



July 24, 2018

The Honorable Lamar Smith
Chairman
Committee on Science, Space, and Technology
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Eddie Bernice Johnson
Ranking Member
Committee on Science, Space, and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Smith and Ranking Member Johnson,

Environmental Defense Fund (EDF) strongly opposes the Improving Science in Chemical Assessments Act being marked up by the full committee on July 24, 2018. This bill is an attempt to dismantle the vitally important Integrated Risk Information System (IRIS) program at the Environmental Protection Agency (EPA)—stripping away a core scientific function of the agency that serves to protect public health.

The IRIS program is a non-regulatory program within EPA's Office of Research and Development (ORD) National Center for Environmental Assessment (NCEA) that provides critical chemical hazard information to support a variety of public health decision-making needs inside and outside the agency. EPA program and regional offices as well as other federal, state, and local authorities rely on IRIS chemical human health hazard assessments, or toxicological reviews, to characterize and ultimately manage risks of toxic chemicals present in our air, water, land, and in the products we encounter in our everyday lives.

The Improving Science in Chemical Assessments Act would transfer the development of chemical toxicological reviews out of the IRIS program and into agency program offices that lack the full complement of specialized expertise provided by the scientific staff of the IRIS program and

broader NCEA. Likewise, the bill gives no consideration to the substantial additional workload and resource drain the program offices would incur as a result.

Indeed, the bill appears to ignore key factors that motivated the inception of the IRIS program originally and that are still relevant today. These include creating efficiency in the development of chemical assessments at the agency, in part by playing a coordinating role; supporting scientific consistency in the development of chemical assessments; and providing independence between the scientific review of chemicals and regulatory decisions informed by those reviews.

With regard to efficiency, the bill would establish a “chemical hazard identification and dose response” steering committee to coordinate assessments and avoid duplication of efforts. However, the IRIS program currently provides this function from the scientifically advantageous and sensible vantage of ORD.

With regard to supporting scientific consistency, EPA’s website notes, “The IRIS Program was created by EPA in 1985 to provide an internal database of human health assessments for chemicals found in the environment. The goal of the IRIS Program was to foster consistency in the evaluation of chemical toxicity across the Agency. Since then, the IRIS Program has become an important public resource as well.”¹ It is worth noting that the IRIS program is responsible for spearheading the advent of systematic review in the development of chemical assessments at EPA. Born out of the clinical sciences, systematic review employs structured approaches to evidence identification, evaluation, and synthesis in a manner that promotes scientific rigor, consistency, transparency, objectivity, and reduction of bias.² IRIS is a leader in the application of systematic review in environmental health, and through its assessments, IRIS is building institutional proficiency and capacity at the agency in this area.

With regard to the importance of scientific independence, EPA’s website states, “The placement of the IRIS Program in ORD is intentional. It ensures that IRIS can develop impartial toxicity information independent of its use by EPA’s program and regional offices to set national standards and clean up hazardous sites.”³

This bill has a number of provisions that could result in a weakening of scientific independence and integrity in the development of chemical assessments. For instance, the bill allows third parties to submit covered chemical assessments, an opportunity that undoubtedly will be used primarily by industry, raising significant conflict of interest concerns. The bill also promotes the development of a range of toxicity values for a chemical, deviating from the current practice of single toxicity values. This provision would lead to disparate risk management decisions as different regulators could choose different toxicity values to inform their decisions. Moreover, effective use of ranges of toxicity values requires a level of expertise and expert judgment that risk managers on the ground may not have.

¹ <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system>

² <https://ehp.niehs.nih.gov/1307175/>

³ <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system>

Section 4 of the bill includes a list of scientific considerations to be used in the development of covered assessments. Many of these raise red flags. For example, sections 4(3) and 4(6) introduce the possibility that a high quality scientific study may be excluded from use in an assessment unless its underlying data are publicly available or unless the study has been repeated. Section 4(7) dictates expectations for how dose-response modeling is to be performed in a manner that is at odds with conventional, health protective approaches. These scientific considerations mirror troubling issues raised in EPA's "Strengthening Transparency in Regulatory Science" proposed rule,⁴ a hugely problematic and widely criticized proposal.⁵

IRIS has received high marks from the National Academies in its most recent 2014⁶ and 2018⁷ reviews of the program. The program has also received praise from EPA's Scientific Advisory Board.⁸ Despite this, and despite the enormous reliance on the program from all levels of government, there have been numerous attempts to dismantle IRIS by segments of industry, political leadership at EPA, and some members of Congress.

EDF has deep concerns with the bill you are marking up today, and we strongly affirm the significance of the IRIS program's work. The IRIS program serves the needs of not only program offices at EPA, but also the needs of its regional offices, other federal agencies, states, local government, and tribes. Indeed, a recent letter from the Environmental Council of States to Congress noted, "The IRIS Program's identification and characterization of chemical health hazards plays a vital role in states' efforts to protect their residents and environments against harmful toxic exposures."⁹ IRIS plays a critical role in ensuring regulatory decisions are based on sound science, serving the best interests of the public. We strongly urge the committee to vote against the Improving Science in Chemical Assessments Act.

Sincerely,



Jennifer McPartland, PhD
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Environmental Defense Fund

⁴ <https://www.epa.gov/osa/strengthening-transparency-regulatory-science>

⁵ <http://blogs.edf.org/health/2018/07/17/edf-calls-on-epa-withdraw-censored-science/>

⁶ <https://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process>

⁷ <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=25086>

⁸ [https://yosemite.epa.gov/sab/sabproduct.nsf/0/A9A9ACCE42B6AA0E8525818E004CC597/\\$File/EPA-SAB-17-008.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/A9A9ACCE42B6AA0E8525818E004CC597/$File/EPA-SAB-17-008.pdf)

⁹ <https://www.ecos.org/wp-content/uploads/2018/03/IRIS-Letter.pdf>