

1-Bromopropane (1-BP) Proposed Rulemaking Under TSCA Section 6(a)

Public Webinar

August 28, 2024

RIN 2070-AK73



Agenda

- Purpose and Overview of Rulemaking
- 1-BP Background
- TSCA Regulatory Toolbox
- Developing Effective Regulations
- Proposed Regulation
- Alternative Regulatory Action
- Benefits
- Requests for Comment and Opportunities for Engagement
- Next Steps
- Additional Resources

EPA's Proposal and the Toxic Substances Control Act (TSCA)

- In June 2016, Congress amended the Toxic Substances Control Act (TSCA)
 - EPA must assess and address risks from chemicals currently in commerce
 - Statutory timeframes for regulation
 - Protection for the public and predictability for the regulated community
- 1-BP was identified in 2016 as one of the first chemicals for risk evaluation
 - 2020 Risk Evaluation followed a public draft and peer review process
 - 2022 Revised Unreasonable Risk Determination
 - EPA determined 1-BP presents an unreasonable risk under its conditions of use (COUs)

Purpose and Overview Of Rulemaking

- Addresses the unreasonable risk identified in the risk evaluation of 1-BP
- Rule will protect consumers and occupational users through workplace requirements, prescriptive controls, and prohibitions
- Public comment period open until September 23, 2024
- EPA will consider public comments as it develops a final regulation

1-BP Background

- 1-BP is a volatile chemical with a low global warming potential. It is used in vapor degreasing, as an industrial solvent in aerospace and defense applications, and in a variety of commercial and consumer products.
 - Annual production volume of 1-50 million pounds reported in 2020 Chemical Data Reporting (CDR)
- Risk to workers, occupational non-users (ONUs), consumers, and bystanders for 23 of the 25 conditions of use contribute to the unreasonable risk from 1-BP.
- Timeline:
 - August 8, 2024: EPA Proposed Rule for the Regulation of 1-BP under TSCA Section 6(a)
 - September 23, 2024: Public comment period closes
 - 2025: Publication of 1-BP Final Rule (estimated)

1-BP Risk Evaluation: Unreasonable Risk for Workers and Consumers

Cancer (skin, intestinal, and lung tumors) from chronic inhalation and dermal exposures

Non-cancer adverse effects from chronic inhalation and dermal exposures

Non-cancer adverse effects from acute inhalation and dermal exposures

- Cancer from chronic inhalation and dermal exposure is the most sensitive endpoint
- Additional adverse effects from acute and chronic non-cancer exposures include other developmental toxicity (i.e., post-implantation loss), reproductive toxicity, liver toxicity, kidney toxicity, and neurotoxicity
- No unreasonable risk to the environment

TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
 - Manufacturers (including importers) 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 levels 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

TSCA Section 6(a) Regulatory Options (cont.)

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture (includes import), 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

The section 6(a) menu of regulatory options can be applied alone or in combination.

Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement during risk management helps EPA develop practical and protective regulations
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Consultation and coordination with other Federal agencies
 - OSHA, NIOSH, and CPSC for a consistent approach, facilitate compliance, and avoid duplicative requirements
 - DOD, DOE, and NASA for uses that might affect U.S. critical infrastructure or national security and to facilitate compliance
 - SBA Advocacy and OMB/OIRA for a Small Business Advocacy Review panel to obtain advice and recommendations from small entity representatives
- Extensive dialogue helps people understand risk evaluation findings, the TSCA risk management process, and available options for managing unreasonable risks
- Have been seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers

Developing Effective Regulations

EPA's mandate is to address unreasonable risk

- EPA must consider:
 - Effects and magnitude of exposure to human health and the environment
 - Potentially Exposed or Susceptible Subpopulations
 - Benefits of a chemical substance
 - Economic consequences of the rule
 - Availability of alternatives
- Proposal is based on best available science and reasonably available information

Developing Effective Regulations (cont.)

EPA's goal is protective and practical regulations. The 1-BP proposal:

- Prohibits most consumer uses via prohibition on manufacturing, processing, and distribution for consumer use
- Prohibits occupational uses where EPA determined there would likely be an inability to comply with the proposed worker protection requirements or where alternatives are readily available
- For continuing occupational uses that can implement strict workplace controls, require worker protections and self certification
- Meets TSCA requirement to address unreasonable risk to the extent necessary so that it is no longer unreasonable, including risk to potentially exposed or susceptible subpopulations
- Requires recordkeeping to ensure rule is enforceable

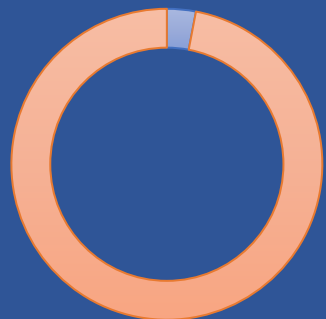
Developing Effective Regulations (cont.)

- Requesting comment on all elements of the proposed and alternative regulatory actions
- EPA may in the final rule modify elements of the proposed regulatory action
- Public comments could result in changes when this rule is finalized

The Proposed Regulation

EPA's proposed rule would:

By End Use
Production Volume:



■ Prohibit

■ WCPP + Prescriptive

- Prohibit the manufacture (including import), processing, and distribution for consumer use (except use in insulation)
- Prohibit the manufacture (including import), processing, and distribution for occupational COUs that are not continuing under a Workplace Chemical Protection Program (WCPP) or prescriptive controls
- Require occupational safety measures for certain COUs:
 - WCPP and self certification for 6 COUs
 - WCPP for 1 COU (Manufacturing)
 - Prescriptive controls for 6 COUs
- Establish recordkeeping and downstream notification requirements

Proposed Regulation: Prohibition of Certain Consumer COUs

- EPA is proposing to prohibit the manufacture (including import), processing, and distribution for consumer use (except use in insulation)
 - 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)
- EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
- Available information suggests minimal ongoing use or that alternatives are available
- EPA is proposing a timeframe that provides time for retailers to phase out their consumer product inventory

Proposed Regulation: Prohibition of Occupational COUs

- EPA is proposing to prohibit the manufacturing (including import), processing, distribution in commerce, and use of 1-BP for occupational COUs that are not continuing under WCPP or prescriptive controls
 - 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); functional fluids (close/open-systems) – refrigerant/cutting oils
- Available information suggests alternatives are available for most of the uses or ongoing use is minimal
- EPA is uncertain regarding feasibility to implement controls to reduce exposures sufficient to address the unreasonable risk associated with 1-BP exposures
- Additional information about these uses, including about the feasibility of implementing workplace exposure controls, could reduce EPA's uncertainty and be considered in any changes in the final regulation

Proposed Regulation: Workplace Chemical Protection Program (WCPP)

- EPA is proposing strict workplace controls, including an inhalation exposure limit (ECEL of 0.05 ppm), while also providing flexibility in implementation and compatibility with existing OSHA requirements wherever possible
 - OSHA Method 1017 is fully validated and has a limit of quantification of 1.2 ppb
 - Owners or operators is broader than “employers”
 - Includes additional recordkeeping, dermal, and exposure control plan requirements
- EPA expects some workplaces already have these controls in place
 - Uncertainty regarding ability to comply with WCPP is the primary driver of difference between the proposed approaches
- Longer compliance timeframes for Federal agencies and Federal contractors acting for or on behalf of the Federal Government

Proposed Regulation: Workplace Chemical Protection Program (WCPP) (Cont.)

- EPA is proposing to require a WCPP for occupational COUs not prohibited or subject to other prescriptive controls:
 - Manufacturing: domestic manufacturing and import
 - Processing: incorporation into a formulation, mixture, or reaction products
 - Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners
 - Industrial and commercial use as solvent in aerosol spray degreaser/cleaner
 - Other industrial and commercial uses: electronic and electronic products and metal products; asphalt extraction, laboratory chemicals; and temperature indicator – coatings
 - Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – open-top, in-line vapor degreaser)
 - Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – closed-loop)

Proposed Regulation: Prescriptive Controls

- EPA is proposing specific prescriptive controls (gloves) for certain occupational COUs with only dermal exposure driving the unreasonable risk
 - Manufacturing (Import)
 - Processing as a reactant
 - Processing: incorporation into articles
 - Processing: repackaging
 - Processing: recycling
 - Disposal
- EPA is also proposing workplace training requirements in accordance with OSHA's general PPE requirement standards.

Proposed Regulation: Self Certification, Recordkeeping and Downstream Notification

- Self Certification: certifies the ability of regulated entities to implement the ECEL
 - For the degreasing COUs, self certification would ensure only facilities with sophisticated closed-loop degreasers capable of achieving an ECEL have access to 1-BP
- Recordkeeping requirements include maintenance of normal business records and records related to WCPP requirements, monitoring, and compliance
- Downstream notification of the prohibitions would be carried out through Safety Data Sheet updates
 - Spreads awareness throughout the supply chain of the restrictions on 1-BP under TSCA and provides information to commercial end users about timeframes for allowable uses

Alternative Regulatory Actions Considered

- The primary alternative regulatory action differs from the proposed regulatory action by:
 - Proposing prescriptive controls instead of WCPP for 2 COUs
 - Industrial and commercial use as a solvent in open-top and in-line batch vapor degreasing
 - Industrial and commercial use as a solvent in closed-loop vapor degreasing
 - Including longer compliance timeframes (take effect 6 months later)
- Second alternative regulatory action: Prohibition (36-months without supply chain stagger)

Proposed Compliance Dates

Regulatory Requirement	Proposed time until requirement is effective after the publication date of the final rule
Prohibition	6 months for manufacturers (including import) 9 months for processors 12 months for distributing to retailers 15 months for all distributors (including retailers) 18 months for industrial and commercial users
WCPP	6 months for initial monitoring, (*33 months) 9 months to institute a training program (*36 months) 9 months to establish a regulated area (*36 months) 9 months to ensure that no person is exposed above the ECEL (*36 months) 9 months to provide PPE (if needed) (*36 months) 12 months to establish an exposure control plan (*36 months)
Prescriptive Controls	6 months (*36 months)
Self Certification	At time of purchase

*Timeline for Federal agencies and Federal contractors acting for or on behalf of the Federal Government

Benefits of Proposed Rule

- Would address unreasonable risks for consumers and workers and provide regulated community with confidence in a protected and healthier workforce
- Ensures the unreasonable risk is adequately addressed with workplace protections while allowing for important uses of 1-BP to continue, including:
 - In vapor degreasing, aerospace and defense applications

Request for Comments

Requesting comments and substantiative information regarding several topics, including:

- The Workplace Chemical Protection Program (WCPP) and its various components (e.g., ECEL, restricted areas, monitoring frequency)
- Timeframes for implementation of the requirements
- Specific engineering or administrative controls that could address the unreasonable risk
- Feasibility of alternatives to 1-BP and their availability
- Timeframes for prohibitions for any uses that are currently proposed to be prohibited
- The need for and associated costs of ambient air monitoring or facility emissions source monitoring to prevent inadvertent releases associated with WCPP compliance
- Whether to include a regulatory threshold limit of 1-BP in formulations

Types of Information that Best Inform Comments

Potentially useful information for comments should include relevant data from the last 20 years.

- Descriptions of commercial worker activities and associated sources of exposure
- Process emission factors
- Product formulation information
- Relevant unpublished data

Next Steps

Process Step	Date
Publication of 1-BP proposed rule in docket (EPA-HQ-OPPT-2020-0471) and open comment period	August 8, 2024
Closure of comment period: EPA will review and consider new information submitted	September 23, 2024
Publication of 1-BP Final Rule (estimated)	2025
Prohibition and WCPP for most uses would be in full effect 12 months after date of the final rule (<i>36 months for Federal agencies and Federal contractors acting for or on behalf of the Federal Government</i>) (estimated)	2026

Additional Resources

- Risk management for 1-BP: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-1-bromopropane-1-bp>
- 1-BP risk evaluation, supplemental risk evaluation materials, and proposed rulemaking are in dockets EPA-HQ-OPPT-2019-0235, EPA-HQ-OPPT-2016-0741, and EPA-HQ-OPPT-2020-0471 respectively, and may be accessed through www.regulations.gov
- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Chemicals Undergoing Risk Evaluation under TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>

Contact Us

- All comments in order to be considered should be submitted to the docket at [EPA-HQ-OPPT-2020-0471](https://www.epa.gov/dockets/oppt-2020-0471)
- For general questions, email EPA at 1BP_TSCA@epa.gov