

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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March 3, 2021

Ms. Jane Nishida
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Acting Administrator Nishida:

As Ranking Members on the Committee on Science, Space, and Technology, we write to express our concern about the broad reconsideration that has been proposed for the systematic review methods utilized under the Toxic Substances Control Act (TSCA). On February 16, 2021, the U.S. Environmental Protection Agency (EPA) announced that it will refine its approach to selecting and reviewing the scientific studies that are used to inform TSCA chemical risk evaluations, known as systematic review.¹ This decision was based on a report from the National Academies of Sciences, Engineering, and Medicine.²

We share your commitment to using the highest quality and best available science when developing chemical risk evaluations. As noted in EPA's announcement, the 2018 *Application of Systematic Review in TSCA Risk Evaluations* document—which laid out EPA's evolving approach to systematic review as it began its first evaluations under amended TSCA—was never intended to be a long-term guideline.³ As such, it should be updated based on the experience gained during completion of the first ten risk evaluations, along with stakeholder input. Our concern arises from EPA's apparent desire to duplicate the Integrated Risk Information System (IRIS) Program in its efforts to refine TSCA's systematic review.

¹ U.S. Environmental Protection Agency, *EPA Commits to Strengthening Science Used in Chemical Risk Evaluations*, EPA.GOV (Feb. 16, 2021), <https://www.epa.gov/newsreleases/epa-commits-strengthening-science-used-chemical-risk-evaluations>.

² National Academies of Sciences, Engineering, and Medicine, *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations*, NAP.EDU (2021), <https://doi.org/10.17226/25952>.

³ U.S. Environmental Protection Agency, *supra* note 1.

The Science Committee has long conducted oversight of the IRIS Program and the issues that have plagued it for more than a decade. In 2009, the U.S. Government Accountability Office (GAO) added the IRIS Program to its High-Risk List—a biannual list of federal programs in need of transformation due to their high vulnerability to waste, fraud, abuse, and mismanagement—where it remains to date with seven open recommendations.⁴

Numerous authoritative reports have also criticized the IRIS Program for its lack of transparency, process and procedural flaws, and the utilization of improper and unsound science.⁵ In 2011, the National Academies published a review of the draft formaldehyde IRIS assessment which found the draft “was not prepared in a consistent fashion; it lacks clear links to an underlying conceptual framework; and it does not contain sufficient documentation....”⁶ In December of 2019, TSCA identified formaldehyde as a High-Priority Substance and it is currently undergoing a risk evaluation.⁷ Repeating the flaws of the IRIS assessment by using the same process would be negligent and irresponsible.

Furthermore, in 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act amended TSCA to provide specific criteria that EPA must use to assess risk and prioritize chemicals for review.⁸ It also prescribed strict time frames within which EPA must perform its review process.⁹ There are no similar statutorily mandated requirements for the IRIS Program.¹⁰ Therefore, EPA should take steps to ensure TSCA is not duplicating flawed and lengthy IRIS processes or approaches to evaluating science. Despite making progress in recent years, it has taken IRIS nearly 10 years to address troubling issues, and many remain unresolved.¹¹ On average, it still takes the IRIS Program seven years to complete an assessment while the TSCA Program is statutorily mandated to complete a risk assessment in no more than three and a half years.¹² That is why the suggestion that TSCA would fully adopt any part of the IRIS Program—whether it be IRIS’s tailored use of systematic review or a long-delayed draft handbook that is only still in the review process—is disconcerting.¹³

⁴ U.S. Government Accountability Office, *High Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO.GOV (Mar. 2019), GAO-19-157SP.

⁵ Committee on Science, Space, and Technology Hearing, *EPA’s IRIS Program: Reviewing its Progress and Roadblocks Ahead* (Mar. 27, 2019).

⁶ National Research Council, *Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde*, NAP.EDU (2011), <https://doi.org/10.17226/13142>.

⁷ U.S. Environmental Protection Agency, *Risk Evaluation for Formaldehyde*, EPA.GOV, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-formaldehyde> (last visited Feb. 24, 2021).

⁸ Pub. L. 114–182, 15 USC Ch. 53, §2604-2629.

⁹ *Id.*

¹⁰ U.S. Environmental Protection Agency, *supra* note 6.

¹¹ U.S. Government Accountability Office, *supra* note 4.

¹² U.S. Government Accountability Office, *Chemical Assessment: Challenges Remain with EPA’s Integrated Risk Information System Program*, GAO.GOV (Dec. 2011), GAO 12-42.

¹³ U.S. Environmental Protection Agency, *supra* note 1.

Acting Administrator Nishida

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We urge the Agency to expedite any reevaluation of TSCA's systematic review methods, in a transparent and inclusive manner that includes stakeholder input, to avoid further delay of the pending evaluations. We ask for your commitment that, in accordance with congressional intent to operate with flexibility and speed, TSCA does not fully or consistently adopt program processes or procedures implemented by IRIS. If elements developed by the IRIS Program are incorporated into TSCA, we expect the Agency to assess their benefits and impacts thoroughly, while also adhering to the statutorily prescribed deadlines and scientific standards mandated.

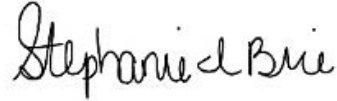
TSCA risk evaluations should not be delayed by the desire to incorporate potentially unwarranted and burdensome processes and procedures, many of which are yet unproven, from the IRIS Program. We urge you to consider these concerns so that TSCA can function in an effective and efficient manner into the future, while avoiding the pitfalls that have plagued the IRIS Program. Anything less would be an abdication of EPA's charge to protect human health and the environment.

If you have any questions, please contact Mr. Daniel Dziadon with the Committee minority staff at 202-225-6371. Thank you for your attention to this matter.

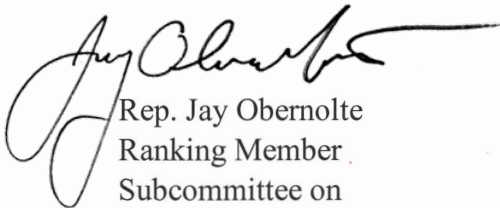
Sincerely,



Rep. Frank D. Lucas
Ranking Member
Committee on Science,
Space, and Technology



Rep. Stephanie Bice
Ranking Member
Subcommittee on
Environment



Rep. Jay Obernolte
Ranking Member
Subcommittee on
Investigations and Oversight

cc: Mr. Michael Regan, Administrator Nominee, Environmental Protection Agency.

The Honorable Eddie Bernice Johnson, Chair, Committee on Science, Space, and Technology.

The Honorable Mikie Sherrill, Chair, Subcommittee on Environment.

The Honorable Bill Foster, Chair, Subcommittee on Investigations and Oversight.