U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

December 13, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

Re: Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act, regulations.gov Docket ID EPA-HQ-OPPT-2023-0496

Dear Administrator Regan:

On October 30, 2023, the Environmental Protection Agency (EPA) published a proposed rule entitled "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)."[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule.

Advocacy has significant concerns about the proposed procedures and the impact these changes will have on the risk management rulemakings that will result. This proposed risk evaluation process will likely lead to unnecessary and duplicative regulation with minimal public health benefits. Advocacy recommends that EPA maintain as narrow a scope of its risk evaluation as possible, relying on the authorities and expertise of other federal offices. EPA should bolster outreach and consult with small entities, other federal agencies, and peer reviewers, to better understand the diversity of the conditions of use of each chemical and the risks presented by existing chemicals as they are actually used in commerce.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA) 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

[1] 88 Fed. Reg. 74,292 (Oct. 30, 2023).

views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

The Regulatory Flexibility Act (RFA),[2] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] gives small entities a voice in the rulemaking process. For all rules that are expected to have a 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.[4] Additionally, section 609 of the RFA requires the Consumer Financial Protection Bureau, the Occupational Safety and Health Administration, and the Environmental Protection Agency to conduct special outreach efforts through a review 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] If a rule will not have a significant economic impact on a substantial number of small entities, agencies may certify the rule.[7] The agency must provide a statement of factual basis that adequately supports its certification.[8]

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[9] 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.[10]

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."[11]

B. The Proposed Rule

In 2017, EPA published procedures for chemical risk evaluations under TSCA, as amended by the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act.[12] This rule established the process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. Advocacy conducted a Small Business

[2] Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[3] Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).
[4] 5 U.S.C. § 603.
[5] *Id.* § 609.
[6] *Id.*
[7] *Id.* § 605(b).
[8] *Id.*
[9] Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).
[10] *Id.*
[11] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[12] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726 (July 20, 2017).

Environmental Roundtable on the proposal of this rule and filed a public comment letter on the proposal.[13]

EPA announced policy changes for TSCA risk evaluations on June 30, 2021.[14] These policy changes included expanding the scope of risk evaluations to include exposure pathways otherwise covered by other federal statutes, such as the Clean Air Act. EPA also announced that it would assume that personal protective equipment (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. Finally, EPA announced that it would make unreasonable risk determinations based on each chemical as a whole rather than separately for each the conditions of use of the chemical.

Under these policy changes, EPA has completed risk evaluations and proceeded to risk management for most of the first ten high priority chemicals. For seven of these ten chemicals, EPA convened panels under section 609, recognizing that the risk management of these chemicals would likely impose a significant economic impact on a substantial number of small entities. Of these, EPA has proposed risk management measures for methylene chloride,[15] perchloroethylene,[16] and trichloroethylene.[17] Advocacy has filed public comments on these risk management proposals.[18]

In this proposed rule, EPA would amend the 2017 regulations to codify the 2021 policy changes. In addition, EPA has proposed, among other things, limits to the requirement for peer review and the process for revisiting a completed risk evaluation. Advocacy held a Small Business Environmental Roundtable on this proposal on November 17, 2023.

II. Advocacy's Small Business Concerns

A. EPA's proposal risks unnecessary regulation, including bans, and duplicative requirements on safe activities while delaying needed protections.

EPA has proposed a broad scope for its risk evaluations under TSCA. It suggests that it is appropriate to evaluate all conditions of use, even those of which it is unaware, evaluate all

[13] U.S. Small Bus. Admin, Off. of Advocacy, Comment Letter on Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (Mar. 16, 2017), https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0654-0008.
[14] Press Release, Env't. Prot. Agency, EPA Announces Path Forward for TSCA Chemical Risk Evaluations (June 30, 2021), https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.
[15] Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 28284 (May 3, 2023).
[16] Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 39652 (June 16, 2023).
[17] Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74712 (Oct. 31, 2023).
[18] U.S. Small Bus. Admin, Off. of Advocacy, Comment Letter on Proposed Rule for Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA) (July 3, 2023), https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0465-0235; U.S. Small Bus. Admin, Off. of Advocacy, Comment Letter on Proposed Rule for Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA) (Aug. 15, 2023), https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0720-0272.

pathways of exposure, regardless of the authority and expertise of other agencies in the federal government, and requests comment on adding additional factors, such as cumulative risk and climatological risk. However, TSCA gives statutory deadlines for each stage of EPA's process, almost none of which EPA has met. Further, EPA has acknowledged that it is operating under significant resource limitations. Given that the existing chemicals program needs to review tens of thousands of chemicals in commerce, EPA should be taking all available actions to reduce its effort expended on conditions of use that do not present an unreasonable risk.

1. **A single determination that a chemical imposes an unreasonable risk raises uncertainty for small businesses and will lead to unnecessary regulation on safe activities.**

By changing its policy, EPA has shifted from a regime that requires regulatory action only for conditions of use with an unreasonable risk to one in which all conditions of use will be addressed in regulation. This change raises the likelihood that most important industrial chemicals will be found to pose an unreasonable risk because it does not distinguish between consumer uses and commercial and industrial uses. Where consumers do not have the benefit of industrial hygiene practices and OSHA standards, commercial and industrial operations can and do engage in practices to minimize exposure to hazardous chemicals. Small businesses that are good actors and protect their workers will nonetheless feel the impact of issues with consumer uses.

For any small entity engaged in a condition of use not found to pose an unreasonable risk, a requirement to address the chemical under a single determination imposes a significant burden.

First, small entities will have to remain engaged in EPA's risk management process. Small businesses already have difficulty devoting the time and expertise necessary to participate fully in policy development. The requirement that their use of a chemical be subjected to new regulation, even after found to be safe as they use it creates a further delay before they can proceed with their existing industrial processes with some certainty.

Second, if the condition of use does not impose an unreasonable risk, EPA suggests that they can simply require existing practices by rule and that would represent sufficiently addressing the risk. For small businesses, however, any additional provisions of regulation that apply to their operations is a burden. Whether it be recordkeeping, testing and monitoring, or training mandates, these requirements to ensure existing practices are followed impose compliance burden but provide no additional public health benefit.

2. **Expansion of the scope of risk evaluation into areas of other agency authorities will risk wasting federal resources and imposing duplicative regulation.**

Under the 2021 policy and this proposed rule, EPA now evaluates risks that are well within other existing statutory authorities. For example, EPA evaluates fenceline exposures via air emissions that are otherwise subject to regulation under the section 112 of the Clean Air Act. Similarly, EPA evaluates workplace exposures that are otherwise subject to regulation by the Occupational Safety and Health Administration (OSHA). While there is a role for EPA to evaluate these

exposures where they are not otherwise covered, it is not a good use of EPA's resources to duplicate the effort and expertise of these other federal offices.

Further, if a chemical is found to pose an unreasonable risk due to these exposure pathways, EPA would be issuing regulations that overlap with these other regulatory programs. Risk management would impose a new set of requirements of which small businesses must be aware and would require a regulatory relationship with a new regulatory authority, likely with a different set of reporting, recordkeeping, and disclosure requirements. This burden would exist even if the risk management measures were substantively similar to existing requirements. For example, if EPA adopts a workplace safety standard under TSCA, that standard does not preempt any OSHA standards with which a small business must comply. Nor would OSHA inspectors have a choice of which requirements to enforce based on which were more stringent.

EPA can resolve this conflict by declining to take risk management action where there are other appropriate regulatory authorities. But if EPA choses that direction, the 2021 policy and this proposal would nonetheless require EPA to duplicate the effort and resources that might be better spent on exposure pathways not otherwise covered by federal law.

> "EPA requests comment on how the Agency could consider potential climate-related risks in a risk evaluation."[19]

For these same reasons, EPA should not be further diverting its resources to develop a new set of tools to consider impacts that are highly uncertain, both for the timeframe and the scale. Further, climate impacts are not expected to be uniform across the country, so EPA would be making risk evaluation determinations based on regional or local impacts. If climate influences chemical exposures, it should be considered a factor that affect the ability to comply with risk management requirements.

3. Assumptions that PPE are not used in occupational settings will lead to confusion and unnecessary regulation.

EPA's assumption that PPE is not used when evaluating risk harms small businesses that follow OSHA standards and strive toward protecting their employees. In conjunction with the whole chemical approach, this will lead to risk management requirements that duplicate OSHA standards. EPA would be imposing additional reporting, recordkeeping, disclosure, and training requirements that EPA must enforce separately from the OSHA standards.

EPA insists that "EPA is not suggesting that there is widespread non-compliance with applicable OSHA standards."[20] Nonetheless, this policy would inherently overestimate risk. EPA would address this concern by accepting information on a case-by-case basis. "EPA would distinguish between an 'assumed' use of PPE and a use that is supported by the reasonably available information and therefore known to be inherent in the performance of an activity. For example, where EPA has reasonably available information that substantiates use and effectiveness of PPE

[19] 88 Fed. Reg. at 74,316.
[20] *Id.* at 74,304.

(*e.g.,* information demonstrating that performance of a condition of use is impossible in the absence of PPE), EPA generally expects to take that information into account in the risk determination."[21] It will thus be up to the small businesses to develop during the comment period on draft risk evaluations the arguments and supporting data to counter the assumption that PPE is generally not used, in compliance with OSHA standards or otherwise.

This policy also creates confusion for small businesses trying to understand the consequences of the risk evaluation. Where EPA publishes a determination that ignores existing federal requirements and industry standards, most small businesses do not have the capacity to project whether their condition of use presents a risk to their workforce. They have limited ability to relate their business to the risk evaluation and would not be able to anticipate possible future risk management measures.

Advocacy strongly recommends that EPA consider federal PPE requirements and industry standard work practices as an inherent part of the condition of use. If EPA believes that there is widespread disregard for OSHA requirements such that exposure without PPE is "reasonably foreseeable," then EPA should support that assumption with a clear record, and EPA should adopt that assumption only where supported, industry-by-industry. In the unreasonable risk determination, EPA should include a clear statement whether unreasonable risk exists with using such protections for workers.

4. EPA should clearly identify the conditions of use considered in the risk evaluation and not use catch-all categories to cover conditions of use of which it is unaware.

In several of the small entity consultations conducted in advance of risk management, small entities have raised significant concerns about the completeness of the risk evaluations. These risk evaluations did not have information on their conditions of use but nonetheless purported to cover these conditions of use under a catch-all condition. Advocacy strongly recommends that risk evaluations clearly identify the conditions of use being addressed. EPA should not assume that conditions of use not specifically addressed in the risk evaluation have nonetheless been addressed for the purposes of risk management.

Advocacy recommends that EPA include a formal process by which it reviews new information about conditions of use not clearly included in the risk evaluation. This review would determine whether they are sufficiently like other included conditions of use or whether the risk evaluation would need to be amended prior to risk management of that condition of use. Advocacy recommends that a finding that the risk evaluations need not be amended be subject to notice and comment so affected entities would have a reasonable opportunity to engage with EPA on the science rather than awaiting the policy judgments inherent in the risk management rulemakings.

[21] *Id.* at 74,305.

B. EPA should include a formal process for engagement with small entities early in the scoping and risk evaluation process.

> "EPA requests comment on general approaches or best practices for improving engagement with small entities. Early engagement with and feedback from all those who manufacture, process, distribute, use or dispose of a chemical is critical for the Agency to be able to accurately identify and characterize that chemical's conditions of use for consideration in the risk evaluation. EPA is seeking comment on how to improve its outreach to the stakeholder community, including education on the TSCA risk evaluation process for small entities."[22]

Advocacy agrees that early engagement with small entities is critical. There are recent examples in which small entities consulted during the risk management process identified conditions of use EPA had not considered in risk evaluation or provided information to demonstrate misconceptions about a condition of use.

Advocacy recommends EPA engage small businesses in the draft scoping phase. Working with other federal agencies, including Advocacy, and national and state trade associations, EPA should publicly solicit self-nominations for small businesses willing to work with EPA on a continuing basis. The goal would be to develop a working group of small business representatives for each chemical that could participate in briefings and consultations through the entire scoping and risk evaluation process. Consultations should be regular and meaningful, with EPA providing insight on the risk evaluation as it is being developed. Small businesses should be invited to join as new information becomes available and EPA becomes aware of additional conditions of use. These small businesses would naturally become small entity representatives for the panel required under the RFA, if necessary, making the panel process itself more efficient and productive.

C. EPA should include a more robust role for interagency coordination and collaboration.

In this proposal, EPA retains the regulatory text that requires consultation with other federal agencies during the risk evaluation process. Unfortunately, neither the preamble nor current EPA practice reflect the commitment to interagency collaboration described in the 2017 rule preamble.[23] Advocacy strongly favored the interagency review of the draft and final risk evaluations before they were released to the public. First, small businesses represent a sizeable portion of federal procurement, as prime contractors and subcontractors. Federal agency purchasers are in a strong position to recognize problems with EPA's characterization of conditions of use relevant to their supply chain, including work practices and industry standards that may affect exposure scenarios. Second, other federal agencies have significant expertise that is relevant to risk evaluation, including experts in toxicology, industry hygiene, and the relevant industrial processes. EPA should welcome review of the draft and final risk evaluations by these experts before its release to the public.

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[22] *Id.* at 74,316.
[23] 82 Fed. Reg. at 33,738.

Advocacy believes it is important for the federal family to have the opportunity to engage fully prior to public notice and comment. EPA should recommit to a robust interagency process for review of the draft and final risk evaluations,

D. EPA should include a formal process by which it establishes ECELs used in risk management.

"EPA requests public comment on how the Agency can provide a transparent and detailed basis for the proposed unreasonable risk determination and existing chemical exposure limits derived from the risk evaluation process.**"**[24]

In recent proposed risk management rules, EPA has proposed requiring a workplace chemical protection program (WCPP), which would include a requirement to meet an existing chemical exposure limit (ECEL), as well as exposure monitoring and training. Small businesses have raised concerns about the process by which the ECEL has been calculated, but they have limited opportunity to engage in the specifics of the ECEL because EPA has not generally provided it until publication of the draft risk management rulemaking. To the extent that the ECEL is derived from the risk evaluation, EPA should be providing more opportunities to engage on this science.

Advocacy recommends that EPA commit to a process for developing and promulgating the ECEL in advance of risk management. Such a process should be transparent and informed by experts on industrial hygiene and monitoring technology within EPA and other federal agencies. Any proposed ECEL should be subject to peer review and notice and comment. EPA should consider whether such a process should be done in conjunction with the risk evaluation or afterwards.

E. The full risk evaluation should be subject to peer review.

In this proposal, EPA is proposing to include the discretion to only peer review a portion of a risk evaluation rather than in its entirety. "EPA requests comments on the proposed changes with respect to peer review, including whether the proposed addition of 'or portions thereof' is consistent with OMB and Agency guidance."[25] EPA explains:

> Rather than peer reviewing an entire risk evaluation, in adhering to applicable guidance, it may be appropriate for EPA to conduct peer review on only portions or sections that constitute unreviewed influential information. EPA also expects that a TSCA risk evaluation may use peer reviewed products (*e.g.,* risk assessments, hazard assessments, models), or portions thereof, conducted by another EPA office or other authoritative body (*e.g.,* state, national, or international programs), for which both the best available science and weight of scientific evidence standards were adhered to (see Unit III.I.1.).[26]

[24] 88 Fed. Reg. at 74,316.
[25] *Id.* at 74,308.
[26] *Id.*

Advocacy does not support this change. Part of peer review is a determination that the product is fit for its purpose. In this case, the risk evaluation is a necessary precursor to and the scientific basis for regulatory action. Peer reviewers should be considering whether the scientific basis for the risk evaluation is sufficiently robust to support imposition of risk management measures, including bans or other economically significant interventions. Past peer reviews of portions of the risk evaluation are not a substitute for review of the complete document and its findings.

III. Conclusion

The policy changes EPA announced in 2021 and these proposed risk evaluation procedures create a significant risk that the resulting risk management regulations will impose unnecessary and duplicative burdens on small businesses with minimal public health benefits. Advocacy recommends that EPA avoid risk evaluations under TSCA that duplicate the work of other federal agencies and lead to regulations that overlap with other federal authorities. TSCA envisions that EPA should rely on the authorities and expertise of other federal offices. EPA should focus on using its limited resources to bolster outreach and consult small entities, other federal agencies, and peer reviewers, to better understand the diversity of the conditions of use of each chemical and the risks presented by existing chemicals as they are actually used in commerce.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Dave Rostker at (202) 205-6966 or by email at david.rostker@sba.gov.

Sincerely,

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/s/

Major L. Clark, III
Deputy Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

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Copy to: The Honorable Richard L. Revesz, Administrator
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