



September 23, 2024

VIA ELECTRONIC SUBMISSION

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

**Re: 1-Bromopropane (1-BP); Regulation Under the Toxic Substances Control Act (TSCA)  
(Docket ID: EPA-HQ-OPPT-2020-0471-0032)**

Dear Administrator Regan:

On August 8, 2024, the Environmental Protection Agency (EPA) published a proposed rule titled “1-Bromopropane (1-BP); Regulation Under the Toxic Substances Control Act (TSCA).”<sup>1</sup> This letter constitutes the Office of Advocacy’s (Advocacy) public comments on the proposed rule.

Advocacy is concerned with the ability of small businesses to comply with the EPA’s proposed workplace protection program for the use of 1-BP-containing products. Additionally, the economic analysis prepared by the EPA does not adequately reflect the impact of the proposed rule on small businesses. Advocacy recommends the EPA allow the continued use of 1-BP in industries that can prevent exposure risk and include longer compliance timelines for industries to comply with any prohibitions or new regulations. Further, Advocacy asks the EPA to reconsider the proposed existing chemical exposure limit (ECEL) in favor of a more attainable ECEL that would not place an unnecessary burden on small businesses.

## **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

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<sup>1</sup> 89 Fed. Reg. 65066 (Aug. 8, 2024).

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 Regulatory Flexibility Act (RFA),<sup>2</sup> as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup> If a rule will not have a significant economic impact on a substantial number of small entities, agencies may certify the rule.<sup>7</sup> The agency must provide a statement of factual basis that adequately supports its certification.<sup>8</sup>

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.<sup>9</sup> 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.<sup>10</sup>

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."<sup>11</sup>

## **B. The Proposed Rule**

On August 8, 2024, the EPA published a proposed rule to manage risk associated with the use of 1-BP under the TSCA. 1-BP is used as a solvent in cleaning and degreasing applications, spray adhesives, dry cleaning, and insulation. The act requires that the EPA address and identify any unreasonable risk of injury to health or the environment in a TSCA risk evaluation to the extent necessary that the chemical no longer presents an unreasonable risk.<sup>12</sup> The EPA evaluated 25

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<sup>2</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

<sup>3</sup> Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).

<sup>4</sup> 5 U.S.C. § 603.

<sup>5</sup> *Id.* § 609.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* § 605(b).

<sup>8</sup> *Id.*

<sup>9</sup> Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).

<sup>10</sup> *Id.*

<sup>11</sup> Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

<sup>12</sup> 15 U.S.C. §2605(a).

conditions of use of 1-BP and determined that all those conditions of use present an unreasonable risk of injury to health for workers and consumers.

Based on these risk determinations, the EPA proposes to ban the manufacture, processing, and distribution of 1-BP for all consumer uses; prohibit the manufacture, processing, and distribution of 1-BP for four commercial uses; and require strict workplace and prescriptive controls for conditions of use where 1-BP is not banned. The workplace chemical protection program (WCPP) would apply to six conditions of use and includes the use of an existing chemical exposure limit (ECEL), a respiratory personal protective equipment (PPE) program, and the requirement to use chemical-resistant gloves. The EPA is also proposing prescriptive controls for six conditions of use dictating the requirements for the use of chemical-resistant gloves. Conditions of use subject to these regulations would also be required to provide self-certification of compliance with a WCPP to purchase and use 1-BP. The proposal also includes recordkeeping and downstream notification requirements consistent with other chemical risk management rules.

The TSCA requires the EPA to discuss one or more primary alternative regulatory actions.<sup>13</sup> In this case, the agency provides two alternative regulatory actions. The primary alternative includes a WCPP for several additional conditions of use and prohibitions instead of prescriptive controls for certain industries. It also provides longer compliance timeframes for prohibitions. The secondary alternative is to prohibit all occupational uses of 1-BP.

In advance of this proposed rule, the EPA convened a small business advocacy review panel under SBREFA to consult with small entity representatives (SERs). The report issued by that panel is available in the docket.<sup>14</sup>

## **II. Advocacy's Small Business Concerns**

Advocacy has several concerns with the proposed rule. First, Advocacy is concerned that the EPA is exceeding its statutory authority under the TSCA by proposing to ban 1-BP for entities that can demonstrate the ability to comply with a WCPP. Second, Advocacy is concerned that some of the proposed policies, specifically the proposed ECEL, create a disproportionate impact on small businesses, potentially resulting in a *de facto* ban on the use of 1-BP for entities that could comply with a WCPP. Advocacy is concerned that the EPA is underestimating the costs of the rule and has not properly identified all the potential economic impacts on small businesses. Further, Advocacy remains concerned generally with the EPA's approach to its risk management rules and suggests the agency accept information submitted after the comment period.

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<sup>13</sup> 15 U.S.C. §2605(c)(2)(A)(iv)(II)-(III).

<sup>14</sup> U.S. ENV'T PROT. AGENCY, FINAL REPORT OF THE SMALL BUSINESS ADVOCACY REVIEW PANEL ON EPA'S PLANNED PROPOSED RULE UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA) SECTION 6(A) FOR 1-BROMOPROPANE (1-BP) (Dec. 16, 2021), <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0471-0066>.

**A. Advocacy recommends that the EPA allow the continued industrial and commercial use of 1-BP for industries that can prove compliance with the WCPP.**

As expressed in Advocacy’s public comments on the proposed risk management rules for methylene chloride, perchloroethylene, and n-Methylpyrrolidone,<sup>15</sup> Advocacy remains concerned about the EPA’s practice of prohibiting uses based on its independent determination about a business’s compliance capability with the WCPP.

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 apply one or more requirements listed in section 6(a) “to the extent necessary so that the chemical substance or mixture no longer presents such risk.”<sup>16</sup> In the proposal, the EPA determines that inhalation of 1-BP presents an unreasonable risk to human health.

The EPA proposes to ban or implement prescriptive controls for many of the industrial uses of 1-BP rather than allow the regulated entities to determine compliance feasibility. The EPA cites uncertainties regarding the feasibility of implementing workplace safety control measures and the availability of alternatives as reasons to prohibit or require prescriptive controls for the use of 1-BP. It is important to note that the TSCA does not specify any level of certainty or compliance capability. It simply requires that the unreasonable risk must be addressed only to the extent necessary. Because the EPA has identified controls and WCPP requirements that could prevent exposure in some conditions of use, a user that can comply with these requirements should be able to eliminate unreasonable risk. Speculating about compliance capability goes beyond the scope of the statute.

If a WCPP is indeed protective of health and the environment in certain uses, as the EPA claims, then banning those uses that can demonstrate compliance with the WCPP would go beyond the “extent necessary.” If a workplace can document and demonstrate compliance with a WCPP, such a use should be allowed to continue. Imposing regulations on a use that can meet the WCPP exceeds the agency’s statutory authority under the TSCA. Therefore, the EPA should not propose banning the use of 1-BP for entities that can demonstrate compliance with a WCPP.

**1. Advocacy recommends that the EPA address concerns with the proposed ECEL.**

Advocacy is concerned that the proposed ECEL of 0.05 parts per million (ppm) is too low to be reliably measured by most businesses and thus creates a *de facto* ban on the use of 1-BP. The

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<sup>15</sup> 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://advocacy.sba.gov/2023/07/03/advocacy-provides-public-comment-on-epas-proposed-risk-management-for-methylene-chloride-under-the-toxic-substance-control-act/>. U.S. Small Bus. Admin., Off. of Advocacy, Comment Letter on Proposed Rule Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA) (Aug. 15, 2023), <https://advocacy.sba.gov/2023/08/15/advocacy-provides-public-comment-on-epas-proposed-risk-management-for-perchloroethylene-under-the-toxic-substance-control-act/>. U.S. Small Bus. Admin., Off. of Advocacy, Comment Letter on Proposed Rule Regulation under the Toxic Substances Control Act: n-Methylpyrrolidone) (July 29, 2024), <https://advocacy.sba.gov/wp-content/uploads/2024/07/Comment-Letter-NMP-Risk-Management-Under-TSCA-72624.pdf>.

<sup>16</sup> 15 U.S.C. §2605(a) (emphasis added).

EPA assumes that a regulated entity has the necessary means to detect those levels because the agency understands them to be above the detection limit. However, Advocacy spoke with several small businesses that expressed their disagreement with this assumption. This was also discussed in the Small Business Advocacy Review (SBAR) Panel convened in 2021, where several SERs discussed the challenges associated with achieving an ECEL of 0.05 ppm, especially in vapor degreasing operations.<sup>17</sup>

While there may be commercially available methods to detect exposure at the proposed levels, it may be costly or burdensome to implement and may not be readily available to all potentially regulated entities at this time. Considering this feedback from small entities, Advocacy recommends that the EPA consider adjusting the requirements for the ECEL to allow more small entities in regulated industries to comply with the requirements of the WCPP.

## **2. Advocacy recommends that the EPA provide a longer compliance timeframe for small entities.**

Advocacy is concerned that the EPA's proposal does not provide a practicable compliance timeline for small entities. According to the TSCA, when the agency is contemplating a prohibition or a substantial restriction on the use of a chemical, it is required to set an appropriate transition period.<sup>18</sup> To make this determination, "the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."<sup>19</sup>

Advocacy is concerned that the agency did not adequately account for the limited resources available to small entities to ensure timely compliance. The uses subject to prohibition will require additional time and costs for researching alternative processes or substitutes, securing financing for testing such alternatives, and implementing the use of an alternative into their process/product. Similarly, other small entities will have to utilize their limited staff and financial resources to implement procedures, equipment, and other necessities to comply with the proposed requirement of the WCPP.

Several small businesses noted that the alternatives for 1-BP include fluorinated chemicals, 1,2-trans-dichlorethylene, and per- and polyfluoroalkyl substances (PFAS). These businesses stated that while several industries have been moving away from the use of 1-BP for several years, there is concern that the alternative substances, all of which are currently in a regulation process from the EPA, would soon be subject to their own restrictions and/or bans. Additionally, many of these substances raise health and safety concerns for workers and/or the environment. For example, some alternatives are flammable, raising other safety concerns for workers in small businesses. Another alternative is a water-based solution, which could have additional environmental impacts on small businesses where water is not an abundant resource. Small

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<sup>17</sup> U.S. ENV'T PROT. AGENCY, *supra* note 14.

<sup>18</sup> 15 U.S.C. § 2605(c)(2)(a)(iv)(I).

<sup>19</sup> *Id.* § 2605(a).

businesses are hesitant to invest significant time and resources into these alternatives if they are also going to be regulated or prohibited in the future.

Further, as noted in this letter, Advocacy does not believe that the costs associated with alternative substances have been fully evaluated by the EPA. The SBAR panel report notes that the costs of these substances can be 3 to 4 times the cost of 1-BP, not including any investment in different machinery that would be required to perform the same function with the new chemical.<sup>20</sup> Therefore, Advocacy urges the EPA to consider the amount of time and resources necessary to adopt alternative solutions and methods for the uses of 1-BP identified in this rule.

**B. Advocacy recommends that the EPA consider all important adverse effects of the proposed rulemaking.**

Under the TSCA, the EPA is obligated to consider the reasonably ascertainable economic consequences of the rule, including the likely effect of the rule on the national economy, small businesses, technological innovation, the environment, and public health.<sup>21</sup> The EPA is also obligated to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives in a proposed rule. Advocacy is concerned that the EPA's economic analysis underestimates the impact to small businesses by failing to include costs small businesses might incur when switching away from 1-BP to other alternative solvents. For example, under some conditions of use, the EPA does not include cost estimates beyond rule familiarization. Although alternative solvents for 1-BP exist, there are costs associated with switching to these solvents including the potential need for new machinery, protections against flammable substances, and a higher cost per liter for the alternative chemical solvent as well as costs whenever a change in procedure occurs, such as employee training.<sup>22</sup> Advocacy recommends that the EPA consider all costs associated with the proposals in this rule prior to finalizing the regulation.

Further, for four conditions of use related to processing, the EPA estimates costs but no benefits from the proposals in this rule. While a reduction in noncancer risks could not be quantified, it should decrease proportionally to quantified cancer risk. This suggests that these industries have managed to handle the risk of using 1-BP in a way that does not contribute to cancer risks, such as by using protections to prevent inhalation or dermal contact with 1-BP. Based on the economic impact of these conditions of use, Advocacy recommends that these conditions of use be subject to a WCPP instead of prescriptive controls or a total prohibition.

**C. Advocacy recommends that the EPA adjust aspects of the risk management process to be more inclusive of small business concerns.**

The EPA should consider allowing regulated entities to submit requested data after the public comment period has closed. This issue has been consistently raised by small businesses for this

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<sup>20</sup> U.S. ENV'T PROT. AGENCY, *supra* note 14.

<sup>21</sup> 15 U.S.C. §2605(c)(2)(A)(iv)(I).

<sup>22</sup> U.S. ENV'T PROT. AGENCY, *supra* note 14.

rule and others due to the limited public comment period of 45 days. Advocacy recognizes the legitimate concerns for the regulated entities to review and respond to rulemaking of a massive scope which will significantly impact most industrial and commercial uses of a widely used chemical. Advocacy also understands that the EPA has publicly stated they will not be extending comment periods for the TSCA risk management rules. However, Advocacy urges the agency to remain open to receiving additional feedback from the regulated entities in response to its proposal.

In particular, the proposed rule indicates that the EPA is looking for specific data to support a proposal or alternative regulatory action. This includes the request for technical information that would indicate with certainty that relevant regulated entities for these conditions of use could sufficiently mitigate identified unreasonable risk for complying with elements of the WCPP. However, generating such responsive data and aggregating relevant information may require more than the 45 days provided for public comments. Therefore, Advocacy recommends that the agency develop a line of communication that allows for additional information to be considered by the agency before developing its final rule. By doing so, the EPA can ensure that all relevant data and perspectives are thoroughly evaluated, leading to a more comprehensive and effective final rule.

**1. Advocacy remains concerned that the EPA’s chemical risk management rules do not align with other rulemakings the agency is undertaking.**

Advocacy spoke with several small businesses that stated concerns that the identified alternatives to 1-BP, specifically for precision cleaning and vapor degreasing, are also substances that are likely to be regulated or prohibited by the EPA in the coming years. These include 1,2-trans-dichloroethylene, for which the EPA released a final scoping document for risk evaluation in August 2020,<sup>23</sup> as well as fluorinated substances and substances that are believed to be PFAS. Small business stakeholders identified concerns that the large investment in moving to these substances—many of which require new equipment, are more expensive, and are potentially flammable—deterred small businesses from switching to alternative substances as they may be subject to a different prohibition soon. As the EPA works through high-priority chemicals, Advocacy encourages the agency to consider other potential regulations that may impact proposed alternatives prior to finalizing any rules.

**III. Conclusion**

Advocacy is concerned that the agency’s proposal exceeds its statutory authority by prohibiting commercial and industrial uses of 1-BP in a way that disproportionately impacts small entities. As noted in the final report of the SBAR panel, Advocacy strongly recommends that the EPA allow the use of 1-BP by entities who can prove compliance with the requirements of a WCPP. This includes not finalizing policies that might indirectly create a barrier to the safe use of 1-BP, such as an ECEL that is so restrictive it creates a *de facto* ban on the use of 1-BP.

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<sup>23</sup> U.S ENV’T PROT. AGENCY, FINAL SCOPE OF THE RISK EVALUATION FOR TRANS-1,2-DICHLOROETHYLENE, (Sept. 4, 2020), <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0465-0042>.

Advocacy recommends the EPA reconsider the proposed rule and urges the agency to consider feedback from small businesses on these important issues.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Emily Jones at (202) 205-6368 or by email at [Emily.Jones@sba.gov](mailto:Emily.Jones@sba.gov).

Sincerely,

/s/

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/s/

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Copy to: Richard L. Revesz, Administrator  
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