1)(B)(ii)(II), and, in developing the National Primary Drinking Water Regulations, "the [EPA] Administrator shall use the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," *id.* § 300g-1(b)(3)(A)(i).

The Clean Water Act

41. Congress passed the Clean Water Act ("CWA"), 33 U.S.C. §§ 1251–1387, "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." *Id.* § 1251(a). A central goal of the CWA is "to support and aid research relating to the prevention, reduction, and elimination of pollution." *Id.* § 1251(b).

42. Under the CWA, EPA must set water quality standards that "shall . . . protect the public health or welfare, enhance the quality of water and serve the purposes of [the CWA]." *Id.* § 1313(c)(2)(A). Water quality standards are regulations that identify designated surface water uses, along with the requisite water quality criteria necessary to protect those uses. Thus, EPA must also establish water quality criteria that "accurately reflect[] the latest scientific knowledge" and the impacts of pollutants on public health and the environment. *Id.* § 1314(a)(1).

The Toxic Substances Control Act

43. The Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§ 2601–2697, protects human health and the environment by requiring EPA to test and place restrictions on the use of chemical substances. *Id.* § 2601.

44. In its regulatory decision-making under TSCA, EPA must "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." *Id.* § 2625(h). Likewise, in carrying out enumerated sections of the Act, EPA must "take into consideration information relating to a chemical substance or mixture . . . that is reasonably available." *Id.* § 2625(k).

45. TSCA also directs EPA to make regulatory decisions using a "weight of the scientific evidence" approach, which requires EPA to evaluate the strengths and weaknesses of any study reasonably available to the Agency. *Id.* § 2625(i). EPA regulations define "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. 40 C.F.R. § 702.33.

The Emergency Planning and Community Right-to-Know Act

46. Congress passed the Emergency Planning and Community Right-to-Know Act ("EPCRA"), 42 U.S.C. §§ 11001–11050, to help local communities protect public health and the environment from chemical hazards. The Act also requires industry to report on the storage, use, and releases of hazardous substances to federal, state, and local governments.

47. To this end, EPCRA established the Toxics Release Inventory ("TRI") program, which tracks the management of toxic chemicals that may pose a threat to human health and the environment.

48. EPCRA requires that any determination by EPA to add a chemical to the TRI "be based on generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to [EPA]." *Id.* § 11023(d)(2).

The Federal Insecticide, Fungicide, and Rodenticide Act

49. The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136–136y, protects human health and the environment by requiring EPA to evaluate data before registering and when reviewing registration for pesticides sold or used in the United States. *Id.* § 136a. FIFRA directs EPA to cancel or deny registration to pesticide products where the pesticide or labeling does not comply

with FIFRA requirements or the use generally causes unreasonable adverse effects on the environment. *Id.* § 136d.

50. 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). 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).

51. EPA's pesticide registration decisions are subject to evaluation by scientific review panel and peer review. *Id.* §§ 136w(d)(1), 136w(e).

FACTUAL BACKGROUND

52. Science is the backbone of EPA's regulatory decision-making. EPA relies on epidemiological studies that use dose-response data to link exposure to a pollutant, contaminant, or substance to a public health or environmental harm. Using these data, EPA sets quantitative limits and tolerances sufficient to protect public health and the environment, thereby fulfilling the Agency's responsibilities under substantive environmental statutes.

53. Dose-response data gathered in epidemiological studies have been instrumental in strengthening public health and environmental protections.

54. For example, in the landmark Harvard "Six Cities" study, researchers investigated the long-term effects of exposure to fine particulate air pollution ("PM2.5") on over 8,000 adults and 14,000 children across six U.S. cities by linking personal medical histories, occupational histories, and home locations to detailed air quality data. Based on the underlying dose-response data, researchers concluded

that individuals exposed to higher levels of PM2.5 faced a significantly higher risk of premature death. The Six Cities study, and others like it, were foundational to EPA's development of the first NAAQS for PM2.5 in 1997. *See* 62 Fed. Reg. 38,652 (July 18, 1997).

55. The dose-response data underlying epidemiological studies often consist of confidential medical or other personally identifiable information. Both the law and medical research ethics generally prohibit the public disclosure of these data. *See e.g.*, Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rules, 45 C.F.R. Parts 160 and 164, Subparts A & E (establishing safeguards to protect the privacy of personal health information, and setting limits and conditions on the uses and disclosures that may be made of such information without patient authorization); 21st Century Cures Act, 42 U.S.C. § 241 (requiring government agencies to provide a certificate of confidentiality to protect the privacy of individuals participating in biomedical, behavioral, clinical, or other research); Privacy Act of 1974, 5 U.S.C. § 552a (precluding disclosure of personally identifiable information or records by government agencies except in very limited enumerated circumstances).

56. However, underlying data need not be publicly available to ensure that studies are scientifically valid. Rather, the scientific community has developed longstanding methodologies and peer-review procedures to evaluate the strength and accuracy of scientific studies and epidemiological findings that link exposure levels to environmental and public health harms. Specifically, scientists and peer

reviewers are trained to assess research publications "by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results." Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel, and Deborah Sweet, *Joint Statement on EPA Proposed Rule and Public Availability of Data*, Nature (Apr. 30, 2018) ("Editors' Joint Statement"), https://www.nature.com/articles/d41586-018-05026-y.

57. Using these procedures, scientific researchers can independently validate epidemiological studies without publicly disclosing data and analytic methods. For example, in 2000, the Health Effects Institute published its independent reanalysis of the Six Cities study, which replicated and validated the original findings, without disclosure of private data.

58. EPA uses these well-established methodologies and peer review procedures to evaluate scientific studies used in its regulatory decision-making. *See* U.S. Env't Prot. Agency, *Peer Review Handbook: 4th Ed.* (2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf. Indeed, prior to selecting key studies to inform Agency regulations, EPA performs an extensive hazard identification and assessment process so that the quantitative limits and exposure levels ultimately chosen are supported by the overall body of scientific literature. *See, e.g.*, National Academies of Sciences, Engineering, & Medicine, *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation* (2018),

https://www.nationalacademies.org/our-work/review-of-advances-made-to-the-iris-process. By vetting studies through these review mechanisms, EPA ensures that the studies and data the Agency relies upon in its regulatory decision-making are scientifically valid.

EPA's Initial Proposal

59. Despite this well-established framework, on April 30, 2018, EPA proposed a rule purportedly intended to "enhanc[e] the transparency and validity of the scientific information relied upon by EPA" in its regulatory decision-making. Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,768–69 (Apr. 30, 2018) ("Initial Proposal"). The Initial Proposal provided that, in developing regulations, EPA would ensure that dose response data and models underlying pivotal regulatory science were publicly available in a manner sufficient for validation and analysis. *Id*. EPA defined "pivotal regulatory science" as "studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point of departure from which a reference value is calculated." *Id*. at 18,770. EPA stated that this science is "critical to the calculation of a final regulatory standard or level" under environmental statutes enacted to protect human health. *Id*. In other words, EPA's Initial Proposal would preclude the use of valid, probative scientific studies on the sole basis that the underlying data were not publicly available.

60. The Initial Proposal included a provision allowing the Administrator of the EPA, on a case by case basis, to "exempt significant regulatory decisions" from

the rule if he or she determined that compliance was "impracticable" because it was not "feasible to ensure" that the underlying data is publicly available. *Id*. at 18,772.

61. EPA did not provide objective parameters as to how the Administrator's discretionary authority would be utilized, nor did EPA define "impracticable" or "feasible."

62. As rationale for the Initial Proposal, EPA claimed that "[u]sing scientific information that can be independently validated will lead to better outcomes, and strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions." *Id*. at 18,770.

63. EPA did not articulate how independent validation would lead to "better outcomes" in public health and environmental protections, or how the purported benefits of the Initial Proposal would justify the significant change in EPA's long-standing policies in using and evaluating peer-reviewed science as the foundation of the Agency's decision-making.

EPA's Alleged Statutory Authority for the Initial Proposal

64. In promulgating the Initial Proposal, EPA asserted that it was acting "under the authority of the statutes it administers"—specifically: CAA, 42 U.S.C. §§ 7403, 7601(a); CWA, 33 U.S.C. §§ 1254, 1361; SDWA, 42 U.S.C. §§ 300j-1, 300j-9(a)(1); the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. §§ 6912(a)(1), 6979; the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. §§ 9616, 9660; EPCRA, 42 U.S.C. § 11048;

the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136r(a), 136w; and TSCA, 15 U.S.C. § 2609. 83 Fed. Reg. at 18,768.

65. Many of the statutory provisions cited by EPA either authorize or mandate the Agency to undertake research or to promulgate rules "necessary" to achieve the goals of the substantive environmental statutes. *See, e.g.*, 42 U.S.C. § 7403 (requiring EPA to "establish a national research and development program for the prevention and control of air pollution"); 33 U.S.C. § 1361 (authorizing the Administrator to "prescribe such regulations as are necessary to carry out his functions under this chapter"). Other statutory provisions cited by EPA require the Agency to collect and disseminate the best available science. *See* 33 U.S.C. § 1254(l) (requiring EPA to "develop and issue . . . 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 water").

66. On May 25, 2018, in its notice extending the comment period for the Initial Proposal and adding a public hearing, EPA claimed a new source of authority for the Initial Proposal, 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." 83 Fed. Reg. 24,255, 24,256 (May 25, 2018).

67. Section 301 of Title 5, known as the Federal Housekeeping Statute, imbues "[t]he head of an Executive department or military department" with authority to "prescribe regulations for the government of his [or her] 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." 5 U.S.C. § 301.

68. The Federal Housekeeping Statute is "simply a grant of authority to the agency to regulate its own affairs." *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979). The statute "authoriz[es] what the APA terms 'rules of agency organization procedure or practice' as opposed to '"substantive rules."' *Id.* at 309–10.

69. Section 101 of Title 5 includes an exclusive list of executive departments covered by the Housekeeping Statute; EPA is not included in that list. 5 U.S.C. § 101.

Criticism of the Initial Proposal from the Scientific Community

70. EPA's Initial Proposal faced significant criticism. EPA received more than 590,000 comments on the proposed rule, and the scientific community—including SAB and NAS—roundly criticized the Initial Proposal.

71. In a July 2018 letter to EPA, leading scientists at NAS warned that the Initial Proposal's overly stringent transparency requirement "pose[d] a threat to the credibility of regulatory science." Letter from Marcia McNutt, President, Nat'l Acad. of Sciences, C.D. Mote, Jr., President, Nat'l Acad. of Eng. & Victor J. Dzau, President, Nat'l Acad. of Med., to Andrew Wheeler, Acting Administrator, U.S. Envtl. Prot. Agency (July 16, 2018) ("NAS 2018 Letter"), http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf. NAS also expressed concerns about the EPA Administrator's broad discretion to grant exemptions based

on impracticability because "[d]ecisions about exemptions should be based on formal agency guidance and not according to criteria established by a single EPA employee." *Id*. at 3.

72. A group of scientists and editors-in-chief at scientific journals echoed these criticisms, warning that excluding data on the basis of transparency could undermine the rigor of EPA's decision-making: "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." Editors' Joint Statement. The group explained that excluding relevant and probative studies simply because of arbitrary notions of transparency will adversely affect the Agency's decision-making processes. *Id*.

EPA's Supplemental Proposal

73. On March 18, 2020, EPA issued a Supplemental Notice of Proposed Rulemaking ("Supplemental Proposal") "to clarify, modify and supplement certain provisions included in the [Initial Proposal]." 85 Fed. Reg. 15,396 (Mar. 18, 2020).

74. In the Supplemental Proposal, EPA broadened the scope of the Initial Proposal in two significant respects. *First*, EPA proposed to expand the scope of the rule to all "data and models, not only dose-response data and dose-response models." *Id*. at 15,398. EPA listed a wide range of data and models that included, but were not limited to, "environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on

environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies." *Id*. at 15,400.

75. *Second*, EPA proposed to expand the scope of the rule to apply to "influential scientific information," not only to "significant regulatory decisions." *Id*. at 15,398. This expanded scope would include "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." *Id*. at 15,398 n.5.

76. The Supplemental Proposal also proposed to modify key aspects of the regulatory text. Specifically, the Supplemental Proposal would allow EPA to rely on studies with underlying data and models that are publicly available "as well as studies with restricted data and models (i.e., those with confidential business information ("CBI"), proprietary data, or personally identifiable information ("PII") if there is tiered access to these data and models in a manner sufficient for independent validation." *Id*. at 15,399. EPA defined "tiered access" as techniques to reduce risks of re-identification and mitigate disclosure privacy risks. *Id*. EPA did not explain which type of information would be available at each tier or the parameters for obtaining access to data at higher, more protected tiers.

77. EPA also identified an alternative approach to modifying the Initial Proposal, whereby EPA would "give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because they are publicly available or because they are available through tiered access[.]" *Id*.

78. Under this alternative approach, EPA could consider studies for which the underlying data are not publicly available or where access to such data are "limited." However, any consideration of such studies would be at EPA's discretion, and the Agency could consider such studies to a "lesser" degree. *Id.* at 15,405. The Supplemental Proposal did not indicate criteria for when or how EPA would exercise discretion either to consider or to give lesser weight to such studies.

79. Like the Initial Proposal, the Supplemental Proposal proposed to allow the EPA Administrator to grant case-by-case exemptions from the rule based on his or her subjective determination that compliance with the rule is "impracticable." *Id.* at 15,406; 83 Fed. Reg. at 18,774.

80. The Supplemental Proposal narrowed the grounds for exemption to cases where compliance is impracticable because: (1) technological barriers make sharing the data or models infeasible; (2) development of the data or model was completed before the date of the rule; or (3) making the data and models publicly available is contrary to law. 85 Fed. Reg. at 15,406. The Supplemental Proposal, however, did not provide definitions or standards to guide the EPA Administrator's determination of what is "practicable" or "feasible," or what would constitute a "technological barrier." Nor did the Supplemental Proposal require the Administrator to delineate the criteria applied in granting an exemption.

EPA's Alleged Statutory Authority for the Supplemental Proposal

81. In the Supplemental Proposal, EPA stated that it no longer "propose[d] to interpret provisions of a particular statute or statutes that it administers." 85

Fed. Reg. at 15,398. Rather, EPA suggested that it had full authority to promulgate the rule under the Federal Housekeeping Statute as a result of Reorganization Plan No. 3 of 1970. *Id.*

82. In alleging this authority, EPA maintained that the proposed rule "exclusively pertains to the internal practices" of the Agency because it "describes how EPA will handle studies when data and models underlying science that is pivotal to EPA's significant regulatory decisions or influential scientific information are or are not publicly available in a manner sufficient for independent validation and analysis." *Id.* EPA contended that the Supplemental Proposal should be understood as an internal "housekeeping" measure. *Id.* at 15,397–98.

83. However, an agency cannot rely on general "housekeeping authority" to promulgate regulations or develop policies that are otherwise inconsistent with more specific statutory directives. *Glob. Van Lines, Inc. v. Interstate Commerce Comm'n*, 714 F.2d 1290, 1293–97 (5th Cir. 1983).

Criticism of the Supplemental Proposal from the Scientific Community

84. Like the Initial Proposal, the Supplemental Proposal drew broad criticism from the scientific community, stakeholders and the public, receiving over 396,000 public comments.

85. In its comments on the Supplemental Proposal, SAB critiqued EPA's justifications, maintaining that "[t]here is minimal justification provided in the Proposed Rule for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate." Science

Advisory Board Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled "Strengthening Transparency in Regulatory Science" (Apr. 24, 2020). SAB questioned how the Supplemental Proposal would actually "improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner." *Id.*

86. SAB also expressed considerable concerns about the expanded scope of the Supplemental Proposal "to include studies relied upon in influential scientific information (i.e., scientific information that will or does have a clear and substantial impact on important public policies or private sector decisions)." *Id.* at 2. According to SAB, "[i]n some cases, this requirement could be complex and/or impractical because studies could be considered when integrating the evidence but not directly used to determine specific regulatory standards or levels." *Id.* at 4.

87. SAB warned that the lack of objective criteria in the Supplemental Proposal could bring systematic bias into EPA's regulatory decision-making. Specifically, "[EPA's] exclusion of segments of the scientific literature, with the possibility of inclusion of other selected information without pre-defined criteria, could allow systematic bias to be introduced with no easy remedy. The proposed exception process applies no constraints on how this mechanism could be used or that it be restricted to the issue of confidential data." *Id.* at 16. SAB concluded that "[s]uch a proposal is inconsistent with the scientific method that requires all credible data be used to understand an issue and to allow systematic review to evaluate past research." *Id.*

EPA's Final Rule

88. On January 6, 2021, EPA published the Final Rule in the Federal Register, 86 Fed. Reg. 469. The Final Rule provides that "when promulgating significant regulatory actions or developing influential scientific information, [EPA] will determine which studies constitute pivotal science and give greater consideration to those studies determined to be pivotal science for which the underlying dose-response data are available in a manner sufficient for independent validation." *Id.* at 470. Under the Final Rule, EPA will give greater consideration to pivotal science based on dose-response data that include confidential business information, proprietary data, or personally identifiable information if those data are available through restricted access sufficient for independent review. *Id.* at 492.

89. EPA retreats in the Final Rule, narrowing the scope of the Final Rule to dose-response data underlying pivotal science, as opposed to all underlying data, "because of the influence [dose-response] data have on particularly impactful decisions at the Agency." *Id.* at 474–75. Under the Final Rule, "pivotal science" includes scientific studies "that are integral to characterizing dose-response relationships" and that "drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information." *Id.* at 480.

90. In the Final Rule, EPA acknowledges that underlying dose-response data may not be publicly available due to technological infeasibility or privacy reasons. *Id.* at 477. In such cases, "EPA may still use the pivotal science after either

giving it lesser consideration or receiving an exemption from the [EPA] Administrator." *Id.*

91. The Final Rule also states that if there are conflicts between the Final Rule and environmental statutes and regulations, the Final Rule "will yield and the statutes and regulations will be controlling." *Id.* at 470; *see also* Final Rule § 30.3(b). However, EPA does not explain what would constitute a "conflict," who would make the determination of a "conflict," what criteria the person(s) identifying the conflict would apply, or what it would mean for the Final Rule to "yield" to substantive environmental statutes or regulations.

92. The Final Rule retains the exemption provision for the EPA Administrator, with additional considerations. *Id.* at 487. Specifically, the Final Rule allows the Administrator to grant exemptions on a case-by-case basis if he or she determines (1) technological or other barriers render sharing the data infeasible; (2) the dose-response data were completed prior to publication of the Final Rule; (3) public availability of underlying data would conflict with various laws and regulations; (4) a third-party has conducted reanalysis; or (5) factors used in determining the consideration to afford pivotal science indicate that full consideration is justified. *Id.* at 493. EPA also added a provision requiring the Agency to "document the rationale for any exemptions granted by the Administrator in the significant regulatory action or influential scientific information" as part of the proposed rulemaking. *Id.*

EPA's Alleged Statutory Authority for the Final Rule

93. In promulgating the Final Rule, EPA relies exclusively on the Federal Housekeeping Statute as its legal authority, maintaining that the Final Rule "pertains to the internal practices of the EPA." *Id*. at 471. While acknowledging that EPA is "not one of the 'Executive departments' referred to in 5 U.S.C. 101," EPA again alleges that it gained housekeeping authority through Section 301 of the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970). *Id*.

94. EPA argues that because "Section 2(a)(1)-(8) of the Reorganization Plan transferred to the EPA functions previously vested in several agencies and Executive departments including the Departments of the Interior and Agriculture," and Section (2)(a)(9) transferred to the EPA administrator "authority, provided by law, to prescribe regulations relating primarily to the transferred functions," among other things, "the concomitant federal housekeeping authority to issue procedural rules was transferred to EPA." *Id*.

95. However, the Reorganization Plan No. 3 of 1970 simply transferred certain functions from the Department of Health, Education, and Welfare ("HEW") to the newly established EPA. HEW was later divided into the Departments of Education and Health and Human Services. EPA fails to note that Congress amended 5 U.S.C. § 101 to add the Departments of Education and Health and Human Services but did not add EPA. Subsequently, Congress amended 5 U.S.C. § 101 to add other federal entities, but declined to add EPA, reflecting clear

congressional intent not to confer the authority of the Federal Housekeeping Statute to EPA.

96. EPA also cites a 2008 opinion from the Office of Legal Counsel of the Department of Justice ("2008 OLC Opinion") on EPA's authority to establish regulations on government personal property, such as government-issued cell phones, as the basis for its rulemaking authority under the Federal Housekeeping Statute. *Id*. (citing Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property, 32 O.L.C. 79, 2008 WL 4422366 (May 28, 2008)).

97. But the 2008 OLC Opinion explicitly finds that "EPA is not an 'Executive department' within the meaning of section 301," and that any housekeeping authority would come from EPA's organic statute. 2008 OLC Opinion at 82. And, unlike the Final Rule, the EPA policy addressed in the 2008 OLC Opinion had no effect outside of EPA and was not inconsistent with specific statutory directives on the subject matter of the policy.

98. In addition, EPA cites decisions by the Second and Fourth Circuits that "recognized that the EPA has the authority to issue regulations governing its internal affairs and assumed that authority comes from section 301." *Id.* (citing *EPA v. General Elec. Co*., 197 F.3d 592, 595 (2d Cir. 1999); *Boron Oil Co. v. Downie*, 873 F.2d 67, 69 (4th Cir. 1989)).

99. These decisions, however, are inapposite, because they did not address the question of EPA's authority to promulgate regulations, such as the Final Rule, under the Federal Housekeeping Statute.

Effective Date of the Final Rule

100. EPA declared the Final Rule immediately effective upon publication in the Federal Register on January 6, 2021. 86 Fed. Reg. at 472.

101. EPA asserts that the Final Rule governs internal Agency organization, procedure, and practice, and therefore is exempt from the 30-day delayed-effective date requirements of the APA. *Id.* (citing 5 U.S.C. §§ 553(d)(2)).

102. EPA also maintains that, even if the delayed-effective date requirements applied to the Final Rule, there would be "good cause" for making the Final Rule immediately effective "because immediate implementation of the rule . . . is crucial for ensuring confidence in EPA decision-making." *Id.* (citing 5 U.S.C. § 553(d)(3)).

103. Yet EPA did not explain why immediate implementation is crucial. To the contrary, EPA admitted that the Agency still needs to issue implementation guidelines to execute the Final Rule consistently across programs, including a process for designating key studies as pivotal science, documenting the availability of dose-response data, and requesting an Administrator's exemption.

104. "Good cause" exceptions are appropriate only in limited circumstances, such as emergency rulemakings and cases of impracticability. *See, e.g.*, *Reeves v. Simon*, 507 F.2d 455, 457 (Temp. Emer. Ct. App. 1974) (finding good cause to

dispense with thirty-day publication requirement because of a national gasoline shortage emergency); *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1486 (9th Cir. 1992) (finding good cause to make a final rule immediately effective because the record showed that it was impossible for the Secretary of Agriculture to estimate orange volume restrictions more than thirty days in advance). Any "good cause" exceptions under the APA must be "narrowly construed and only reluctantly countenanced." *New Jersey v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980).

HARM TO THE PLAINTIFFS

105. Contrary to EPA's assertion, the Final Rule will have substantial direct effects on the Plaintiffs. Specifically, the Final Rule harms the Plaintiffs' substantive, proprietary, and informational interests. An order from this Court vacating the Final Rule would preclude EPA from arbitrarily and unlawfully giving less weight to relevant and probative scientific studies, models, or other information in its regulatory decision-making and development of scientific information, therefore preventing these harms to the Plaintiffs.

The Final Rule Injures the Plaintiffs' Substantive Interests in the Health and Safety of Our Residents and Our Natural Resources

106. The Final Rule will harm the Plaintiffs' substantive interests in protecting the health and safety of our residents and our natural resources because it will weaken the body of scientific information relied upon by the Agency in its regulatory decision-making.

107. For decades, EPA has relied on dose-response data gathered in epidemiological studies to set quantitative limits and tolerances sufficient to protect

public health and the environment. These underlying data necessarily include personally identifiable information that cannot be disclosed under law and medical ethics. For instance, as discussed above, the Six Cities Study was instrumental in establishing the first NAAQS for PM2.5, a dangerous air pollutant linked to respiratory conditions and premature death.

108. The Final Rule, however, directs EPA to give less weight to critical studies like the Six Cities Study, likely resulting in less protective NAAQS for pollutants like PM2.5 and ozone. Because of weakened NAAQS, the Plaintiffs' residents will be subject to greater air pollution that will cause or exacerbate public health harms, such as respiratory conditions like asthma in children and adults, cardiovascular disease, diabetes, and cancer, resulting in premature deaths.

109. The Final Rule will also result in environmental harms. As the Supreme Court has recognized, State Plaintiffs are entitled to "special solicitude" in seeking to remedy environmental harms. *Massachusetts v. EPA*, 549 U.S. 497 519–22 (2007). State Plaintiffs have a concrete interest in preventing harm to their natural resources, including their state-owned and state-regulated water and air, as a result of regulations promulgated with less than the best available science.

110. For instance, regulations promulgated by EPA under the CWA and the CAA impact water and air quality in the States. Unlawful regulations, based on arbitrarily restricted science due to implementation of the Final Rule, could lead to harmful levels of pollutants in the air and water of the States.

111. Weakened federal regulations will be especially harmful because many Plaintiffs' environmental and public health laws and regulations explicitly adopt substantive standards set by EPA or require an express justification for any deviation. For example, Pennsylvania's Department of Environmental Protection may not promulgate air quality control measures to implement NAAQS if the control measures are more stringent than federal measures unless it demonstrates that the higher standard is necessary to attain or maintain NAAQS, to satisfy related CAA requirements, to prevent assessment or imposition of CAA sanctions, or to comply with a final federal court decree. *See* Pa. Consol. Stat. § 4004.2. Similarly, New Jersey's Department of Environmental Protection must justify any deviation from federal standards pursuant to N.J. Executive Order 27 (Whitman 1994). For these Plaintiffs, weakened federal standards resulting from the application of the Final Rule will either weaken the standards applicable at the State level or require the Plaintiffs to initiate proceedings to impose and justify the imposition of different standards based on rigorous, comprehensive science, thus imposing economic and administrative burdens on such Plaintiffs that would not be imposed absent EPA's action challenged here.

112. In addition, many federal laws explicitly preempt States from adopting more stringent standards than EPA. For example, FIFRA prohibits a State from imposing pesticide labeling or packaging requirements in addition to or different from what EPA requires. 7 U.S.C. § 136v(b). This prohibition will prevent States from implementing more stringent labeling requirements in response to weakened

federal pesticide regulations. Plaintiff States will therefore be unable to adequately warn their residents of the public health and environmental harms resulting from pesticides.

113. Still more, many Plaintiffs have limited expertise to develop their own standards to protect public health and the environment and rely on EPA's standards. For instance, States may have little toxicology or risk assessment expertise and rely on EPA to promulgate appropriate quantitative limits and exposure levels to protect the health and safety of their residents. Some cities rely on EPA to set air quality standards due to a lack of resources and expertise.

114. Even for Plaintiffs that have the capacity to adopt and implement more stringent regulatory standards than EPA, those Plaintiffs may still face environmental and public health harms because other States may rely on EPA's weakened standards. For example, even if a State has cancelled the use of a pesticide due to its human health or environmental effects, that State will not able to prevent produce containing that pesticide residue from entering the State if EPA has established a tolerance for the pesticide residue. As a result, despite their best efforts, the Plaintiffs may not be able to fill the regulatory gaps created by the Final Rule.

The Final Rule Injures the Plaintiffs' Proprietary Interests

115. The Final Rule also harms the Plaintiffs in their proprietary capacity. By undermining the quality of scientific studies, models, and other information used by EPA in setting regulatory standards and limits to protect public health and the

environment, the Final Rule will force the Plaintiffs to expend resources to conduct their own research and implement more protective standards.

116. In addition, the Final Rule impairs the Plaintiffs' proprietary interests by increasing healthcare costs and requiring the Plaintiffs to expend more resources to address public health disparities. For example, the New York State Department of Environmental Conservation's Office of Environmental Justice directs resources to disproportionately impacted communities and enhances public participation through grant opportunities, enforcement of environmental laws and programs, and consultation with local industries. California's Community Air Protection Program ("CAPP") helps to reduce exposure in communities most impacted by air pollution. CAPP works with communities throughout California to measure and reduce adverse health impacts from air pollution, including through targeted incentive funding to deploy cleaner technologies in communities experiencing localized air pollution. The Final Rule hinders these efforts by adopting changes that allow EPA to avoid consideration of the impacts on public health and environmental justice, as shown in epidemiological studies, in promulgating environmental regulations.

The Final Rule Injures Plaintiffs' Informational Interests

117. Lastly, the Final Rule harms the Plaintiffs in their informational capacity. Because many Plaintiffs lack the resources or expertise to conduct their own scientific research, they rely on scientific reports and information published by EPA to inform their own regulatory decision-making. Because of the Final Rule, EPA's published scientific resources will no longer be informed by the "latest,"

"generally accepted," and "best available" science. This scientifically deficient information will stymie the efforts of the Plaintiffs to develop quantitative standards and limits adequate to protect public health and the environment.

118. The Plaintiffs have suffered concrete substantive, proprietary, and informational harms caused by EPA's promulgation of the Final Rule. A judgment from this Court vacating the entire Final Rule will redress these harms to the Plaintiffs by requiring that EPA continue to utilize the best available science in fulfilling its statutory duties. Therefore, the Plaintiffs have standing to bring this action.

FIRST CLAIM FOR RELIEF
The Final Rule is *Ultra Vires* Agency Action

119. The Plaintiffs reallege and incorporate by reference the allegations set forth in all preceding paragraphs.

120. The APA provides that this Court "shall" "hold unlawful and set aside" agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

121. EPA cannot promulgate the Final Rule under the Federal Housekeeping Statute because the statute, by its plain terms, grants no authority to EPA. As EPA concedes, 5 U.S.C. § 101 provides an exclusive list of executive departments covered by the Federal Housekeeping Statute—and EPA is not on that list.

122. Even if EPA does have "housekeeping" authority under the Federal Housekeeping Statute or from some other source, the Final Rule does not constitute

a "housekeeping measure," given its considerable substantive impact on EPA's regulatory decision-making. The Final Rule would alter substantive standards for evaluating scientific research, undermining the integrity of the EPA's regulatory decision-making and inhibiting the Agency's ability to protect public health and the environment.

123. Finally, EPA cannot rely on the Federal Housekeeping Statute's general grant of authority to promulgate regulations or develop policies that are inconsistent with the Agency's specific statutory directives to use the "latest," "generally accepted," and "best available" science as the foundation of the EPA's regulatory decision-making. *See* 42 U.S.C. § 7408(a)(2) (CWA); *id*. §§ 300g-1(b)(1)(B)(ii)(II), 300g-1(b)(3)(A)(i) (SDWA); 33 U.S.C. § 1314(a)(1) (CWA); 15 U.S.C. §§ 2625h, 2625k (TSCA); 42 U.S.C. § 11023(d)(2) (EPCRA); 7 U.S.C. § 136a(c)(5)(D) (FIFRA).

124. No statute authorizes the Final Rule, and EPA lacks any inherent authority to regulate absent a statutory basis.

125. Accordingly, the Final Rule is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." The Final Rule should be held unlawful and set aside under the APA, 5 U.S.C. § 706(2)(C).

SECOND CLAIM FOR RELIEF
The Final Rule Conflicts with EPA's Statutory Responsibilities

126. The Plaintiffs reallege and incorporate by reference the allegations set forth in all preceding paragraphs.

127. The APA provides that this Court "shall" "hold unlawful and set aside" agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

128. As explained above, EPA administers numerous environmental statutes that require use of the "latest," "generally accepted," and "best available" science as the foundation of the Agency's regulatory decision-making.

129. The Final Rule—which directs EPA to give less weight to scientific information based on the availability of underlying dose-response data for independent validation—conflicts with EPA's legal responsibilities under those substantive environmental statutes:

a. The Clean Air Act: In establishing air quality criteria under the CAA, EPA must consider "all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air," and "include information" on defined factors, "to the extent practicable." 42 U.S.C. § 7408(a)(2). EPA cannot ensure that air quality criteria "accurately reflect the latest scientific knowledge" if the Agency weighs scientific studies, models, or other information based on a criterion—the public availability of underlying data—that does not reflect the scientific validity of the studies models or other information. Moreover, EPA must set NAAQS at levels requisite to protect public health with an adequate margin of safety,

which requires EPA to weigh studies and information based on their scientific merit, not based on public availability of the underlying data. *Id.* § 7409(b). The Final Rule conflicts with these clear congressional mandates under the CAA.

b. The Safe Drinking Water Act: Under the SDWA, EPA must rely "on the best available public health information" when deciding whether to regulate a drinking-water contaminant. In developing the National Primary Drinking Water Regulations, "to the degree that an Agency action is based on science, the [EPA] Administrator shall use the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." *Id.* §§ 300g-1(b)(1)(B)(ii)(II), 300g-1(b)(3)(A)(i). EPA's action to give less weight to relevant scientific information when regulating drinking water is unlawful under the SWDA.

c. The Clean Water Act: The CWA directs EPA to establish water quality standards that "shall . . . protect the public health or welfare, enhance the quality of water and serve the purposes of [the CWA]," 33 U.S.C. § 1313(c)(2)(A), and establish water quality criteria that "accurately reflect[] the latest scientific knowledge" and the impacts of pollutants on public health and the environment, *id.* § 1314(a)(1). The Final Rule requires EPA

to give less weight to the "latest scientific knowledge" if such knowledge did not meet the Final Rule's arbitrary transparency requirements, therefore conflicting with the CWA's command. Accordingly, EPA's Final Rule is unlawful under the CWA.

d. The Toxic Substances Control Act: Numerous provisions of TSCA make clear that EPA may not prohibit the consideration of non-public data in regulatory decision-making. *See* 15 U.S.C. §§ 2625(h), 2625(k). Because it arbitrarily limits EPA's consideration of relevant and probative scientific studies, models, and information in setting standards, the Final Rule is inconsistent with TSCA's directives and is therefore unlawful.

e. The Emergency Planning and Community Right-to-Know Act: 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). The Final Rule undermines this mandate to consider scientifically accepted toxicological studies, and therefore, the Final Rule is unlawful under EPCRA.

f. The Federal Insecticide, Fungicide, and Rodenticide Act: Before registering or re-registering a pesticide under FIFRA, EPA must

determine that its use "will not generally cause unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(D). The Final Rule is unlawful under FIFRA because it subverts this statutory mandate by directing EPA to arbitrarily downplay probative, peer-reviewed scientific studies on adverse environmental effects of pesticides.

130. Because it conflicts with EPA's duties under the statutes discussed above, the Final Rule is "in excess of [EPA's] statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706(2)(C).

131. Nor is the Final Rule saved by EPA's inclusion of an exemption provision, Final Rule § 30.7, or its addition of a vague, catchall disclaimer provision that the Final Rule will yield in the event of conflict with "statutes EPA administers, or their implementing regulations." Final Rule § 30.3(b).

132. As a result, the Final Rule should be held unlawful and vacated under the APA, 5 U.S.C. § 706(2)(C).

THIRD CLAIM FOR RELIEF
The Final Rule Is Arbitrary and Capricious

133. Plaintiffs reallege and incorporate by reference the allegations set forth in all preceding paragraphs.

134. The APA provides that this Court "shall" "hold unlawful and set aside" agency action that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A). An agency action is arbitrary and capricious for purposes of the APA "if the agency has relied on factors which Congress has not intended it to consider,

entirely failed to consider an important aspect of the problem, offered 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. EPA acted arbitrarily and capriciously in promulgating the Final Rule in several respects:

135. *First*, EPA acted arbitrarily and capriciously by promulgating a Final Rule that is inconsistent with well-established standards of scientific practice and that fails to address criticisms from the nation's science experts, including those from SAB and NAS. The Final Rule's arbitrary emphasis on data availability rather than data accuracy will weaken—not enhance—the body of scientific evidence available to the Agency. EPA's explanation for the Final Rule runs counter to the evidence before the Agency, and thus, the Final Rule is not the result of reasoned decision-making nor can it be ascribed to Agency expertise.

136. *Second*, EPA acted arbitrarily and capriciously by failing to provide a reasoned explanation of how or why EPA's longstanding practices are inadequate, or how the new procedures would enhance the scientific integrity of EPA's rulemaking. Deviating from well-established scientific review procedures, without a reasoned, rational explanation of how the new procedures will enhance the integrity of EPA's regulatory decision-making, threatens both public health and the environment and is unlawful under the APA.

137. *Third*, EPA acted arbitrarily and capriciously by investing the EPA Administrator with vast discretion regarding the consideration of important

scientific information without objective criteria to guide that discretion to ensure that the Administrator's decisions are not arbitrary. The Administrator's ability to include certain studies at his or her discretion compounds the extent to which EPA could deviate from its science-based decision-making requirements of the substantive statutes the Agency is charged with implementing. The added requirement that the Agency document the Administrator's exemption decisions does not cure the unlawful grant of discretion. As a result, the Final Rule does not constitute reasoned decision-making under the APA.

138. *Fourth*, EPA acted arbitrarily and capriciously in promulgating the Final Rule because the Agency considered factors that Congress did not intend for it to consider. No environmental statute allows EPA to give less weight to relevant, probative science based on public availability of the underlying data, or to create a time- and resource-intensive process inconsistent with well-accepted scientific procedures. Rather, Congress directed EPA to promulgate regulations using the "latest," "generally accepted," and "best available" science as the foundation of the Agency's regulatory actions in order to protect public health and the environment.

139. *Fifth*, EPA acted arbitrarily and capriciously by providing only vague explanations for key aspects of the Final Rule. For example, EPA declined to identify which stage of data would need to be available to allow for independent validation. 86 Fed. Reg. at 479. EPA also failed to explain its logic regarding the requirements for reanalysis. For instance, EPA states "that reanalysis studies are most cost-effective when they are focused on studies of the greatest interest to the

scientific community," but the Agency does not provide any justification or support for this contention. *Id.* at 480. EPA also indicated that it "may opt, at its discretion, to incur the costs associated with making data available when it is in the public interest to do so," but the Agency gave no indication of what would constitute the public interest. *Id*. at 488. Because many aspects of the Final Rule are vague or left wholly unexplained, EPA failed to engage in reasoned decision-making or adequately consider important aspects of the problem.

140. *Sixth*, EPA acted arbitrarily and capriciously by failing to consider relevant Executive Orders and Office of Management and Budget memoranda, further demonstrating the agency's lack of reasoned decision-making:

a. Executive Order No. 13,132: The Final Rule violates Executive Order No. 13,132, which requires agencies to have an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications. The Final Rule has substantial federalism implications because state and local communities are directly and significantly impacted by health- and risk-based standards established by EPA.

b. Executive Order No. 12,866: The Final Rule violates Executive Order No. 12,866, which provides that federal agencies should promulgate only such regulations that are required by law, are necessary to interpret the law, or are made necessary by

compelling public need. EPA acted arbitrarily and capriciously because it established a Final Rule that is inconsistent with EPA's longstanding policy and procedures for review of scientific studies for the sake of transparency of scientific data that is unlawful, unnecessary, and inconsistent with standard scientific practices, in contravention of Executive Order No. 12,866.

c. OMB Memorandum M-05-03: The Final Rule violates OMB Memorandum M-05-03, Final Information Quality Bulletin for Peer Review, which establishes government-wide guidance to enhance the practice of peer review of government science documents, as it prevents and limits EPA's reliance on peer-reviewed research unless the underlying data can be made available for public review.

d. Executive Order No. 12,898: The Final Rule violates Executive Order No. 12,898, which requires agencies to identify and address the disproportionately high and adverse human health or environmental effects of their actions on environmental justice communities—minority populations or low-income communities—already overburdened by environmental harms. By shifting EPA's regulatory decision-making from the best available peer-reviewed science to a system that restricts consideration of studies based on public availability of

underlying dose-response data, the Final Rule has significant, impermissible environmental justice implications, as it limits the use of relevant, probative studies when setting standards for air pollution or other toxic exposure levels.

141. For these reasons, EPA's Final Rule should be held arbitrary and capricious, and be vacated under the APA, 5 U.S.C. § 706(2)(A).

FOURTH CLAIM FOR RELIEF
EPA Illegally Declared the Rule Immediately Effective

142. Plaintiffs reallege and incorporate by reference the allegations set forth in all preceding paragraphs.

143. EPA acted arbitrarily and capriciously and not in accordance with law in declaring that the Final Rule is immediately effective upon publication. 86 Fed. Reg. at 472–73.

144. Because the Final Rule is a substantive rule and not an interpretative rule or statement of policy, EPA cannot exempt the Final Rule from the 30-day delayed effective-date requirement under the APA. 5 U.S.C. § 553(d)(2).

145. In addition, EPA cannot rely on the "good cause" exception to the thirty-day delayed effective-date requirement. 5 U.S.C. § 553(d)(3).

146. For these reasons, EPA's declaration that the Final Rule is immediately effective should be rejected as arbitrary and capricious and not in accordance with law under the APA, 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter

judgment:

A. Declaring that the Final Rule is in excess of EPA's statutory jurisdiction, authority, or limitations; is not in accordance with law; and is arbitrary and capricious;

B. Vacating the Final Rule;

C. Awarding Plaintiffs their reasonable fees, costs, and expenses, including attorneys' fees, pursuant to 28 U.S.C. § 2412; and

D. Granting such further relief as the Court deems just and proper.

Dated: January 19, 2021

Respectfully submitted,

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