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)

December 16, 2021

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1. INTRODUCTION

This final Panel report is presented by the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened to review the planned proposed rulemaking by the U.S. Environmental Protection Agency (EPA) under section 6(a) of the Toxic Substances Control Act (TSCA) to regulate the unreasonable risks of 1-bromopropane (1-BP) to the extent necessary so that the chemical no longer presents an unreasonable risk. Section 6 provides EPA the authority to address unreasonable risks resulting from the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal of chemicals. Under section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Panel is required to be convened prior to publication of the initial regulatory flexibility analysis (IRFA) that an agency may be required to prepare under the RFA. In addition to EPA's Small Business Advocacy Chairperson, the Panel consists of the Deputy Director of the Office of Pollution Prevention and Toxics, the Acting Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Acting Chief Counsel for Advocacy of the Small Business Administration.

This report includes the following:

- Background information on the proposed rule being developed;
- Information on the types of small entities that would be subject to the proposed rule;
- A description of efforts made to obtain the advice and recommendations of representatives of those small entities; and
- A summary of the comments that have been received to date from those representatives.

Section 609(b) of the RFA directs the Panel to report on the comments of small entity representatives and make findings on issues related to elements of an IRFA under section 603 of the RFA. Those elements of an IRFA are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- Projected reporting, record keeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all other relevant federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- Any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

Once completed, the Panel report is provided to the Agency issuing the proposed rule and it is included in the rulemaking record. The Agency is to consider the Panel's findings when completing the draft of the proposed rule. In light of the Panel report, and where appropriate, the Agency is also to consider whether changes are needed to the IRFA for the proposed rule or the decision on whether an IRFA is required.

The Panel's findings and discussion will be based on the information available at the time the final Panel report is drafted. For example, as the work of the panel was nearing completion, EPA announced several intended policy changes regarding risk evaluations,[1] described in section 2.1. EPA will continue to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process.

Any options identified by the Panel for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, and consistent with TSCA and its amendments.

2. BACKGROUND

2.1 Risk Evaluation for 1-BP

In December 2016, EPA selected 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 document[2] in June 2017 (82 FR 31592, July 7, 2017), the 1-BP problem formulation document[3] in June 2018 (83 FR 26998, June 11, 2018), and the 1-BP draft risk evaluation[4] 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 evaluation[5] (85 FR 48687, August 12, 2020)[6].

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[1] Available at https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

[2] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0741-0049.

[3] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0741-0067.

[4] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0235-0022.

[5] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0235-0064.

[6] 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.

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 determination is due to developmental toxicity endpoints from acute exposures, and developmental toxicity and cancer endpoints from chronic exposures to 1-BP.[7]

On June 30, 2021, as the Panel was concluding its report, EPA announced policy changes intended to enhance public trust, provide regulatory certainty, and ensure that all populations that may be exposed to these chemicals are protected from unreasonable risk.[8] EPA announced that the policy changes listed below would allow the agency to move forward with actions to supplement some of the first six risk evaluations if warranted, to ensure the public is protected from unreasonable risk from chemicals in a way that is supported by science and the law:

- consideration of exposure pathways such as ambient air and drinking water to the general population and fenceline communities,
- revisiting the assumption that personal protective equipment (PPE) is always used in occupational settings when making a risk determination for a chemical. Rather, EPA will no longer assume that PPE is always used when determining whether a chemical substance presents unreasonable risk, and
- making the determination of unreasonable risk for the whole chemical rather than on a condition of use by condition of use basis. EPA will continue to assess and characterize risks from each condition of use with and without PPE, but then make one determination of unreasonable risk for the whole chemical, rather than making separate determinations for each condition of use.

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 businesses 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

[7] For additional information please see Section 2.2 under other regulations and actions that apply to 1-BP.

[8] See announcement at: https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

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.

Table 1 below lists the conditions of use of 1-BP that drive EPA's determination that the chemical poses unreasonable risk. EPA acknowledges that there may be some conditions of use that do not drive the determination of unreasonable risk, but may still be subject to regulation due to uses down the supply chain (e.g., consumer uses) that drive the unreasonable risk determination.

Table 1. Conditions of Use of 1-BP that EPA has Determined Present an Unreasonable Risk to Human Health (August 12, 2020, Final Risk Evaluation)

Processing that Presents an Unreasonable Risk
• Incorporation into a formulation, mixture or reaction product

Industrial and Commercial Uses that Present an Unreasonable Risk
• Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – open-top, inline vapor degreaser) • Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – closed-loop) • Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners • Industrial and commercial use as solvent in aerosol spray degreaser/cleaner • Industrial and commercial use in adhesives and sealants • Industrial and commercial use in dry cleaning solvents, spot cleaners and stain removers • Industrial and commercial use in liquid cleaners (*e.g.,* coin and scissor cleaner) and liquid spray/aerosol cleaners • Other industrial and commercial uses: arts, crafts, hobby materials (adhesive accelerant); automotive care products (engine degreaser, brake cleaner, refrigerant flush); anti-adhesive agents (mold cleaning and release product); electronic and electronic products and metal products; functional fluids (close/open-systems) – refrigerant/cutting oils; asphalt extraction; laboratory chemicals; and temperature indicator – coatings

Consumer Uses that Present an Unreasonable Risk
• Consumer use as solvent in aerosol spray degreasers/cleaners • Consumer use in spot cleaners and stain removers • Consumer use in liquid cleaners (*e.g.,* coin and scissor cleaners)

- Consumer use in liquid spray/aerosol cleaners
- Consumer use in arts, crafts, hobby materials (adhesive accelerant)
- Consumer use in automotive care products (refrigerant flush)
- Consumer use in anti-adhesive agents (mold cleaning and release product)

2.2 Regulatory History

1-BP has been the subject of U.S. federal regulations by EPA. EPA has issued several final rules and notices pertaining to 1-BP under EPA's various statutory authorities, summarized below:[9]

- *Toxic Substances Control Act*: 1-BP manufacturing (including importing), processing, and use information is reported under the Chemical Data Reporting (CDR) rule (85 FR 20122, April 9, 2020; 40 CFR 711.5).
- *Emergency Planning and Community Right-To-Know Act (EPCRA)*: 1-BP is a listed substance on the Toxics Release Inventory (TRI) pursuant to Section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA). 1-BP is listed under 40 CFR 372.65 effective as of January 1, 2016.
- *Clean Air Act (CAA) section 112(b)*: EPA received petitions from the Halogenated Solvent IndustryAlliance and the New York State Department of Environmental Conservation to list 1-BP as a hazardous air pollutant (HAP) under Section 112(b)(1) of the Clean Air Act (80 FR 6676, February 6, 2015). On January 9, 2017, EPA published a draft notice on the rationale for granting the petitions to add 1-BP to the list of hazardous air pollutants (HAPs) (82 FR 2354, January 9, 2017), and issued a final notice to grant the petition to add 1-BP to the list of HAPs contained in Section 112(b)(1) of the CAA, 42 U.S.C. 7412 (85 FR 36851, June 18, 2020). This triggers a regulatory process for reducing air emissions of 1-BP under the CAA, as outlined in the final notice (85 FR 36851, June 18, 2020) at page 36854 (see section IV. Reducing Emissions from Sources of 1-BP). In addition, on June 11, 2021, EPA published an Advance Notice of Proposed Rulemaking (ANPRM) soliciting data and information on 1-BP usage, emission controls, and costs to inform the process to address the implementation of the upcoming listing action and to ensure that the regulatory infrastructure is in place to effectively and efficiently control the emissions of 1-BP (86 FR 31225). The docket number for the draft and final EPA notices granting the petition as well as for the ANPRM is Docket ID No. EPA-HQ-OAR-2014-0471.
- *Clean Air Act (CAA) section 183(e)*: 1-BP is listed under the National Volatile Organic Compound (VOC) Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). 1-BP has a reactivity factor of 0.35 g O3/g VOC.

[9] U.S. EPA Risk Evaluation for 1-Bromopropane (n-Propyl Bromide). Office of Pollution, Prevention, and Toxics. Washington, DC. August 2020. (Docket EPA-HQ-OPPT-2019-0235).

- *Clean Air Act (CAA) section 612*: Under EPA's Significant New Alternatives Policy (SNAP) program, EPA evaluated 1-BP as an acceptable substitute for ozone-depleting substances. In 2007, EPA listed 1-BP as an acceptable substitute for chlorofluorocarbon (CFC)-113 and methyl chloroform in the solvent and cleaning sector for metals cleaning, electronics cleaning, and precision cleaning. EPA recommended the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing (72 FR 30142, May 30, 2007). In 2007, the Agency also proposed to list 1-BP as an unacceptable substitute for CFC-113, hydrochlorofluorocarbon (HCFC)-114b and methylchloroform when used in adhesives or in aerosol solvents; and in the coatings end use (subject to use conditions) (72 FR 30168, May 30, 2007). The proposed rule has not been finalized by the Agency.

Regulations and other actions on 1-BP by other federal agencies include:

- 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 Alert[10] regarding 1-BP providing information regarding health effects, how workers are exposed, and how to control exposures. The Hazard Alert indicates thatthe American Conference of Governmental Industrial Hygienists (ACGIH) "currently recommends a 10 ppm time-weighted average threshold limit value but has proposed lowering the value to 0.1 ppm [ACGIH 2013]." However, since then, the ACGIH has recommended 0.1 ppm as the time-weighted average threshold limit value (TWA-TLV) for 1-BP.[11]

2.3 Estimates of Exposed Populations

As described in the risk evaluation, populations exposed to 1-BP include workers, occupational non-users (ONUs), consumer users, and bystanders to consumers using 1-BP or products containing 1-BP for the conditions of use that drive unreasonable risk (including potentially exposed or susceptible subpopulations).

For conditions of use that according to the 2020 final risk evaluation drive unreasonable risk, EPA estimates that, annually, there are between approximately 17,000 and 50,000 workers at between 2,500 and 8,800 commercial operations either processing or using products containing 1-BP[12]. The number of consumers that use products containing 1-BP each year is unknown.

[10] Available at https://www.osha.gov/sites/default/files/publications/OSHA_3676.pdf.

[11] U.S. EPA. Risk Evaluation for 1-Bromopropane (n-Propyl Bromide). Office of Pollution, Prevention, and Toxics. Washington, DC. August 2020. (EPA Docket EPA-HQ-OPPT-2019-0235).

[12] U.S. EPA. Risk Evaluation for 1-Bromopropane (n-Propyl Bromide). Office of Pollution, Prevention, and Toxics. Washington, DC. August 2020. (EPA Docket EPA-HQ-OPPT-2019-0235).

2.4 Description of Section 6(a) Regulatory Options and Scope

EPA is developing a proposed regulation under section 6(a) of TSCA for conditions of use of 1-BP that EPA has determined present unreasonable risk. EPA made this determination in the final risk evaluation for 1-BP, completed in August 2020. EPA is initiating this action so that the chemical no longer present an unreasonable risk under the conditions of use.

Table 2 below summarizes regulatory requirements EPA can utilize, separately or in combination, under TSCA section 6(a).

Table 2. Regulatory Requirements Available under TSCA Section 6(a)

TSCA Section	Option
6(a)(1)	A requirement **(A)** prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or **(B)** limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.
6(a)(2)	A requirement **(A)** prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for **(i)** a particular use or **(ii)** a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or **(B)** limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for **(i)** a particular use or **(ii)** a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.
6(a)(3)	A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.
6(a)(4)	A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.
6(a)(5)	A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

TSCA Section	Option
6(a)(6)	**(A)** A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.[13]
6(a)(7)	A requirement directing manufacturers or processors of such substance or mixture **(A)** to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, **(B)** to give public notice of such risk of injury, and **(C)** to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

EPA has determined that current federal regulations discussed previously in Section 2.2 do not address the unreasonable risks that EPA has identified for this chemical substance. While regulations issued under EPA's other statutory authorities regulate 1-BP for certain specific exposure pathways, they do not address exposure to 1-BP in all workplace settings or from consumer products, which EPA found present an unreasonable risk under TSCA.[14] In the 2020 final risk evaluation, EPA identified unreasonable risks for 1-BP despite federal regulations currently in place, indicating that existing regulations are not adequately addressing risks from 1-BP under these conditions of use. EPA acknowledges that there may be some conditions of use in the 2020 final risk evaluation that EPA has determined do not drive the unreasonable risk, but may still be subject to regulation due to uses down the supply chain (e.g., consumer uses) that drive the unreasonable risk.

2.5 Overview of Options Under Consideration

EPA is considering a number of regulatory options under TSCA section 6(a). In assessing these options, EPA is considering a wide range of risk reduction practices and options. Through Agency review and stakeholder input, the following potential options have been identified as reducing exposures so that 1-BP no longer presents an unreasonable risk under the conditions of use. These options are currently being considered and evaluated by EPA and are not final at this time. Any regulatory option can be used alone or in combination so that 1-BP no longer presents an unreasonable risk under any condition of use.

For consumer conditions of use, EPA has the authority to regulate at the manufacturing,

[13] A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

[14] For more information, see the Risk Evaluation for 1-Bromopropane (Docket EPA-HQ-OPPT-2019-0235).

processing, and/or distribution level in the supply chain to address unreasonable risks for consumer uses. EPA does not have the authority to directly regulate the consumer's use of a chemical substance.

2.5.1 Establish an Existing Chemical Exposure Limit (§6(a)(2) and §6(a)(5))

Under this option, EPA would use authority under TSCA section 6 to establish an Existing Chemical Exposure Limit (ECEL) and mandate that occupational workplaces meet the air exposure limit. Similar to an OSHA PEL, an ECEL establishes a performance-based standard that allows businesses the flexibility to determine the best risk reduction activities that would achieve the exposure limit. An ECEL is a risk management option for most processing, industrial, and commercial conditions of use.

EPA has developed an 8-hour ECEL in support of this rulemaking:

- EPA calculated the ECEL to be 0.05 ppm (0.25 mg/m^3) for inhalation exposures to1-BP as an 8-hour time-weighted average (TWA) for use in workplace settings.
- The value is based on the chronic cancer inhalation unit risk (IUR) for lung tumors at a risk level of one in ten thousand for workers. EPA expects that a worker would also be protected from developmental effects resulting from chronic or acute (8-hour) exposure to 1-BP if ambient exposures are kept below this ECEL.
- The ECEL is above the limits of detection or quantification. The costs for monitoring equipment to detect at this level is estimated to range between $4,000 to 7,000 per daily monitoring fee. ECEL costs will vary based on the complexity of the site and how many times the site will require monitoring to demonstrate compliance. Costs of engineering controls or PPE to achieve the ECEL level are not captured in these estimates.
- EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate any unreasonable risk of injury to health.

If EPA puts in place ECEL requirements, businesses could meet the ECEL by changing their process or formula, using different equipment, using personal protective equipment (PPE), substituting the chemical, or some combination. The decision on how to meet the ECEL is up to the business; however, additional requirements might be necessary to demonstrate compliance, such as monitoring and recordkeeping. If EPA puts in place ECEL requirements, EPA will provide information in the small entity compliance guide issued with the final rule on ways to reduce exposure using the hierarchy of controls to reduce risk. As described by NIOSH, the hierarchy of controls can be used to implement feasible and effective controls to protect workers; it typically includes elimination, substitution, engineering controls, administrative controls, and PPE on a scale of most to least protective.[15] As described earlier, any regulatory option can be used alone or in combination so that 1-BP no longer presents an unreasonable risk under any condition of use.

[15] NIOSH Hierarchy of Controls Overview: https://www.cdc.gov/niosh/topics/hierarchy/default.html

Potential impacts to small businesses include (but may not be limited to) the cost of a monitoring program including the cost of monitoring equipment, reporting or recordkeeping costs, larger capital investments of engineering controls, and other expenses related to industrial hygiene. Businesses could also incur the costs of switching to using a different chemical or method of performing the task currently being completed by 1-BP. There may be instances where small firms drop the line of business or close instead of switching to alternative chemicals or methods.

During the Pre-Panel and Panel outreach meetings as well as in SER comments, SERs noted the burdens they anticipated from potentially needing to comply with an ECEL. SERs discussed both compliance and monitoring issues with the ECEL, indicating that the cost of compliance with an ECEL would be considered a "*de facto* ban" of 1-BP for vapor degreasing. In addition, SERs also provided a description of the challenges of monitoring for an ECEL of 0.05 ppm, including costs associated with such monitoring.

2.5.2 Establish prescriptive controls, including personal protective equipment, administrative controls, engineering controls, or some combination thereof (§6(a)(5))

Under this option, EPA would require specific prescriptive controls to reduce the exposure to 1- BP. While this option could potentially establish a requirement for workers and ONUs to wear certain personal protective equipment (PPE), it may be less burdensome to control exposures to ONUs through administrative controls, as they do not directly handle 1-BP in their normal course of work. Prescriptive controls such as requiring use of PPE, administrative controls, and engineering controls are risk management options for processing, industrial, and commercial conditions of use. The requirements could include, but are not limited to:

- Engineering controls that reduce worker or ONU exposure by implementing physical changes to the workplace. Examples of engineering controls include:
  - Install new equipment to reduce the exposure to the chemical.
  - Install or upgrade ventilation systems to help control and/or eliminate air contaminants.
  - Enclose or confine operations to avoid or reduce employee exposure.
- Administrative controls could reduce exposures to workers or ONUs by implementing processes or procedures in the workplace. Examples of administrative controls include:
  - Prohibit ONU access to the work area where the chemical is being handled.
  - Limit the amount of time workers handle the chemical.
- Use of PPE with a specific respirator assigned protection factor (APF) or glove protection factor (PF) could reduce exposures to workers or ONUs.

Potential impacts to small businesses include (but may not be limited to) the cost of a monitoring program including the cost of monitoring equipment, reporting or recordkeeping costs, larger

capital investments of engineering controls, PPE respirators and maintenance with related medical monitoring, additional space, and other expenses related to industrial hygiene. Businesses could also incur the costs of switching to using a different chemical or method of performing the task currently being completed by 1-BP. Administrative controls could result in increased costs as new work practices are developed and implemented. There may be instances where small firms drop the line of business or close instead of switching to alternative chemicals or methods or incurring capital expenditures.

EPA will consider information provided by SERs during the development of proposed regulatory options, including prescriptive controls, which will be informed by the experiences and existing best practices described by SERs, including but not limited to, use of PPE, use of a closed system, enhanced ventilation, particular airflow rates, or other ventilation changes related specifically to 1-BP activities, procedures related to line breaks and maintenance situations, and potentially adjusting work practices in order to limit exposures to 1-BP.

During the re-Panel and Panel outreach meetings, as well as in SER comments, SERs provided information regarding the costs associated with use of vacuum degreasers that would reduce exposures to 1-BP. SERs also provided feedback on various engineering controls used to reduce emissions and exposures, use of PPE such as respirators and gloves, and work practice trainings.

2.5.3 Establish restrictions on the concentration of 1-BP for certain uses (§6(a)(2))

Under this option, EPA would establish a concentration limit or maximum weight fraction of 1-BP in products or formulations. A concentration limit may impact the efficacy of a product. A concentration limit of 1-BP is a risk management option for processing, industrial, commercial, and consumer uses.

Potential impacts to small businesses include the cost of reformulating existing products, developing new products, and recordkeeping costs. Businesses could also incur the costs of switching to using a different chemical or method of performing the task currently being completed by 1-BP. There may be instances where small firms drop the line of business or close instead of switching to alternative chemicals or methods.

SERs did not provide feedback regarding the establishment of restrictions on the concentration of 1-BP for certain uses.

2.5.4 Prohibition (§6(a)(2) and §6(a)(5))

Under this option, EPA would prohibit the manufacturing (including import), processing, and distribution of 1-BP for particular conditions of use or prohibit certain industrial and commercial conditions of use. Prohibition is a risk management option for processing, industrial, commercial, and consumer conditions of use where an ECEL, prescriptive controls, and/or a concentration limit would not be feasible or sufficient to reduce exposures to 1-BP, such that those conditions of use no longer present an unreasonable risk. EPA may also prohibit conditions of use that have minimal ongoing use or have been or will be phased out.

Potential impacts to small businesses include the cost of reformulating existing products, developing new products, reporting or recordkeeping costs. Businesses could also incur the costs of switching to using a different chemical or method of performing the task currently being completed by 1-BP. There may be instances where small firms drop the line of business or close instead of switching to alternative chemicals or methods.

SERs emphasized their support of prohibition of all consumer uses of 1-BP, while allowing uses of 1-BP in commercial settings with workplace controls.

During the Pre-Panel and Panel outreach meetings, as well as in SER comments, SERs noted the benefits to their business of using 1-BP and their concerns with potential substitutes and alternative methods such as aqueous cleaning. SERs cited various chemical and economic properties which make 1-BP a good choice, including low flammability and low cost. SERs identified possible substitutes, described in more detail in Section 8. Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in any manner that substantially prevents a specific condition of use, and in setting an appropriate transition period for such action, EPA is required to consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. To that end, the information provided by SERs will inform any analysis completed under TSCA section 6(c)(2)(C) of potential prohibitions under TSCA section 6(a)(2) or 6(a)(5). Also, under TSCA section 6(g)(1), EPA may, as part of a rule promulgated under section 6(a), or in a separate rule, grant a time-limited exemptions for a specific condition of use if EPA finds that (A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; (B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or (C) the specific condition of use of the chemical substance or mixture, as compared with reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

During the Pre-Panel and Panel outreach meetings, as well as in SER comments, SERs described the use of 1-BP as a vapor degreaser for many critical applications, including aerospace, defense, electronics, and medical.

2.5.5 Regulatory options applied broadly with other restrictions

The TSCA section 6(a) activities listed below are options that could support the implementation of the regulatory approaches outlined in the preceding sections.

- *Recordkeeping and monitoring (§ 6(a)(4)):* This option would require records and documentation including monitoring for the purposes of demonstrating compliance with any option described above (e.g., requirements to meet an ECEL, prescriptive controls). Recordkeeping would be required of businesses in the supply chain, not for consumers, and would aim to consist of ordinary business records already maintained to the extent possible.

- *Downstream notification (§ 6(a)(3)):* This option would support any of the control options described above (e.g., requirements to meet an ECEL, prescriptive controls, prohibitions) to disseminate information about restrictions and requirements through the supply chain.
- *Limited access program (§ 6(a)(4)):* This option would restrict access to the chemical only to certain users, who could ensure that the unreasonable risk was addressed. This could, for example, allow some users in industrial or commercial settings to continue to have access to the chemical while restricting access for consumer uses.
- *Labeling (§ 6(a)(3)):* This option would inform users of products containing 1-BP of the risks. For example, EPA could require manufacturers, processors and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain. Labeling could apply to industrial, commercial, and consumer conditions of use in support of other restrictions described above.

Potential impacts to small businesses could include the cost of recordkeeping, new labels or containers for existing product lines, and a limited access program. During the Pre-Panel and Panel outreach meetings, as well as in SER comments, SERs provided comments related to downstream notification and labeling, such as adding information to safety data sheets (SDS) and shipping labels. Additionally, EPA will consider information and best practices shared by SERs related to shipping labels and notifications through Safety Data Sheets.

3. APPLICABLE SMALL ENTITY DEFINITIONS

The Regulatory Flexibility Act (RFA) defines small entities as including "small businesses," "small governments," and "small organizations" (5 USC 601). The regulatory revisions being considered by EPA for this rulemaking are expected to affect a variety of small businesses, small governments, and small organizations. The RFA references the definition of "small business" found in the Small Business Act, which authorizes the Small Business Administration (SBA) to further define "small business" by regulation. The SBA definitions of small business by size standards using the North American Industry Classification System (NAICS) can be found at 13 CFR 121.201[16].

The detailed listing of SBA definitions of small business for affected industries or sectors, by NAICS code, is included in Table 3 in Section 4, below.

4. SMALL ENTITIES THAT MAY BE SUBJECT TO THE PROPOSED REGULATION

Entities potentially regulated by this rulemaking include those relevant to 16 conditions of use that support EPA's determination of unreasonable risk according to the 2020 final risk evaluation,

[16] U.S. Small Business Administration Table of Small Business Size Standards are available at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.

including processing of 1-BP into formulation, mixtures, or reaction products, most industrial and commercial uses of 1-BP (*e.g.*, vapor degreasers, cold cleaners, aerosol spray degreasers/cleaners, adhesives and sealants, dry cleaning solvents, liquid cleaners, automotive care products), and all consumer uses[17] (*e.g.*, aerosol spray degreasers/cleaners, spot cleaners and stain removers, liquid cleaners, adhesive accelerant, anti- adhesive agents, automotive care products) with the exception of insulation. Entities may include processors, formulators, commercial users, or retailers of 1-BP or products containing 1-BP within the scope of this rulemaking. A full list of conditions of use subject to this rulemaking is in Table 1 in Section 2.1 above, and in the non-technical summary[18] of the 1-BP risk evaluation.

Potentially affected entities will include both employer and non-employer firms and establishments identified within these sections by the U.S. Census for each applicable North American Industry Classification System (NAICS) code. Since the SBA size standard varies by NAICS code, they are also included in Table 3 below. NAICS codes of potentially affected entities may include, but are not limited to:

Table 3: Industry Sectors and Small Entities Potentially Affected by EPA's Planned Action

NAICS	NAICS Description	SBA Size Standard
211120	Crude Petroleum Extraction	1,250 employees
211130	Natural Gas Extraction	1,250 employees
212111	Bituminous Coal and Lignite Surface Mining	1,250 employees
212112	Bituminous Coal Underground Mining	1,500 employees
212113	Anthracite Mining	2,500 employees
213111	Drilling Oil and Gas Wells	1,000 employees
213112	Support Activities for Oil and Gas Operations	$41.5 million
213113	Support Activities for Coal Mining	$22 million
221111	Hydroelectric Power Generation	500 employees
221112	Fossil Fuel Electric Power Generation	750 employees
221113	Nuclear Electric Power Generation	750 employees
221114	Solar Electric Power Generation	250 employees
221115	Wind Electric Power Generation	250 employees
221116	Geothermal Electric Power Generation	250 employees
221117	Biomass Electric Power Generation	250 employees
221118	Other Electric Power Generation	250 employees

[17] Though consumers (and bystanders to consumer use) would be protected by regulations to address the unreasonable risks from 1-BP in consumer uses, they are not the potentially regulated entity. Rather, the entities potentially regulated and impacted by any requirements and restrictions would be the formulators and distributors of consumer products, with potentially some requirements relevant to manufacturers and processors of 1-BP when the chemical is in consumer products. Additionally, small businesses may be impacted to the extent that the same products may be used for commercial and consumer activities.

[18] U.S. EPA. EPA. Nontechnical Summary of the Risk Evaluation for 1-Bromopropane (n-Propyl Bromide). Office of Pollution, Prevention, and Toxics. Washington, DC. August 2020. (EPA Docket EPA-HQ-OPPT-2019-0235-0069).

NAICS	NAICS Description	SBA Size Standard
221121	Electric Bulk Power Transmission and Control	500 employees
221122	Electric Power Distribution	1,000 employees
221210	Natural Gas Distribution	1,000 employees
237120	Oil and Gas Pipeline and Related Structures Construction	$39.5 million
237130	Power and Communication Line and Related Structures Construction	$39.5 million
237310	Highway, Street, and Bridge Construction	$39.5 million
238220	Plumbing, Heating, and Air-Conditioning Contractors	$16.5 million
314999	All Other Miscellaneous Textile Product Mills	500 employees
315210	Cut and Sew Apparel Contractors	750 employees
315220	Men's and Boys' Cut and Sew Apparel Manufacturing	750 employees
315240	Women's, Girls', and Infants' Cut and Sew Apparel Manufacturing	750 employees
315280	Other Cut and Sew Apparel Manufacturing	750 employees
315990	Apparel Accessories and Other Apparel Manufacturing	500 employees
321113	Sawmills	500 employees
323111	Commercial Printing (except Screen and Books)	500 employees
324110	Petroleum Refineries	1,500 employees
324121	Asphalt Paving Mixture and Block Manufacturing	500 employees
325110	Petrochemical Manufacturing	1,000 employees
325120	Industrial Gas Manufacturing	1,000 employees
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1,000 employees
325520	Adhesive Manufacturing	500 employees
325612	Polish and Other Sanitation Good Manufacturing	750 employees
325613	Surface Active Agent Manufacturing	750 employees
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 employees
326121	Unlaminated Plastics Profile Shape Manufacturing	500 employees
326122	Plastics Pipe and Pipe Fitting Manufacturing	750 employees
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	500 employees
326160	Plastics Bottle Manufacturing	1,250 employees
326191	Plastics Plumbing Fixture Manufacturing	750 employees
326199	All Other Plastics Product Manufacturing	750 employees
326211	Tire Manufacturing (except Retreading)	1,500 employees
326220	Rubber and Plastics Hoses and Belting Manufacturing	750 employees
326291	Rubber Product Manufacturing for Mechanical Use	750 employees
326299	All Other Rubber Product Manufacturing	500 employees
327212	Other Pressed and Blown Glass and Glassware Manufacturing	1,250 employees
327215	Glass Product Manufacturing Made of Purchased Glass	1,000 employees
327999	All Other Nonmetallic Mineral Product Manufacturing	500 employees

NAICS	NAICS Description	SBA Size Standard
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	1,000 employees
331221	Rolled Steel Shape Manufacturing	1,000 employees
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	1,000 employees
331420	Copper Rolling, Drawing, Extruding, and Alloying	1,000 employees
331512	Steel Investment Foundries	1,000 employees
332111	Iron and Steel Forging	750 employees
332112	Nonferrous Forging	750 employees
332117	Powder Metallurgy Part Manufacturing	500 employees
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	500 employees
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	750 employees
332216	Saw Blade and Handtool Manufacturing	750 employees
332311	Prefabricated Metal Building and Component Manufacturing	750 employees
332313	Plate Work Manufacturing	750 employees
332410	Power Boiler and Heat Exchanger Manufacturing	750 employees
332431	Metal Can Manufacturing	1,500 employees
332510	Hardware Manufacturing	750 employees
332618	Other Fabricated Wire Product Manufacturing	500 employees
332721	Precision Turned Product Manufacturing	500 employees
332722	Bolt, Nut, Screw, Rivet, and Washer Manufacturing	500 employees
332811	Metal Heat Treating	750 employees
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	500 employees
332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	500 employees
332912	Fluid Power Valve and Hose Fitting Manufacturing	1,000 employees
332913	Plumbing Fixture Fitting and Trim Manufacturing	1,000 employees
332919	Other Metal Valve and Pipe Fitting Manufacturing	750 employees
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing	1,000 employees
332996	Fabricated Pipe and Pipe Fitting Manufacturing	500 employees
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	750 employees
333132	Oil and Gas Field Machinery and Equipment Manufacturing	1,250 employees
333249	Other Industrial Machinery Manufacturing	500 employees
333314	Optical Instrument and Lens Manufacturing	500 employees
333316	Photographic and Photocopying Equipment Manufacturing	1,000 employees
333318	Other Commercial and Service Industry Machinery Manufacturing	1,000 employees
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	500 employees

NAICS	NAICS Description	SBA Size Standard
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment	1,250 employees
333511	Industrial Mold Manufacturing	500 employees
333921	Elevator and Moving Stairway Manufacturing	1,000 employees
333994	Industrial Process Furnace and Oven Manufacturing	500 employees
333996	Fluid Power Pump and Motor Manufacturing	1,250 employees
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	500 employees
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	1,250 employees
334413	Semiconductor and Related Device Manufacturing	1,250 employees
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	500 employees
334417	Electronic Connector Manufacturing	1,000 employees
334418	Printed Circuit Assembly (Electronic Assembly) Manufacturing	750 employees
334419	Other Electronic Component Manufacturing	750 employees
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	1,250 employees
334512	Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use	500 employees
334513	Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial	750 employees
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals	750 employees
334519	Other Measuring and Controlling Device Manufacturing	500 employees
335121	Residential Electric Lighting Fixture Manufacturing	750 employees
335220	Major Household Laundry Equipment Manufacturing	1,500 employees
335312	Motor and Generator Manufacturing	1,250 employees
335313	Switchgear and Switchboard Apparatus Manufacturing	1,250 employees
335911	Storage Battery Manufacturing	1,250 employees
335921	Fiber Optic Cable Manufacturing	1,000 employees
335929	Other Communication and Energy Wire Manufacturing	1,000 employees
335931	Current-Carrying Wiring Device Manufacturing	500 employees
335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing	500 employees
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	1,000 employees
336340	Motor Vehicle Brake System Manufacturing	1,250 employees
336411	Aircraft Manufacturing	1,500 employees
336412	Aircraft Engine and Engine Parts Manufacturing	1,500 employees
336413	Other Aircraft Parts and Auxiliary Equipment Manufacturing	1,250 employees
336414	Guided Missile and Space Vehicle Manufacturing	1,250 employees
336510	Railroad Rolling Stock Manufacturing	1,500 employees

NAICS	NAICS Description	SBA Size Standard
337110	Wood Kitchen Cabinet and Countertop Manufacturing	750 employees
337121	Upholstered Household Furniture Manufacturing	1,000 employees
337125	Household Furniture (except Wood and Metal) Manufacturing	750 employees
337127	Institutional Furniture Manufacturing	500 employees
337214	Office Furniture (except Wood) Manufacturing	1,000 employees
337910	Mattress Manufacturing	1,000 employees
339112	Surgical and Medical Instrument Manufacturing	1,000 employees
339113	Surgical Appliance and Supplies	750 employees
339114	Dental Equipment and Supplies Manufacturing	750 employees
339115	Ophthalmic Goods Manufacturing	1,000 employees
339910	Jewelry and Silverware Manufacturing	500 employees
339992	Musical Instrument Manufacturing	1,000 employees
339999	All Other Miscellaneous Manufacturing	500 employees
423460	Ophthalmic Goods Merchant Wholesalers	150 employees
423730	Warm Air Heating and Air-Conditioning Equipment and Supplies Merchant Wholesalers	150 employees
423740	Refrigeration Equipment and Supplies Merchant Wholesalers	100 employees
446130	Optical Goods Stores	$22.0 million
486110	Pipeline Transportation of Crude Oil	1,500 employees
486210	Pipeline Transportation of Natural Gas	$30.0 million
486910	Pipeline Transportation of Refined Petroleum Products	1,500 employees
541713	Research and Development in Nanotechnology	1,000 employees
541714	Research and Development in Biotechnology (except Nanobiotechnology)	1,000 employees
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	1,000[a] employees
712110	Museums	$30.0 million
811111	General Automotive Repair	$8.0 million
811112	Automotive Exhaust System Repair	$8.0 million
811113	Automotive Transmission Repair	$8.0 million
811118	Other Automotive Mechanical and Electrical Repair and Maintenance	$8.0 million
811191	Automotive Oil Change and Lubrication Shops	$8.0 million
811198	All Other Automotive Repair and Maintenance	$8.0 million
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Main	$8.0 million
812320	Drycleaning and Laundry Services (except Coin-Operated)	$6.0 million
812332	Industrial Launderers	$41.5 million

NAICS	NAICS Description	SBA Size Standard
Source: U.S. Small Business Administration Table of Small Business Size Standards. Available at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf [a]1500 for aircraft, aircraft engine, and engine part; 1250 for other aircraft parts and auxiliary equipmentand guided missile and space vehicles, their propulsion units, and propulsion parts.		

The estimated number of small firms by COU is in Table 4. Related conditions of use with overlapping NAICS codes have been grouped to avoid double counting of firms.

Table 4. Estimated Number of Small Firms by COU

Condition of Use	Numbers of Firms[1]		Percentage of Firms Meeting SBA Definition of a Small Business[2]	Estimated Number of Small Firms	
	Low	High		Low	High
Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – open-top, inline vapor degreaser)	1,300	3,300	96%	1,243	3,156
Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – closed-loop).	100		96%	96	
Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners.	10[3]		97%	10	
Industrial and commercial use as solvent in aerosol spray degreaser/cleaner and liquid spray/aerosol cleaners.	1,000	5,000	97%	972	4,859
Industrial and commercial use in liquid cleaners (e.g., coin and scissor cleaner)	unknown[4]				
Industrial and commercial use in adhesives and sealants.	100	280	99%	99	277
Industrial and commercial use in dry cleaning solvents.	0	3	100%	0	3
Industrial and commercial use in spot cleaners and stain removers.	unknown[5]				
Other industrial and commercial uses.	500[3]		97%	486	
Processing: incorporation into a formulation, mixture, or reaction product.	33	99	56%[6]	18	55
All COUs Combined	**3,043**	**9,292**	**-**	**2,924**	**8,942**

[1] Estimates are from the risk evaluation except where otherwise noted.

Condition of Use	Numbers of Firms[1]		Percentage of Firms Meeting SBA Definition of a Small Business[2]	Estimated Number of Small Firms	
	Low	High		Low	High

[2] Estimated based on percentage of small businesses for similar methylene chloride COUs (except for processors; see footnote 4).
[3] Placeholder for an expected small number of affected firms. Estimate will be refined at a future date.
[4] EPA identified only one discontinued coin cleaner containing 1-BP and one scissor cleaner that contained 1-BP.
[5] EPA identified one dry cleaning spot remover product containing 1-BP, but its current usage as a spot remover is believed to be very small.
[6] Estimated as the percentage of 2019 TRI reporters that appear to have 1-BP releases from the processing condition of use that are defined to be small.

5. *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 Small Entity Representatives (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.[19]

After identifying a list of potential SERs (shown in Section 6), EPA conducted a Pre-Panel outreach webinar with potential SERs on November 5, 2020. To help them prepare for the virtual meeting/teleconference, EPA sent materials to each of the potential SERs via email. A list of the materials shared with the potential SERs during the Pre-Panel outreach meeting is in Appendix A1. For the November 5, 2020, Pre-Panel outreach meeting with the potential SERs, EPA also invited representatives from SBA and OMB. A total of 10 potential SERs participated in the meeting. EPA presented an overview of the SBAR Panel process and section 6 of TSCA, an explanation of the forthcoming rulemaking, potential regulatory approaches, and cost estimates. EPA also provided opportunities for questions and feedback, with a meeting structure that aimed to provide productive discussion by grouping conditions of use.

The Pre-Panel outreach meeting was held to solicit feedback from the potential SERs on their

[19] 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-BP risk evaluation and next steps for risk management (September 30, 2020).

suggestions for the upcoming rulemaking. EPA asked the potential SERs to provide written comments by November 18, 2020. Comments made during the November 5, 2020, outreach meeting and written comments submitted by the potential SERS are summarized in Section 7.2 of this document. Written comments submitted after the meeting appear in Appendix B1.

The Panel conducted an outreach meeting with the SERs via a virtual meeting/teleconference on May 11, 2021. To help SERs prepare for the virtual meeting/teleconference, on April 27, 2021, EPA sent materials to each of the SERs via email. A list of the materials shared with the SERs during the Panel outreach meeting is contained in Appendix A2. A total of 15 SERs (15 individuals representing 11 entities) participated in the meeting. EPA presented an overview of pertinent background information, the risk assessment, and requirements under consideration for the rulemaking.

This Panel outreach meeting was held to solicit feedback from the SERs on their suggestions for the upcoming rulemaking. EPA asked the SERs to provide written comments by May 25, 2021. Comments raised during the May 11, 2021, Panel outreach meeting and written comments submitted by the SERs are summarized in Section 7.4 of this document. Written comments submitted after the meeting appear in Appendix B2.

6. LIST OF SMALL ENTITY REPRESENTATIVES

Table 5. 1-BP Risk Management Panel Potential SERs

Name	Entity
Ram Singh Director	Amity International
Terry Miller Vice President of Technical Operations	AMZ Manufacturing Corp.
Chuck Babb Safety Manager	Asko Processing, Inc.
Kevin Hackworth Operations Manager	Choice Adhesives
Chris Carnell Director of Environmental Health and Safety	Custom Synthesis LLC
Richard Morford CEO and General Council	Enviro Tech International, Inc.
Jeff Davis Senior Vice President, Business Development & Distribution	Hubbard-Hall
Thomas M. Forsythe Executive Vice President	Kyzen Corporation

Name	Entity
Jay Tourigny Senior Vice President	Microcare Corp.
Jeff Hannapel Vice President	National Association for Surface Finishing (NASF)
David Crandell	Parts Cleaning Technologies

7. *SUMMARY OF COMMENTS FROM SMALL ENTITY REPRESENTATIVES*

7.1 Summary of Oral Comments and Pre-Panel meeting discussions, November 5, 2020

7.1.1 Overview of Comments

At the Pre-Panel outreach meeting, SERs provided information on the number and type of entities that would be affected (including how their products are used and limited uses of 1-BP); potential compliance requirements (including current exposure monitoring and reductions practices, anticipated impacts of potential prohibitions, and considerations for substitute chemicals); related Federal rules; and potential regulatory flexibility alternatives (including recommendations). SERs emphasized that more specificity on what exposure level (ECEL) EPA might require was necessary before they could fully describe potential impacts to their businesses. SERs also emphasized that 1-BP was primarily useful for industrial degreasing uses and that they supported prohibitions on consumer or small-scale commercial uses, due to the risks to users and availability of alternatives.

Verbal comments from the meeting are summarized in the following subsections. Written comments were received from the following SERs and appear in Appendix B1.

1. ASKO Processing, Inc. “ASKO Processing Vapor Degreaser Operation Description.” November 20, 2020.
2. Enviro Tech International, Inc. “EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for 1-Bromopropane under TSCA Section 6(a).” November 20, 2020.
3. Enviro Tech International, Inc. “Use of 1-bromopropane (N-propyl bromide) in dry cleaning is rare and rapidly declining toward obsolescence.” (Toxicology Research and Application Volume 4: 1–6; 2020). November 20, 2020.

7.1.2 Number and Types of Entities Affected

SERs discussed their processing or use of 1-BP, as well as their customer base and how their

products are used. Specifically, SERs described:

- Degreasing:
  - One SER described the use of 1-BP as a degreaser and parts cleaner before the application of surface finishing. The SERs stated that 1-BP works very well, and that many firms use it as an alternative to trichloroethylene (TCE).
  - Another SER described how 1-BP is often specified by customers, especially in degreasing for aerospace applications. The SERs stated that the alternative, aqueous cleaners, do not work as well and take up more space and the user prefer 1-BP if they have multiple applications.
- Small-scale uses:
  - SERs described how many "other" uses tend to be used infrequently, such as brake cleaning or engine degreasing, mold cleaning and release, in coatings, and in coin and scissor cleaning.
  - One SER described how some users prefer 1-BP in electronics for spot cleaning or repair; however, newer processes do not require 1-BP.
  - Similarly, another SER stated that 1-BP is used for asphalt extraction, mostly in small-scale use in laboratory situations.
- Extremely limited or no uses of 1-BP:
  - No SER could identify use of 1-BP in refrigerants or as a temperature indicator.
  - A SER stated that there is no significant commercialization of spot remover or stain removers.
  - Similarly, several SERs described how they have not seen any distribution or retail of consumer-type products containing 1-BP, and that 1-BP has not been in consumer markets the same way methylene chloride has.

7.1.3 Potential Reporting, Recordkeeping, and Compliance Requirements

SERs described their exposure monitoring and reduction practices, anticipated changes due to potential requirements from EPA, and considerations for substitute chemicals or processes. Specifically, SERs described, for themselves or their customers:

- Engineering controls:
  - A SER indicated that most users of 1-BP in industrial applications have transitioned to closed loop systems or have significantly reduced releases.
  - Another SER indicated that there is a wide range of degreaser equipment in use, not only closed loop systems, and the new equipment has better controls.

- Exposure limits:
  - Throughout the meeting, many SERs stated a strong interest in knowing what level EPA might set for an ECEL. The SERs emphasized that formulators will have a hard time determining how the final rule will affect them without knowing the exposure limit that will be set.
  - One SER stated that EPA should take into consideration that the threshold limit value (TLV) rated for 1-BP has a 0.1 to 0.2 % by weight contamination of isopropyl bromide, and the 1-BP they are using today is at least 1, if not 2, orders of magnitude below that.
  - Another SER stated that it is not clear if small business can achieve the ECEL in degreasing applications. The SER described how this will depend on the final number. As the SER stated, achieving 0.1 ppm will be a challenge. Most SERs agreed that setting exposure limits in the double digits is achievable, but exposure limits below 1 ppm would be more challenging to reach.
- Other exposure and risk reductions:
  - One SER described how, as required by the Occupational Safety and Health Administration (OSHA) and other regulatory entities, formulators use various techniques such as shipping labels; Globally Harmonized System (GHS) information; PPE (including respirators and dermal protection); engineering controls; ventilation systems; and enclosed mixing systems.
- Use of substitute chemicals in industrial uses:
  - A SER indicated that new alternatives to 1-BP have been explored, but most alternatives tend to come at significantly higher costs.
  - Another SER described how there are many alternative choices for liquid cleaners which vary in effectiveness and tend to be costly, like aqueous cleaning, or have other environmental impacts, such as global warming.
- Prohibition:
  - Several SERs agreed that banning 1-BP in degreasing operations would lead to significant costs to switch to alternatives.
  - In contrast, SERs did not think 1-BP should be used in consumer and small-scale commercial products. Many SERs supported a prohibition of these uses and did not anticipate that a consumer ban would negatively affect small retailers and distributors.

7.1.4 Related Federal Rules

When discussing related Federal rules, the SERs specifically described:

- One SER described how, during the risk evaluation, this SER had requested that EPA describe how the underlying risk evaluation differs from the 2007 Significant New

Alternatives Policy (SNAP) (72 FR 30142, May 30, 2007) with respect to the acceptable air concentration levels for acute and chronic exposures. The SER indicated that the explanation was missing from the risk evaluation.

- One SER described how requirements by OSHA (*e.g.*, Hazard Communication Standard) and other regulatory entities result in their use of various exposure and risk reduction techniques labeling; GHS information; PPE; and multiple types of engineering controls.
- A SER indicated that their customers have made substantial investments to be compliant under National Emission Standards for Hazardous Air Pollutants (NESHAP) rules, though they did not specify which NESHAP rules. Since 1-BP is not a Hazardous Air Pollutant, currently, there are no NESHAPs. The SER recommended that any actions taken under this regulation should be consistent with existing NESHAP regulations in place.

7.1.5 Regulatory Flexibility Alternatives

SERs identified several potential flexibility alternatives, challenges for small business, questions for EPA regarding the regulatory approach, and provided recommendations:

- Exposure limits:
  - One SER stated that an exposure limit may not provide the desired flexibility forsmall businesses. Small businesses may prefer a checklist of requirements or a maintenance requirement rather than a performance standard that could be challenging to implement.
- Engineering and related controls:
  - A SER indicated that engineering controls, such as retrofitting ventilation, could lead to space issues and additional costs.
  - Another SER indicated that cost of closed-loop system can be three times higher than of a regular vapor degreaser.
  - Several SERs stated that EPA should consider the potential management option of requiring periodic maintenance on degreasing machines. These SERs described how maintenance improves the speed and efficiency of the process and reduces worker risk.
- Monitoring:
  - Several SERs suggested that monitoring through a badge worn on the exposed worker could provide data to indicate which activities have the highest risks, so they can focus their attention on where they need controls and safeguards. Several SERs indicated that most shops do not have workers at the vapor degreaser all day.
- Labeling:
  - A SER that formulates products with 1-BP indicated that cost of changing labels is minimal.

- Reporting requirements:
  - It was mentioned that it would be helpful to reduce the reporting burden from small businesses.
- Prohibitions for certain uses:
  - Most SERs supported a ban of consumer uses, and one stated that consumers should not need to use 1-BP in or around their homes.
  - Similarly, most SERs supported a ban of 1-BP in dry cleaning uses, adhesives, coatings, inks, and other miscellaneous uses. For example, a SER indicated that 1-BP should not be used in automotive brake cleaning since 1-BP can damage plastic or rubber parts of the brake system.

7.2 Summary of Written Comments following the Pre-Panel meeting, November 5, 2020

7.2.1 Overview of Comments

SERs provided written responses to the Pre-Panel outreach questions for discussion, which aimed to seek feedback on 1-BP use, workplace specific practices and experiences with 1-BP, importance of 1-BP to the individual business, relative advantages and disadvantages of different substitutes and/or processes, and current risk management controls.

7.2.2 Number and Types of Entities Affected

Following the Pre-Panel outreach meeting, SER written comments relevant to the number and type of small entities included:

- One SER provided written comments regarding the formulation of 1-BP as solvent for use in industrial cleaning, mainly vapor degreasing, with a primary use in aerospace manufacturing and repair, automotive manufacturing, optics, oxygen cleaning, medical device manufacturing, and asphalt testing sectors.
- Another SER provided written comments on the use of 1-BP in vapor degreasing, primarily for the aerospace industry, for the removal of magnetic particle inspection oils before further processing activities can occur, and for removing greases, oils and masking materials not readily removed by other means.

7.2.3 Potential Reporting, Recordkeeping, and Compliance Requirements

Following the Pre-Panel outreach meeting, in written comments:

- SERs described current exposure monitoring, PPE use, and other exposure reduction practices. One SER provided a copy of a study previously submitted to EPA, and described the modifications made to reduce exposure to employees, such as doubling ventilation at

the main source of emissions and other improvements to the ventilation system, including use of carbon filters; rotation of employees and work from home; and re-configuration of laboratory/quality control area to reduce concentrations in the office area. The SER described the costs of updating the ventilation system as about $76,000 and estimated that cost have likely increased since the work was done. The SER described the costs of relocating the laboratory as low due to the space available; otherwise, the improvements could have been more expensive.

- One SER indicated that most of the exposures to 1-BP are via inhalation and that only in the mixing room are dermal exposures expected. The SER described how this could be reduced by the mandatory use of gloves. The SER described their intent to provide workers with a respirator with a full-face mask with an APF of 50 to reduce exposures to near non-detectable levels. At this facility, the SER described how currently respirators with APF of 10 are used, and how supplied-air respirators would interfere with the manufacturing process.
- One SER described additional controls in place to minimize exposures to 1-BP, including yearly training on all work practices, compliance with standards such as ISO 9001, and monthly inspection reports of all equipment.
- One SER described physical features of vapor degreasers to limit fugitive emissions, such as refrigeration coils, “freeboard area,” (the area within the solvent cleaning machine that extends from the solvent/air interface to the top of the solvent cleaning machine) sliding covers, barriers to minimize drafts, and limited hoist speeds.
- One SER described best practices to limit fugitive emissions, such as use of racks or baskets to minimize entrapment of solvent, slow introduction of loads to minimize collapsing the vapor layer, judicious use of the spray wand, not removing parts until all condensation has stopped, and making sure parts are hot when degreasing is complete to minimize impact to the cold zone.
- SERs also described consideration for substitute chemicals or processes, including efficacy and safety concerns associated with the use of alternative chemicals, with one SER noting the additional costs that could be incurred to guard against more flammable substitutes.
- One SER indicating that re-labeling is rare, unless mandated by regulations; however, they stated that the cost is not substantial.
- One SER indicated that 1-BP is a significant part of their businesses, and stated that if 1-BP is not available, there will be cuts to employment wages and benefits until they could pivot to other products that could replace 1-BP.
- One SER indicated that using closed loop system could be 2 to 3 times more expensive that a regular vapor degreaser.

7.2.4 Related Federal Rules

Following the Pre-Panel outreach meeting, SER written comments:

- Provided information on compliance with current OSHA Hazard Communication Standards, which were updated to conform to the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals regarding SDS and shipping labels.
- One SER indicated that they develop their cleaning solvent as a replacement for ozone depleting solvents under the SNAP program (72 FR 30142, May 30, 2007).

7.2.5 Regulatory Flexibility Alternatives

Following the Pre-Panel outreach meeting, SER written comments relevant to regulatory flexibility alternatives include:

- One SER provided written comments noting reformulation would result in a new product intended for a specified use, as opposed to resulting in a reformulated replacement. This SER also detailed the increased costs that are associated with the research and development for reformulating current products or finding alternatives, such as patents, compatibility with existing equipment, approvals by end user of the parts that are cleaned, testing (including under "real life" situations), and inclusion in new specifications.
- One SER indicated that they don't support using 1-BP products in a consumer setting.
- One SER indicated that the use of 1-BP in the dry cleaning industry has been small and that they would discontinue all sales of their 1-BP product for the dry cleaning industry as of September 1, 2021.
- SERs pointed out that EPA is in the process of initiating regulations on several halogenated solvents, and the remining substitutes might have negative costly and unintended effects. For example, hydrofluorocarbons (HFCs) and hydrofluoroethers (HFEs) can be costly, not suitable for many vapor degreasing operations, and the majority are considered global warming compounds. Another substitute, 1,2 trans-dichloroethylene is flammable and must by mixed with HFEs, HFCs, or other compounds, resulting in blends with lower boiling points and corresponding safety concerns (e.g., pressurized drums are needed) and questions regarding whether the blends are truly azeotropic. Regarding other substitutes, modified alcohols are flammable and require additional fire prevention and suppression systems; other gases marked for cleaning require specific new equipment and processes. As an additional example, a SER described how aqueous cleaning has several drawbacks: it is not allowed by the aerospace industry (due to potential rusting, leading to liability and rework costs); the systems require larger space; and there are significant costs associated with disposing or cleaning water, plus increased energy use.
- One SER supported an ECEL as a regulatory requirement, stating that "[i]t would generally be the most efficient for individual companies to have workplace exposure level to work

toward, as every situation will have its own issues that must be dealt with. Also, an objective standard adds certainty to the entire process."

7.3 Summary of Oral Comments and Panel meetings discussions, May 11, 2021

7.3.1 Overview of Comments

At the Panel outreach meeting, SERs provided information on the number and type of entities that would be affected (including descriptions of their processing or use of 1-BP and their customer base); potential compliance requirements (including current exposure monitoring and reduction, anticipated changes due to future requirements, and considerations for substitute chemicals or alternative processes); related Federal rules; and potential regulatory flexibility alternatives (including descriptions of challenges for small businesses and questions for EPA regarding the regulatory approach). In the meeting materials, SERs were provided the exposure level EPA might require, and discussions included feasibility considerations related to that level.

7.3.2 Number and Types of Entities Affected

- SERs exclusively discussed vapor degreasing with 1-BP.
- SERs discussed the benefits for use of 1-BP in vapor degreasing, including the equipment's smaller footprint and the versatile use across multiple substrates, materials, and lubricants. A characteristic that its particularly important for some small businesses that do not have control over the substrate they have to clean. Another SER described how degreasers need to provide reliable and consistent product quality despite the variety of types of parts received for cleaning.
- One SER discussed how regulation of 1-BP could disrupt the vapor degreasing operations, particularly in the aerospace and defense sectors.
- Another SER also noted that the current use of closed-loop systems in the vapor degreasing industry is declining, largely due to the cost of the closed-loop machines.
- One SER described the cost and type of currently-installed chemical spray systems and ventilation in their vapor degreasing operation, indicating how difficult is to vent vapor degreasing operations.

7.3.3 Potential Reporting, Recordkeeping, and Compliance Requirements

- One SER discussed the challenges of achieving an ECEL of 0.05 ppm in vapor degreasing operations, even when combining personal protective equipment (PPE) and other controls. The SER specified that one particular challenge would be exposures during fluid changeover and system maintenance, which would likely exceed the ECEL.
- SERs discussed how worker exposures could be lowered by building new vapor degreasers outdoors, which may result in meeting the ECEL of 0.05. A SER raised questions regarding

the available monitoring technology.

- SERs also discussed the economic implications of purchasing new equipment and new or additional control measures (such as PPE, ventilation, or hoods), higher costs of the substitute chemical, and the timeframe businesses need to switch to and implement the substitute chemicals. Several SERs described "high boiler" systems using other chemicals that are gaining in popularity in Europe (referred to as "A Vacuum degreasers"), with additional types of low-price vacuum degreasers in North America.
- Regarding vapor degreasing, SERs emphasized the flammable properties and global warming potential (GWP) of certain alternative chemicals. A SER indicated that temperature is critical to cleaning and how difficult is to reach higher temperatures with alternative solvents.
- One SER noted that a switch to aqueous cleaning could have additional environmental impacts on small businesses and communities in areas where water is not a reliable or abundant resource. Another SER indicated that aqueous systems can be 3 to 4 times more expensive and require 2 to 3 years to transition to the new system.
- SERs also mentioned the challenges of estimating the costs of substitute chemicals such as hydrofluoroolefins (HFOs) due to unpredictable costs. SERs also voiced concerns with costs of other alternatives.
- One SER noted that the regulation of 1-BP in the United States could cause larger companies to move offshore, pushing the market out of the U.S. and small businesses inability to support that cost burden.

7.3.4 Related Federal Rules

Discussion at the Panel outreach meeting did not address related federal rules.

7.3.5 Regulatory Flexibility Alternatives

Discussion at the Panel outreach meeting did not address regulatory flexibility alternatives.

7.4 Summary of Written Comments following the Panel Meeting, May 11, 2021

7.4.1 Overview of Comments

EPA received five written comments:

- One SER provided written comments and information on possible impacts that small businesses providing cleaning services could incur from a requirement to meet the ECEL, namely as a result of process efficiency costs.
- One SER provided comments on the feasibility of implementing the kind of PPE EPA described and the proposed ECEL of 0.05 ppm, specifically in vapor degreasing operations.

This SER also provided information on their use of 1-BP and the impacts of switching to alternative solvents with higher flammability.

- Another SER suggested a requirement to meet the ECEL would be a *de facto* ban on use of 1-BP by small businesses and other vapor degreasing operations for many critical applications in the surface finishing industry, which could lead facilities to choose a substitute chemical with health or environmental risks.
- One SER provided written comments on the feasibility of small businesses meeting the ECEL; a comparison of cost differences between 1-BP and alternative, non-flammable solvents in vapor degreasing operations; and a general timeline of the purchase to installation of a degreaser.
- Another SER provided written comments and information on the characteristics of vapor degreasing solvents and alternative solvents to 1-BP (e.g., flammability, ozone depleting and global warming, Kauri Butanol (KB) value, boiling point, cost, azeotropic stability), equipment and facility modifications that can be made to mitigate risk, and workplace practices in the vapor degreasing industry.

7.4.2 Number and Types of Entities Affected

- One SER provided written comments expressing strong interest in ensuring the risk management actions taken by EPA account for the significant economic impact on firms that use 1-BP in their surface finishing operations and that serve the aerospace, defense, electronics, and medical sectors.
- SERs provided written comments on process descriptions for using 1-BP in vapor degreasing operations, specifically for metal finishing and surface finishing.
- One SER provided information on the economic benefits of the surface finishing industry and how regulations would negatively impact small businesses within the industry and other industries throughout the United States.
- One SER provided written comments on the cost burden of replacing current equipment with equipment that better mitigates exposure to 1-BP, such as closed-loop systems, with price ranges of $400,000-$700,000. This SER also noted that smaller, less expensive units costing approximately $100,000 may still be too costly for the smallest operations, but not a large enough unit for the larger small businesses. In addition, purchasing closed-loop equipment could take a year or more.
- Another SER estimated that the annual cost of changing to an acceptable replacement for vapor degreasing solvent would be between $100,000 and $200,000.
- One SER noted the cost of using 1-BP in vapor degreasing is approximately $3-$4/lb, compared to the costs of using alternative, non-flammable solvents, which can range between $9-20/lb. Another SER also provided information on the differences in end-user

costs between chlorinated solvents ($900/drum), 1-BP ($1,500/drum), 1,2-trans mixtures ($5,000-$7,000/drum), various hydrofluoroethers (HFEs) ($10,500/drum), and some hydrofluoroolefins (HFOs) (over $20,000/drum).

- One SER described how the regulation of 1-BP may affect small businesses, including availability of financing for small business to fund new equipment and/or equipment modifications.
- A SER described the additional type of costs that a small business could have if it replaced 1-BP with a flammable solvent.

7.4.3 Potential Reporting, Recordkeeping, and Compliance Requirements

- SERs described the benefits to their business of using 1-BP, specifically its efficacy as a cleaning solvent. SERs explained their concerns with potential alternatives, such as: the high flammability properties associated with modified alcohols and additional costs (capital investment for vacuum degreaser and approval by customers), the residue left when using methyl ethyl ketone, the cost of other solvents approved by the aerospace industry (2.25 times more expensive than 1-BP), and additional need for maintenance.
- One SER described the costs associated with environmental, health, and safety compliance. This SER noted that some planting "operations spend nearly 28% of their total capital expenditures on pollution prevention and regulatory controls" and "total compliance operating costs for an average job shop is approximately 6.5% of sales, or nearly $200,000 for a company with a sales volume of $3 million."
- One SER indicated that the impact of switching to a substitute product or method would include: costs (initial investment, and process costs, such as: chemistry, equipment, energy, waste treatment and regulatory), cleaning performance (ability to clean a wide range of contaminants on a wide range of substitutes), and consistency of cleaning operations (impacts on maintenance and downtime). In addition, the SER indicated that alternative solvents are prohibitively more expensive and other type of equipment, such as closed loop or vacuum degreasers, require a substantial investment and lead times of 6 to 12 moths per machine. Another SER described lead times of 4 to 12 months from purchase order to installation, depending on the size and complexity of the vapor degreaser.
- One SER commented on the challenges to achieve the ECEL limit of 0.05 ppm with open top vapor degreasers, and the need to provide respirators even if they switch to a closed-loop vapor degreaser. The SER also described challenges with relocating the vapor degreaser as a way to control emissions. Another SER also commented on the difficulty of achieving the ECEL of 0.05 ppm and the challenges associated with monitoring at that level.
- One SER noted that the anticipated increased costs of compliance with future regulatory requirements could not be absorbed and their customer base would diminish.

- Regarding alternative chemicals, one SER provided written comments on trans-dichlorethylene as a substitute solvent to 1-BP in aerospace vapor degreasing operations. This SER noted that due to trans-dichlorethylene having a lower boiling point than 1-BP, additional costs would be incurred due to the need for additional exposure management controls. Additionally, this SER provided comments on trans-dichlorethylene possibly being subject to future regulatory bans or restrictions. Other SERs noted that aqueous cleaners are not a suitable alternative for all applications and the aqueous cleaning tends to be more expensive. Additionally, most facilities do not have the physical space to accommodate multiple cleaning systems, or may need additional equipment, longer cycle times, and increased power. These facilities could also face challenges with aqueous cleaning due to drought conditions. Another SER indicated that there is a need to understand EPA's future regulations of other solvents for which rulemakings under TSCA section 6 are underway, so that small business could determine if those are viable alternatives.
- One SER provided information on the feasibility of retrofitting newer vapor degreasing machines with additional equipment to allow for "drop-in" alternative chemistries, estimating costs for small degreasers at $15,000-$20,000 with price increasing with the size of the degreaser. This SER also noted that the time to retrofit a degreaser may take months, and that such a process takes the degreaser out of service until retrofitting has been completed.
- One SER commented on the burdens associated with engineering controls in vapor degreasing to mitigate risk, such as increased costs of modifying equipment with lip exhaust systems and ventilation systems; equipment modifications and enclosure systems; and new airless degreaser.
- One SER indicated that complying with the regulations for 1-BP would mean additional costs, making U.S. business less competitive than global competitors, particularly in Asia.

7.4.4 Related Federal Rules

- One SER commented on the challenges associated with engineering and sourcing new equipment in a regulatory environment where access to alternative chemistries is currently or could potentially be regulated under multiple regulations, such as HFCs under the American Innovation and Manufacturing (AIM) Act and other chemicals under amended TSCA.
- One SER noted that any substitute that is ozone-depleting must first be approved by EPA under the Significant New Alternatives Program (SNAP). This SER also provided information on other aspects of consideration of the Clean Air Act (CAA), including air permit requirements and costs associated with some substitutes.
- One SER also noted that many substitute solvents available for vapor degreasing have

GWPs ranging from low to extraordinarily high; they stated that only solvents with the lowest GWPs should be used to achieve the current administration's goals and policies related to climate change.

7.4.5 Regulatory Flexibility Alternatives

- One SER provided information on the option of out-sourcing the cleaning process from small businesses to large industries; however, the SER noted that the feasibility of such a process depends on a variety of factors including location of the off-site service.
- One SER recommended that EPA should allow at least five years to implement any regulations on the use of 1-BP for critical applications.
- One SER indicated that implementation of the rule by August 2022 would be unworkable, and they need time to explore alternatives and implement needed changes, particularly, since they want to make a change that will be acceptable to EPA for years to come.
- One SER recommended that EPA allow for a 24-to 36-month lead time for current 1-BP users to transition to alternatives.
- One SER described the characteristics of effective and advantageous vapor degreasing solvents, including: non-flammable; non-ozone depleting and low GWP; high KB value; high boiling point; lower cost; azeotropic. This SER also noted the properties of alternative chemistries or processes that are disadvantageous, including: higher flammability; increased solvent cost and usage; increased energy costs; increased time needed for cleaning; reduced thru-put; higher emissions of greenhouse gases; and necessitating major capital spending on equipment and on the physical plant.
- Regarding the use of vacuum degreasers, one SER noted the considerable cost differences between an entry-level open top vapor degreaser priced at $22,800 and the equivalent vacuum degreaser quoted at $180,000.
- One SER also noted the existing Cal OSHA workplace exposure level of 5 ppm for 1-BP is supported in the vapor degreasing industry and can be easily achieved with less costly and fewer equipment modifications, and is more accurately monitored. Such level can be further reduced to 0.5 ppm by wearing a half face respirator.

8. PANEL FINDINGS AND DISCUSSION

8.1 Number and Types of Entities Affected

The proposed rule potentially affects commercial users of 1-BP, as well as any business that manufactures (including import), processes, distributes or disposes of 1-BP and 1-BP-containing products for commercial or consumer use. During the Panel outreach meeting, SERs discussed the types of small entities affected and included information on their processing or use of 1-BP and how their products are used, with a strong focus on vapor degreasing. The SERs specifically

emphasized the use of 1-BP in vapor degreasing for metal and surface finishing operations that serve the aerospace, defense, electronics, and medical sectors. Most SERs supported a ban of 1-BP for consumer use and in dry cleaning uses, adhesives, coatings, inks, and other miscellaneous uses.

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. Estimates of potential affected entities by condition of use are in Table 4. For a complete description of the small entities to which the proposed rule may apply, see Section 3 of this document. EPA acknowledges the SER concerns related to the use of 1-BP in vapor degreasing and will consider the information provided by SERs to inform the risk management rulemaking.

8.2 Potential Reporting, Recordkeeping, and Compliance Requirements

Several SERs raised concerns regarding compliance with monitoring for an ECEL, available monitoring technology, and the challenges of achieving a low airborne concentration level, including during fluid changeover and system maintenance, which would likely exceed the ECEL. SERS indicated that the cost of compliance with the ECEL developed by the agency would be considered a "*de facto* ban" of 1-BP for vapor degreasing. SERs also expressed concerns regarding 1-BP use in vapor degreasing specified by customers for many critical applications, including aerospace, defense, electronics, and medical.

Additionally, SERs provided several comments about their concerns with substitute chemicals, including trans-1,2-dichloroethylene, hydrofluorocarbons, and hydrofluoroethers including concerns related to the future regulation and availability of these chemicals. SERs also provided comments about their concerns with alternative technologies such as aqueous cleaning. The potential EPA reporting, recordkeeping, and compliance requirements are still under development.

SERs provided information on cost implications associated with compliance, alternative technologies, substitute chemicals, retrofitting current machinery, and purchasing new equipment. SERs noted the cost of purchasing a new vapor degreaser can range between $25,000-$700,000, with prices correlating to size, fill capacity, and sophistication of the cleaning system. While smaller, less expensive units are now on the market, the SER emphasized such a cost may still be out of budget for smaller businesses, and the size of the units too small for larger small businesses. Another SER noted the average price of nonflammable substitutes can be 2.25 times higher than the cost of 1-BP. This SER also noted the average vapor degreaser used by small businesses can hold about 50-100 pounds of solvent, approximately equating to a fill cost of $150-$400 for 1-BP; switching to an alternative chemistry for the same machine could equate to $450-$2,000. Similarly, another SER commented that the average end-user price for 1-BP solvents can range from $900-$1,500 per drum, $5,000-$7,000/drum for 1,2-trans mixtures, $10,500/drum for hydrofluoroethers, and over $20,000/drum for hydrofluorocarbons. SERs also estimated the cost of retrofitting or modifications to range between $15,000-$20,000, or indicated a total cost of $169,000 which included a new machine costing $77,500, and emphasized that the degreaser

would need to be taken out of service during the retrofitting period. EPA will be considering these and other potential compliance cost, the availability and feasibility of alternative technologies and chemistries, and financial implications of retrofitting or purchasing new equipment.

8.3 Related Federal Rules

1-BP has been the subject of U.S. federal regulations by EPA. EPA has issued several final rules and notices pertaining to 1-BP under its various statutory authorities, summarized in Section 2.2 of this document. During the Pre-Panel and Panel meeting and in written comments, several SERs described their concerns with potential substitutes for 1-BP in vapor degreasing. SERs also expressed concern regarding the fact that several potential substitutes are or were subject to risk evaluations under TSCA, and that some chemicals, such as trichloroethylene and perchloroethylene, are undergoing rulemaking regarding their unreasonable risks. EPA is also currently evaluating trans-1,2-dichloroethylene and its use in vapor degreasing as part of the next 20 high priority substances for risk evaluation. Other alternatives to 1-BP identified by SERs includes hydrofluorocarbons and hydrofluoroethers that may have a global warming potential, and therefore less desirable from the point of view of climate change than 1-BP. EPA recognizes the SERs' concerns, particularly given the October 5, 2021, rule phasing down hydrofluorocarbons[20], and will consider the implications of potential alternatives during development of regulatory approaches. In addition to the alternatives described by the SERs, EPA will consider the available information on alternatives and alternative methods, as required under TSCA section 6(c)(2)(C): "...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."

8.4 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,

[20] Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act (86 FR 55116, October 5, 2021).

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 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.

APPENDIX A: Outreach Materials Shared with Small Entity Representatives

Appendices A1 and A2 (separate documents) are compilations of all outreach materials shared with SERs for the Pre-Panel Outreach meeting and the Panel Outreach meeting. Below are lists of those materials.

Appendix A1: Materials Shared with Potential Small Entity Representatives for the Pre-Panel Outreach Meeting, November 5, 2020

- Agenda
- Presentation: An Overview of the SBAR Panel Process
- Presentation: 1-Bromopropane: Small Entity Consultation on Proposed Rulemaking under TSCA Section 6
- Handout: Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown
- Handout: Potential Regulatory Options
- Pre-Panel Outreach SER Questions for Discussion

Appendix A2: Materials Shared with Small Entity Representatives for the Panel Outreach Meeting, May 11, 2021

- Agenda
- Presentation: 1-Bromopropane: Small Entity Consultation on Proposed Rulemaking under TSCA Section 6
- Handout: 1-Bromopropane ECEL
- Handout: Regulations Appendix Table
- 1-Bromopropane Key Takeaways from Pre-Panel Outreach
- Panel Outreach SER Questions for Discussion

APPENDIX B: Written Comments Submitted by Small Entity Representatives

Appendices B1 and B2 (separate documents) are compilations of all written comments submitted by SERs following the Pre-Panel Outreach meeting and the Panel Outreach meeting. Below are the SERs that submitted comments.

Appendix B1: Written Comments Submitted by Potential Small Entity Representatives following the November 5, 2020 Pre-Panel Outreach Meeting

- ASKO Processing, Inc.
- Enviro Tech International, Inc. (2 documents)

Appendix B2: Written Comments Submitted by Small Entity Representatives following the May 11, 2021 Panel Outreach Meeting

- ASKO Processing, Inc.
- Hubbard Hall
- National Association for Surface Finishing
- MicroCare, LLC
- Enviro Tech International, Inc