




Environmental Justice Consultation on Forthcoming Proposed Rulemakings under TSCA Section 6(a)

Methylene Chloride
1-Bromopropane

November 16 and 19, 2020
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency





Today's Consultation

- Welcome
- Purpose of today's consultation
- Risk management under TSCA section 6(a)
- Proposed rulemaking for methylene chloride
 - Questions and discussion
- Proposed rulemaking for 1-bromopropane
 - Questions and discussion
- Next Steps



Opening Remarks and Consultation Overview



E.O. 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

- The purpose of E.O. 12898 is to focus federal attention on the environmental and human health effects of federal actions on minority and low-income populations with the goal of achieving environmental protection for all communities.
- Under E.O. 12898, EPA is seeking input from stakeholders interested in environmental justice issues during this consultation and encourages participation and comments to inform EPA's upcoming proposed regulation.



Risk Management under TSCA Section 6(a)



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:
 - 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



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



TSCA Section 6(a)

- TSCA provides EPA with authority to address unreasonable risks in occupational settings, and to regulate entities including:
 - Manufacturers and processors (e.g., formulators)
 - Distributors
 - Commercial users (workplaces and workers)
 - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
 - Under TSCA, EPA has authority to regulate at the manufacturing, processing, and distribution level in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
 - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers



Examples of Regulatory Options

- Set a concentration for a particular use, for example, product formulations cannot contain more than a certain percentage by weight
- Provide a prominent label securely attached to each container with specific directions, limitations, and precautions, or that describe the health endpoints
- Prohibit manufacturing, processing and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls, ventilation requirements, and personal protective equipment (PPE) at occupational sites



Examples of Regulatory Options

- Require manufacturers, processors, and distributors to maintain ordinary business records
- Require manufacturers, processors and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain
- Set an occupational air exposure limit, for example, establish an Existing Chemical Exposure Limit (ECEL)
- Restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification



Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue about the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective



Your Comments

- Please provide specific comments on:
 - Do you have any concerns related to environmental justice about these uses of methylene chloride or 1-bromopropane?
 - How do you anticipate these rulemakings would have an environmental justice impact?
 - Other thoughts on the rulemakings?



Your Advice for EPA

- Please provide specific examples of:
 - Any experience with use of methylene chloride or 1-bromopropane
 - Any experience with regulation of methylene chloride or 1-bromopropane
 - Any risk management experience with specific conditions of use of methylene chloride or 1-bromopropane



Methylene Chloride

- Background on risk evaluation and findings for methylene chloride
- Focused discussion on specific conditions of use
- Consultation comments
- Your advice for EPA



Overview of Risk Evaluation for Methylene Chloride

- Final risk evaluation published June 24, 2020
 - 53 conditions of use were evaluated
 - Methylene chloride (MC) draft risk evaluation: October 2019; MC problem formulation: June 2018; MC scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
 - 41 public comments received on the draft risk evaluation (comment period closed December 30, 2019)
 - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (December 2019)
- The final risk evaluation and supplemental materials are in docket [EPA-HQ-OPPT-2019-0437](#), with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0742](#), on www.regulations.gov



Unreasonable Risk Determinations

- EPA determined that 47 of the 53 conditions of use of MC present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
 - Workers and occupational non-users (ONUs) during occupational exposures
 - Consumers and bystanders during exposures to consumer use
- EPA's risk evaluation identified unreasonable risks for cancer and non-cancer adverse effects from acute (central nervous system) and chronic (liver) inhalation and dermal exposure to MC
- EPA used central nervous system effects to identify unreasonable risks because relatively small increases in exposure can range from central nervous system effects to more severe effects, including death



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

- Import
- Processing: incorporation into formulation, mixture, or reaction products
- Processing: repackaging
- Industrial and commercial use as solvent for batch vapor degreasing
- Industrial and commercial use as solvent for in-line vapor degreasing
- Industrial and commercial use as solvent for cold cleaning
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- Industrial and commercial use in adhesives, sealants and caulks
- Industrial and commercial use in paints and coatings
- Industrial and commercial use in paint and coating removers
- Industrial and commercial use in adhesive and caulk removers
- Industrial and commercial use in metal aerosol degreasers
- Industrial and commercial use in metal non-aerosol degreasers
- Industrial and commercial use in finishing products for fabric, textiles and leather
- Industrial and commercial use in automotive care products (functional fluids for air conditioners)
- Industrial and commercial use in automotive care products (interior car care)
- Industrial and commercial use in automotive care products (degreasers)
- Industrial and commercial use in apparel and footwear care products
- Industrial and commercial use in spot removers for apparel and textiles



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

- Industrial and commercial use in liquid lubricants and greases
- Industrial and commercial use in liquid lubricants and greases
- Industrial and commercial use in spray lubricants and greases
- Industrial and commercial use in aerosol degreasers and cleaners
- Industrial and commercial use in non-aerosol degreasers and cleaners
- Industrial and commercial use in cold pipe insulations
- Industrial and commercial use as solvent that becomes part of a formulation or mixture
- Industrial and commercial use as a processing aid
- Industrial and commercial use as propellant and blowing agent
- Industrial and commercial use for electrical equipment, appliance, and component manufacturing
- Industrial and commercial use for plastic and rubber products manufacturing
- Industrial and commercial use in cellulose triacetate film production
- Industrial and commercial use as anti-spatter welding aerosol
- Industrial and commercial use for oil and gas drilling, extraction, and support activities
- Industrial and commercial use in toys, playground and sporting equipment
- Industrial and commercial use in lithographic printing plate cleaner
- Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner



Consumer Uses that Present an Unreasonable Risk

- Consumer use as solvent in aerosol degreasers/cleaners
- Consumer use in adhesives and sealants
- Consumer use in brush cleaners for paints and coatings
- Consumer use in adhesive and caulk removers
- Consumer use in metal degreasers
- Consumer use in automotive care products (functional fluids for air conditioners)
- Consumer use in automotive care products (degreasers)
- Consumer use in lubricants and greases
- Consumer use in cold pipe insulation
- Consumer use in arts, crafts, and hobby materials glue
- Consumer use in an anti-spatter welding aerosol
- Consumer use in carbon removers and other brush cleaners



Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of MC:
 - Central nervous system effects from acute inhalation
 - Liver effects from chronic inhalation
 - Cancer effects (liver and lung tumor) from chronic inhalation
- In some cases acute exposures to MC have led to fatalities
- Personal Protective Equipment (PPE):
 - The OSHA Methylene Chloride Standard sets a Permissible Exposure Limit (PEL) of 25 ppm and requires air supplied respirators for occupational use.
 - Many conditions of use presented an unreasonable risk to workers even with use of respirators assigned protection factor (APF) 25 or 50
 - No unreasonable risk to workers due to acute and chronic dermal exposures assuming use of gloves with protection factor (PF) of 5 or 10 in commercial settings and PF of 5 or 20 in industrial settings (exception: use of methylene chloride in spot removers for apparel and textiles)
 - EPA does not assume ONUs use PPE because they do not handle the chemical



Basis for Unreasonable Risk Determination: Consumers and Bystanders

- The unreasonable risk determinations for consumers and bystanders are based on the following health hazards during consumer exposures of MC:
 - Central nervous system effects from acute inhalation and dermal exposure
- EPA does not assume dermal exposure to MC for bystanders
- EPA does not assume consumers or bystanders use PPE
- The unreasonable risk determinations were based on the high-end risk estimates for consumers and bystanders. Unreasonable risk was also presented for central tendency risk estimates for many conditions of use (COUs)



In-Depth Discussion on Conditions of Use

1. Industrial vapor degreasing and cold cleaning uses
2. Commercial use of paints, coatings, and their removers
3. Industrial and commercial uses of packaged or “off-the-shelf” formulated products
4. Industrial and commercial uses of formulations made on-site or facility-specific formulations containing MC
5. Other industrial and commercial uses
6. Consumer uses
7. Formulators and processors



Group 1: Industrial vapor degreasing and cold cleaning uses

- Relevant conditions of use:
 - Industrial and commercial use as a solvent for batch vapor degreasing
 - Industrial and commercial use for in-line vapor degreasing
 - Industrial and commercial use as a solvent for cold cleaning
- What is MC used for? How is it applied?
 - MC is used as a degreasing solvent to remove drawing compounds, cutting fluids, coolants, and lubricants from metal parts
 - It can be used open top vapor degreasing, conveyORIZED vapor degreasing, or in cold cleaning
 - Cold cleaning operations include spraying, brushing, flushing, and immersion



Potential Regulatory Options (Group 1)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace. Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE, in some cases there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit
- Prohibition
 - For COUs where ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 2: Commercial use of paints, coatings, and their removers

- Relevant conditions of use
 - Industrial and commercial use in paints and coatings
 - Industrial and commercial use in paint and coating removers
- What is MC used for? How is it applied?
 - Typical industrial and commercial coating applications include manual application with roller or brush, air spray systems, airless and air-assisted airless spray systems, electrostatic spray systems, electrodeposition/electrocoating and auto deposition, dip coating, curtain coating systems, roll coating systems, and supercritical carbon dioxide systems. After application, solvent-based coatings typically undergo a drying stage in which the solvent evaporates from the coating
 - Paint strippers can be used by professional contractors to strip paint and varnish from walls, wood flooring, and kitchen and wood cabinets



Potential Regulatory Options (Group 2)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE, in some cases there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit
- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigated
- Prohibition
 - For COUs where ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 3: Industrial and commercial uses of “off-the-shelf” products

- Relevant conditions of use:
 - Industrial and commercial use in solvent for aerosol spray degreaser/cleaner
 - Industrial and commercial use in metal aerosol degreasers
 - Industrial and commercial use in aerosol degreasers and cleaners
 - Industrial and commercial use in adhesives, sealants and caulks
 - Industrial and commercial use in cold pipe insulations
 - Industrial and commercial use in anti-splatter welding aerosol
 - Industrial and commercial use in spot removers for apparel and textiles
 - Industrial and commercial use for apparel and footwear care products
 - Industrial and commercial use for finishing products for fabric, textiles, and leather
 - Industrial and commercial use in liquid lubricants and greases
 - Industrial and commercial use in spray lubricants and greases
 - Industrial and commercial use in adhesive and caulk removers
 - Industrial and commercial use in carbon remover, wood flood cleaner, and brush cleaner
 - Industrial and commercial use in automotive care products (functional fluids for air conditioners)
 - Industrial and commercial use in automotive care products (interior car care)
 - Industrial and commercial use in automotive care products (degreasers)
 - Industrial and commercial use in non-aerosol degreasers and cleaners
 - Industrial and commercial use in metal non-aerosol degreasers



Use and Application of Methylene Chloride (Group 3)

- What is MC used for? How is it applied?
 - MC is found in many packaged or “off-the-shelf” formulated products for industrial and commercial use in automotive care, adhesives and sealants, lubricants and greases, and spot removers, among others
 - MC serves as a solvent and evaporates during adhesive and sealant drying and curing
 - MC is used in post-market wax and polish applied to footwear (e.g., shoe polish)
 - MC is applied to fabrics at industrial fabric mills in textile finishing and impregnating/surface treatment products (e.g., water repellent)
 - MC is used in spot remover for apparel and textiles in spot cleaning products either before or after a garment is dry cleaned
 - MC is used as a solvent in lithographic printing to clean the blankets and rollers. Press operators commonly apply the solvent to a wipe cloth and wipe the blanket to remove the ink, while companies have automated blanket wash systems where the solvent is applied to the blankets with a spray bar



Potential Regulatory Options (Group 3)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE, in some cases there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit
- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigated
- Prohibition
 - For COUs where ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 4: Industrial uses of facility-specific formulations

- Relevant conditions of use:
 - Industrial and commercial use in adhesives, sealants and caulks
 - Industrial and commercial use in paint and coating removers
 - Industrial and commercial use in adhesive and caulk removers
 - Industrial and commercial use in liquid lubricants and greases
 - Industrial and commercial use in spray lubricants and greases
 - Industrial and commercial use in lithographic printing plate cleaner
 - Industrial and commercial use in carbon remover, wood flood cleaner, and brush cleaner



Use and Application of Methylene Chloride (Group 4)

- What is MC used for? How is it applied?
 - MC may be used in various formulations made on on-site and in facility-specific formulations, including in paints and coatings for industrial, commercial, and consumer applications; in lubricants and greases; and in adhesive and caulk removers
 - Paint and coating applications include manual application with roller or brush, air spray systems, airless and air-assisted airless spray systems, electrostatic spray systems, electrodeposition/electrocoating and auto deposition, dip coating, curtain coating systems, roll coating systems, and supercritical carbon dioxide systems
 - After application, solvent-based coatings typically undergo a drying stage in which the solvent evaporates from the coating
 - MC is used as a solvent in lithographic printing to clean the blankets and rollers
 - Press operators commonly apply the solvent to a wipe cloth and wipe the blanket to remove the ink, while companies have automated blanket wash systems where the solvent is applied to the blankets with a spray bar



Potential Regulatory Options (Group 4)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity.
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE, in some cases there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit
- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigated
- Prohibition
 - For COUs where ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 5: Other industrial and commercial uses

- Relevant conditions of use:
 - Other industrial and commercial uses
- What is MC used for? How is it applied?
 - A variety of uses for MC, including as a solvent or carrier in crafting glues and cements, novelty items, and miscellaneous cleaners and in interfacial polymerization for polycarbonate plastic manufacturing



Potential Regulatory Options (Group 5)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity.
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE, in some cases there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit
- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigated
- Prohibition
 - For COUs where ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 6: Consumer uses

- Relevant conditions of use:
 - Consumer use as solvent in aerosol degreasers/cleaners
 - Consumer use in adhesives and sealants
 - Consumer use in brush cleaners for paints and coatings
 - Consumer use in adhesive and caulk removers
 - Consumer use in metal degreasers
 - Consumer use in automotive care products (functional fluids for air conditioners)
 - Consumer use in automotive care products (degreasers)
 - Consumer use in lubricants and greases
 - Consumer use in cold pipe insulation
 - Consumer use in arts, crafts, and hobby materials glue
 - Consumer use in an anti-spatter welding aerosol
 - Consumer use in carbon removers and other brush cleaners
 - Other industrial and commercial uses



Potential Regulatory Options (Group 6)

- Regulate manufacturing, processing or distribution of products for consumer use
- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigate
- Prohibition
 - For COUs where restrictions on the concentration limit are not feasible or sufficient or that may be phasing out
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 7: Formulating and Processing

- Relevant conditions of use:
 - Processing – incorporation into a formulation, mixture, or reaction products
 - Industrial and commercial use as a solvent that becomes part of a formulation
- What is MC used for? How is it applied?
 - The uses of methylene chloride that may require incorporation into a formulation include paint removers; adhesives and sealants; paints and coatings; degreasers, cleaners, and spot removers; and lubricants
 - The formulation of paints and coatings typically involves dispersion, milling, finishing and filling into final packages
 - Adhesive/sealant formulation involves mixing volatile and non-volatile chemical components in sealed, unsealed or heated processes
 - Sealed processes are most common for adhesive/sealant formulation because many adhesives/sealants are designed to set or react when exposed to ambient conditions
 - Many of these formulated products may be packed in aerosol form. Methylene chloride cannot function alone as a propellant because of its low vapor pressure relative to other propellants
 - A solvent such as methylene chloride brings the active ingredient into solution with the propellants



Potential Regulatory Options (Group 7)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity.
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE, in some cases there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit
- Prohibition
 - For COUs where ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Your Comments

- Please provide specific examples of:
 - Any experience with use of MC
 - Any experience with regulation of MC
 - Any risk management experience with specific conditions of use of methylene chloride
- Please provide specific comments:
 - Do you have any concerns related to environmental justice about these uses of methylene chloride?
 - How do you anticipate this rulemaking would have an environmental justice impact?
 - Other thoughts on the rulemaking?



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>
- Methylene chloride: Ingrid Feustel (Feustel.ingrid@epa.gov, 202-564-3199), <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride>
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)



1-Bromopropane

- Background on risk evaluation and findings for 1-bromopropane
- Focused discussion on specific conditions of use
- Consultation comments
- Your advice for EPA



Overview of Risk Evaluation for 1-Bromopropane

- Final risk evaluation published August 11, 2020
 - 25 conditions of use were evaluated
 - 1-Bromopropane (1-BP) draft risk evaluation: August 2019; 1-BP problem formulation: June 2018; 1-BP scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
 - 32 public comments received on the draft risk evaluation (comment period closed October 11, 2019)
 - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (September 10-12, 2019)
- The final risk evaluation and supplemental materials are in docket [EPA-HQ-OPPT-2019-0235](https://www.regulations.gov/docket/EPA-HQ-OPPT-2019-0235), with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0741](https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0741), on www.regulations.gov



Unreasonable Risk Determinations

- EPA determined that 16 of the 25 conditions of use of 1-BP present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
 - Workers and occupational non-users (ONUs) during occupational exposures
 - Consumers and bystanders during exposures to consumer uses
- 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
- For non-cancer adverse effects, developmental toxicity (post-implantation loss in animal studies) was used as the most sensitive endpoint



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



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)



Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of 1-BP:
 - Developmental toxicity from acute and chronic inhalation exposures
 - Cancer from chronic inhalation exposures
- Personal protective equipment (PPE):
 - 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 PPE because they do not handle the chemical



Basis for Unreasonable Risk Determination: Consumers and Bystanders

- The unreasonable risk determinations for consumers and bystanders are based on the following health hazards during consumer exposures of 1-BP:
 - Developmental toxicity from acute inhalation and dermal exposure
- 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)



In-Depth Discussion on Conditions of Use

1. Processing into formulations
2. Industrial and commercial use in degreasing operations
3. Other industrial and commercial users
4. Consumer uses



Group 1: Processing into formulations

- Relevant conditions of use:
 - Processing – incorporation into a formulation, mixture, or reaction products
- What is 1-BP used for? How is it applied?
 - Processing is the process of mixing or blending several raw materials to obtain a single product or preparation
 - 1-BP may be incorporated into various products and formulations at varying concentrations for further distribution. For example, formulators may add stabilizing packages to 1-BP for specialized vapor degreasing uses or mix 1-BP with other additives to formulate adhesives, sealants, and other products



Potential Regulatory Options (Group 1)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit
- Prohibition
 - If ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient; however, impacts downstream users
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Limited access program



Group 2: Industrial and commercial use in degreasing operations

- Relevant conditions of use:
 - 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
- What is 1-BP used for? How is it applied?
 - 1-BP is used as a degreasing solvent to remove drawing compounds, cutting fluids, coolants, and lubricants from metal parts. It can be used in cold cleaning, open-top vapor degreasing, conveyorized vapor degreasing, or aerosol sprays
 - Cold cleaning operations include spraying, brushing, flushing, and immersion
 - Aerosol spray operations include general purpose degreasing, engine degreasing, brake cleaning, and metal product cleaning



Potential Regulatory Options (Group 2)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE, in some cases there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit. (e.g. use of closed-loop vapor degreasers)
- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigated
- Prohibition
 - If ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Limited access program



Group 3: Other industrial and commercial users

- Relevant conditions of use
 - Industrial and commercial uses 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
- What is 1-BP used for? How is it applied?
 - 1-BP is used in foam cushion manufacturing and fabrication, typically through the use of spray guns. After application, workers assemble the cushions by hand-pressing together pieces of foam
 - 1-BP based dry cleaning formulations, which were marketed as “drop-in” replacements for perchloroethylene, and dry cleaning machines that were designed to use 1-BP
 - A spotting agent can be applied from squeeze bottles, hand-held spray bottles, or spray guns connected to pressurized tanks. Under certain circumstances, after application, the spotted agent can be further applied using a brush, spatula, pressurized air or steam, or their fingers to remove or flush away the stain
 - 1-BP can be used in a variety of products to clean coins, scissors, as adhesive accelerant, in automotive care products, mold release, as refrigerant flush and in laboratory applications



Potential Regulatory Options (Group 3)

- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - It establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive PPE controls
 - Potential alternative to an ECEL, though it may limit flexibility for the regulated entity
 - PPE was considered in the unreasonable risk determination
 - Even assuming use of PPE, in some cases there was unreasonable risk to workers
- Prescriptive engineering and administrative controls
 - Potential alternative to an ECEL, prescriptive engineering and/or administrative controls would reduce exposure or achieve a specific air concentration limit
- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigated
- Prohibition
 - For COUs where ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient
 - For COUs that are phasing out
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Limited access program



Group 4: Consumer Uses

- Relevant conditions of use
 - 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)
- What is 1-BP used for? How is it applied?
 - 1-BP may be incorporated into various products used by consumers
 - The products might be in aerosol or spray form, or in a liquid formulation where the consumer would dip the item for cleaning, such as coins



Potential Regulatory Options (Group 4)

- Regulate manufacturing, processing or distribution of products for consumer use
- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigated
- Prohibition
 - For COUs that might be phasing out
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Limited access program



Your Comments

- Please provide specific examples of:
 - Any experience with use of 1-bromopropane
 - Any experience with regulation of 1-bromopropane
 - Any risk management experience with specific conditions of use of 1-bromopropane
- Please provide specific comments:
 - Do you have any concerns related to environmental justice about these uses of 1-bromopropane?
 - Do you anticipate this rulemaking would have an environmental justice impact?
 - Other thoughts on the rulemaking?



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>
- 1-Bromopropane: Ana Corado (corado.ana@epa.gov, 202-564-0140), <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-1-bromopropane>
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)



Next Steps

- Please send written comments by January 18, 2021, to Amanda Hauff at Hauff.Amanda@epa.gov with a cc: to Feustel.Ingrid@epa.gov for methylene chloride or Corado.Ana@epa.gov for 1-bromopropane



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>