Environmental Protection Network

Resetting the Course of EPA

Restoring Science as the Backbone of EPA Decision-making

This paper is part of the Resetting the Course of EPA project by the Environmental Protection Network (EPN), a bipartisan network of more than 500 former EPA career employees and political appointees across the country who served under multiple Democratic and Republican administrations.

Resetting the Course of EPA outlines specific and actionable steps that EPA leadership can take to reset the course of the agency to address the most significant and pervasive threats to public health and our environment. As there is no single roadmap, EPN looks forward to collaborating with others to advance the dialogue around the future of EPA and set ideas into motion that will better protect the health and wellbeing of everyone.

Additional Resetting the Course of EPA documents are available here:
https://www.environmentalprotectionnetwork.org/reset

For more information, please contact EPN: reset@environmentalprotectionnetwork.org

For press inquiries, please contact: press@environmentalprotectionnetwork.org

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Summary

Science needs to be the foundation for EPA's policies and decisions. Science at EPA means many things. It can include basic, cutting-edge environmental research; the independent review of scientific studies performed by others; informed regulatory decisions authorized by law; and support for implementation of activities carried out by EPA or state/local/tribal environmental agencies. All of these are part of EPA's fundamental mission to protect human health and the environment, and all require appropriate funding and support. Many of these functions are carried out by EPA's Office of Research and Development (ORD), but both program and regional offices participate in ongoing scientific work.

Over the last 50 years, EPA's mission has been enhanced greatly by having its own research program, ORD. The focus of this research helps to provide the scientific and technical foundation to meet statutory obligations. The research also helps EPA, states, tribes, and other partners address their most pressing environmental and public health challenges.

The agency's scientific work has been most successful when program offices can articulate longer-term research priorities that permit the interplay between basic and applied research. Decision-makers also benefit from having access to world-class scientists who can provide advice and work on assessments of the state of the science underlying key issues. EPA's research arm also has a unique capability to assess and develop approaches to address adverse effects of unique environmental incidents in local areas.

In recent years, adverse changes to the way science is used and managed by EPA has: marginalized the scientific basis for EPA policies and decisions; significantly reduced the credibility of EPA actions and efforts; jeopardized human health and the environment; and provided opportunities for special interests to have a disproportionate influence on EPA actions.

EPA must restore science as the backbone of decision-making, building on its strength in understanding ecological systems to develop better systems-based approaches for addressing complex issues. Such system-based scientific approaches are needed to reveal interventions that may positively impact multiple outcomes, while avoiding unintended consequences. The increasing availability of very large datasets and massive computing capacity, which has driven fundamental discovery in understanding the complexity of the human genome and health, has yet to be fully tapped for the purpose of environmental public health.

Recommendations

1. **Eliminate the inappropriately-named "transparency" rule**. [Read More]
2. **Restore the integrity of the science peer-review process**. [Read More]
3. **Rebuild EPA's research program**. [Read More]
4. **Update risk assessment practices**. [Read More]

Recommendation #1: Eliminate the inappropriately-named "transparency" rule.

EPA has a long-established history of using the latest juried science in decision-making. EPA's "Strengthening Transparency in Regulatory Science" rulemaking is detrimental to high-quality impartial decision-making on behalf of the health and safety of the public. The rulemaking would:

- Reverse the decades-old EPA practice of using the best available science in carrying out the responsibilities Congress placed on the agency.
- Deprive agency decision-makers of access to vetted, published scientific studies for which some of the underlying data cannot be made publicly available.
- Undermine epidemiological studies that have been critical in setting protective air standards for the public. Often these studies rely on personal information, which, if disclosed, would violate the privacy of subjects of the studies. Examples include sensitive groups such as children, or adults exposed to polluted air who have serious conditions like asthma or cardiovascular disease. Providing information that makes it easy to identify people as subjects of a research study could haunt them throughout their lifetimes, making it hard to obtain medical insurance or possibly employment.
- Open for review every aspect of the decision regardless of the relevance to the science or policy outcome.
- Give excessive authority to the Administrator to pick and choose what studies, regardless of their source or vetting, to include in policy evaluations without transparent criteria or disclosure of the rationale.

Immediate Actions

- Suspend or rescind the proposal, depending on its status.

Early Actions, Including the First 100 Days

- If the rule has been finalized:
    - Announce that EPA will be drafting realistic science-based guidance, not rules, through an open process to ensure decision-process integrity.
    - Establish the scope of this guidance across EPA's science-based decision authorities, including incorporation of dose-response assessments into cancer guidelines.
    - Prepare additional guidance that addresses data collection, storage, and sharing expectations, including who will bear the costs. The guidance would be modeled after guidance being developed for the National Institutes of Health intramural and extramural programs, with implementation prospectively, not to be applied retrospectively to science already published and vetted.

Recommendation #2: Restore the integrity of the science peer-review process.

The numerous changes to the peer-review process used by the Science Advisory Board (SAB) and the Clean Air Science Advisory Committee (CASAC) have compromised EPA's effectiveness and credibility. These committees and other agency science boards (e.g., Board of Scientific Counselors) should have their processes reviewed, and corrective actions should be taken when needed.

Immediate Actions

- Immediately commit to changing back to the formerly well-established process of selecting and supporting advisory groups.
- Meet with program offices and regions to identify topics for review and expertise needed for new members.
- Eliminate the so-called streamlining memo process that has compromised the criteria and National Ambient Air Quality Standards review process in CASAC.
- A number of existing SAB members, including the current SAB chair, should be seriously considered for reappointment.

Early Actions, Including the First 100 Days

- Seek input and support from other independent science organizations.
- Re-compete all board/committee positions after lifting the exclusion for EPA grant recipients.
- Develop strategies to initiate reviews much earlier in the process to reduce timing issues.
- Augment SAB with new members and develop a process to adjust term limits so that there is consistent turnover. Bring back some former SAB members to ensure process consistency.
- Restore the use of pollutant-specific expert panels to assist CASAC.

First Year and Sustained Actions

- Engage advisory/committee members on broad issues of science credibility for EPA.
- Take steps to change the CASAC chair and restore a balance in terms of scientific discipline vs. state and local representatives.

Recommendation #3: Rebuild EPA's research program.

EPA's research strategy has recognized three cross-cutting topics: nitrogen and co-pollutants, environmental justice, and children's environmental health. Yet progress has been limited in part by in-house budget cuts and a phasedown of extramural programs, including the children's health centers as well as environmental justice programs generally. ORD funding and staffing have been cut by nearly one-quarter over the past decade.

In the long run, EPA science needs to build on its strengths in understanding ecological systems to develop better systems-based approaches for addressing countless complex issues. Such systems-based scientific approaches are needed to reveal interventions that may positively impact multiple outcomes, while avoiding unintended consequences. Accountability research to evaluate the effectiveness of EPA regulations and other interventions is an important need. The increasing availability of very large datasets and massive computing capacity, which has driven fundamental discovery in understanding the complexity of the human genome and health, has yet to be fully tapped for the purpose of environmental public health.

Immediate Actions

- Restore intramural funding and staff.
  - Ensure that EPA will be positioned to address new and emerging areas of science.
  - Use Title 42, a special federal hiring authority, to allow EPA to directly recruit world-renowned scientists and engineers from academia, private industry, and other government agencies. With these scientific leaders in-house, EPA will be able to pioneer solutions to the nation's most pressing environmental and human health challenges.
  - Seek permanent authorization with appropriate funding.

Early Actions, Including the First 100 Days

- Identify and expand opportunities, such as Science to Achieve Results (STAR) and American Association for the Advancement of Science Fellowship Programs, to educate and train the next generation of scientists and improve their understanding of EPA and the regulatory process.
  - Meet with the National Science Foundation and other relevant science organizations to strategize on how best to proceed.
  - Establish a timetable for program development and implementation.
- Align ORD's work with the needs of the agency.
  - Ensure that program offices and regions are involved with this process as equal partners.
  - Fully fund and support the National Program Director Title 42 positions that support this need. Evaluate the need for Title 42 hires by program offices.

First Year and Sustained Actions

- Reinvigorate the EPA STAR Fellowship Program.
    - Within the budget process, provide adequate justification for expanding the program.
    - Evaluate the success of the program and make modifications and improvements as needed.
- Review intramural funding and staff, and review reorganization (including Title 42).
    - Develop a policy for extension of use beyond ORD as appropriate.
    - Develop communication materials on success measures.

Recommendation #4: Update risk assessment practices.

EPA should issue new and update existing risk assessment guidelines. From the mid-1980s through the 1990s, EPA developed guidelines for cancer, mutagenicity, reproductive and developmental toxicity, neurotoxicity, chemical mixtures, ecological effects, and exposure assessment. Many other EPA-wide policies; principles; and risk assessment guidance, databases, models, and other tools have been developed since then. The problem is that only the cancer guidelines have ever been updated—and that update occurred 15 years ago. All of the existing guidelines are out-of-date, beset by the absence of consideration of new and better science and/or updated interpretations of still valid scientific principles. Furthermore, additional risk assessment guidelines have never been issued for other important endpoints of concern.

EPA should (1) engage with staff to increase the effectiveness and timeliness of EPA's Integrated Risk Assessment System (IRIS) program and (2) implement the Risk Characterization Policy and stress its importance with senior managers and staff as assessments are developed, evaluated, and implemented.

Immediate Actions

- Empower EPA staff to build on the strong existing foundations, including their redesign of the IRIS assessment workflow, application of systematic review, and streamlining of the multi-step review process. Efforts should allow an assessment to be complete in under three years from release of the initial draft. Remove completely all entries for currently registered and post-1990 cancelled pesticides that do not have other commercial uses.

Early Actions, Including the First 100 Days

- Issue the updated, peer-reviewed mutagenicity risk assessment guidelines.
- Complete and implement all phases of an IRIS systematic review process that meets the National Academy of Sciences standards.
    - Re-evaluate the IRIS calendar by soliciting nominations from the program offices.
    - Release the IRIS Handbook for public comment.

First Year and Sustained Actions

- Revise as appropriate and re-issue the cancer, reproductive, developmental, neurotoxicity, chemical mixture, and ecological effects guidelines.
- Issue guidelines for cumulative risk assessment, immunotoxicity, and epidemiology studies. As guidelines are completed, provide *mandatory* training for agency risk assessors and managers involved in risk management decision-making and, upon request, to outside parties such as those in state, local, or tribal governments.
- Ensure program office risk assessments are following best scientific practice.

Participants in the EPN Workgroup
Restoring Science as the Backbone of EPA Decision-making

Christopher S. Zarba [Workgroup Leader]	Former Director, EPA Science Advisory Board (SAB) Staff Office; former Director and Deputy Director, National Center for Environmental Research, EPA Office of Research and Development (ORD); former Chief of Staff, EPA ORD
John Bachmann	Former Associate Director for Science/Policy and New Programs, EPA Office of Air Quality Planning and Standards
Dan Costa, Sc.D	Former National Program Director, EPA Air, Climate, and Energy Research Program
Penny Fenner-Crisp, PhD	Former Director, Health Effects Division, EPA Office of Pesticide Programs (OPP); former Deputy Office Director, EPA OPP; former Senior Science Advisor to the Director, EPA OPP
John "Jack" R. Fowle III, PhD, DABT	Former Deputy Director, Health Effects Division, EPA OPP; former Acting Director, Neurotoxicology Division, EPA's National Health and Environmental Effects Research Laboratory; former Assistant Lab Director for Toxics and Pesticides, EPA ORD; former Deputy Director, SAB
Ruth Greenspan Bell	Former Assistant and Acting Associate General Counsel, EPA Office of General Counsel
Bernie Goldstein, MD	Former Assistant Administrator, EPA ORD
Robert Kavlock, PhD	Former Acting Assistant Administrator, EPA ORD; former EPA Deputy Assistant Administrator for Science; former Director, National Center for Computational Toxicology, EPA ORD
Trish Koman, MPP, PhD	Former Senior Environmental Scientist and Program Manager in Office of Transportation and Air Quality, EPA Office of Air Quality Planning and Standards and Region 9
Tina Levine, PhD	Former Director, Health Effects Division, EPA OPP
Bob Sussman	Former EPA Deputy Administrator; former Senior Policy Counsel to the EPA Administrator
Gary Timm	Former Chief, Chemical Testing Branch, EPA Office of Pollution Prevention and Toxics