Wed Aug 15 15:02:37 EDT 2018
CMS.OEX@epamail.epa.gov
FW: Rescinding EPA's proposed rule, "Strengthening Transparency in Regulatory Science"
To: "cms.oex@domino.epamail.epa.gov" <cms.oex@domino.epamail.epa.gov>

From: Hope, Brian
Sent: Wednesday, August 15, 2018 7:02:34 PM (UTC+00:00) Monrovia, Reykjavik
To: CMS.OEX
Subject: FW: Rescinding EPA's proposed rule, "Strengthening Transparency in Regulatory Science"

DRF

From: Yogin Kothari [mailto:YKothari@ucsusa.org]
Sent: Wednesday, August 15, 2018 2:47 PM
To: Wheeler, Andrew <wheeler.andrew@epa.gov>
Cc: Darwin, Henry <darwin.henry@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Subject: Rescinding EPA's proposed rule, "Strengthening Transparency in Regulatory Science"

Dear Acting Administrator Wheeler:

Attached, please find a letter from nearly 80 public health, science, labor, transparency, accountability, and environmental organizations requesting that you withdraw the proposed rule entitled "Strengthening Transparency in Regulatory Science." This proposal is flawed beyond repair and in fact make it more difficult for EPA to use the best available science to protect public health and the environment. If you have any questions or are interested in meeting with our organizations about this matter, please let me know.

Sincerely,

Yogin Kothari

Yogin Kothari

Senior Washington Representative, Center for Science and Democracy

Union of Concerned Scientists

desk: 202-331-5665 | c Personal Matters / Ex. 6

Personal Matters / Ex. 6

August 15, 2018

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

Re: Rescinding EPA's Proposed Rule, "Strengthening Transparency in Regulatory Science"

Dear Acting Administrator Wheeler:

The undersigned public health, science, labor, transparency, accountability, and environmental organizations urge you to withdraw the proposed rule entitled "Strengthening Transparency in Regulatory Science," issued by former EPA Administrator Scott Pruitt on April 30, 2018.[1] The ill-conceived, badly written, and unlawful proposal is flawed beyond repair and should be rescinded. Further, this proposed rule runs counter to your stated commitment to "robust and civil dialogue with the public."[2] Any further time and money spent on this proposal would be a waste of valuable public resources. EPA and OMB should focus their limited resources on protecting public health and the environment rather than continuing to consider such a flawed proposal.

In your first address to EPA staff, you emphasized that you "will seek the facts" and aim to carry out "the vital mission of protecting human health and the environment."[3] To extend the benefits of science to all people, including those communities that already bear a disproportionate burden of environmental pollution, EPA must preserve the role of science as a key input for crafting public policy.

Unfortunately, the implementation of this rule would do just the opposite, undermining the ability of the Agency to use the best available science to protect public health and the environment. The proposal will not improve the use of science at EPA, but instead would restrict the types of science the Agency may use in regulatory decisionmaking. This includes, but is not limited to, studies that rely on personal health data, confidential business information, intellectual property, or older studies where the authors or data sources may not be accessible. Restricting the use of robust and well-established scientific information prevents EPA from meeting its mission.

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[1] Federal Register. 2018. Strengthening Transparency in Regulatory Science, April 30. Vol 83, No. 83. Online at https://www.gpo.gov/fdsys/pkg/FR-2018-04-30/pdf/2018-09078.pdf, Accessed July 31, 2018.
[2] Wheeler, A.R. 2018. Message from the Acting Administrator: Public Participation and Transparency in EPA Operations, July 30. Online at https://www.eenews.net/assets/2018/07/30/document_pm_02.pdf, Accessed July 31, 2018.
[3] Environmental Protection Agency (EPA). 2018. Acting Administrator Wheeler Addresses EPA Staff (News Release), July 11. Online at https://www.epa.gov/newsreleases/acting-administrator-wheeler-addresses-epa-staff, Accessed July 31, 2018.

Equally problematic, the proposed rule is not authorized by any authority delegated to EPA by Congress and is contrary to a number of statutes under EPA's authority. This includes, but is not limited to, the Clean Air Act; Clean Water Act; Toxic Substances Control Act; Lautenberg Chemical Safety Act; Safe Drinking Water Act; Federal Insecticide, Fungicide, and Rodenticide Act; and more. Substantively, the rule violates numerous public health and environmental provisions contained in these laws, as well as requirements to use the best available science or to consider all available information, while procedurally, it violates the Administrative Procedure Act and a number of other laws that set forth specific procedures EPA must follow during its rulemaking process. It also lacks an environmental justice analysis even though the rule will have the greatest impact on low-income and minority communities that benefit from protections based on the very studies the rule restricts from consideration when setting exposure limitations for pollution and toxic chemicals. Simply put, the proposal cannot withstand legal scrutiny.

The proposed rule also lacks justification and has little information on what implementation would mean for external researchers or how it would affect EPA's work to protect public health and the environment. It was developed without meaningful input from the scientific community. EPA's Science Advisory Board (SAB), tasked with reviewing the Agency's regulatory agenda and recommending actions that merit independent review, only learned about the rulemaking after it was already proposed. As a result, an SAB workgroup recommended that the advisory body review the merits of the rule because "it deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board."[4] After a nearly unanimous vote concurring with the memo, the SAB wrote in a June 28 letter to former Administrator Scott Pruitt that "[t]he SAB urges the Agency to … request, receive, and review scientific advice from the SAB before revising the proposed rule."[5]

Numerous scientific voices have spoken out in opposition to the proposed rule, including those with standards EPA claimed were consistent with the proposed rule. For example, the editors of leading peer-reviewed scientific journals, *Science*, *Nature, Public Library of Science (PLoS), Proceedings of the National Academy of Sciences,* and *Cell* wrote:

> "[I]t 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."[6]

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[4] Cullen, A. EPA Science Advisory Board, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science. 2018. Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14), May 12. Online at https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf, Accessed May 14, 2018.

[5] Honeycutt, M. 2018. Letter Re: Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science, June 28. Online at https://yosemite.epa.gov/sab/sabproduct.nsf/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf, Accessed July 18, 2018.

[6] Berg, J., P. Campbell, V. Kiermer, N. Raikhel, and D. Sweet. 2018. Joint statement on EPA proposed rule and public availability of data. *Science*, April 30. DOI: 10.1126/science.aau0116. Online at http://science.sciencemag.org/content/early/2018/04/30/science.aau0116/, Accessed July 30, 2018.

Among those not consulted in the crafting of this rule were the National Academies of Sciences, Engineering, and Medicine (NASEM), though EPA nonetheless frequently cited the NASEM in the proposed rule. EPA's reliance on the NASEM is misrepresented, as the Academies have held several committee meetings and carried out a series of reports detailing how scientific literature can be evaluated transparently without the full disclosure of underlying datasets.[7] In a comment on the rule, the NASEM urged EPA to seek objective and expert guidance in evaluating scientific standards at EPA and offered itself as an independent review body.[8]

Likewise, the Bipartisan Policy Center (BPC) clarified in a comment to the agency that "the proposed rule is not consistent" with its report on the use of science in policymaking that EPA cited in "substance or intent."[9] BPC supports enhanced transparency, but "the report never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available."[10]

The damage inflicted by this rule would have far-reaching consequences beyond undermining EPA's scientific research processes. It would weaken public health and environmental protections that keep people safe from toxic chemicals and hazardous pollution, and would ultimately mean less protection for communities who already bear the brunt of environmental contamination and associated health impacts.

Decision makers and the public need access to the best-available scientific evidence, and our health and safety depend on using that valuable information to make regulatory decisions. It is critical that as acting Administrator you follow through on your pledge to "seek the facts," by withdrawing this flawed proposal that would politicize science and prevent the agency from fulfilling its mission.

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[7] National Academies of Science, Engineering, and Medicine. 2017. *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals.* Washington, DC: The National Academies Press. DOI: 10.17226/24758; National Academies of Science, Engineering, and Medicine. 2014. *Review of EPA's Integrated Risk Information System (IRIS) Process.* Washington, DC: The National Academies Press. DOI: 10.17226/18764.; Institute of Medicine. 2011. *Finding What Works in Health Care: Standards for Systematic Reviews.* Washington, DC: The National Academies Press. DOI: 10.17226/13059; National Research Council. 2009. *Science and Decisions: Advancing Risk Assessment.* Washington, DC: The National Academies Press. DOI: 10.17226 /12209.; National Research Council. 2007. *Models in Environmental Regulatory Decision Making.* Washington, DC: The National Academies Press. DOI: 10.17226/11972.; National Academies of Science, Engineering, and Medicine. 2017. *Innovations in Federal Statistics: Combining Data While Protecting Privacy.* Washington, DC: The National Academies Press. DOI: 10.17226/24652.; National Academies of Science, Engineering, and Medicine. 2017. *Federal Statistics, Multiple Data Sources, and Privacy Protections: Next Steps.* Washington, DC: The National Academies Press. DOI: 10.17226/24893.

[8] McNutt, M., C.D.Mote, Jr., and V.J. Dzau. 2018. Comment Re: Strengthening Transparency in Regulatory Science (Docket ID No. EPA-HQ-OA-2018-0259), July 16. Online at http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf, Accessed July 23, 2018.

[9] Grumet, J. 2018. Bipartisan Policy Center comments on "Strengthening Transparency in Regulatory Science," Docket ID No. EPA-HQ-OA-2018-0259, May 22. Online at https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0670, Accessed July 30, 2018.

[10] *Id.*

Signed,

AFGE Local 704
Alaska Community Action on Toxics
American Medical Student Association
American Rivers
Anacostia Watershed Society
Association of Reproductive Health Professionals (ARHP)
Association of Research Libraries
Blackwater Nottoway RiverGuard
Breast Cancer Prevention Partners
Buffalo River Watershed Alliance
Cahaba River Society
CATA - The Farmworker Support Committee
Center for Biological Diversity
Center for Food Safety
Center for Inquiry
Center for Progressive Reform
Clean Water Action
ClimateTruth.org
Coming Clean
Concerned Citizen
CRLA Foundation
Des Moines County Farmers and Neighbors for Optimal Health
Earthjustice
Endangered Species Coalition
Environmental Defense Fund
Environmental Law & Policy Center
Environmental Protection Network
Farmworker Association of Florida
Farmworker Justice
Friends of the Earth
Gasp
Government Accountability Project
Government Information Watch
Green Science Policy Institute
Greenpeace USA
Gulf Restoration Network
Harpeth Conservancy
Helping Others Maintain Environmental Standards (HOMES)
Jacobs Institute of Women's Health
Kentucky Resources Council, Inc.
Kentucky Waterways Alliance
League of Conservation Voters
Massachusetts Rivers Alliance
Mississippi River Collaborative

Moms Clean Air Force
National Equality Action Team (NEAT)
National Family Farm Coalition
National Health Law Program
National LGBTQ Task Force
National Organization for Women
National Parks Conservation Association
National Partnership for Women & Families
Natural Resources Defense Council
New Hampshire Rivers Council
Northwest Watershed Institute
Ohio River Foundation
Pequabuck River Watershed Association
Pesticide Action Network
Pesticide Action Network North America
Physicians for Social Responsibility
Pollinate Minnesota
Poweshiek CARES
Public Justice
Rivanna Conservation Alliance
River Network
Save EPA
Schuylkill Pipeline Awareness
Science and Environmental Health Network
Sciencecorps
Sierra Club
Union of Concerned Scientists
United Steelworkers
US PIRG
Waterkeeper Alliance
West Virginia Rivers Coalition
Women's Voices for the Earth
Yukon River Inter-Tribal Watershed Council

Cc: Acting Deputy Administrator Henry Darwin
Principal Deputy Assistant Administrator for Science for the Office of Research and Development and EPA Science Advisor Jennifer Orme-Zavaleta
Deputy Assistant Administrator for the Office of Research and Development Richard Yamada