

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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October 20, 2021

The Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator Regan,

I write to call your attention to an important matter of scientific process within the Office of Chemical Safety and Pollution Prevention (OCSP). I am concerned that the uncertainty surrounding the Systematic Review framework for risk evaluations conducted under the Toxic Substances Control Act (TSCA) could undermine confidence in the chemical risk assessments currently being developed by OCSP.

Under the 2016 **Frank R. Lautenberg Chemical Safety for the 21st Century Act**, EPA is required to make decisions about chemical risks based on “the best available science” and “the weight of the scientific evidence.”¹ EPA issued a rulemaking in June 2017 that further defines “weight of the scientific evidence” as:

A systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.”²

OCSP’s Office of Pollution Prevention and Toxics (OPPT) used the *Application of Systematic Review in TSCA Risk Evaluations*, finalized in 2018, as its pre-established protocol for

¹ Public Law 114-182. [PUBL182.PS \(congress.gov\)](https://www.congress.gov/bills/114/182)

² <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0654-0108>

evaluating the relevant science during its review of the first ten chemicals under TSCA.³ However, in February 2021, a National Academies of Sciences, Engineering and Medicine (NASEM) Committee issued a consensus report which identified a number of alarming deficiencies in the 2018 Systematic Review methodology and declared that “the processes used by OPPT do not meet the evaluation criteria specified in the Statement of Task (i.e., comprehensive, workable, objective, and transparent).”⁴

More specifically, the NASEM Committee noted,

Another problematic element of the TSCA evaluation framework is that the studies that are scored unacceptable are excluded from further analyses. Any fatal flaws in the methodology or conduct that preclude including a study should be used as eligibility criteria during the screening process. Once a study is determined to be eligible, the study should be included in the synthesis and the risk-of-bias assessment, with its limitations accounted for in any qualitative or quantitative synthesis. Given the large number of metrics scored for these data types, the possibility that a single unsatisfactory rating could completely nullify the use of a particular study from synthesis is problematic as it may lead to a biased review. Statistical power and statistical significance are not markers of risk of bias or quality. Statistical significance is not a measure of association or strength of association and should not be used to evaluate studies. In fact, combining multiple small, low-powered but similar studies in a synthesis is one of the benefits of systematic review.

Several of the problems that the National Academies identified in the 2018 Systematic Review were reminiscent of the Agency’s pernicious “Strengthening Transparency in Regulatory Science” rule, which was finalized by the previous Administration on January 6, 2021 and overturned by a federal judge in Montana a few weeks later. The Science Committee spent the better part of a decade working to prevent this dangerous proposal from becoming either law or Agency policy because it would have systematically suppressed epidemiological studies that are critical for understanding environmental hazards and protecting public health, while allowing Agency staff to eliminate “inconvenient” research findings on an arbitrary basis.⁵

In response to the NASEM report, the Agency immediately moved to discard the 2018 Systematic Review methodology and vowed to replace it with a superior framework that would incorporate approaches from the Office of Research and Development’s Integrated Risk Information System (IRIS), in accordance with the NASEM recommendations.⁶ I applaud EPA for taking this appropriate action, which was necessary to restore the integrity of TSCA’s risk evaluation process, so quickly and decisively.

However, eight months have now passed since that statement, and OCSPP has yet to publicly release its replacement for the 2018 Systematic Review. In the meantime, EPA has taken up

³ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/application-systematic-review-tsca-risk-evaluations>

⁴ [National Academies Recommend Changes to EPA’s TSCA Systematic Review Process | National Academies](#)

⁵ [Chairwoman Johnson - Letter re EPA Transparency Final Rule - 1.7.21.pdf \(house.gov\)](#)

⁶ [EPA Commits to Strengthening Science Used in Chemical Risk Evaluations | US EPA](#)

another 20 chemicals for TSCA risk assessments, for which it has presumably been performing literature reviews and synthesis throughout 2021.⁷ While I am relieved that EPA has discarded the 2018 Systematic Review methodology, I am concerned about the uncertainty that surrounds the current Systematic Review framework. It is troubling that EPA has failed to clarify whether TSCA evaluations are being performed without any structured Systematic Review protocol in place, or through the use of a different protocol that has not been made available for public comment or peer review. It is not only a requirement of TSCA but a foundational principle of scientific integrity to utilize a consistent, documented process for synthesis and review of relevant research when crafting public policy. Transparency in TSCA's scientific procedures is critical to ensuring the public's trust in the Agency's work products, which have a direct effect upon the health and safety of every American.

I ask EPA to quickly formalize a TSCA Systematic Review methodology that satisfies the recommendations in the February 2021 NASEM report. If the delay is in part a matter of resource constraints for staff who are also tasked with conducting chemical evaluations, I would remind the Agency that while the deadlines for these chemical evaluations are prescribed in law via the Toxic Substances Control Act, so is the requirement to use a pre-established protocol for those efforts. EPA must not subordinate its obligations to document a transparent, objective method for synthesizing evidence to its statutory deadlines for the pace of chemical reviews.

In its updated methodology, EPA must also wholly supplant the "numerical scoring system" from the 2018 Systematic Review. This unusual method for data synthesis is out of step with common scientific practice. It has already resulted in credible, meaningful health studies being eliminated from consideration in TSCA risk assessments of the basis of deficiency in just one of over two dozen quality domains and metrics. EPA's own Children's Health Protection Advisory Committee (CHPAC) opined on the risks of arbitrary exclusion of high-quality research in detailed letters to the Agency in February 2020 and January 2021.⁸⁹

In the interest of both quality and efficiency, EPA should leverage the resources within the IRIS program and other sources as it establishes the replacement framework. As the National Academies recommended, there are existing, widely-recognized, peer-reviewed methods for systematic review that have been tested over time, including those promulgated by the University of California-San Francisco's Program on Reproductive Health and the Environment (PHRE) and the National Toxicology Program's Office of Health Assessment and Translation (OHAT). OCSPP should not feel compelled to develop a unique, TSCA-specific Systematic Review framework in a vacuum when other widely accepted toxicological systematic review processes can serve as models for the Agency's work.

Finally, when a new revised Systematic Review is completed, EPA should disclose that document to the public as soon as possible.

⁷ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca>

⁸ [2021.01.26_chpac_tsca_charge_response_letter.pdf \(epa.gov\)](#)

⁹ [Committee Members: \(epa.gov\)](#)

I also seek Agency responses to the following questions no later than November 3rd, 2021:

1. When does EPA expect to publicly release a revised protocol to replace the 2018 TSCA Systematic Review methodology?
2. EPA indicated in February 2021 that it would no longer use the 2018 Systematic Review methodology. What protocol has EPA been using since February 2021 to identify and evaluate the stream of evidence to support ongoing TSCA reviews?

I thank you for your consideration and look forward to working together to strengthen scientific integrity in EPA's decision-making. If you have any questions, please have your staff contact Janie Thompson of the Committee on Science, Space and Technology staff at 202-225-6375.

Sincerely,

A handwritten signature in blue ink that reads "Eddie Bernice Johnson". The signature is written in a cursive, flowing style.

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, & Technology