

Department of Obstetrics, Gynecology & Reproductive Sciences

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Administrator Michael S. Regan

U.S. Environmental Protection Agency

1101A

1200 Pennsylvania Avenue NW

Washington DC 20460

Re: Draft Toxic Substances Control Act (TSCA) Systematic Review Protocol

Dear Administrator Regan,

We write to you as experts in conducting systematic reviews of environmental chemicals, with multiple peer-reviewed publications applying well-established best practices. EPA must urgently make critical revisions to its flawed approach to systematic review for conducting risk evaluations under the Toxic Substances Control Act (TSCA). Using established systematic review methods is a foundational step for the Environmental Protection Agency (EPA) to conduct risk evaluations using “best available science” of chemicals under TSCA. These established methods have been demonstrated to increase transparency and minimize bias when evaluating a body of evidence.^{1,2,3} Six years have passed since Congress updated TSCA, yet EPA still does not have an appropriate method for conducting systematic reviews of chemical risks, which is critical to protecting the public’s health. EPA’s failure to establish scientifically defensible systematic review methods for its TSCA risk evaluations means further delays in EPA action to protect the public from toxic chemical exposures.

Amended TSCA requires EPA to make decisions about chemical risks based on the “weight of the scientific evidence.”⁴ EPA 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.”⁵ Additionally, TSCA requires EPA to “use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.”⁶

¹ National Academies of Sciences Engineering, and Medicine. (2017). Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, D.C.: The National Academies Press; 2011

² National Academies of Sciences, Engineering, and Medicine. 2022. A Review of U.S. EPA’s ORD Staff Handbook for Developing IRIS Assessments: 2020 Version. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26289>.

³ Lam J, Koustas E, Sutton P, Padula AM, Cabana MD, Vesterinen H, Griffiths C, Dickie M, Daniels N, Whitaker E, Woodruff TJ. Exposure to formaldehyde and asthma outcomes: A systematic review, meta-analysis, and economic assessment. PLoS One. 2021 Mar 31;16(3):e0248258. doi: 10.1371/journal.pone.0248258. PMID: 33788856; PMCID: PMC8011796.

⁴ 15 USC §2625 (h)-(i)

⁵ 40 CFR 702.33

⁶ U.S. Environmental Protection Agency. Toxic Substances Control Act (TSCA), Vol. Fifteen USC ch. 53 subch. I §§ 2601–2629.

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In February 2021, the National Academies of Sciences, Engineering, and Medicine (NASEM) provided extensive comments and recommendations to EPA, including that there was “strong consensus” that the *2018 TSCA Method* “did not meet the standards of systematic review methodology.”⁷ This prompted EPA to make a statement that it would no longer be using this systematic review method and was in the process of developing a new approach incorporating recommendations from the NASEM.⁸

In December 2021, EPA released a revised *2021 Draft TSCA Method*, saying the Agency “has significantly updated the TSCA systematic review process and developed a systematic review protocol to address NASEM’s recommendations.”⁹ In July 2022, EPA’s Science Advisory Committee on Chemicals (SACC) issued over 200 recommendations for improvements to EPA’s *2021 Draft TSCA Method* and identified numerous NASEM recommendations from February 2021 that had not been addressed.¹⁰

The *2021 Draft TSCA Method* is inconsistent with current, established, best available empirical methods for systematic review. This is the clear conclusion taken from reading the most recent peer review of EPA’s methods by EPA’s SACC.

The University of California San Francisco’s Program on Reproductive Health and the Environment (UCSF PRHE) has previously provided detailed comments to EPA,^{11,12} the NASEM and EPA’s SACC regarding EPA’s TSCA systematic review method and how it is not consistent with the “best available science.”¹³

EPA can take several steps in relatively quick fashion to move toward a systematic review method “consistent with the best available science,” by addressing the key problems with approaches that have been empirically demonstrated to minimize bias and increase transparency. We have identified priority areas for improvement below, along with the relevant SACC recommendations to improve the method.

⁷ NASEM. (2021). The use of systematic review in EPA’s Toxic Substances Control Act Risk Evaluations. <https://www.nap.edu/catalog/25952/the-use-of-systematic-review-in-epas-toxic-substances-control-act-risk-evaluations>

⁸ EPA Press Office. (2021). EPA commits to strengthening science used in chemical risk evaluations. <https://www.epa.gov/newsreleases/epa-commits-strengthening-science-used-chemical-risk-evaluations>

⁹ US EPA. (2022). Draft Protocol for Systematic Review in TSCA Risk Evaluations. Available: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/draft-protocol-systematic-review-tsca-risk-evaluations>

¹⁰ US EPA. (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2 DOCKET ID NUMBER: EPA-HQ-OPPT-2021-0414

¹¹ UCSF PRHE. (2020). Comments from Academics, Scientists and Clinicians on: The Application of Systematic Review in TSCA Risk Evaluations. Available: https://prhe.ucsf.edu/sites/g/files/tkssra341/f/wysiwyg/NAS_TSCA%20SR%20Method%20comments.pdf

¹² UCSF PRHE. (2022). Comments on the Draft Toxic Substances Control Act (TSCA) Systematic Review. Available <https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0414/comments>

¹³ US EPA. (2018). Application of systematic review in TSCA risk evaluations. https://www.epa.gov/sites/default/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf

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Need for a pre-published protocol for each chemical risk evaluation

A critical step to conducting a transparent and unbiased review is establishing a pre-published protocol that details the specific methods to be used in conducting the systematic review. EPA created confusion by calling its *2021 Draft TSCA Method* a “systematic review protocol,” when it was actually a generic description of methods to be applied across assessments. EPA did not develop assessment-specific protocols for the 23 ongoing chemical risk evaluations.

The SACC recommends: “Develop the document reviewed here as a general handbook for conducting TSCA systematic reviews. In addition, chemical specific protocols should be developed, and peer reviewed to note chemical-specific deviations from the general protocol.”¹⁴

Need to improve study inclusion criteria to include all toxicity findings

A PECO (Population, Exposure, Comparator, Outcome) statement provides criteria that researchers use to decide which studies are relevant to include in a systematic review. EPA’s PECO statements for most of the 23 chemicals under evaluation placed limitations on the types of health effects that would be included by excluding studies demonstrating early biological changes (like reduced thyroid hormone levels or reduced red blood cell counts) that represent health hazards.

The SACC recommends: “EPA should not limit PECO/RESO statements to apical endpoints but consider expanding outcomes to include known upstream markers of effect such as biochemical markers of effect or other outcomes at the cellular level.”¹⁵

Need for improved approaches to study quality assessment that don’t use scoring

Study quality refers to assessing if a study was conducted to the highest possible standard, and is important for understanding the strengths and limitations of a study when synthesizing evidence regarding a chemical. The NASEM previously identified several problems with the *2018 TSCA Method*’s approach to assessing study quality, in particular objecting to EPA’s use of quantitative scoring for study quality assessment and exclusion from a systematic review of studies deemed to be flawed. These problems with EPA’s approach to study quality assessment continued in its *2021 Draft TSCA Method*.

The SACC recommends: “EPA should follow NASEM recommendations and best practices of systematic review by removing its approach to determine an overall quality score based on the

¹⁴ US EPA. (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2. Pp 41 DOCKET ID NUMBER: EPA-HQ-OPPT-2021-0414

¹⁵ US EPA. (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2. Pp 29 DOCKET ID NUMBER: EPA-HQ-OPPT-2021-0414

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combination of quantitative ratings of each individual data quality evaluation metric, which is essentially a quantitative scoring approach.”¹⁶

“As recommended by NASEM (IRIS Handbook review (NASEM. (2021b)), the results of study evaluation should not be used as exclusionary criteria; however, quality issues should be narratively discussed.”¹⁷

Need to account for funding bias in individual studies

Industry-sponsored studies or authors with a financial conflict of interest (COI) are more likely to have results and conclusions in favor of the sponsor’s product than studies without.^{18, 19, 20, 21, 22, 23} This bias must be identified and accounted for when evaluating studies in EPA risk assessments so that evidence is not inappropriately skewed away from identifying hazards.

The SACC recommends: “The systematic review should assess funding bias for all included studies.”²⁴

Use existing methodologies to save time and money and to improve the basis for the decisions made

The 2021 Draft TSCA Method has significant problems as indicated by the 200 SACC recommendations to improve EPA’s process for identifying and evaluating evidence in a TSCA chemical risk evaluation. These deficiencies could be remedied if EPA implements existing, validated systematic review methods.

The SACC recommends: “Previous recommendations from SACC and NASEM pointed out existing methodologies that could, and should, be used to both improve the basis for the decisions made and to save time and money. These recommendations should be re-reviewed.”²⁵

¹⁶ US EPA. (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2. Pp 71 DOCKET ID NUMBER: EPA-HQ-OPPT-2021-0414

¹⁷ US EPA. (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2. Pp 98 DOCKET ID NUMBER: EPA-HQ-OPPT-2021-0414

¹⁸ Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L: Industry sponsorship and research outcome: systematic review with meta-analysis. *Intensive Care Med* 2018, 44(10):1603-1612.

¹⁹ Barnes DE, Bero LA: Why review articles on the health effects of passive smoking reach different conclusions. *JAMA* 1998, 279(19):1566-1570.

²⁰ Huss A, Egger M, Hug K, Huwiler-Müntener K, Rössli M: Source of funding and results of studies of health effects of mobile phone use: systematic review of experimental studies. *Environ Health Perspect* 2007, 115(1):1-4.

²¹ Yank V, Rennie D, Bero LA: Financial ties and concordance between results and conclusions in meta-analyses: retrospective cohort study. *BMJ* 2007, 335(7631):1202-1205.

²² Bero L, Anglemeyer A, Vesterinen H, Krauth D: The relationship between study sponsorship, risks of bias, and research outcomes in atrazine exposure studies conducted in non-human animals: Systematic review and meta-analysis. *Environ Int* 2016, 92-93:597-604.

²³ Mandrioli D, Kearns CE, Bero LA: Relationship between Research Outcomes and Risk of Bias, Study Sponsorship, and Author Financial Conflicts of Interest in Reviews of the Effects of Artificially Sweetened Beverages on Weight Outcomes: A Systematic Review of Reviews. *PLoS One* 2016, 11(9):e0162198.

²⁴ US EPA. (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2. Pp 78 DOCKET ID NUMBER: EPA-HQ-OPPT-2021-0414

²⁵ US EPA. (2022). Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-2. Pp 28 DOCKET ID NUMBER: EPA-HQ-OPPT-2021-0414

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EPA is unfortunately using its limited time and resources to maintain a deeply flawed systematic review method as reflected in the *2021 Draft TSCA Method*,²⁶ instead of applying one of the three existing and validated methods widely used in environmental health: the National Toxicology Program's Office of Health Assessment and Translation (NTP OHAT) method,²⁷ UCSF PRHE's Navigation Guide²⁸ and EPA's Integrated Risk Information System (IRIS) systematic review method.²⁹ These methods could all be applied for evaluating the health hazards of chemicals (the first critical step in the risk evaluation process) without delay, and subsequently adapted for evaluating the other streams of evidence EPA evaluates under TSCA, including exposure data, as has been demonstrated with use of The Navigation Guide by the World Health Organization (WHO) and International Labor Organization (ILO) to evaluate the global burden of disease from occupational exposures.³⁰ This would improve the efficiency and effectiveness of the risk evaluation process. Additionally, empirical evidence has demonstrated that applying EPA's TSCA method to conduct risk of bias or study quality assessments for the individual studies takes approximately twice as long as using the NTP OHAT method, thus significantly and unnecessarily increasing the length of time it takes to complete the systematic reviews.³¹ PRHE's Navigation Guide and the NTP OHAT's method have been used or recommended by the NASEM multiple times^{32,33,34,35} and demonstrated in case studies in the peer-reviewed

²⁶ US EPA. (2021). Draft systematic review protocol supporting TSCA risk evaluations for chemical substances version 1.0: A generic TSCA systematic review protocol with chemical-specific methodologies. https://www.epa.gov/system/files/documents/2021-12/draft-systematic-review-protocol-supporting-tsca-risk-evaluations-for-chemical-substances_0.pdf

²⁷ National Toxicology Program Office of Health Assessment and Translation. Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. National Institute of Environmental Health Sciences; 2015

²⁸ Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. *Environ Health Perspect.* 2014;122(10):1007-1014. doi:10.1289/ehp.1307175.

²⁹ US EPA (2020) ORD Staff Handbook for Developing IRIS Assessments EPA/600/R-20/137. Available: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=350086

³⁰ Li J, Pega F, Ujita Y, Brisson C et al. The effect of exposure to long working hours on ischaemic heart disease: A systematic review and meta-analysis from the WHO/ILO Joint Estimates of the Work-related Burden of Disease and Injury. *Environ Int.* 2020 Sep;142:105739. doi: 10.1016/j.envint.2020.105739. Epub 2020 Jun 5. PMID: 32505014; PMCID: PMC7339147.

³¹ Eick SM, Goin DE, Chartres N, Lam J, Woodruff TJ. Assessing risk of bias in human environmental epidemiology studies using three tools: different conclusions from different tools. *Syst Rev.* 2020 Oct 29;9(1):249. doi: 10.1186/s13643-020-01490-8. PMID: 33121530; PMCID: PMC7596989.

³² National Academies of Sciences Engineering, and Medicine. (2017). Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, D.C.: The National Academies Press; 2011

³³ National Research Council. (2014). Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press; 2014.

³⁴ National Academies of Sciences Engineering, and Medicine. (2018). Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press; 2018.

³⁵ NASEM. (2021). The use of systematic review in EPA's Toxic Substances Control Act Risk Evaluations. <https://www.nap.edu/catalog/25952/the-use-of-systematic-review-in-epas-toxic-substances-control-act-risk-evaluations>

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literature.^{36, 37, 38, 39, 40, 41, 42, 43} Further, EPA's Office of Research and Development (ORD) has adopted a systematic review methodology for conducting IRIS assessments.⁴⁴ While there are some inadequacies in the current IRIS systematic review method that should be addressed,^{45, 46} it is a fundamentally stronger methodology than the *2021 Draft TSCA Method* and represents a much-needed opportunity to unify methodologies across offices within EPA.

Unification of systematic reviews in EPA should include an upgrade in methods applied by the Office of Pesticides Program (OPP). The 2016 *Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides* states that "OCSPP employs fit-for-purpose systematic reviews that rely on standard methods for collecting, evaluating and integrating the scientific data supporting our decisions."⁴⁷ This "fit-for-purpose systematic review framework" was used to evaluate the postulated association between paraquat exposure and Parkinson's disease.⁴⁸ The OPP method, however, failed to adhere to established best practice methods for systematic review, including the foundational step of a pre-published systematic review protocol to minimize bias and increase transparency.

³⁶Johnson PI, Sutton P, Atchley DS, Koustas E, Lam J, Sen S, Robinson KA, Axelrad DA, Woodruff TJ. The Navigation Guide - evidence-based medicine meets environmental health: systematic review of human evidence for PFOA effects on fetal growth. *Environ Health Perspect.* 2014;122(10):1028-39. Epub 2014/06/27. doi: 10.1289/ehp.1307893. PubMed PMID: 24968388; PMCID: 4181929.

³⁷Koustas E, Lam J, Sutton P, Johnson PI, Atchley DS, Sen S, Robinson KA, Axelrad DA, Woodruff TJ. The Navigation Guide - evidence-based medicine meets environmental health: systematic review of nonhuman evidence for PFOA effects on fetal growth. *Environ Health Perspect.* 2014;122(10):1015-27. Epub 2014/06/27. doi: 10.1289/ehp.1307177. PubMed PMID: 24968374; PMCID: 4181920.

³⁸Lam J, Koustas E, Sutton P, Johnson PI, Atchley DS, Sen S, Robinson KA, Axelrad DA, Woodruff TJ. The Navigation Guide - evidence-based medicine meets environmental health: integration of animal and human evidence for PFOA effects on fetal growth. *Environ Health Perspect.* 2014;122(10):1040-51. Epub 2014/06/27. doi: 10.1289/ehp.1307923. PubMed PMID: 24968389; PMCID: 4181930.

³⁹Vesterinen H, Johnson P, Atchley D, Sutton P, Lam J, Zlatnik M, Sen S, Woodruff T. The relationship between fetal growth and maternal glomerular filtration rate: a systematic review. *J Maternal Fetal Neonatal Med.* 2014;1-6. Epub Ahead of Print; PMCID: 25382561.

⁴⁰Johnson PI, Koustas E, Vesterinen HM, Sutton P, Atchley DS, Kim AN, Campbell M, Donald JM, Sen S, Bero L, Zeise L, Woodruff TJ. Application of the Navigation Guide systematic review methodology to the evidence for developmental and reproductive toxicity of triclosan. *Environ Int.* 2016;92-93:716-28. doi: 10.1016/j.envint.2016.03.009. PubMed PMID: 27156197.

⁴¹Lam J, Sutton P, Halladay A, Davidson LI, Lawler C, Newschaffer CJ, Kalkbrenner A, Joseph J, Zilber School of Public Health, Windham GC, Daniels N, Sen S, Woodruff TJ. Applying the Navigation Guide Systematic Review Methodology Case Study #4: Association between Developmental Exposures to Ambient Air Pollution and Autism. *PLoS One.* 2016;21(11(9)). doi: 10.1371/journal.pone.0161851.

⁴²Lam J, Lanphear B, Bellinger D, Axelrad D, McPartland J, Sutton P, Davidson LI, Daniels N, Sen S, Woodruff TJ. Developmental PBDE exposure and IQ/ADHD in childhood: A systematic review and meta-analysis. *Environmental Health Perspectives.* 2017;125(8). doi: 10.1289/EHP1632.

⁴³Lam J, Koustas E, Sutton P, Padula AM, Cabana MD, Vesterinen H, Griffiths C, Dickie M, Daniels N, Whitaker E, Woodruff TJ. Exposure to formaldehyde and asthma outcomes: A systematic review, meta-analysis, and economic assessment. *PLoS One.* 2021 Mar 31;16(3):e0248258. doi: 10.1371/journal.pone.0248258. PMID: 33788856; PMCID: PMC8011796.

⁴⁴National Academies of Sciences Engineering, and Medicine. (2018). *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation.* Washington, DC: The National Academies Press; 2018.

⁴⁵National Academies of Sciences, Engineering, and Medicine. 2022. *A Review of U.S. EPA's ORD Staff Handbook for Developing IRIS Assessments: 2020 Version.* Washington, DC: The National Academies Press. <https://doi.org/10.17226/26289>

⁴⁶UCSF PRHE. (2022). Availability of the ORD Staff Handbook for Developing IRIS Assessments. Comment submitted by UCSF Program on Reproductive Health and the Environment. Available from <https://www.regulations.gov/document/EPA-HQ-ORD-2018-0654-0001/comment>

⁴⁷US EPA. Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides. 2016. Available: <https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf>

⁴⁸US EPA. (2019). Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review. Available: <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0121>

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EPA has had ample opportunity to establish a systematic review approach for TSCA risk evaluations that is based on established best practices and must not get this wrong again. The *2021 Draft TSCA Method* reviewed by the SACC does not reflect best available science and is outside of scientific norms for evaluating health hazards from chemical exposures. The need to fix the methods will add to delays in assessing these chemicals, but improvements in tools and approaches will minimize delays while building a solid foundation for more efficient reviews in the future. We urge EPA to cease use of the *2021 Draft TSCA Method* and follow the NASEM recommendation that “the methods for developing IRIS assessments can serve as a model for other EPA programs that are implementing systematic review methods.”⁴⁹

Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,

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⁴⁹ NASEM. (2022). Review of US EPA’s ORD staff handbook for developing IRIS assessments: 2020 version. pp 12.
<https://www.nap.edu/catalog/26289/review-of-us-epas-ord-staff-handbook-for-developing-iris-assessments>

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