Environmental Protection Network

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Michael S. Regan, Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
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Washington, DC 20460

Dear Administrator Regan:

Founded in 2017, the Environmental Protection Network (EPN) harnesses the expertise of more than 550 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former scientists and regulators with decades of historical knowledge and subject matter expertise.

EPA has a reputation for considering the highest quality science in its decision-making, and the agency's commitment to quality assurance, independent peer review, and scientific integrity ranks among the best across all federal agencies. Even so, in recent years, EPA's use of scientific information in its regulatory decision-making has been attacked. These efforts sought to control how the agency conducts its scientific work and undermine EPA's ability to meet the highest scientific standards. Public health remains vulnerable to those who diminish, manipulate, or discredit scientific findings that do not support their interests. Many people distrust science and, because of this, those who seek to undermine it are emboldened. We recommend you take immediate action to increase public confidence in EPA, enhance transparency in EPA's use of science for decision-making, and prevent future efforts to interfere with EPA's high-quality scientific work. Actions taken now to restore public confidence in EPA and build the EPA's science infrastructure will protect the scientific soundness of tomorrow's actions. Your leadership is critical.

The mission of EPA is to protect public health and the environment from harmful agents in the air, water, food, and earth. EPA does so by using the authority conferred by over twenty different environmental protection laws, including the Clean Air Act, the Safe Drinking Water Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation, and Liability Act, and the Federal Insecticide, Fungicide, and Rodenticide Act, and the Toxic Substances Control Act. These statutes and their implementing regulations are premised on the notion that EPA will make regulatory decisions based on scientific information about the risks and benefits of exposure to environmental substances, e.g., hazardous wastes, air and water pollutants, and pesticide residues.

EPA processes science in risk assessments, guidance, and risk evaluations. While the methods used to do so may differ from one office and program to another, EPA must use the best scientific information to make the best regulatory decisions. That said, in early January 2021, at the tail end of the Trump Administration, EPA finalized its *Strengthening Transparency in Regulatory Science* rule, establishing controls clearly favoring the regulated community on the inclusion/exclusion of scientific findings used in environmental regulations. It was the culmination of an embattled twenty-year effort to prevent EPA from using selected scientific studies in its rulemakings. The final rule required the public to have full access to the raw data in studies to be used

by EPA in its consideration of scientific findings in regulatory decision-making, despite existing laws preventing such access. Those pressing for this rule asserted that data that were not, or could not be released, were "secret" and subject to manipulation. Ignoring nearly one million opposing public comments, then-EPA Administrator Andrew Wheeler finalized the rule on January 6, 2021, without congressional authorization, without evidence of its need or utility, and with compelling unanswered questions about its implementation. Alarmingly, the transparency rule would enable industry to raise (presumably unwarranted) data concerns and limit EPA's use of science, thus biasing the available information in their favor and adversely impacting disadvantaged communities.

On February 1, 2021, the rule was overturned by the courts on the basis that its justification under the *Housekeeping Rule* was inappropriate[1] and on May 24, 2021,[2] you concurred. Despite these outcomes, the rule provides a roadmap for any future administration that may, once again, seek to remove from consideration in rulemaking high quality human research that, if considered, would protect people's health.

The following recommendations were prepared by EPN volunteers. Based on their experiences as former EPA senior scientists, the attachments below include our recommendations supporting the January 27, 2021, *Memorandum Restoring Trust in Government through Scientific Integrity and Evidence-Based Policymaking*. We believe that proactively acting upon these recommendations will increase public trust in EPA science and ultimately protect public health.

- **Attachment 1** provides specific recommendations for actions that are within your capacity to complete.
- **Attachments 2-6** provide background rationale for our recommendations.

We would be happy to discuss these with you or your staff and/or provide any additional information.

Preventing EPA or any federal or state regulatory agency from considering high-quality and relevant research findings in rulemaking threatens public health and the environment. The public is only protected when EPA has access, without constraint, to the best available science.

Sincerely,

Michelle Roos
Executive Director
Environmental Protection Network

cc: Faisal Amin, Chief Financial Officer, Office of the Chief Financial Officer
Barry Breen, Acting Assistant Administrator, Office of Land and Emergency Management
Radhika Fox, Assistant Administrator, Office of Water
Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention
Christopher Frey, Assistant Administrator, Office of Research and Development
Joseph Goffman, Acting Assistant Administrator, Office of Air and Radiation

[1] Vacatur and Remand Final Order Case 4:21-cv-00003-BMM
[2] Implementation of Vacatur - Strengthening Science Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information

Jane Nishida, Assistant Administrator, Office of International and Tribal Affairs
Sean O'Donnell, Inspector General, Office of Inspector General
Jeffrey Prieto, General Counsel, Office of General Counsel
Lawrence Starfield, Acting Assistant Administrator, Office of Enforcement and Compliance Assurance

Attachments

Attachment 1: Recommended Actions to Enhance Science Transparency, Increase Public Access to Data, and Block Political Interference

1. Maintain and promote independent peer review, quality assurance, and scientific integrity.

2. Improve transparency, consistency, and block political interference in agency clearance processes.
    a. Adopt as **policy**, with modification, EPA's Best Practices in Clearance of Scientific Products at EPA.[3] EPA needs a single and consistent policy for the submission, review, approval, reconsideration, and tracking of scientific product clearance. The policy must define the roles and responsibilities, and hold accountable scientists, supervisors, and approving officials to assure the **timely** release of high-quality scientific products without political interference.
    b. Strengthen internal controls prohibiting political appointees from interfering in scientific products.
        i. Exclude political appointees from the approval chain.
        ii. Brief political appointees on important products so they review and comment during the clearance process given pre-established timelines and document their comments.
        iii. Submit scientific products authored by political appointees into the clearance process and cleared in the same manner as any scientific product.
    c. Assure effective linkage to external peer review, quality control, and other administrative approval processes.
    d. Establish an agency-wide electronic clearance system that registers and tracks submission, approvals, and publication/release of all scientific products. Link electronic clearance to implementation of public access to scientific data and publications.

3. Extend EPA's implementation to increase access to results of EPA-funded scientific research[4] (see **Attachment 2**).
    a. Assure that EPA funded data are uniformly available, easily searchable, and of considerable value to the public.
        i. Make datasets posted on Science Hub publicly accessible from the EPA website. Although this is currently required, they do not appear to be at the present time.
        ii. Enable public-use datasets to be searchable in a manner that promotes use by the public. Make useful descriptions of each dataset readily accessible together with links to the published manuscripts.
        iii. Assign dedicated staff trained in data access, data security, and protected data to quality control posted datasets. Instruct intramural researchers to provide appropriate datasets to these dedicated staff.
        iv. Assign dedicated staff to track access to, and utility of, EPA public use datasets.
    b. Establish a secure data enclave, making available protected information that satisfies regulations for protecting personal identifying information, certificates of confidentiality, confidential business information, and trade secrets.
        i. Make industry-funded research provided to EPA as confidential business information or trade secret available within the secure data enclave if used for an EPA action.
    c. Include additional datasets in EPA's portal.

[3] Best Practices for Clearance of Scientific Products at EPA
[4] Increasing Access to Results of EPA - Funded Scientific Research | US EPA

i. Take necessary administrative actions to post or link extramural research datasets funded by EPA to the EPA website.
ii. Make unpublished and programmatic datasets available to the public on the EPA portal because they have value and represent a public investment. Establish a timeline for posting unpublished EPA-funded datasets on the data portal.

4. Establish definitions, guidance, regulatory and other actions promoting consistent use of *best available science* and *transparency* across the agency (see **Attachment 3**).
    a. Identify and evaluate external and agency practices of *best available sciences* and *transparency*.
    b. Consult the Science Advisory Board to establish agency definitions consistent with best practices and existing legal text.
    c. Finalize a guidance document or policy order instructing the agency on how to use these concepts in their work, including science-based regulatory and other high-profile actions.

5. Further emphasize scientific integrity (see **Attachment 4**).
    a. Embed language promoting scientific integrity within EPA regulations.
    b. Require political appointees to undergo scientific integrity training and pledge (in writing) their agreement to adhere to its requirements.
    c. Extend further the Scientific Integrity Policy into EPA's Federal Advisory Committees.
        i. Assure that EPA research funding is not declared a conflict-of-interest and does not disqualify membership on an EPA advisory committee
        ii. Always seek review of science-based agency rulemaking by the appropriate advisory committee
        iii. Actively consult with the scientific integrity official and OGC to evaluate if a designated federal official should recuse themselves from a specific activity based on a potential conflict of interest.
    d. Require those submitting scientific data to EPA for consideration have their own scientific integrity policy or are in compliance with EPA's policy.

6. Revitalize the role of the EPA Chief Scientist, promote consistency in agency-wide scientific procedures, and establish effective processes for resolving scientific disagreements without political interference (see **Attachment 5 and** *Memorandum on Restoring Trust in Government Through Science Integrity and Evidence-Based Policymaking*, Section 6).
    a. Remove the title *Science Advisor* from the position *Assistant Administrator Office of Research and Development.*
    b. Create an executive-level *Chief Scientist*position who is not a political appointee and works across the agency to assure that scientists and science activities are of high quality and conducted appropriately, free from political interference, and holds the final approval authority for all scientific products. Consider placing this position within the Office of the Administrator.
    c. Provide the Chief Scientist with sufficient infrastructure to conduct his/her work. Consider relocating cross-agency scientific activities formerly within the Office of the Science Advisor under the Chief Scientist (e.g., scientific integrity, human subjects research protection, public access to data and publications, science and technology policy, and risk assessment forum)
    d. Consider providing the Chief Scientist oversight of cross-agency scientific activities located within the Office of the Administrator including the Office of Children's Health and the Science Advisory Board.

e. Promote consistent scientific procedures across the agency unless prohibited by legislation. For example, establish a consistent approach to systematic review protocols that ensures the best available science is used for both hazard and exposure assessments.
f. Under the Chief Scientist and in conjunction with scientific clearance reconsideration protocols and the Differing Scientific Opinion Policy, establish policies and processes for resolving scientific disagreements protected from political interference. Assure the procedures are documented for transparency, fairness, and objectivity.

Attachment 2: Background Relevant to Extend EPA's Implementation to Increase Access to Results of EPA-funded Scientific Research

EPA has established guidelines and implemented procedures to increase public access to EPA-funded research data in compliance with guidance issued by the Office of Science and Technology Policy in 2013. EPA guidelines were finalized in November 2016, and implementation policies have been completed for all EPA-funded intramural and extramural research. These policies require datasets underlying EPA-funded research published (intramural) or funded (extramural) after the relevant implementation policy be made available. The policies prevent protected personal information and confidential business information data from public release. EPA defers to each office to implement the policy. Intramural researchers are asked to determine if their data are protected or can be posted on the EPA Science Hub. EPA datasets are also listed on the federal-wide website Data.gov. Extramural researchers now must describe how their data will be made available when they apply for funding. Extramural data should be posted on an acceptable data portal that is not supported by EPA. EPA has developed a time-limited Memorandum of Understanding with the National Center for Health Statistics Research Data Center (RDC) to support up to five EPA datasets in its restricted data enclave. To date, only two EPA datasets have been posted on the RDC. Public use of posted datasets, including those in the RDC, is unknown.

Attachment 3: Background Relevant to Establishing Definitions, Guidance, Regulatory and Other Actions Promoting Consistent Use of *Best Available Science* and *Transparency* Across the Agency

EPA can reinforce and extend its transparency practices to protect influential scientific information and further build public trust. A useful step would be to adopt definitions for transparency and best available science for use across the agency preventing others from projecting biased definitions upon EPA. Codifying definitions establishes a standard for the agency and the public. Once the definitions have been adopted, guidance or policy documents focused on transparency and best available science could be prepared to provide uniformity across EPA.

Best Available Science

EPA's statutory authorities include inconsistent legal text describing the scientific information that EPA is to use in regulatory decisions. Text from ten sections across seven acts establish the science to be used by the agency in rulemaking (see **Attachment 6**). Two sections call for the use of the *best available science*, although neither law defines *best available science*. Two sections require the use of the *latest scientific knowledge*, another section identifies only *peer-reviewed* science, and yet another the *weight-of-evidence.* None of these legal phrases are defined. As a result, the agency is free to include or set aside even the highest quality, most relevant research if, in EPA's judgment, it does or does not meet the undefined criteria for *best, available,* and/or *latest.* This inconsistency does not build public trust. The available text does not restrict the agency from creating a consistent definition to be applied across all of its regulations.

A definition for *best available science* requires flexibility and context. Several examples of definitions for *best available science* are available to consider. The *best* research is judged on type, quality, and relevance.

In medicine, the *gold-standard* type of research is the double-blinded controlled trial where patients are randomized into treatment groups. Because it isn't ethical to knowingly expose people to hazardous levels of pollutants, the best human environmental health research may be observational, following cohorts, often workers, exposed to relatively high levels of hazardous substances over time. Other types of epidemiologic studies may be available and should be considered such as case-control and cross-sectional studies. These are often considered less influential than cohort studies. Biological plausibility is a standard component of considering the strength of epidemiological findings and usually is based on animal or *in vitro* experiments. In the absence of compelling human studies, such toxicological research may be the best available. Research models may also be influential, but independent validation of model elements is important. EPA's definition should recognize that in many instances the only human data will come from unplanned and uncontrolled exposures that cannot achieve the "gold standard" of a double-blind study of volunteers.

The quality of research is judged on accuracy, precision, and validity. Measures of exposure and effect are particularly important, validated quantifiable data being more useful than qualitative metrics. For example, a pathology report confirming a specific cancer type and stage is more accurate than an individual's self-report. Quality controlled personal breathing zone measurements taken over time in the workplace are more valuable than the use of a job-exposure matrix suggesting relative levels of exposure based on job title alone.

The best available science should be relevant to the issue for which it is to be used. Influential studies of human health, if available, are more relevant to actions protecting human health than are most animal studies. Research studies with exposure levels that match those for which guidelines are being evaluated are

more relevant than studies with lower or higher exposure levels. An important caveat, however, is that compared to research studies with high exposure levels, studies with low exposure levels require more exposed people or animals followed over longer observation times before an effect may be observed. New alternative methods are increasingly being used in place of animal studies and must also be incorporated into policies on transparency and best available science.

The research to be considered should focus on high-quality and peer-reviewed studies. Inclusion and exclusion criteria may vary across different types of reviews but must be defined early in the process. Inclusion/exclusion criteria might limit research to studies published in English-language peer-reviewed journals or extend to non-English peer-reviewed journals. Peer-reviewed research considered confidential business information might be included, but if so, efforts should be made to make it available to the public. Published governmental research that does not appear in a scientific journal might be considered if it has been adequately peer reviewed.

Transparency

Bill Ruckelshaus, two-time EPA Administrator, was a champion for EPA's transparency culture. In his *fishbowl memo*, he linked public trust with openness and integrity: "I am relying on EPA employees to use their common sense and good judgment to conduct themselves with the openness and integrity which alone can ensure public trust in the Agency." Science transparency includes aspects of openness long practiced by EPA, such as providing accurate information about study design, execution, data analysis, and results. These factors are used by EPA and peer reviewers to judge research quality, validity, and value. EPA openness includes publishing guidelines for how it conducts research reviews used in risk assessments and other actions. For example, the Integrated Risk Information System (IRIS) developed by EPA has published multiple guidelines on its process. Furthermore, the agency has published many consensus issue-specific risk assessment guidelines which are used by scientists in all program areas agency-wide.

Unbiased definitions of research transparency have been provided by social scientists. One such definition states research transparency is "*the obligation to make data, analysis, methods, and interpretive choices underlying their claims visible in a way that allows others to evaluate them*."[5] Social scientists include three dimensions in their definition: 1) data access, 2) production transparency, and 3) analytic transparency. The data access dimension includes the statement …"*If you generatedor collected those data yourself, [share] those data or [explain] why you cannot do so*."[6] This piece of the definition was ignored by those writing the Strengthening Transparency in Regulatory Science rule. Any definition of research transparency adopted by EPA that includes data access must emphasize that data access is not an indicator of study quality or relevance, is the responsibility of the data owner, and is dependent upon existing laws and regulations that restrict access to personal identifying information, confidential business information, and trade secret information.

[5] Transparency in Qualitative Research

[6] Managing Qualitative Data: Research Transparency and Qualitative Data

Attachment 4: Background relevant to: Further emphasize scientific integrity

The *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking* emphasizes the critical need for agencies to invest in scientific integrity. EPA has a robust scientific integrity program that meets most of the conditions described in the memorandum. The EPA Scientific Integrity Policy[7] increases transparency and trust in EPA science and creates a workplace where high-quality science is produced and protected. It assures objectivity and prevents undue political interference with scientific research and scientists. It applies to "every agency employee, contractor, grantee, volunteer and collaborator who conducts, utilizes, supervises, manages, communicates, or influences scientific activities." This includes political employees. The program seeks input from non-governmental organizations. It investigates claims of a loss of scientific integrity and publishes summaries of its findings. The authority for the program is based on its support from the EPA Administrator as no environmental law or regulation has authorized it. Reinforcement of scientific integrity goals by each administration provides support, albeit temporary, for EPA's programs. The Office of Science and Technology Policy is actively working to expand and strengthen scientific integrity policies across all the Federal agencies that conduct, fund, use, or communicate scientific information landscape.

The Scientific Integrity Policy should apply to EPA's Federal Advisory Committees and its members. EPA uses Federal Advisory Committees to promote transparency and trust in EPA science-related issues. The Science Advisory Board (SAB), Clean Air Science Advisory Board (CASAC), Board of Scientific Counselors (BoSC), and Science Advisory Committee on Chemicals (SACC) are a few of those that examine scientific products developed by the agency. These committees provide independent review and advice on agency science products. Selection of members to serve on EPA external scientific advisory committees should adhere to standard approaches used to obtain unbiased scientific advice and avoid or, at a minimum, balance conflicts of interest among committee members. Committee members should have ample time to consider the pertinent scientific literature and to engage in a deliberative process relevant to their determination. Committee members should be chosen to encompass the requisite scientific disciplines pertinent to their deliberations. Employment or paid consultation by the regulated community, including trade associations or environmental advocacy organizations, is a potential conflict of interest. In such cases, committee membership must be balanced. Paid consultation on specific issues deliberated by a committee is a conflict of interest and those members should be recused from participation.

[7] EPA's Scientific Integrity Policy

Attachment 5: Background Relevant to Revitalize the Role of EPA's Chief Scientist

The *Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking* calls upon every agency to have a Chief Scientific Officer who "serve[s] as the principal advisor to the head of the agency on scientific issues and ensure[s] that the agency's research programs are scientifically and technologically well-founded and conducted with integrity." While EPA has a Scientific Integrity Official, it does not have a chief scientist who works across the agency to assure that science activities are of high quality and conducted appropriately, free from political interference, and holds the final approval authority for all scientific products. Instead, EPA has a Science Advisor, who is a Senate-confirmed political appointee and concurrently the Assistant Administrator for the Office of Research and Development. This arrangement works well only when the appointee is a well-qualified scientist, has significant administrative experience, holds the respect of the Administrator, and is not in conflict with other EPA programs or political appointees. However, when programs are in conflict over a scientific product, the Administrator must determine how to resolve the conflict. In these situations, political influence, not an unbiased scientific evaluation, could decide the outcome of the conflict if there is no Chief Scientific Officer. In addition, a Chief Scientific Officer can enable, rather than prevent, programs that have similar scientific processes to conduct them in different ways. For example, weight-of-evidence and risk assessment approaches differ across EPA regions and program offices. This may be appropriate when required by legislation, but should not be protected because of individual preference.

Attachment 6: Selected Congressional Text Defining Science Used in Selected EPA Actions

Act	Section	Text	Action
Clean Air Act	Section 7408(a)(2)	*Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.*	Air quality criteria for pollutants
	Section 7412(f)(2)(A)	*Emission standards (for hazardous) pollutants shall provide an ample margin of safety to protect public health…unless a more stringent standard is needed to prevent…an adverse environmental threat. If standards apply to a pollutant classified as a known, probable, or possible human carcinogen...the Administrator shall promulgate standards that reduce lifetime excess cancer risks to the individual most exposed…to less than one in one million.*	Air emission standards for hazardous pollutants
Clean Water Act	Section 304(a)(1)	*The Administrator…shall develop and publish, within one year after the date of enactment of this title (and from time to time thereafter revise) criteria for water quality accurately reflecting the latest scientific knowledge on their effects and concentrations and dispersal.*	Water quality criteria for pollutants
Comprehensive Environmental Response, Compensation, and Liability Act	Section 104 Response Authorities [ATSDR]	*Any toxicological profile or revision thereof shall reflect the Administrator of the Agency for Toxic Substances and Disease Registry assessment of all relevant toxicological testing which has been peer reviewed.*	Minimal Risk Levels for toxic pollutants
	Section 104(a)(1)	*Whenever there is a release or substantial threat of release of any hazardous substance or any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare, the President is authorized to act, consistent with the national contingency plan…to protect public health or welfare or the environment.*	Removal Action Levels for pollutants

Comprehensive Environmental Response, Compensation, and Liability Act (*cont.*)	Section 121 Cleanup Standards	*Remedial actions selected under this section…shall attain a degree of cleanup of hazardous substances, pollutants, and contaminants released into the environment and of control of further releases at a minimum which assures protection of human health and the environment.*	Remediation Standards
Federal Insecticide, Fungicide, and Rodenticide Act	Section 2 (bb)	*The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under Section 408 of the Food, Drug, and Cosmetic Act.*	Pesticide use limitations
Resource Conservation and Recovery Act	Section 6921(b)(1)	*The Administrator, in cooperation with the Agency for Toxic Substances and Disease Registry and the National Toxicology Program, shall also identify or list those hazardous wastes which shall be subject to the provisions of this subchapter solely because of the presence in such wastes of certain constituents (such as identified carcinogens, mutagens, or teratogens) at levels in excess of levels which endanger human health.*	Hazardous waste treatment, storage, transport and disposal regulations
Safe Drinking Water Act	Section 1412 (b)(3)(A) - *Use of Science in Decision-Making*	*In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) 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)*	Maximum contaminant level goals, Drinking water health advisories for pollutants

Toxic Substances Control Act	Section 26(h)	… *to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science…*	Chemical risk evaluations
	Section 26(i)	*The Administrator shall make decisions…based on the weight of the scientific evidence*	Chemical risk evaluations