

December 16, 2021

The Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Regan:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened for EPA's planned proposed rulemaking entitled "1-Bromopropane Risk Management under the Toxic Substances Control Act." This notice of proposed rulemaking is being developed by the U.S. Environmental Protection Agency (EPA) under section 6(a) of the Toxic Substances Control Act (TSCA), which requires EPA to take action to address unreasonable risks resulting from the manufacture (including import), processing, distribution in commerce, use of, and disposal of existing chemicals that have undergone TSCA risk evaluation.

In December 2016, EPA selected 1-bromopropane (1-BP) as one of the first 10 chemicals for risk evaluation under section 6 of TSCA. In August 2020, the risk evaluation was finalized. The risk evaluation was conducted pursuant to TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to conduct 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 identified as relevant to the risk evaluation by the Administrator, under the conditions of use". EPA published the scope of the risk evaluation document¹ in June 2017 (82 FR 31592, July 7, 2017), the 1-BP problem formulation document² in June 2018 (83 FR 26998, June 11, 2018), and the 1-BP draft risk evaluation³ in August 2019 (84 FR 39830, August 12, 2019). EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of 1-BP on September 10-12, 2019. Public comments and external scientific peer review informed the development of the 1-BP final risk evaluation⁴ (85 FR 48687, August 12, 2020).⁵

In the 2020 final risk evaluation, EPA evaluated 25 conditions of use of 1-BP and determined that 16 conditions of use present an unreasonable risk. Small businesses may be represented under all 16 conditions of use that present an unreasonable risk. EPA's unreasonable risk determinations for conditions of use of 1-BP are based on unreasonable risk of injury to health for workers and occupational non-users (ONUs) (workers who do not directly handle 1-BP but perform work in an area where 1-BP is present) during occupational exposures, and for consumers and bystanders during exposures to consumer use. EPA's unreasonable risk determinations are due to developmental toxicity endpoints from acute exposures, and developmental toxicity and cancer endpoints from chronic exposures to 1-BP.

On April 27, 2021, EPA's Small Business Advocacy Chairperson convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). In addition to its chairperson, the Panel consists of the Deputy Director of EPA's Office of Pollution Prevention and Toxics, the Acting Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Acting Chief Counsel for Advocacy of the Small Business Administration (SBA). It is important to note that the Panel's findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during this process as well as from public comment on the proposed rule. The

¹ Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0741-0049>.

² Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0741-0067>.

³ Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0235-0022>.

⁴ Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0235-0064>.

⁵ The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0235, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0741, on www.regulations.gov.

options the Panel identified for reducing the rule's economic impact on small entities will require further analysis and/or data collection to ensure that the options are practicable, enforceable, protective of public health, environmentally sound and consistent with TSCA section 6(a).

On June 30, 2021, as the Panel was conducting its report, EPA announced policy changes for risk evaluations and associated risk management actions to protect human health and the environment and align more closely with the statutory requirements. These policy changes include consideration of ambient air and drinking water pathways to the general population and fence-line communities; making the unreasonable risk determination without assuming use of PPE, and making an unreasonable risk determination for the whole chemical rather than condition of use by condition of use. These policy changes follow review of the risk evaluations and are consistent with Executive Orders and other directives, including those on environmental justice, scientific integrity, and regulatory review (i.e., Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities through the Federal Government, Executive Order 13990: Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crises, January 27, 2021 Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking). The Panel's findings and discussion are based on the information available at the time the final Panel report is drafted. As the policy changes are implemented, there is a chance that some impacts of the proposed rulemaking may not have been fully considered by the Panel during its work. In light of these particular and unusual circumstances, if EPA intends to consider additional requirements impacting small business related to conditions of use that were not presented to Small Entity Representatives (SERs) during the May 2021 SBAR Panel Outreach meeting, then EPA will determine whether those additional requirements may have a significant impact on a substantial number of small entities. Under these unique circumstances, EPA would organize a supplemental opportunity for the Panel to consult with the SERs and additional small entities that might be significantly impacted prior to proposal of the rule. EPA continues to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process.

SUMMARY OF SMALL ENTITY OUTREACH

EPA conducted an online solicitation to identify small businesses and trade associations interested in participating in the SBAR Panel process by serving as SERs. EPA issued a press release inviting self-nominations by affected small entities to serve as SERs. The press release directed interested small entities to a web page where they could indicate their interest. EPA launched the website on September 16, 2020 and accepted self-nominations until September 30, 2020. EPA also contacted potential SERs directly throughout the fall of 2020 to generate interest and organized or participated in three events in September 2020 to specifically generate small business interest in engagement during the risk management process.⁶

Prior to convening the Panel, EPA conducted outreach with small entities that will potentially be affected by these regulations. In November 2020, EPA invited SBA, OMB, and 10 potentially affected small entity representatives to a conference call and solicited comments from them on preliminary information sent to them. EPA shared the small entities' written comments with the Panel as part of the Panel convening document.

After the SBAR Panel was convened, the Panel distributed additional information to the SERs on April 27, 2021, for their review and comment and in preparation for another outreach meeting. On May 11, 2021, the Panel met with the SERs to hear their comments on the information distributed in these mailings. The SERs were asked to provide written feedback on ideas under consideration for the proposed rulemaking and responses to questions regarding their experience with the existing requirements. The Panel received written comments from the SERs in response to the discussions at this meeting and the

⁶ Presentation at National Training for Small Business Environmental Assistance Providers (organized by EPA Office of Small and Disadvantaged Business Units, September 9, 2020); SBA Environmental Roundtable (organized by SBA Advocacy, September 11, 2020); and public webinar on the 1-bromopropane risk evaluation and next steps for risk management (September 30, 2020).

outreach materials. See Section 7 of the Panel Report for a complete discussion of SER comments. Their full written comments are also included in Appendix B. In light of these comments, the Panel considered the regulatory flexibility issues specified by RFA/SBREFA and developed the findings and discussion summarized below.

PANEL FINDINGS AND DISCUSSION

Under section 609(b) of the RFA, the Panel is to report its findings related to these four items:

- A. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.
- B. A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.
- C. Identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap or conflict with the proposed rule.
- D. A description of any significant alternatives to the planned proposed rule which would minimize any significant economic impact of the proposed rule on small entities consistent with the stated objectives of the authorizing statute.

The Panel's most significant findings and discussion with respect to each of these items are summarized below. To read the full discussion of the Panel findings and recommendations, see Section 8 of the Panel Report.

A. Number and Types of Entities Affected

The proposed rule potentially affects commercial users of 1-BP as well as any business that manufactures (including imports), processes, or distributes 1-BP and 1-BP-containing products for commercial or consumer use. During the Panel outreach meeting, SERs discussed the number and types of small entities affected and included information on their processing or use of 1-BP, their customer base, and how their products are used, with a strong focus on vapor degreasing. EPA estimates that a total of 8,942 small firms could be potentially affected by regulations to address the unreasonable risks from 1-BP, of which between 1,339 to 3,252 firms use 1-BP in vapor degreasing.

B. Recordkeeping, Reporting, and Other Compliance Requirements

Several SERs raised concerns regarding compliance with monitoring for an existing chemical exposure limit (ECEL), available monitoring technology, and the challenges of achieving a low airborne concentration level. Additionally, SERs provided several comments about their concerns with substitute chemicals, including trans-1,2-dichloroethylene, hydrofluorocarbons, and hydrofluoroethers. SERs also provided comments about their concerns with alternative technologies such as aqueous cleaning.

The potential reporting, recordkeeping, and compliance requirements are still under development. Based on SER comments, EPA will be considering the potential compliance costs and the availability and feasibility of alternative technologies, such as aqueous cleaning.

C. Related Federal Rules

1-BP has been the subject of federal regulations by EPA. EPA has issued several final rules and notices pertaining to 1-BP under its various statutory authorities including: reporting under the Chemical Data Reporting (CDR) rule (85 FR 20122, April 9, 2020; 40 CFR 711.5), and adding 1-BP as a listed substance

on the Toxics Release Inventory (TRI) pursuant to Section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA) (40 CFR 372.65, January 1, 2016). 1-BP is also subject to the Clean Air Act (CAA): section 183(e) under the National Volatile Organic Compound (VOC) Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E); section 612 under EPA's Significant New Alternatives Policy (SNAP) program (72 FR 30142 and 30168, May 30, 2007); and under section 112(b) petitioners requested that 1-BP be listed as a hazardous air pollutant (HAP) (80 FR 6676, February 6, 2015). EPA granted the section 112(b) petitions, and published a draft and final notice, as well as an Advance Notice of Proposed Rulemaking (ANPRM) on June 11, 2021⁷.

The Occupational Safety and Health Administration (OSHA) has not issued a permissible exposure limit (PEL) for 1-BP. OSHA and the National Institute for Occupational Safety and Health (NIOSH) issued a Hazard Alert⁸, which indicates a recommended time-weighted average threshold limit value (TWA-TLV) of 10 ppm by the American Conference of Governmental Industrial Hygienists [ACGIH 2013]. However, since then, ACGIH has recommended 0.1 ppm as the TWA-TLV value for 1-BP.

Based on SER comments, EPA will consider existing federal regulations and the possibility of aligning with existing regulations where possible, as well as existing best practices relative to OSHA's General Duty Clause and related regulations during the development of regulatory options. EPA also communicates regularly with OSHA throughout the development of the regulatory options and proposed rule.

D. Regulatory Flexibility Alternatives

The Panel recommends that EPA consider additional activities listed below to determine if they are appropriate to provide flexibility to lessen impacts to small entities. Many of the recommended flexibilities may lessen impacts to all entities, and not just small entities.

Regulatory Options Based on SER comments:

1. The Panel recommends that EPA should request comment in the NPRM on feasibility of complying with and monitoring for an ECEL of 0.05 ppm, and in particular comments on changes that may be needed and costs that may be incurred in order to meet such a standard, for example changes related to elimination of 1-BP, substitution including testing, engineering controls, process changes, obtaining new equipment, additional space needed, and monitoring frequency.
2. With respect to the possible establishment of an ECEL, the Panel recommends that EPA consult and communicate with OSHA to clearly explain respective regulatory requirements applicable to workers and workplaces who must comply with standards set by both agencies, and to minimize confusion by aligning definitions and other requirements where possible. In addition, EPA and OSHA should communicate on implementation and EPA should also provide clear and specific guidance for complying with any potential ECEL. Furthermore, the Panel recommends that EPA continue to engage with federal partners to work towards establishing a policy on its relationships to other federal laws administered by EPA (e.g., 1-BP listing as a HAP under the CAA) and/or other federal agencies to ensure transparency and that the statutory obligations under TSCA to address the unreasonable risk are met.
3. The Panel recommends that EPA should also request comment in the NPRM on reasonable compliance timeframes for small businesses, including timeframes for reformulation of products or processes containing 1-BP; implementation of new engineering or administrative controls; changes to labels, SDS, and packaging; implementation of new PPE, including training and monitoring practices; and supply chain management issues regarding the use of 1-BP in vapor degreasing, including potential challenges with obtaining 1-BP. The Panel also recommends that EPA request comment in the NPRM on establishing differing compliance or reporting requirements or timetables that account for the resources

⁷ Available at <https://www.regulations.gov/docket/EPA-HQ-OAR-2014-0471>

⁸ Available at https://www.osha.gov/sites/default/files/publications/OSHA_3676.pdf

available to small entities. The Panel recommends that EPA specifically request comments in the NPRM on whether to provide five years to implement any regulations on the use of 1-BP for critical applications.

4. The Panel recommends that EPA should request comment in the NPRM on workplace monitoring for implementation of an ECEL. EPA should specify that it is soliciting information related to the frequency of monitoring, including initial monitoring and periodic monitoring for workplace exposure levels. Specifically, EPA should request comment on the burden to small businesses associated with periodic monitoring if initial monitoring shows that employee exposures are above the level that would initiate requirements for compliance with the ECEL.

5. The Panel recommends that EPA request comment in the NPRM on the feasibility and availability of various prescriptive engineering controls to reduce exposure levels, and information on any additional technologies or prescriptive control options that could be used alone or in combination for addressing the unreasonable risk.

6. The Panel recommends EPA request public comment in the NPRM to solicit information regarding options for complying with the ECEL, for example by implementing various administrative and engineering controls, including information on how a small business can demonstrate that such controls eliminate the unreasonable risks for that use.

7. The Panel recommends that if EPA proposes limitations on distribution for consumer uses while allowing commercial uses to continue, then EPA should seek public comment in the NPRM on means by which small businesses can maintain access for industrial and commercial uses including establishing a certification and limited access program to allow access to 1-BP at the point of sale based on requirements suitable to small businesses.

8. The Panel recommends that EPA request public comment in the NPRM on establishing a certification program for the use of 1-BP by the vapor degreasing industry and take comments on measures to address the unreasonable risks for industrial and commercial uses of 1-BP by small businesses, including what kind of documentation would be needed to demonstrate that these measures would address the unreasonable risk.

9. The Panel recommends that EPA request public comment in the NPRM on TSCA section 6(g)(1) exemptions for any small businesses with applications of 1-BP in defense, aerospace or medical uses if 1-BP is specified or required for a specific end use application. The Panel also recommends that EPA should continue to engage with SERs whose products may be used for defense, aerospace or medical purposes to identify circumstances where 1-BP may be specified with no available alternatives.

10. The Panel recommends that EPA request public comment in the NPRM on temporary work practices to allow for limited circumstances, including but not limited to equipment failure or maintenance activity, where monitoring may need to be modified to comply with an ECEL by small businesses.

11. The Panel recommends that EPA request public comment in the NPRM on its regulatory approach in considering the availability of potential alternatives that may also be subject to risk management or other regulatory actions by EPA.

Sincerely,

**WILLIAM
NICKERSON**

Digitally signed by
WILLIAM NICKERSON
Date: 2021.12.17
14:49:37 -05'00'

William Nickerson
Small Business Advocacy Chair
Office of Policy
U.S. Environmental Protection Agency

**SHARON
BLOCK**

Digitally signed by
SHARON BLOCK
Date: 2021.12.17
11:28:10 -05'00'

Sharon Block
Associate Administrator
Office of Information and Regulatory Affairs
U.S. Office of Management and Budget

**MAJOR
CLARK**

Digitally signed by
MAJOR CLARK
Date: 2021.12.17
06:21:04 -05'00'

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

**Hartman,
Mark**

Digitally signed by
Hartman, Mark
Date: 2021.12.16
15:20:38 -05'00'

Mark Hartman
Deputy Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Enclosure