



November 7, 2025

VIA ELECTRONIC SUBMISSION

The Honorable Lee Zeldin
Administrator
U.S. Environmental Protection Agency
Washington, DC 20460

Re: Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA); Docket No. EPA-HQ-OPPT-2025-0260.

Dear Administrator Zeldin:

On September 23, 2025, the U.S. Environmental Protection Agency (EPA) published a proposed rule on TSCA chemical risk evaluation procedures.¹ This letter constitutes the Office of Advocacy's (Advocacy) public comments on the EPA's proposed rule.

Advocacy supports the EPA's proposed changes to the TSCA risk evaluation process. The recommended changes will allow the agency to focus its efforts on how chemicals are used by small businesses and ensure those chemicals are reviewed in a thorough, efficient manner. Additionally, the EPA's proposal reduces duplicative regulatory efforts already undertaken by other federal agencies and EPA program offices. Finally, Advocacy urges the EPA to allow for peer review of full chemical risk evaluations.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy in 1976 under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent voice within the Executive Branch that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),² gives small entities a voice in the rulemaking process. For all rules that are expected to have a

¹ 90 Fed. Reg. 45690 (Sept. 23, 2025).

² Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).

significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.³ If a rule is not expected to have a significant economic impact on a substantial number of small entities, agencies may certify it as such and submit a statement of the factual basis for such a determination that adequately supports its certification.⁴

Additionally, Section 609 of the RFA requires the EPA to conduct special outreach efforts through a small business advocacy review (SBAR) panel.⁵ The panel must carefully consider the views of the impacted small entities, assess the impact of the proposed rule on small entities, and consider less burdensome alternatives for small entities.⁶ Since SBREFA's enactment, there have been nine SBAR panels involving the TSCA risk evaluation process.⁷ The EPA has also proposed two additional SBAR panels involving TSCA risk evaluations.⁸

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."⁹

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.¹⁰ The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the Federal Register, unless the agency certifies that the public interest is not served by doing so.¹¹

B. EPA's Proposed Revisions to the TSCA Risk Evaluation Process.

TSCA Section 6 requires the EPA to establish a chemical risk evaluation process.¹² Small chemical manufacturers and distributors will be impacted by this process, but the impacts extend much further. The breadth of chemicals that undergo TSCA risk evaluations is so extensive that almost any industry that handles a product with a designated chemical in it could be impacted. Formaldehyde (which is the subject of a forthcoming TSCA risk evaluation), for example, has multiple uses including furniture manufacturing, funeral preparation and spacecraft production.

In 2017, the EPA issued a final rule for the TSCA risk evaluation process.¹³ In 2024, the EPA updated the regulations.¹⁴ The current proposal reexamines the 2024 updates to ensure the best

³ 5 U.S.C. § 603.

⁴ *Id.* § 605(b).

⁵ *Id.* § 609.

⁶ *Id.*

⁷ U.S. Env't Prot. Agency, *Small Business Advocacy Review (SBAR) Panels*, <https://www.epa.gov/reg-flex/small-business-advocacy-review-sbar-panels#current-sbar> (last updated Aug. 8, 2025).

⁸ *Id.*

⁹ Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

¹⁰ Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).

¹¹ *Id.*

¹² 15 U.S.C. § 2605 (b).

¹³ 82 Fed. Reg. 33726 (July 20, 2017).

¹⁴ 89 Fed. Reg. 37028 (May 3, 2024).

reading of the TSCA and to prevent regulations from impeding the timely completion of risk evaluations or impairing the effective and efficient protection of health and the environment. Specifically, the EPA is considering the following issues:

- Whether the TSCA necessitates a single risk determination for each chemical evaluated versus a risk determination for each condition of use.
- Whether the EPA must evaluate all conditions of use and all exposure routes and pathways in a risk evaluation.
- Whether and how the use of personal protective equipment (PPE) and engineering and administrative controls in an occupational work environment should be considered.
- Whether regulatory definitions should be broader than TSCA definitions.
- What process should the EPA follow when reconsidering aspects of a risk evaluation.¹⁵

The EPA also proposes amendments to the requirements that manufacturers (including importers) are required to follow when they request an agency-conducted TSCA risk evaluation.¹⁶

II. The 2024 TSCA Risk Evaluation Rule Placed Unnecessary Regulatory Burdens on Small Businesses and Must be Changed.

Changes made to the TSCA risk evaluation process in 2024 included:

- Expanding the scope of risk evaluations to include exposure pathways otherwise covered by other federal statutes, such as the Clean Air Act.
- Assuming PPE would generally not be used in occupational settings, even if required by other federal law or regulation, when making unreasonable risk determinations for a chemical.
- Making unreasonable risk determinations based on each chemical as a whole rather than separately for each the conditions of use of the chemical.¹⁷

The 2024 rule altered the TSCA procedures for evaluating chemical risks to human health and the environment, impacting how workers handle the chemical in question and what uses are permitted. Advocacy held an environmental roundtable on these changes where small businesses expressed multiple concerns. These issues were incorporated into a comment letter Advocacy submitted to the EPA¹⁸

Small entities raised concerns about the availability of safe alternatives to chemicals that would be banned or severely restricted by the 2024 rule. Additionally, they were worried that the 2024

¹⁵ 90 Fed. Reg. 45690, 45691 (Sept. 23, 2025).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ U.S. Small Bus. Admin, Off. of Advocacy, Comment Letter on Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (Dec. 13, 2023), <https://advocacy.sba.gov/wp-content/uploads/2023/12/Comment-Letter-TSCA-Process-Rule-508.pdf>.

rule would lead to delays in the chemical review process, creating barriers to innovation for chemical uses in the housing, transportation, and technology sectors.

The EPA's 2024 regulation ran counter to the RFA's requirement that rules not duplicate, conflict, or overlap with one another.¹⁹ Specifically, the rule evaluated fence line exposures via air emissions that are otherwise subject to regulation under Section 112 of the Clean Air Act (CAA)²⁰ and set workplace exposures that are otherwise subject to regulation by the Occupational Safety and Health Administration (OSHA).

In addition to duplicating regulations, the 2024 rule did not give small businesses credit for the rules they were already abiding by. The rule assumed that businesses did not employ the use of worker protections, including PPE required by OSHA, even when existing rules required such measures. By not assuming small businesses were complying with existing laws, the 2024 risk evaluation rule effectively declared small businesses guilty until proven innocent of complying with established worker safety standards.

Finally, the “whole chemical” approach employed by the 2024 rule exceeded the EPA's statutory authority. According to the TSCA, once the EPA determines that a chemical substance presents an unreasonable risk of injury to health or the environment, it must regulate “*to the extent necessary*” so that the chemical substance or mixture no longer presents such risk.”²¹ Thus, if one use of a chemical presents an unreasonable risk and another does not, regulations should be targeted at the specific use of the chemical and not the substance as a whole. To do otherwise would be regulating beyond the “extent necessary” specified by the TSCA.

Advocacy warned the EPA that the 2024 revisions to the TSCA risk evaluation process would “lead to unnecessary and duplicative regulation with minimal public health benefits.”²² We appreciate the EPA's efforts to address these concerns through this proposed rule.

III. The EPA's Proposed Rule Benefits Small Businesses by Effectuating the Best Reading of the TSCA and Correcting Errors Made in 2024.

The EPA's proposed rule seeks to balance the TSCA's obligation to properly evaluate chemical risk with the agency's duty to conduct reviews efficiently. The proposal would:

[r]escind or revise certain 2024 amendments to the procedural framework rule to effectuate the best reading of the statute and ensure that the procedural framework rule does not impede the timely completion of risk evaluations or impair the effective and efficient protection of health and the environment.²³

¹⁹ 5 U.S.C. § 603(b)(5).

²⁰ 42 U.S.C. § 112.

²¹ 15 U.S.C. § 2605(a) (emphasis added).

²² U.S. Small Bus. Admin, Off. of Advocacy, *supra* note 18, at 1.

²³ 90 Fed. Reg. 45690 (Sept. 30, 2025).

On October 15, Advocacy held an environmental roundtable with just under 100 attendees to discuss the EPA's changes to the TSCA risk evaluation process.. The roundtable attendees expressed general support for the EPA's proposed rule and a desire to see greater efficiency in the chemical risk evaluation process.

A. The EPA Should Limit the Scope of Risk Evaluations to Chemical Uses that Pose the Greatest Risk.

Advocacy agrees with the EPA's assertion that:

The TSCA requires the Agency to conduct comprehensive risk evaluations, not multiple risk evaluations for the same chemical, a handful of conditions of use at a time. However, without the ability to decide where unintentional byproduct manufacture will be evaluated, for example, or whether an activity need not be assessed because it is unlikely to result in exposures to a chemical substance, EPA will be unable to focus its risk evaluations on the conditions of use that have the greatest potential for risk and thereby effectively evaluate and manage risks while also meeting the statutory deadlines.²⁴

Allowing the EPA to target its risk evaluations to the uses of a chemical which pose the greatest potential for risk will ensure that regulations properly cover a chemical's more dangerous uses without creating unnecessary regulatory burdens for small businesses who safely use chemicals and chemical products.

Properly targeting the scope of TSCA risk evaluations will help prevent scenarios such as the EPA's 2024 final rule regulating perchloroethylene (PCE), where the agency banned many of the industrial and commercial uses of PCE instead of tailoring the rule towards the uses of PCE with the greatest health and safety risks.²⁵ As Advocacy mentioned in our recent comment on the reconsideration of the PCE rule, the EPA's overly broad risk evaluation forces small businesses to consider less safe (and more flammable) alternative chemicals and incur significant costs (up to \$500,000).²⁶

Advocacy supports the EPA's recommendations to focus the scope of TSCA risk evaluations on those chemical uses which pose the greatest risks to health and safety.

B. De Minimis Allowances for Chemical Exposure Should be Allowed Where Appropriate.

The EPA has also asked for comment on how the agency should consider instances where a de minimis amount of a chemical substance is present, "recognizing that the toxicity of chemical

²⁴ *Id.* at 45,697.

²⁵ 89 Fed. Reg. 103560 (Dec. 18, 2024).

²⁶ U.S. Small Bus. Admin, Off. of Advocacy, Comment Letter on Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (Aug. 27, 2025), https://advocacy.sba.gov/wp-content/uploads/2025/09/Comment-Letter-2025-PCE-Reconsideration_82725.pdf.

substances vary.”²⁷ Allowances for de minimis amounts of chemical substances where appropriate provide flexibility for small businesses who use or produce only trace amounts of chemical substances in their day-to-day operations. This approach has been recommended before by the EPA, Advocacy, the Office of Management and Budget, and by the SBAR panel for n-Methylpyrrolidone.²⁸ Advocacy encourages the EPA to support allowances for de-minimis amounts of chemical substances where appropriate.

C. The EPA Should Refrain from Regulating under the TSCA When Similar Regulations Exist from Other Federal Agencies or EPA Program Offices.

The EPA proposes to remove a provision from the 2024 risk evaluation rule requiring the agency to “assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, *including those that are regulated under other federal statutes.*”²⁹ Advocacy supports the removal of this language as it conflicts with both the RFA and multiple provisions of the TSCA.

Under the RFA, agencies are required to identify any duplicative, overlapping, and conflicting federal rules.³⁰ Rules are considered duplicative or overlapping if they are based on the same or similar reasons for the regulation, the same or similar regulatory goals, and if they regulate the same classes of industry. Conflicting rules impose two conflicting regulatory requirements on the same classes of industry.

The EPA acknowledges in the proposed rule that the 2024 revisions created regulations that duplicate existing CAA and Safe Drinking Water Act requirements.³¹ Also, as Advocacy noted in our comment letter on the EPA’s PCE regulation, the current TSCA risk evaluation process often sets exposure levels which conflict with already established OSHA regulations.³²

Similarly, TSCA Section 9 requires the EPA to consult and coordinate with other federal agencies “for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes.” It seems logical that if EPA is required to consult with other federal agencies to reduce the possibility of duplicative regulations, it should also conduct similar consultations within its own program offices. The proposed rule acknowledges this by noting:

It is not an efficient use of EPA resources to evaluate exposure routes and pathways under TSCA that have been evaluated and are being managed by other EPA offices, or that could be more effectively and efficiently assessed and managed by other

²⁷ 90 Fed. Reg. 45690, 45967 (Sept. 23, 2025).

²⁸ U.S. ENV’T PROT. AGENCY, SMALL BUSINESS ADVOCACY REVIEW PANEL: REPORT ON EPA’S PLANNED PROPOSED RULE “TOXIC SUBSTANCES CONTROL ACT SECTION 6(A) FOR N-METHYLPYRROLIDONE (NMP) 40 (Sept. 14, 2023), <https://www.epa.gov/system/files/documents/2024-06/nmp-sbar-panel-report-508.pdf>.

²⁹ 90 Fed. Reg. 45690, 45968 (Sept. 23, 2025) (emphasis added).

³⁰ 5 U.S.C. § 603(b)(5).

³¹ 90 Fed. Reg. 45690, 45968 (Sept. 23, 2025).

³² U.S. Small Bus. Admin, Off. of Advocacy, *supra* note 26, at 4.

EPA offices. EPA proposes that nothing in TSCA's text or structure requires such a result and that duplicative assessments are contrary to the purpose of TSCA...³³

Additionally, as previously mentioned, TSCA Section 6 directs the EPA to only regulate “*to the extent necessary*” so that the chemical substance or mixture no longer presents such risk.”³⁴ Creating duplicative regulations goes beyond the TSCA’s statutory mandate to regulate “to the extent necessary.”

The EPA should not attempt to supplant existing regulatory frameworks. For small businesses, duplicative and conflicting rules add unnecessary regulatory burdens and increase expenses related to compliance. Advocacy supports the EPA’s proposed modifications to the TSCA risk evaluation which are designed to reduce duplicative regulatory requirements and will, in turn, reduce costs and increase efficiency for small businesses.

D. The 2024 TSCA Risk Evaluation Rule Incorrectly Assumes Small Businesses are Not in Compliance with Existing OSHA Regulations.

The current TSCA risk evaluation process prohibits the EPA from considering “exposure reduction based on assumed use of personal protective equipment as part of the risk determination.”³⁵ The prohibition is based on a variety of factors such as “employers may be out of compliance with OSHA standards, the PPE is not sufficient to address the risk from the chemical, or the PPE does not fit or function properly.”³⁶

This approach violates the RFA by adding unnecessary regulatory burdens to small entities because it both assumes that they do not follow OSHA regulations requiring the use of PPE while also assuming that when PPE is used, it does not work. Thus, small businesses who are compliant with existing OSHA regulations are effectively penalized by having chemicals evaluated as if either no PPE or defective PPE were used.

The EPA’s proposed rule would remedy this problem by focusing on the implementation of existing OSHA regulations and PPE use. Specifically, the agency notes:

In determining whether unreasonable risk is presented, EPA’s consideration of occupational exposure scenarios will take into account reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and personal protective equipment.³⁷

Thus, if a small business is properly complying with OSHA rules and requiring the use of effective PPE, it would be considered in a TSCA risk evaluation. Advocacy supports this change,

³³ 90 Fed. Reg. 45690, 45968 (Sept. 23, 2025).

³⁴ 15 U.S.C. § 2605(a) (emphasis added).

³⁵ 90 Fed. Reg. 45690, 45704 (Sept. 23, 2025).

³⁶ *Id.*

³⁷ *Id.* at 45,704-05.

and it will reduce regulatory burdens on small entities by properly recognizing actions they are already taking to reduce risks from chemical exposure.

E. The EPA Should Allow Peer Review of Full Chemical Risk Evaluations.

The EPA has asked for comment on “how to ensure transparency and accountability in the peer review of risk evaluations.”³⁸ In the 2024 final risk evaluation rule, the EPA stated:

EPA will conduct peer review activities on risk evaluations...EPA expects such activities, including decisions regarding the appropriate scope and type of peer review, to be consistent with the applicable peer review policies, procedures, and methods in guidance promulgated by the Office of Management and Budget and EPA.³⁹

In our 2023 comment letter to the EPA on the TSCA risk evaluation process, Advocacy recommended that “the **full risk evaluation** for any chemical should be subject to peer review.”⁴⁰ This recommendation is consistent with President Donald J. Trump’s Executive Order (EO) 14303, *Restoring Gold Standard Science*, which states that his administration is:

[c]ommitted to restoring a gold standard for science to ensure that federally funded research is transparent, rigorous, and impactful, and that Federal decisions are informed by the most credible, reliable, and impartial scientific evidence available. We must restore the American people's faith in the scientific enterprise and institutions that create and apply scientific knowledge in service of the public good. **Reproducibility, rigor, and unbiased peer review must be maintained.**⁴¹

Advocacy renews its recommendation that the full risk evaluation for all chemicals subject to TSCA regulation (as opposed to portions thereof) be subject to peer review. Regulations promulgated under the TSCA impact small businesses that both manufacture and use everyday chemicals. These decisions should be made with the maximum amount of scientific rigor and transparency.

IV. EPA Should Provide a Complete Description of the Proposed Rule’s Benefits to Small Businesses.

The EPA’s chemical risk evaluation procedures rule is important for small businesses. The risk evaluations influenced by current TSCA procedures lead to risk management rules impact tens of thousands of small manufacturers who use chemicals in their production processes. According to the EPA’s data, the six completed existing chemicals risk management rules in 2024 had a combined cost of almost \$12 billion.

³⁸ *Id.* at 45,706.

³⁹ 89 Fed. Reg. 37028, 37055 (May 3, 2024).

⁴⁰ U.S. Small Bus. Admin, Off. of Advocacy, *supra* note 18, at 8.

⁴¹ 90 Fed. Reg. 22601 (May 23, 2025) (emphasis added).

To describe the economic benefits to small businesses from regulatory cost savings of the proposed rule, Advocacy suggests the EPA focus on three main impacts of the proposed rule:

- Focusing risk evaluations on the conditions of use with the highest risk will minimize the regulatory burdens on low-risk chemical uses.
- Crediting industry for PPE use where required will change the risk evaluation process for some chemical uses and reduce regulatory burdens for industries complying with existing OSHA standards.
- The proposed rule's changes will improve the EPA's ability to conduct additional chemical risk evaluations.

By enabling the EPA to complete risk assessments in a timely manner, the proposed rule will provide increased regulatory certainty to small businesses. Additionally, incorporating conditions of use and use of PPE in its risk evaluations reduces regulatory burden for small businesses. Advocacy stands ready to partner with the EPA to quantify these economic benefits to small businesses in its final rule.

V. Conclusion

Advocacy supports the EPA's proposed revisions to the TSCA risk evaluation process. The recommended changes will preserve essential chemical safety standards while minimizing regulatory burdens for small businesses. The changes also better align the EPA's regulatory authority with TSCA's statutory intent.

Advocacy also recommends the EPA allow, to the greatest extent possible, full peer review for chemical risk evaluations. Finally, a full description of the proposed rule's benefits will help small businesses better understand the impacts of EPA's revisions to the chemical risk evaluation process.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Nick Goldstein at (202) 772-6948 or nick.goldstein@sba.gov.

Sincerely,

/s/

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/s/

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Copy to: Mr. Jeffrey B. Clark, Sr. Acting Administrator
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