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

August 8, 2023

VIA ELECTRONIC SUBMISSION

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

Re: Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA), Docket ID: EPA-HQ-OPPT-2022-0902

Dear Administrator Regan:

On May 26, 2023, the U.S. Environmental Protection Agency (EPA) published a proposed rule entitled "Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)."[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule.

Advocacy is concerned that the agency's RFA certification lacks an adequate factual basis because EPA does not adequately assess the impact of the rule on small entities. Advocacy is also concerned about the agency's use of conservative data and default values instead of using the submitted data. In addition, Advocacy is concerned about the agency's proposal to restart the review process when a submitter provides new data to counter the agency's conservative assumptions and default values.

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). As such, the 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

[1] 88 Fed. Reg. 34100 (May 26, 2023).
[2] 5 U.S.C. §601 et seq.

(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.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[4] 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.[5]

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."[6]

B. The Proposed Rule

On May 16, 2023, EPA published a proposal to update its new chemical procedural regulations under TSCA. Under section 5 of TSCA, a manufacturer (including an importer) of a chemical substance is required to submit a notice to EPA at least 90 days prior to manufacture or processing.[7] The notice must include information about the chemical substance to the extent it is known to or reasonably ascertainable by the submitter, which includes any existing test data in the possession or control of the submitter.[8] Failure to include the specific information required by the regulations may result in EPA declaring the submission incomplete and suspending its review.[9] As part of its review, EPA makes one of five possible determinations pertaining to the likelihood of unreasonable risk of injury to health or the environment, and take any actions required as a result of that determination.[10] During the applicable review period, EPA reviews any amendments made to a notice by a submitter after the initial submission and updates the initial risk assessment accordingly.[11]

In 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act[12] significantly amended TSCA. EPA proposes to amend its existing requirements under section 5 of TSCA to align with the new statutory requirements. To achieve this stated goal, the agency proposes to:

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[3] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).
[4] Small Business Jobs Act of 2010 (PL. 111-240) §1601.
[5] *Id.*
[6] *Id.*
[7] 15 U.S.C. §2604(a)(1).
[8] *See id.* § 2604(d)(1). *See also* 40 CFR §§720.45, 720.50.
[9] *See* 40 CFR §720.65.
[10] *See* 15 U.S.C. §2604(a)(3).
[11] 88 Fed. Reg. at 34,106.
[12] Pub. L. 114-82, 130 Stat. 448 (2016) (codified in various sections of 5 U.S.C. §2601).

- Amend the regulations to specify that EPA must make a determination on each pre manufacturer notice (PMN), significant new use notice (SNUN), and microbial commercial activity notice (MCAN) received before the submitter may commence manufacturing or processing of the chemical substance that is the subject of the notice. In addition, EPA must list the five possible determinations and the actions required in association with those determinations.

- Clarify the level of detail expected for the information that a submitter is required to include in a PMN, SNUN, or exemption notice for the notice to be considered complete.

- Amend the procedures for reviewing PMNs and SNUNsto address those with errors, are those that are incomplete, or that are amended during the applicable review period.

- Amend the regulations for low volume exemptions (LVEs) and low release and exposure exemptions (LoREXs) to:

    - require EPA approval of an exemption notice before the submitter may commence manufacture,

    - allow EPA to inform an LVE or LoREX holder when the chemical substance that is the subject of the exemption becomes subject to a significant new use rule under TSCA and the chemical identity is confidential,

    - make perfluoroalkyl and polyfluoroalkyl substances (PFAS) categorically ineligible for these exemptions, and

    - codify EPA's use of the 1999 certain persistent, bioaccumulative, toxic (PBT) chemical substances policy for these exemptions by making certain PBTs ineligible for these exemptions.

- Amend the regulations pertaining to suspensions for all TSCA section 5 notices to allow submitters to request suspensions for up to 30 days via oral or email request.

The proposal affects small businesses who intend to manufacture (including import) or process a chemical substance, including PFAS, and are required to submit information to EPA under TSCA section 5. EPA proposes to certify, under the RFA, that the proposed rule will not have a significant economic impact on a substantial number of small entities.[13]

II. Advocacy's Small Business Concerns

Advocacy is concerned that the agency's RFA certification lacks an adequate factual basis because EPA does not accurately capture the full impact of the rule on small entities. Advocacy is also concerned about the agency's use of conservative data instead of using the submitted data to assess a chemical under its review process. In addition, Advocacy is concerned about the

[13] 88 Fed. Reg. at 34,117.

agency's proposal to restart the review process when a submitter provides new data to counter the agency's conservative assumptions and default values.

A. EPA Lacks an Adequate Factual Basis to Certify That the Proposed Rule Will Not Have a Significant Economic Impact on a Substantial Number of Small Entities, as Required by the RFA

If, after conducting an analysis for a proposed or final rule, an agency determines that a rule will not have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify. The certification must include a statement providing the factual basis for this determination, and the certification must be published in the *Federal Register* at the time the proposed or final rule is published for public comment. Agency certifications of final rules are subject to judicial review[14] and courts evaluate them by determining whether the statement of basis and purpose accompanying the rule identifies a "factual basis" to support the certification.[15] Advocacy is concerned that the agency's RFA certification lacks an adequate factual basis because the agency does not accurately capture all the direct impacts of the rule on small entities.

The statement of the factual basis for the agency's RFA certification (per 5 USC § 605(b)) should include sufficient information to factually demonstrate that the agency has:

1) accurately counted the number of small entities that would be impacted (i.e., who are these small entities),
2) accurately assessed the economic impact on these small entities (i.e., estimate the cost impact related to its operations such as to revenue), and
3) properly determined as a matter of fact that the proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities.

EPA only assessed costs for its proposed ineligibility of PFAS for LVEs and LoREXs.[16] EPA originally promulgated these exemptions to allow manufacture of up to 10,000 kilograms per year of certain new chemical substances, or certain new chemical substances with low environmental releases and human exposures, without the need for listing of those substances on the TSCA Inventory.[17] Under the proposed rule, PFAS manufacturers would be required to submit a PMN if they wish to manufacture a PFAS.[18] EPA explains that due to the scientific complexities associated with assessing PFAS and the lack of data on most PFAS with regards to toxicity and exposure to human health and the environment, EPA does not expect to be able to determine that PFAS "will not present an unreasonable risk" under the conditions of use within the 30-day review period provided for LVE and LoREX notices.[19]

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[14] 5 U.S.C. §611.
[15] *Id.* §605(b).
[16] U.S. Env't. Prot. Agency, Off. of Pollution, Prevention & Toxics, *Economic Analysis for the Proposed Rule: Updates to New Chemicals Regulations under the Toxic Substances Control Act*, 3-2 (May 2023), https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0902-0035 [hereinafter EA].
[17] 40 CFR §723.50.
[18] EA at 3-1.
[19] 88 Fed. Reg. at 34,113.

Submission of an LVE or LoREX notice entails a shorter review period (compared to 90 days), lower fees, and a smaller regulatory burden than submission of a PMN.[20] As are result of higher costs associated with a PMN submission, EPA's amendment will increase the burden for small entities by $45,863 per notice.[21] EPA's analysis to support its RFA certification contains an inconsistency in the number of fillings per small business. The EPA estimates that twelve PFAS applications, filled by four small businesses, will be submitted as presented in Table 5-2.[22] In Table 5-3, however, compliance costs are assumed based on small manufacturers only filling one submission.[23] Based on Table 5-2, the compliance cost per small business should be three times what is reported.

In addition, EPA's analysis does not focus on the small entities who would no longer be eligible for PFAS LVE or LoREX exemptions. EPA chose to base its analysis on all firms in 6-digit NAICS industries beginning with: 325 (Chemical Manufactures), 324 (Petroleum and Coal Products), and 424 (Chemical, Petroleum and Merchant Wholesalers).[24] The agency should only include industries that produce PFAS by focusing on a narrow group of firms. A narrower industry definition will allow for a more meaningful revenue distribution in Table 5-4 and will change the cost-to-revenue ratios estimated in Table 5-5.[25]

Therefore, Advocacy recommends that the agency revise its analysis, based on the comments provided above, to accurately assess the economic impact on small entities in support of its factual basis for the RFA certification.

The agency does not anticipate any compliance burden related to the proposed changes to its submission forms. Instead, the agency highlights potential cost savings due to an expected decrease in amendments by submitters.[26] According to EPA, most of the new proposed requirements are largely already performed in the baseline because the agency has been "implementing the updated statutory requirements but has not yet codified these updates into regulations."[27]

In presenting its assertion that the proposed changes will force submitters to provide all the information upfront, EPA implies that currently submitters are deliberately withholding known or reasonably ascertainable information. As a result, EPA is proposing to include additional prompts for information.[28] Some of these prompts, however, will require information that was not previously specified. For example, the agency is proposing to add new information

[20] EA at 1-3.
[21] 88 Fed. Reg. at 34,117.
[22] EA at 5-4.
[23] *Id.*
[24] *Id.* at 5-1.
[25] *Id.* at 5-5.
[26] *Id.*
[27] *Id* at 3-1.
[28] 88 Fed. Reg. at 34106-34107.

requirements for the categories of use,[29] for physical and chemical properties,[30] and relevant environmental fate characteristics.[31] Therefore, Advocacy recommends that the agency account for any additional compliance burden that is associated with the proposed new input requirements for small entities.

Advocacy recommends that EPA provide an adequate factual basis for its RFA certification that accurately takes into consideration all the direct impacts of the proposed requirements on small entities. Advocacy urges EPA to conduct outreach with small entities to address their compliance concerns, including feedback shared through the public comments in response to this rulemaking.

B. EPA Should Rely Primarily on Stakeholder Data Rather Than Relying on its Conservative Assumptions

Advocacy is concerned about the agency's use of conservative data and default values instead of using the submitted data to assess a chemical under its new chemical review process. Advocacy is also concerned about the agency's proposal to restart the review process when a submitter provides new data to counter the agency's conservative assumptions.

EPA notes that because of data limitations, they may need to make risk determinations for new chemical substances by using default assumptions.[32] EPA further explains that if a submitter leaves a field blank on a form, the agency will make "conservative assumptions and use conservative default values when assessing risk, which could result in more stringent risk management requirements."[33] According to small business stakeholders, EPA currently relies on conservative worse-case assumptions despite receiving information from stakeholders to make its decisions for new chemicals. There is no basis for using conservative assumptions as a default to make decisions about a chemical substance's risk assessment. TSCA requires EPA to make a decision for a chemical substance under section 5 based on the best available science,[34] on the weight of the scientific evidence,[35] and on reasonable available information.[36]

Advocacy recommends that the agency avoid using its conservative assumptions when a submitter has provided relevant data. If EPA does use its conservative assumptions to make a

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[29] "The information requirements include the types of products or articles that would incorporate the new chemical substance (e.g., household cleaners, plastic articles), how and where a product or article incorporating the new chemical substance would be used (e.g., spray applied indoors, brushed on outdoor surfaces), consumption rates and frequency and duration of use for products or articles containing the new chemical substance, and information related to the use of products or articles containing the new chemical substance by potentially exposed or susceptible subpopulations." *Id.* at 34,107.

[30] "Data on surface tension and ultraviolet–visible (UV–VIS) absorption, as well as any particle size distribution analysis, be submitted as part of the PMN form, to the extent it is known to or reasonably ascertainable by the submitter." In addition, "information requirements for nanomaterial morphology do not currently appear on the pick list for physical and chemical properties on the CDX user interface screen or in the regulations." *Id.*

[31] 88 Fed. Reg. at 34,107.

[32] EA at 1-2.

[33] 88 Fed. Reg. at 34,109.

[34] 15 U.S.C. §2625(h).

[35] *Id.* §2625(i).

[36] *Id.* §2625(k).

decision about a chemical substance's risk, Advocacy recommends EPA provide a robust explanation to justify its decision based on the statutory requirements referenced above.

As noted above, Advocacy is also concerned about EPA's proposal to reset the review period if a submitter provides additional information during the review period.[37] More specifically, EPA proposes that it will restart the review period if a submitter provides required information during the applicable review period without demonstrating that it was not known to or reasonably ascertainable by the submitter at the time of the initial notice submission.[38] EPA is seeking comment on situations when this interpretation may not be appropriate. Based on small business stakeholder feedback, new information submitted to rebut EPA's assumptions should not trigger a restart of the review period. Even if such information was known or reasonably ascertainable by the submitter at the time of the initial submission, if the information is responsive to the agency's conservative assumptions that the submitter could not have anticipated, the review period should not be restarted under these circumstances. Restarting the review process in this case may cause unjustified delays for small entities which can result in increased costs and other burdens. This can include going out of business, especially if the small entity's business planning relied on a timely approval of their chemical.

Therefore, Advocacy recommends that regardless of whether the agency specifically requests an amendment, if a submitter has information to respond to or address EPA's assumption for the review of its chemical substance, the submitter should be able to amend its application without triggering a restart of the review process.

III. Conclusion

Advocacy believes that EPA's RFA certification lacks an adequate factual basis because the agency does not accurately assess the direct impact of the rule on small entities. Advocacy is also concerned about the agency's use of conservative data and default values instead of using the submitted data to assess a chemical under its new chemical review process. In addition, Advocacy is concerned about the agency's proposal to restart the review process when a submitter provides new data to counter the agency's conservative assumptions.

Advocacy recommends that EPA provide an adequate factual basis for its RFA certification that accurately takes into consideration all the direct impacts of the proposed requirements on small entities. Advocacy further recommends that the agency use a submitter's data instead of substituting its own conservative assumptions, where appropriate. If the agency does employ its own conservative assumptions to make a decision about a chemical substance's risk, Advocacy recommends that EPA provide a robust explanation to justify its decision. Advocacy further encourages the agency to allow submitters to provide additional information to address its assumptions without triggering a restart of the review period. Advocacy urges the agency to consider feedback from impacted small businesses and conduct targeted outreach to consider their input on these important issues.

[37] 88 Fed. Reg. at 34,111.
[38] *Id.*

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 798–7405 or by email at tayyaba.zeb@sba.gov.

Sincerely,

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

/s/
Tayyaba Zeb
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Office of Advocacy
U.S. Small Business Administration

Copy to: The Honorable Richard L. Revesz, Administrator
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