



February 23, 2024

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Dr. Francesca Grifo

Scientific Integrity Official, Office of the Science Advisor, Policy, and Engagement

Office of Research and Development

Environmental Protection Agency

1200 Pennsylvania Avenue NW,

Washington, DC 20004

Re: USEPA Scientific Integrity Policy. 89 Fed. Reg. 4606 (December 23, 2023).

Dear Dr. Grifo:

The American Chemistry Council (ACC)¹ appreciates the opportunity to submit comments on the 2024 draft of the USEPA Scientific Integrity Policy.

Please contact Jessica Ryman (jessica_ryman@americanchemistry.com) for questions or to request more information.

Sincerely,

A handwritten signature in black ink, appearing to read "JRyman", is written over a horizontal line.

Jessica Ryman, PhD, DABT

American Chemistry Council (ACC)

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to make innovative products, technologies and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health, safety and security performance through Responsible Care®; common sense advocacy addressing major public policy issues; and health and environmental research and product testing. ACC members and chemistry companies are among the largest investors in research and development, and are advancing products, processes and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy.



Over-Arching Comment

EPA's Scientific Integrity Policy must ensure scientific integrity without inappropriately minimizing or marginalizing the role of political leadership. It must "thread the needle" to prevent both the loss of scientific integrity due to political interference, as well as the misuse of the Scientific Integrity Policy to advance personal agendas.

We strongly encourage the hiring of technically competent scientists at all levels of EPA. The science that EPA deals with covers a broad range of scientific disciplines that are increasingly complex. ACC strongly supports scientific integrity at EPA to promote regulatory decisions that are based on the best available science.

Political appointees "lead the agency"² by working hand in hand with career employees on a daily basis. Consistent with this leadership role, political appointees are not only accountable to Congress about EPA's actions and decisions, but also to the public. As part of this accountability, political appointees are ultimately responsible for the policy and science policy decisions made by the agency. While their decisions are informed by the work and analysis of the career employees, the political appointees often make the difficult decisions regarding budgets, research and regulatory priorities, and appropriate analyses to inform regulatory decisions.

Scientific integrity, as EPA correctly states, must be adhered to by all EPA employees. Political interference is not appropriate and should not be tolerated. However, EPA's scientific integrity policy must not inappropriately marginalize or minimize the role of political leaders. The President's appointees are ultimately accountable for EPA's decisions and as such they must play an appropriate role in the development of EPA's scientific products, including regulations and risk evaluations.

EPA's scientific integrity policy must therefore "thread the needle" to prevent both the loss of scientific integrity due to political interference or other causes, as well as the misuse of the scientific integrity policy to advance personal agendas.

² See, for instance, the Feb. 2, 2021 press release available at: <https://www.epa.gov/newsreleases/epa-announces-additional-biden-harris-appointees-0>.



Definitions

The 2012 Scientific Integrity Policy did not include a separate section on definitions. ACC understands that the definition of ‘scientific integrity’ has been harmonized by the Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council and captured in the January, 2023 Report entitled “Protecting the Integrity of Government Science.”

ACC appreciates that references are provided for many of the definitions. However, further clarification of (or definition of) the following would be helpful:

- *Delay*, as currently defined, does not recognize that re-prioritization due to legitimate political priorities is reasonable. We also note that misuse of this Policy resulting from bad-faith and/or unfounded accusations of violations would also be anticipated to result in *delay*.
- “Scientific justification” is mentioned in the definition of *inappropriate influence*,³ as well as in item c) for protecting the integrity of the scientific process.⁴ It is not clear what level of “scientific justification” is required, particularly in instances in which there is an apparent scientific consensus.
- “Scientific justification” should be separately defined (see above).
- “Reprisal” in the context of this policy should be defined and it should be clear if this definition is consistent with, and how it differs from, the existing definition in the No FEAR Act.
- EPA’s definition of *research misconduct* envisions malfeasance and provides exceptions for “honest errors” or “differences of opinion.” However, it does not recognize “scientific negligence,” which is a form of misconduct.⁵ EPA should include “scientific negligence” in the definition of *research misconduct*, as well as the disclosure of Confidential Business Information.
- EPA should define “scientific negligence.” The publication by Desmond et al. 2021⁵ may be helpful in this regard. Particularly concerning is “scientific negligence” resulting from

³ Draft Scientific Integrity Policy, page 6.

⁴ Id., page 10.

⁵ Desmond H, Dierickx K. Trust and professionalism in science: medical codes as a model for scientific negligence? BMC Med Ethics. 2021 Apr 14;22(1):45. doi: 10.1186/s12910-021-00610-w. PMID: 33853600; PMCID: PMC8046265.



research or analyses conducted by EPA staff or other covered individuals in scientific disciplines in which they have no formal training and/or practical experience and for which they have not sought expert input. Negligence by covered individuals in conducting research and analysis can adversely impact the health, welfare, rights, and economy of the entire country, is avoidable, and should not be viewed by EPA as an “honest error” or “difference of opinion.”

1. Protecting Scientific Processes

1.1 Delay (a), Reprisal (b), Interference (c), Insulation of Programs (e), and “Right of Last Review” (m), Specific Protections for Economic Analysis (r)

As described in our General Comment, EPA’s Scientific Integrity Policy cannot inappropriately marginalize or minimize the role of political leadership, including the determination of priorities and allocation of resources. It is unclear why additional protections for reprisal beyond those provided by the No FEAR Act are necessary in this Policy, as well as how reprisal is defined in the context of this policy. It is concerning that EPA would “insulate” program evaluations from political leadership and that EPA would grant a special “right” (e.g., “right of last review”) to Agency scientists that is not granted by law. Together, these give the impression that an objective of the Scientific Integrity Policy is to encourage, justify, and shelter Agency scientists functioning independently from the structural accountability that is vital to our system of government.

1.2 Conflict of Interest (e)

Conflict of interest provisions should reference federal criminal conflict of interest statutes, the Standards of Ethical Conduct for Employees of the Executive Branch, and EPA’s Peer Review Policy. EPA should ensure the provisions of this Policy are not in conflict with any of these (or other) statutes, regulations, rules or policies. Conflict of interest should also include non-financial considerations, particularly those that could result in ‘white hat bias.’ This type of bias is defined as “bias leading to distortion of information in the service of what may be perceived to be righteous ends.”⁶

1.3 Scientific Conduct and Misconduct (f-k), (s-t), (u)

As described in the Definitions, “scientific negligence” should be considered misconduct. ACC agrees the scientific provisions in this section should be consistent with EPA’s Information Quality Policy, as well as the Information Quality Act and all other applicable EPA policies,

⁶ Cope MB, Allison DB. White hat bias: examples of its presence in obesity research and a call for renewed commitment to faithfulness in research reporting. *Int J Obes (Lond)*. 2010 Jan;34(1):84-8; discussion 83. doi: 10.1038/ijo.2009.239. Epub 2009 Dec 1. PMID: 19949416; PMCID: PMC2815336.



rules, regulations and laws. These should be cited and the language in these sections reviewed to ensure there are no inconsistencies.

1.4 Independent Validation (I)

Scientific Confidence Frameworks (SCFs) are increasingly being proposed as an alternative to traditional validation for NAMs, and it is our understanding that ICVAAM (of which EPA is a member) will issue an SCF soon. It is unclear if or how this provision would conflict with fit-for-purpose, alternative frameworks for NAMs.

2.0 Reviewing Science, Including the Use of Federal Advisory Committees

A. Peer review

ACC is pleased to see the statement that it is the Policy of EPA to “Ensure EPA decisions are based on or informed by science that has completed independent peer review and has been finalized” and to “Ensure peer review charge questions address all relevant scientific questions, including those raised in DSOs, and are free from any interference, especially interference that may inappropriately limit the scope of the review.” However, we do not believe that EPA currently follows this Policy.

B. Review by EPA Scientific or Technical Federal Advisory Committees

ACC is pleased to see the statement that it is the Policy of EPA to “Ensure FAC charge questions address all relevant scientific questions, including those raised in DSOs, and are free from any interference, especially interference that may inappropriately limit the scope of the review.” However, we do not believe that EPA currently follows this Policy.

3.0 Ensuring the Free Flow of Scientific Information without Compromising Confidential Business Information (CBI)

This Policy could reasonably be expected to result in greater engagement of EPA scientists with the public and the media. The issue of whether an EPA scientist is speaking in their personal capacity or professionally as an agent of EPA can be complex, particularly when an EPA scientist is speaking in their professional capacity yet has to disclaim that their views are not necessarily representative of EPA’s. In practice, when an EPA scientist discusses a scientific issue and mentions that they work for EPA, it is not uncommon for people to assume that “this is what EPA thinks,” just by virtue of association. Therefore, as there is greater engagement of EPA scientists with the public, it will become even more necessary for EPA scientists to be very clear about which “hat” they are wearing (e.g., personal or professional capacity, what is an EPA determination versus their own determination, and the consequences of mistakes while wearing each “hat” or inadvertently trying to wear two “hats” at once). More granular ethics training for staff may therefore be required going forward.



We are pleased that EPA has reminded employees about the potential for ethics violations (e.g., “misuse of position”), as well as offering media training to help avoid mistakes. However, there is no discussion in the Policy regarding protection of Confidential Business Information (CBI). Discussing a particular CBI-related situation could risk CBI disclosure if the information shared by the EPA employee, alone or in conjunction with other publicly available information, could provide information regarding manufacturing processes, formulations, or other protected information. We therefore encourage this Policy to remind EPA scientists that disclosure of CBI could result in criminal prosecution and to cite the relevant statutes. CBI violations should also be considered a form of *misconduct* and be included in the definition of *misconduct*.

4.0 Supporting Decision Making Processes

The process for resolving different scientific opinions is reasonable and the reference to the *Approaches for Expressing and Resolving Differing Scientific Opinions* is both necessary and appreciated. For issues that will not go to external peer review, it is unclear how long this process takes and whether or not DSOs related to Agency actions that have regulatory deadlines are prioritized for resolution if the DSO has to be significantly elevated.

The rest of the section deals mostly with the intersection of science and policy, including granting EPA scientists greater latitude in contemplating policy options and providing scientific support for policy development. Greater participation of scientists will necessitate EPA being clearer about what aspects of a policy are “pure science,” what aspects are “science-based” or “informed” by science (and how), and what aspects of a policy are due to pragmatic, legal, or other considerations. Done appropriately, this could be a very positive development that results in greater transparency regarding exactly how science is influencing policy at EPA.

5.0 Ensuring Accountability

In order to prevent the misuse of this Policy to advance personal agendas, EPA should include provisions and consequences for bad-faith misuse of this Policy. These are currently absent, and it is unclear if this would be covered under other policies. Malicious accusations of violation of this Policy, even if unfounded, could be damaging to individuals, could damage workplace morale, could impact deliverable deadlines, and will consume Agency resources. Also unclear is what the consequences are for violations of this Policy under conditions where misuse is absent.

6.0 Protecting Employees

It is not clear what protections this Policy is adding beyond those that are already present in existing laws, policies, and processes (e.g., the No Fear Act, the Merit Systems Protection Board, EPA’s OIG, etc.).



7.0 Professional Development for Government Scientists

ACC strongly encourages the hiring of technically competent EPA scientists, EPA recognition of professional credentials, and the continued professional development of EPA scientific staff. We are pleased this policy encourages opportunities for continued professional development and also request this policy encourage credentialing and advanced degrees. The science at EPA covers a broad range of scientific disciplines that are evolving toward an ever-higher level of complexity. Use of the best available science requires that EPA scientists be encouraged towards state-of-the-science training and credentialing.

