1-Bromopropane: Small Entity Consultation on Proposed Rulemaking under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Small Entity Representative Panel Outreach Meeting
May 11, 2021

Overview

- Consultation with Small Entity Representatives
- Overview of EPA's Rulemaking
- Key Takeaways from Pre-Panel Meeting
- Risk Management Requirements under TSCA
- Regulatory Options (Updated information)
- Additional discussion with Small Entity Representatives
- Closing remarks

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Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)
- EPA will use this information to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation
- Key elements in this analysis:
  - Number of small entities to which the potential rule would apply
  - Projected compliance requirements of the potential rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
  - Any significant alternatives to the potential rule which accomplish the stated objectives and which minimize significant economic impact of the potential rule on small entities

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SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  - Provide specific examples of impacts
  - Provide cost data, if available
  - Please see detailed questions in a separate handout
- We are also seeking alternative methods of regulating these risks
  - Suggest other relevant options, including data costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
  - Provide information on any duplicative or contradictory Federal regulations you are aware of
  - For a list of existing regulations, please see summary of Federal regulations

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Overview of EPA's Rulemaking

- See materials distributed for the Pre-Panel outreach meeting (November 5, 2020) for more detail on:
  - Findings from the risk evaluation
  - Conditions of use in the rulemaking
  - Basis for unreasonable risk determination
  - Risk management requirements under TSCA
  - EPA's authority and "tools in the toolbox"

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Unreasonable Risk Determinations

- EPA determined that 1-bromopropane (1-BP) presents an unreasonable risk of injury to health, based on 16 of the 25 conditions of use
- EPA's determinations are based on unreasonable risks of injury to:
  - Workers and occupational non-users (ONUs) during occupational exposures
    - Many conditions of use present an unreasonable risk to workers even with use of respirators with assigned protection factor (APF) 50
    - No unreasonable risk to workers due to acute and chronic dermal exposures assuming use of gloves with protection factor (PF) of 5 (exception: dry cleaners)
    - EPA does not assume ONUs use personal protective equipment (PPE) because they do not handle the chemical
  - Consumers and bystanders during exposures to consumer uses
    - EPA does not assume dermal exposure to 1-BP for bystanders
    - EPA does not assume consumers or bystanders use PPE
    - The unreasonable risk determinations were based on the high intensity use risk estimates for consumers and bystanders. Unreasonable risk was also presented for low and moderate intensity use risk estimates for many conditions of use (COUs)
- EPA's risk evaluation identified unreasonable risks for cancer and non-cancer adverse effects from acute and chronic inhalation and dermal exposure to 1-BP

Key Takeaways from Pre-Panel Outreach Meeting

- Participants: 10 SERs participated and two SERs submitted written comments
- SERs discussed: Number and types of small entities affected
  - Included how their products are used and identified limited uses of 1-BP
  - Specifically, SERs describe Degreasing (degreaser and parts cleaner before surface finishing and degreasing for aerospace applications)
    - Small-scale uses (brake cleaning or engine degreasing; mold cleaning and release; in coatings; in coin and scissor cleaning; electronics spot cleaning or repair; and asphalt extraction)
    - Extremely limited or no uses (temperature indicator; and spot or stain removers)
    - Consumer uses (extremely limit or no uses identifiable or commercialized in current market)

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Key Takeaways from Pre-Panel Outreach Meeting, cont.

- SERs discussed: Potential reporting, recordkeeping and compliance requirements
  - SERs discussed their experience with:
    - Engineering controls (close-loop systems and newer equipment with better controls)
    - Exposure limits (EPA should take in consideration that the contamination by isopropyl bromide has been reduced significantly; in general, it is difficult to determine the impact of the potential rule without knowing the exposure limit value)
    - Exposure controls used, as required by OSHA (labels, GHS, PPE, engineering controls, ventilation systems and enclosed mixing systems)
    - Substitute chemicals (come at higher cost, are less effective, or have other environmental impacts)
    - Prohibitions (in degreasing operations would lead to significant costs to switch to alternatives; in contrast, support prohibition of consumer and small-scale commercial products)

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Key Takeaways from Pre-Panel Outreach Meeting, cont.

- SERs discussed: Related Federal rules
  - 2007 Significant New Alternatives Policy (SNAP) regarding air concentration levels inconsistent with risk evaluation
  - Various exposure and risk reduction techniques required by OSHA (labeling, GHS, PPE, engineering controls)
  - Compliance with NESHAP rules
- EPA and OSHA have ongoing dialogue in reference to risk management requirements under TSCA

Key Takeaways from Pre-Panel Outreach Meeting, cont.

- SERs discussed: Regulatory flexibility alternatives
  - SERs emphasized strong interest in knowing what level EPA might set for an existing chemical exposure limit (ECEL), and depending on the level, the ECEL might not provide the desired flexibility for small businesses
  - SERs emphasized increased costs related to engineering controls (retrofitting ventilation, close-loop systems)
  - Several SERs suggested requiring periodic maintenance of degreasing machines, to improve the efficiency and reduce risk
  - A SER indicated that cost of labeling is minimal
  - Some SERs suggested utilizing personal breathing zone monitoring badges to obtain monitoring data to identify activities with higher risks and focusing controls and safeguards towards those activities
  - Most SERs supported a ban of multiple conditions of use of 1-BP including dry cleaning, adhesives, coatings, inks, and all consumer uses
  - Some SERs described the burdens on small business regarding reporting and performance standards as potentially challenging to implement

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Critical or Essential Uses: TSCA Section 6(g)

TSCA section 6(g) allows EPA to grant, by rule, a time-limited exemption from a section 6(a) rule for a specific condition of use

- To provide an exemption, EPA must find that:
  - The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;
  - Compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or
  - The specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety
- In granting an exemption, EPA must:
  - Provide a time limit for the exemption
  - Analyze the need for the exemption and make the analysis public
  - Include conditions, such as recordkeeping, monitoring, and reporting requirements, to the extent EPA determines they are necessary to protect health and the environment while achieving the purposes of the exemption

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Effective Dates: TSCA Section 6(d)

- TSCA section 6(d) describes effective dates and compliance dates for TSCA section 6(a) rules.
- In these rules, EPA must specify an effective date, which shall be as soon as practicable
- Except for uses exempted under TSCA section 6(g), EPA must:
  - Specify mandatory compliance dates for all rule requirements, no later than five years after promulgation of the rule, or, in the case of a ban or phase-out:
    - Specify mandatory compliance dates for the start of a ban or phase-out requirements, which shall be as soon as practicable and no later than five years after promulgation of the rule, and
    - Specify mandatory compliance dates for full implementation of a ban or phase-out requirements, which shall be as soon as practicable
- EPA must also provide for a reasonable transition period

Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- Following a determination of unreasonable risk, EPA must issue a TSCA section 6(a) rule so that the chemical no longer presents an unreasonable risk, within two years (with a possible extension):
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements regarding consideration of alternatives depending on the options selected, and a statement of effects for each risk management rule
- Input from stakeholders is critical to the process and EPA is seeking stakeholder input now during the SBAR process and during the public comment period following the proposed rule

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

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Potential Regulatory Options

- EPA has considered a number of regulatory options under TSCA section 6(a), and considered 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 the conditions of use may no longer present an unreasonable risk
- These options are currently being considered and evaluated by EPA, and are not final at this time
- Regulatory options could be used alone or in combination so that 1-BP no longer presents an unreasonable risk under any condition of use

Potential Regulatory Options, cont.

- EPA is seeking feedback on the impacts of applying one or more of the following regulatory options to the conditions of use of 1-BP that present an unreasonable risk
- For processing, industrial, and commercial uses (occupational exposures):
  - Existing Chemical Exposure Limit (ECEL)
    - Establishes a performance-based airborne concentration limit and is non-prescriptive, enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace and the ability to combine prescriptive controls
    - Industries are already familiar with PELs and methods of compliance. EPA and OSHA have ongoing dialogue in reference to risk management requirements under TSCA
    - ECEL would be 0.05 ppm (0.25 mg/m^3) for an 8-hour time-weighted average (TWA)

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Potential Regulatory Options, cont.

- The value is based on the chronic cancer inhalation unit risk (IUR) for lung tumors at a risk level of $1x10^{-4}$ for workers
- At the 8-hour ECEL of 0.05 ppm, EPA expects that a worker would 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
- 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
- EPA is seeking feedback from the SERs on what current recordkeeping and monitoring is applied and feedback on how to apply ECEL recordkeeping and monitoring based on current protocol
- Potential ECEL would consider the Hazard Alert issued by OSHA and the National Institute for Occupational Safety and Health (NIOSH) regarding 1-BP that provides information regarding how to control exposures (see Appendix slides)

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Potential Regulatory Options, cont.

- For processing, industrial, and commercial uses (occupational exposures):
  - Prescriptive Controls: Engineering Controls
    - Would reduce worker or ONU exposure by requiring physical changes to the workplace
    - Examples: Require use of close-loop vapor degreasers, require specific ventilation rates, require spraying booths or laboratory hoods for laboratory applications, or isolate the work area where the 1-BP is present
  - Prescriptive Controls: Administrative Controls
    - Would reduce worker or ONU exposure by requiring processes or procedures in the workplace
    - Examples: Limit access to work areas, control the number of hours workers are exposed to 1-BP

Potential Regulatory Options, cont.

- Prescriptive Controls: PPE Controls
  - PPE: APF of 50 was considered in the unreasonable risk determination and in some cases was insufficient to address unreasonable risk
  - Prescriptive PPE controls as a potential regulatory option could require use of APF of 1,000 or more and could require that ONUs use PPE
- Prohibition
  - For conditions of use where ECEL or prescriptive controls are not sufficient to address the unreasonable risk
  - For conditions of use where 1-BP is no longer in use or the use is phasing out

Potential Regulatory Options, cont.

- For consumer uses:
  - Regulation at key points in the supply chain (manufacturing, processing, and/or distribution) to address unreasonable risks to consumers or bystanders
  - Potential regulatory options:
    - Concentration limit
    - Prohibition

Potential Regulatory Options, cont.

- Regulatory options applied broadly with other restrictions
  - Recordkeeping – example: ordinary business records to demonstrate compliance (for example not selling products to consumers)
  - Downstream notification – example: modify the SDS to indicate that the product should not be used in consumer products or indicate other regulatory requirements
  - Monitoring – example: of air concentration to demonstrate compliance with ECEL
  - Labeling – example: labeling products to indicate that they should not be used by consumers or to describe other regulatory requirements
  - Limited access program – example: access only to those users with certain equipment, for example product only sold to facilities with close-loop vapor degreasers

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Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Substitute products (average per ounce)	Example Prices: 1-BP: $28/gal Trichloroethylene: $51/gal HFE Blends w/trans-DCE: $145/gal HFO Blends: $148/gal Acetone: $49/gal Isopropyl alcohol: $48/gal D-limonene: $90/gal Soy methyl ester: $59/gal Hydrocarbon mixtures: $13/gal	1-BP is more expensive than some substitutes and less expensive than others. Substitutes are expected to have similar costs and efficacy in most cases, but efficacy may be an important cost factor for some specialized products. This list of substitute chemicals or off-the-shelf products are examples and are not exhaustive for all COUs with unreasonable risk determinations.
Substitute Methods	Varies by job labor rate	For vapor degreasing, costs will vary widely across applications and may require large upfront capital investments and transition costs (i.e., as high as $500,000), but should have lower operational costs. Costs for other uses will primarily be labor costs and cost of alternative equipment.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Reformulation of product to reduce or eliminate 1-BP concentration	$16,000-$98,000 per product Dilution: $16,000 Standard: $57,000 Complex: $98,000	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities. The breakdown shows generalized estimates but COU specific information, when available, may result in estimates being at the lower or upper end of the provided range.
Existing chemical exposure limit (ECEL)	$4,000 to $7,400 daily monitoring fee $200 to $325 recordkeeping	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.
Engineering/administrative controls	Varies by control type and needs of user	Engineering controls could be a regulatory option used for 1-BP. Admin controls are expected to have minimal costs, if any. An example would be a sign stating ONUs need to stay out of a given area, at a cost of $10 per sign.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Personal protective equipment (PPE) – inhalation exposure (respirators)	APF 10: $2,000 APF 25: $1,200 APF 50: $500-$2,000 APF 1000: $600-$1,300 APF10000: $1,700-$2,000 See separate handout for detailed breakdown	Costs are per employee and include purchase of equipment (including filters), training, fit-testing, and medical clearance. Does not include existing PPE use nor PPE replacement due to employee turn-over.
Personal protective equipment (PPE) – dermal exposure (gloves)	$7 - $30/pair	For tasks that might subject the gloves to mechanical damage, a more expensive glove might be needed (about $30).
Recordkeeping	$200 - $325 per firm	Annual labor and material costs associated with documentation of ordinary business records.
Downstream notification	$112 - $125 per product	Costs are per product and include labor and material costs to update the product's safety data sheet (SDS).
Product label or warnings	$750 - $8,000 per product	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor.

Additional Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

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Closing Session

- Closing remarks from EPA, SBA, and OMB
- Next steps
  - Written comments by May 25, 2021

Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- Risk Management Activities for 1-Bromopropane: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-1-bromopropane
- 1-Bromopropane: Ana Corado (corado.ana@epa.gov, 202-564-0140)
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Appendix

- Conditions of Use:
  - Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk
  - Consumer Uses that Present an Unreasonable Risk
- OSHA and NIOSH Hazard Alert (https://www.cdc.gov/niosh/docs/2013-150/pdfs/2013-150.pdf?id=10.26616/NIOSHPUB2013150)
- Key takeaways from Pre-Panel Outreach Meeting (separate document)
- Related regulations (EPA, other Federal, state, and international) (separate document)
- Existing Chemical Exposure Limit (ECEL) for Occupational Use of 1-Bromopropane (separate document)

Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk

- Processing: incorporation into formulation, mixture, or reaction products
- 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

Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk cont.

- 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

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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 cleaner (e.g., coin and scissor cleaner)
- 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)

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