Updates on EPA's Activities on Solvents under the Toxic Substances Control Act (TSCA)

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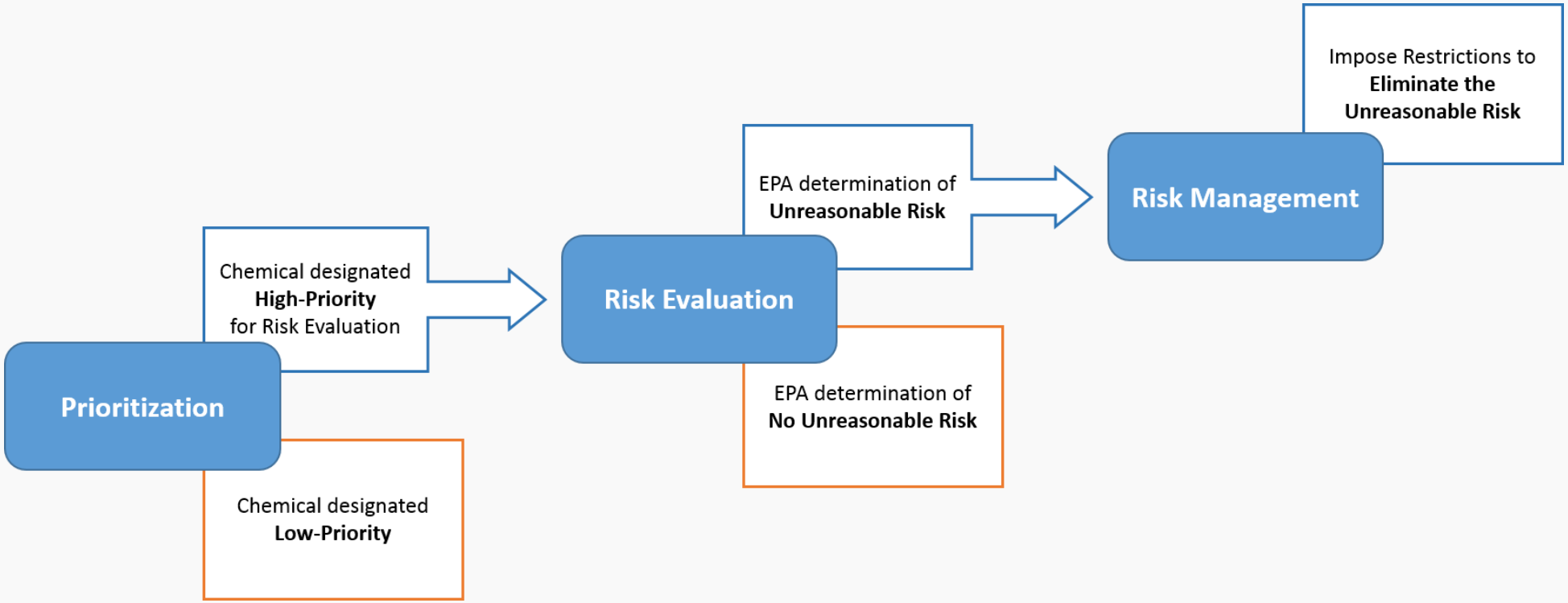
Agenda

- Background on Risk Evaluations under TSCA
- Background on Risk Management under TSCA
- Risk Management for Occupational Exposures
- Tips on Stakeholder Engagement
- Sources for Additional Information

Process to Evaluate Risks of Existing Chemicals



Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical to determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
  - Without consideration of cost or other non-risk factors
  - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3 to 3.5 years

Initial Chemicals with Risk Evaluations

Methylene Chloride	n-Methylpyrrolidone
1-Bromopropane	Perchloroethylene
Pigment Violet 29	Trichloroethylene
Asbestos (Two parts)*	1,4-Dioxane
Carbon Tetrachloride	HBCD

*Risk evaluation for legacy uses of asbestos currently ongoing

Chemicals Undergoing Risk Evaluation

- p-Dichlorobenzene
- **1,2-Dichloroethane**
- **trans-1,2- Dichloroethylene**
- o-Dichlorobenzene
- **1,2-Dichloropropane**
- **1,1,2-Trichloroethane**
- **1,1-Dichloroethane**
- Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2- dibutyl ester)
- Butyl benzyl phthalate (BBP) - 1,2-Benzene-dicarboxylic acid, 1- butyl 2(phenylmethyl) ester
- Di-ethylhexyl phthalate (DEHP) - (1,2-Benzene- dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester)
- Di-isobutyl phthalate (DIBP) - (1,2-Benzene-dicarboxylic acid, 1,2- bis-(2methylpropyl) ester)
- Dicyclohexyl phthalate
- 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)
- Tris(2-chloroethyl) phosphate (TCEP)
- Phosphoric acid, triphenyl ester (TPP)
- Ethylene dibromide
- 1,3-Butadiene
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)
- Formaldehyde
- Phthalic anhydride

Policy Changes for TSCA Risk Evaluations

- Last year, EPA announced policy changes for risk evaluations on the first 10 chemicals and risk evaluations going forward

- As a result:
  - EPA will make the determination of unreasonable risk for the whole chemical where appropriate rather than making separate determinations for each condition of use
  - EPA will continue to assess and analyze each condition of use with and without PPE, but the unreasonable risk determination will not assume PPE is always provided or properly used; rather, PPE use will be considered during the risk management phase
  - EPA will expand consideration of exposure pathways (*e.g.*, ambient air and drinking water), and consider exposures to fenceline communities
  - EPA issued revised risk determinations for PV29, HBCD, methylene chloride, perchloroethylene, carbon tetrachloride, trichloroethylene, 1-bromopropane and n-methylpyrrolidone

Rulemakings Expected in 2023

- Asbestos (Part I) final rule anticipated late 2023
- OMB review is ongoing for Methylene Chloride & Perchloroethylene proposed rules
- In addition, proposals are expected before the end of 2023 for Carbon Tetrachloride, Trichloroethylene, 1-Bromopropane, & N-Methylpyrrolidone
- Risk management for 1,4-Dioxane is pending supplemental risk evaluation

Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on characterizing the effects of the regulation and alternatives
- Input from stakeholders is critical to the process

TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
  - Distributors
  - Manufacturers and processors (e.g., formulators)
  - 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 consumer

TSCA Section 6(a) Regulatory Options

- 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.

TSCA Section 6(c)

In promulgating any rule under TSCA section 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:

- The effects and magnitude of exposure to human health
- The effects and magnitude of exposure to environment
- The benefits of the chemical for various uses
- The reasonably ascertainable economic consequences of the rule, including consideration of:
  - The likely effect on the national economy, small business, technological innovation, the environment, and public health
  - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives
  - The cost effectiveness of the proposed regulatory action and one or more primary regulatory alternatives

TSCA Section 6(c)(2)(C)

- Consideration of Alternatives
  - Based on the statement of effects, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, 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.
- Information on alternatives will be available in the Economic Analysis and Alternatives Analysis for each chemical in the rulemaking docket

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 (*e.g.*, OSHA, NIOSH, and CPSC) to promote a consistent approach, facilitate compliance, and avoid duplicative requirements
- Extensive dialogue will help people understand risk evaluation findings, the TSCA risk management process, and available options 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

Existing Chemical Exposure Limits

- ECELs are:
  - Risk-based
  - Specific to each chemical
  - Typically based on the most sensitive inhalation endpoint driving unreasonable risk
- Unreasonable risk is addressed at or below the ECEL

Existing Chemical Exposure Limits

- Methylene Chloride
  - 8 HR-TWA: 2 ppm
  - 15-minute TWA: 16 ppm
  - Docket: EPA-HQ-OPPT-2020-0465
- PCE
  - 8 HR-TWA: 0.14 ppm
  - Docket: EPA-HQ-OPPT-2020-0720
- Carbon Tetrachloride
  - 8 HR-TWA: 0.03 ppm
  - Docket: EPA-HQ-OPPT-2020-0592
- TCE
  - 8 HR-TWA: 4.0 ppb
  - 8 HR-TWA: 1.1 ppb
  - Docket: EPA-HQ-OPPT-2020-0642
- 1-BP
  - 8 HR-TWA: 0.05 ppm
  - Docket: EPA-HQ-OPPT-2020-0471
- Asbestos (Chrysotile)
  - 8 HR-TWA: 0.005 fibers/cc
  - Docket: EPA-HQ-OPPT-2021-0057

Risk Management Approaches

- Workplace Chemical Protection Plan (WCPP):
  - Includes a proposed inhalation exposure limit, monitoring, recordkeeping requirements, and requirements to prevent direct dermal contact
  - Provides flexibility for preventing exceedances of the identified EPA exposure limit and preventing direct dermal contact
  - Aligns with the existing OSHA requirements wherever possible

Risk Management Approaches cont.

- Workplace protections apply to certain conditions of use
- EPA considers multiple factors in deciding risk management for industrial and commercial conditions of use
- Uncertainty regarding ability to comply with an ECEL or preventing direct dermal contact can influence whether a condition of use is considered to be one that would be a candidate for WCPP or whether prohibition is considered.
- In this way, EPA intends to set strong, but achievable, worker protection standards.

Risk Management Approaches cont.

- Consumer uses can pose severe risks and in many cases alternatives are available
  - Approaches may involve prohibitions at the manufacturing, processing, and distribution in commerce stage of the supply chain to address unreasonable risk associated with consumer uses.
  - For some conditions of use, changes in the weight fraction of the chemical in the formulation maybe utilized.

Tips on Engaging in TSCA Implementation

- Be familiar with the processes and requirements in TSCA
- Keep current on EPA actions, sign up for updates through the OPPT Listserv at https://www.epa.gov/chemicals-under-tsca
- Engage with EPA early, starting with prioritization
- Do not wait for risk management to research chemicals in your supply chain--understand their functionality, exposure scenarios, possible alternatives, and whether their use is essential
- Comment during the comment periods, participate in consultations, and seek meetings to engage with EPA

Tips on Engaging in TSCA Implementation

PRE-PRIORITIZATION	PRIORITIZATION	RISK EVALUATION	RISK MANAGEMENT
- Agency outreach to understand conditions of use - Information Gathering – Voluntary, Section 4, Section 8, CDR, TDR - Refinement of the Risk Evaluation/Problem Formulation		- Data refinement - Peer review of methods or approaches	- Consultations – Federalism, Tribal, Small Business - Site visits - Direct communication

Tips on Engaging in TSCA Implementation

- EPA is particularly interested in information on:
  - Effective methods for addressing unreasonable risks
  - Necessary performance certifications for particular chemicals
  - Information on effective exposure controls, including engineering and administrative controls
  - Uses that have been phased out or can be phased out
  - Safe and effective alternatives

Additional Information

- 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
  - Website includes links to dockets that have more information about each chemical
- Chemical Data Reporting (CDR): www.epa.gov/cdr
- Contact information for Ingrid Feustel: Phone number 202-564-3199; email Feustel.Ingrid@epa.gov