

As Arsenic Science Task Force

February 24, 2025

The Honorable Lee Zeldin
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, D.C. 20460

Dear Administrator Zeldin,

On behalf of the Arsenic Science Task Force¹ (ASTF), I write to request that you direct the Office of Research and Development to withdraw and remove from the website of the U.S. Environmental Protection Agency (EPA) the recently published toxicological review of inorganic arsenic, developed by the Integrated Risk Information System (IRIS) program.² The IRIS toxicological review of inorganic arsenic was posted as final on January 13, 2025, clearly a “midnight” action by the previous Administration. This request fully aligns with President Trump’s recent executive actions related to the regulatory reset, unleashing prosperity through deregulation, and workforce optimization.³

EPA’s IRIS program has been rife with controversy since its inception in 1988. Congress has never authorized IRIS and since 2009 the U.S. Government Accountability Office has flagged IRIS as a “high risk” program vulnerable to waste, fraud, abuse, and mismanagement. The IRIS program has routinely issued overly conservative risk assessments that are not based on an objective review of relevant scientific information, and do not reflect actual exposure experienced by the U.S. population to the chemical substances that are subject to these assessments. Alarming, these risk assessments and their resulting unsubstantiated risk values are used by EPA program offices, states and local governments to make significant decisions for setting costly regulatory levels for air and water quality, pesticides, as well as waste disposal and remediation.

¹ ASTF is an informal organization of arsenic stakeholders whose objective is to ensure that the risk assessment of inorganic arsenic carried out in the development of EPA’s Integrated Risk Information System (IRIS) is based on sound science.

² U.S. EPA, IRIS Toxicological Review of Inorganic Arsenic, CASRN 7440-38-2, EPA/635/R-25/005Fa (January 2025), *available at* <https://iris.epa.gov/static/pdfs/0278tr.pdf>.

³ See Regulatory Freeze Pending Review, 90 Fed. Reg. 8249 (Jan. 20, 2025), *available at* <https://www.govinfo.gov/content/pkg/FR-2025-01-28/pdf/2025-01906.pdf>. See also Executive Order 14192, Unleashing Prosperity Through Deregulation, 90 Fed. Reg. 9065 (Jan. 31, 2025), *available at* <https://www.govinfo.gov/content/pkg/FR-2025-02-06/pdf/2025-02345.pdf>. Executive Order 14210, Implementing the President’s “Department of Government Efficiency” Workforce Optimization Initiative, 90 Fed. Reg. 9669 (Feb. 11, 2025), *available at* <https://www.whitehouse.gov/presidential-actions/2025/02/implementing-the-presidents-department-of-government-efficiency-workforce-optimization-initiative/> (directing the development of agency reorganization plans to identify statutes that establish an agency or subcomponents of an agency and whether it should be eliminated or consolidated).

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This IRIS assessment of inorganic arsenic is a prime example of the systemic problems with the IRIS program which is unauthorized and untethered to EPA's core mission. For example, it derives toxicity values for cancer that result in a risk value 21 times more stringent than the previous value established in 1995. This value is below naturally occurring levels found in the United States.

The January 13, 2025 review suffers from many additional failures, including a failure to acknowledge the mode of action in the human body that demonstrates a safe threshold above the level to which the U.S. population is exposed, as well as failure to include all the literature that was published in the last five years. Literature that disagrees with IRIS' approach was either ignored or degraded.

Further, the IRIS review of inorganic arsenic includes a fundamentally new process to derive noncancer toxicological values. While certain elements of this novel process have been published individually by IRIS employees in peer-reviewed journals,⁴ nowhere other than in the Toxicological Review of inorganic arsenic have all the elements been combined into a single problem-solving approach. To underscore the gravity of the situation, the Science Advisory Board (SAB) review panel "recognized that such risk-based approaches for non-cancer effects would require that EPA make new science-policy decisions, including identification of a target risk level for non-cancer effects."⁵

Although the SAB raised numerous concerns with the IRIS draft, we should note that the peer review panel assembled to review the IRIS assessment of inorganic arsenic was noncompliant with the 2015 Peer Review handbook⁶ and the requirements of the Federal Advisory Committee Act for independence and balanced points of view.

The real-world consequences of this scientifically indefensible toxicological review of inorganic arsenic would be mind-boggling if they were embedded in regulatory determinations. For instance, billions of dollars of scarce federal, state and local resources would be required to meet new drinking water standards, resulting in hardships for rural communities. Additionally, soil remediation levels would necessitate massively costly and scientifically unjustified reopening of Superfund and RCRA sites previously considered safe.

For these reasons, and consistent with President Trump's recent executive actions, we respectfully request that EPA withdraw and remove from the IRIS website the assessment of inorganic arsenic. President Trump's "Regulatory Freeze Pending Review" Executive Memorandum instructed federal agencies to refrain from issuing "any rule in any manner...until a department or agency head appointed or designated by the President...reviews and approves the rule."⁷

⁴ e.g., Allen et al. 2020a, Allen et al. 2020b, Hobbie et al. 2020

⁵ Science Advisory Board, "Review of EPA's draft IRIS Toxicological Review of Inorganic Arsenic, Final Report", November 19, 2024, page 53.

⁶ U.S. EPA, Peer Review Handbook 4th Edition October 2015 EPA/100/B-15/001. Section 5.2.4

⁷ See Regulatory Freeze Pending Review, 90 Fed. Reg. 8249 (Jan. 20, 2025), *available at* <https://www.govinfo.gov/content/pkg/FR-2025-01-28/pdf/2025-01906.pdf>.

The Executive Order defines “rule” broadly to include “guidance documents” as defined in Executive Order 13891. The order is clearly intended to pause ongoing regulatory actions initiated by the previous administration so that new agency leadership has an opportunity to review these actions to ensure alignment with the current administration’s priorities.

In this case, EPA rushed to finalize the IRIS toxicological review of inorganic assessment on Jan. 13, 2025, a scant week before the end of the Biden Administration and just eight weeks after the Science Advisory Board completed its final review with over a hundred of outstanding concerns and recommendations, leaving insufficient time for them to be fully addressed.

While the document was finalized and posted, we believe it is still a prime candidate for withdrawal and reconsideration given IRIS assessments are a relied upon source of toxicity information and an important foundation for future regulatory decisions by EPA program offices and the states.

Additionally, EPA’s executive actions on deregulation and workforce optimization certainly apply to EPA’s IRIS program. The IRIS program was never statutorily authorized and has repeatedly failed to adequately incorporate high quality and relevant science. Notably, the program’s risk values are not subject to rulemaking procedures, interagency review, or appropriate stakeholder engagement. Yet, they form the basis for increased regulation.

We believe this request is fully compliant with the meaning and intent of President Trump’s recent executive actions, and we respectfully request your immediate action.

Sincerely,



Michal Eldan, PhD
Chair