

Congress of the United States
Washington, DC 20515

May 18, 2023

The Honorable Mike Simpson
Chairman
Subcommittee on Interior, Environment and Related Agencies
House Committee on Appropriations
2007 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Simpson:

We write to urge your careful consideration of funding provisions for the Environmental Protection Agency's (EPA) Integrated Risk Information System program (IRIS) in the Fiscal Year 2024 Interior, Environment and Related Agencies bill.

IRIS is an administratively created program at EPA, it issues chemical assessments including toxicity values that are relied upon in regulatory and non-regulatory contexts by federal and state agencies. Past IRIS results have been criticized for their lack of scientific rigor and reliance on precautionary values, resulting in increasingly unaccountable uses of its work to displace the criteria of our environmental laws and costing billions of dollars for consumers and critical industries.

Moreover, the process by which IRIS prioritizes and selects chemicals for assessment is opaque and appears to be inconsistently applied over time. A bipartisan group of Members of Congress have recently raised concerns about the development process for IRIS assessments, including the program's limited public, interagency, and peer review processes.¹ Recent IRIS assessments also suggest that, despite repeated congressional direction, EPA has not fully addressed major issues with IRIS identified by the National Academy of Sciences in 2011.

Additionally, the IRIS program continues to consistently produce assessments that suggest risks below natural, background levels – levels that are inconsistent with the findings of other well-respected international bodies. Several recent examples include:

- EPA's 2022 draft formaldehyde IRIS assessment suggests major health effects at concentrations far below the levels in human breath, what monitors are capable of measuring, natural background levels in rural areas, World Health Organization guidelines, and occupational limits set by countries around the world. For example, EPA's work implies a significantly lower acceptable worker exposure limit – up to 4,000 times lower – than the worker exposure limit expected to be finalized in the EU.

¹ https://babin.house.gov/uploadedfiles/final_iris_letter_to_nasem_pdf.pdf

- EPA’s IRIS value for ethylene oxide is 19,000 times lower than naturally created levels of ethylene oxide in the human body, and three to four orders of magnitude lower than levels from other sources measured in ambient air.
- The draft IRIS assessment for hexavalent chromium, a chemistry essential for a wide variety of national security applications, is at odds with the findings of over 30 peer-reviewed studies and other authoritative bodies, including Health Canada, the World Health Organization, and the Food Safety Commission of Japan.

The continued acceptance of slipshod scientific assessments has consequences. The Biden Administration and Courts have recently used precautionary IRIS assessments to take emergency action to shut down operations under Section 303 of the Clean Air Act²; delay or deny permits for important growth projects; displace science quality requirements and the risk evaluation processes Congress directed EPA to undertake under TSCA; accuse states of violating Title VI of the Civil Rights Act; and shift state regulatory priorities.

Finally, we note the reach of poorly done IRIS assessments beyond Federal rulemakings: the Senate in the State of Maryland is considering legislation to completely ban ethylene oxide based on EPA’s unrealistic IRIS value. This extreme application of the IRIS value could result in major market distributions of many important products that use ethylene oxide directly or use it in product formulations with critical uses – including the sterilization of medical instruments.

These recent legislative and regulatory actions stand in stark contrast to the Agency’s science counsellors’ own warnings that IRIS values are not of the quality suggested by these recent actions. For example, EPA’s Science Advisory board has noted that IRIS values should not be accepted *“at face value, without closely examining the quality or validity of the value(s) chosen.”*³ And the IRIS website warns “In general IRIS values cannot be validly used to accurately predict the incidence of human disease or the type of effects that chemical exposures have on humans.”⁴

Because IRIS was never created by Congress, the appropriations process is one of the few legislative branch venues to address the problems with the program. Therefore, we ask for your consideration of limits on the funding for IRIS or report language to insist EPA address longstanding problems with the program.

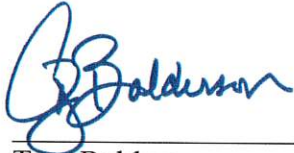
² <https://www.justice.gov/opa/pr/united-states-seeks-preliminary-injunction-against-denka-performance-elastomer-immediately>.

³ <https://www.epa.gov/sites/default/files/2021-02/documents/epa-sab-10-007-unsigned.pdf> (emphasis added). See also Preamble to National Primary Drinking Water Regulations: Minor Revisions to Public Notification Rule and Consumer Confidence Report Rule, Proposed Rule, 66 Fed. Reg. 46928 at 46929 (Sept. 7, 2001); Preamble to National Primary Drinking Water Regulations: Minor Revisions to Public Notification Rule and Consumer Confidence Report Rule, Proposed Rule, 66 Fed. Reg. 46928 at 46929 (Sept. 7, 2001); “EPA recognizes that IRIS is not a comprehensive toxicological database... IRIS values are not rules adopted after notice and comment rulemaking, although... public comments are solicited, IRIS values are not legally binding and are not entitled to conclusive weight in any rulemaking.”

⁴ [Integrated Risk Information System \(IRIS\) | Risk Assessment Portal | US EPA](#).

We are grateful for your consideration of this request and look forward to working with you and your staff on this issue as the Appropriations process moves forward. Thank you for your attention to this matter.

Sincerely,



Troy Balderson
Member of Congress



Glenn Grothman
Member of Congress



Mike Carey
Member of Congress



Earl L. "Buddy" Carter
Member of Congress



Max L. Miller
Member of Congress



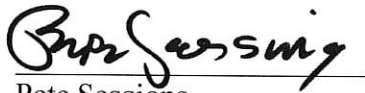
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