

# **TOXIC SUBSTANCES CONTROL ACT:** ***Overview***

**Susanna W. Blair and Ryan Schmit**

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



# Overview of Presentation

- Background on TSCA
- 2016 Amendments
- Existing Chemicals
  - Prioritization
  - Risk Evaluation
  - Risk Management
- New Chemicals
- Confidential Business Information



# Background on TSCA

- Signed into law in 1976
- 62,000 chemicals in commerce
- “Unreasonable risk” determination required a risk and cost/benefits analysis
- 1991 5th Circuit case interpreting TSCA Section 6
  - Overturned EPA’s ban of most uses of asbestos
  - Set high bar for banning or regulating existing chemicals
- For nearly 30 years, EPA largely ceased using TSCA Section 6
- Patchwork of state chemical regulations



# 2016 TSCA Amendments

- “The Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act”
  - Amends and updates the Toxic Substances Control Act (TSCA)
  - Signed by the President on June 22, 2016
  - Effective immediately
- Significance
  - First major update to TSCA in 40 years (1976)
  - Passed with overwhelming bipartisan support in both the U.S. House and Senate
  - Received support from chemical industry and downstream users of chemicals, NGOs, and other stakeholders



## 2016 Amendments: Existing Chemicals

- EPA must evaluate existing chemicals – clear and enforceable deadlines
- Chemical assessment is risk-based; without consideration of costs or other non-risk factors
- Persistent, Bioaccumulative and Toxic Chemicals: Fast-track to address certain PBT chemicals already on TSCA Work Plan
- Must consider risks to potentially exposed or susceptible subpopulations determined to be relevant to the evaluation
- Required to address unreasonable risks identified in risk evaluation
- Expanded authority to require development of chemical information



# Framework Rules

- EPA was required to promulgate rules (collectively, the “Framework Rules”) for procedures EPA uses to implement, and align, EPA’s chemical management program with the new requirements:
  - Fees Rule\*
  - **Active/Inactive Inventory Reporting Rule**
  - **Prioritization Rule**
  - **Risk Evaluation Rule**

\*No statutory deadline for Fees Rule

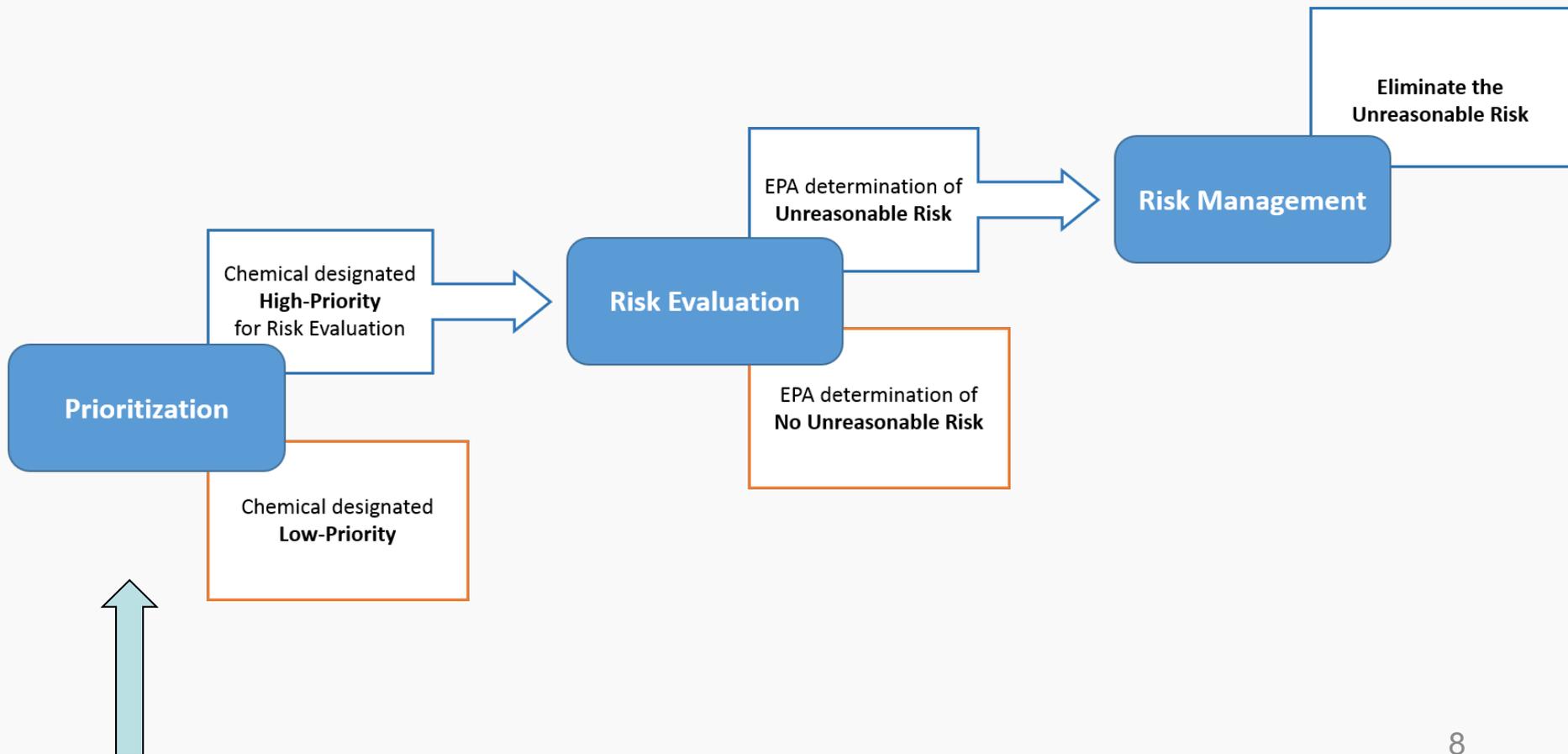


# TSCA Inventory for Active/Inactive Chemicals

- Industry had to report on the chemicals they manufactured, and chemicals they processed (in previous 10 years)
  - Chemicals are designated as *active* or *inactive*
- The list of ~40,000 substances is on the web and is searchable by chemical name or CAS Registry Number.



# Evaluating Risks of Existing Chemicals





# Prioritization

- EPA has established a risk-based screening process and criteria for designating a chemical substance as either:
  - High-Priority Substance, OR
  - Low-Priority Substance
- The process and criteria were specified in TSCA:
  - 9-12 month process
  - 2 public comment periods
  - Preferences for chemicals on the 2014 Update to the TSCA Work Plan
  - Chemicals must be screened against specific criteria (e.g., Hazard, Exposure, Persistence, Bioaccumulation, Toxicity, Cancer)



# Prioritization

## Storage of the chemical substance near significant sources of drinking water

- EPA considered possible adverse effects that could result from an accidental one-time-high-volume release of a substance, and from a slower release over time.
- EPA relied on the chemical's potential human health hazards and environmental fate properties as they relate to the potential for the chemical substance to enter a drinking water source.
- EPA chose this approach for analysis as data regarding storage are not tracked under TSCA and are not generally available.
- EPA also investigated whether the chemical was monitored for and detected in a range of environmental media under other federal statutes and regulations. EPA assumed that if a chemical is regulated under the National Primary Drinking Water Regulations or the Clean Water Act, there is a potential human health hazard from a potential release near a significant source of drinking water.



## Prioritization Outcomes

- ***High-priority substance*** — may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a “potentially exposed or susceptible subpopulation”, without consideration of costs or other non-risk factors
- ***Low-priority substance*** — EPA concludes, based on information sufficient to establish, that the chemical does not meet the standard for high-priority

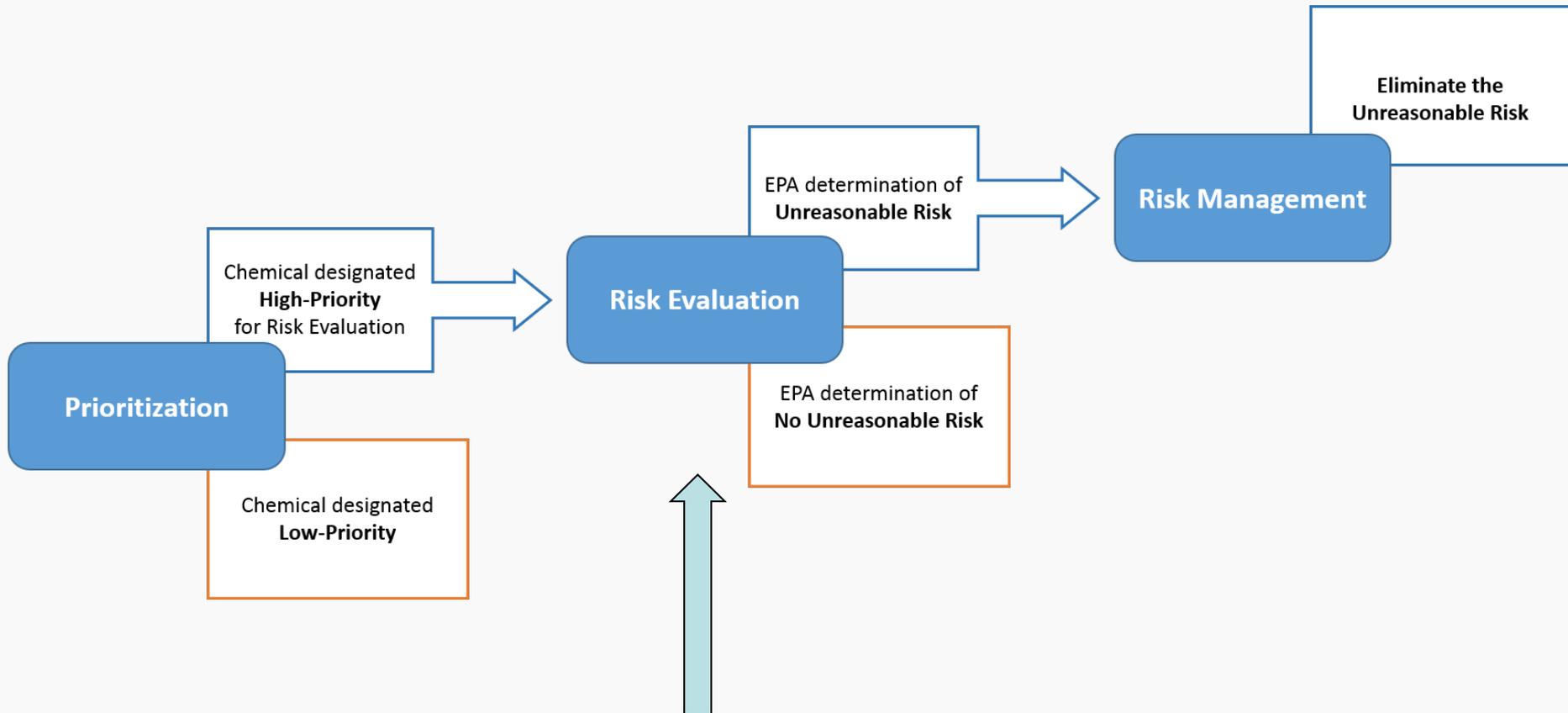


# Prioritization Actions

- EPA designated 20 high-priority substances for risk evaluation in December 2019
- EPA designated 20 low-priority substances in February 2020
  - EPA proposed low-priority designation with two 90-day comment periods prior to finalization
  - Used the Safer Chemical Ingredients List (SCIL) as a starting point
- Considerations for identifying high-priority candidates
  - At least 50% must come from the 2014 Update to the TSCA Work Plan
  - Necessity of sufficient quantity and quality of information
  - Considerations of Agency priorities – EPA Program offices were surveyed prior to finalizing candidate list



# Evaluating Risks of Existing Chemicals





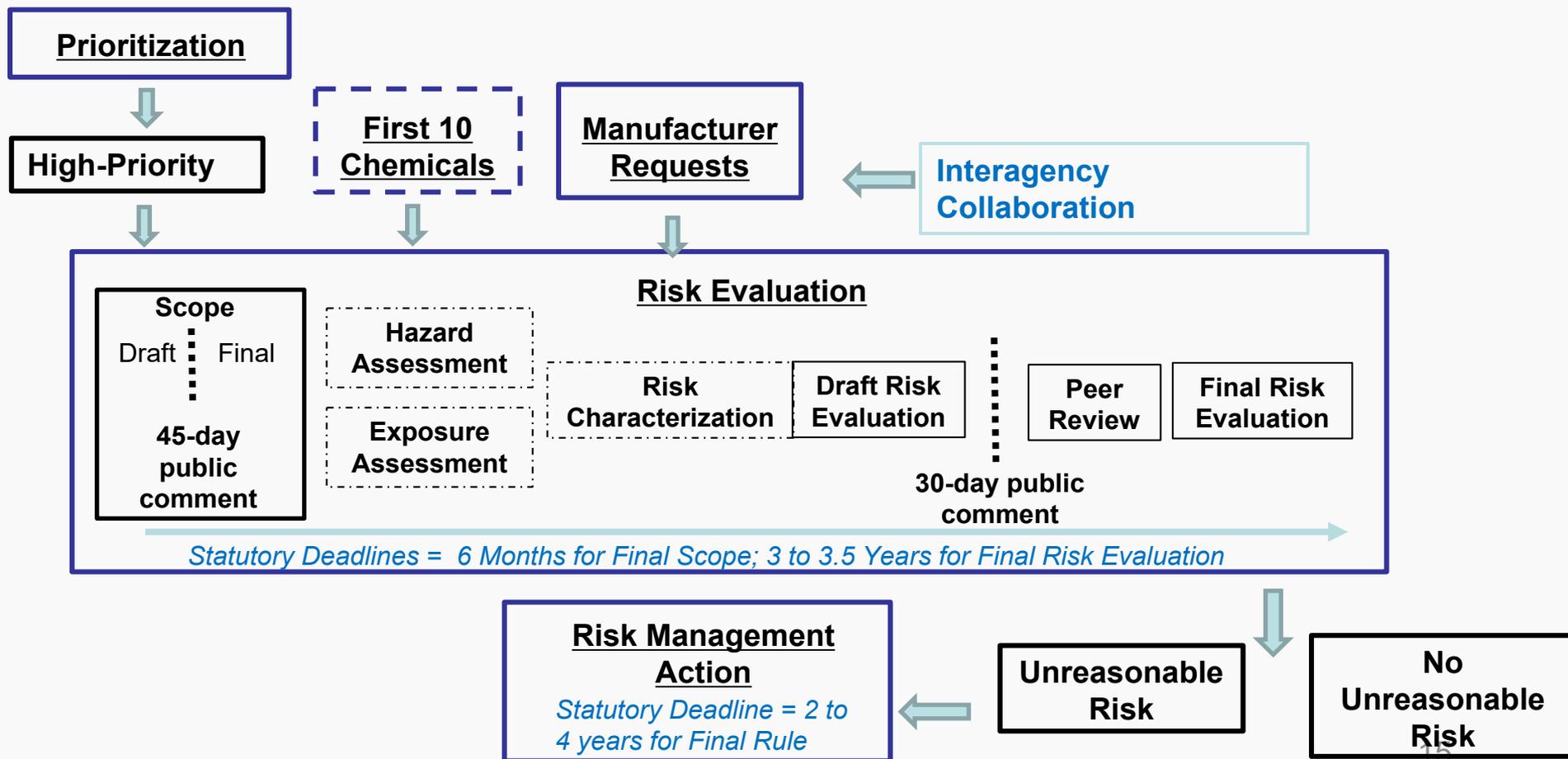
# Risk Evaluation

## *Statutory Requirements*

- EPA must establish by rule a process for risk evaluation
  - Determine if a chemical presents an unreasonable risk of injury to health or the environment under 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
- This process must be completed within 3 – 3.5 years
- For each risk evaluation completed, EPA must designate a new high-priority chemical



# Risk Evaluation Process and Timeline





# Initial 10 Risk Evaluations

- The list of the initial 10 chemicals was published on Dec. 19, 2016

1, 4 Dioxane

1-Bromopropane

Asbestos

Carbon Tetrachloride

Cyclic Aliphatic Bromide Cluster  
(HBCD)

Methylene Chloride

N-Methylpyrrolidone

Pigment Violet 29

Trichloroethylene

Tetrachloroethylene

- Scope documents – June 22, 2017
- Problem Formulation documents – June 2018
- Draft Risk Evaluations – winter 2018-2019
- Final Risk Evaluations – June 2020 - present



## Next 20 Chemicals

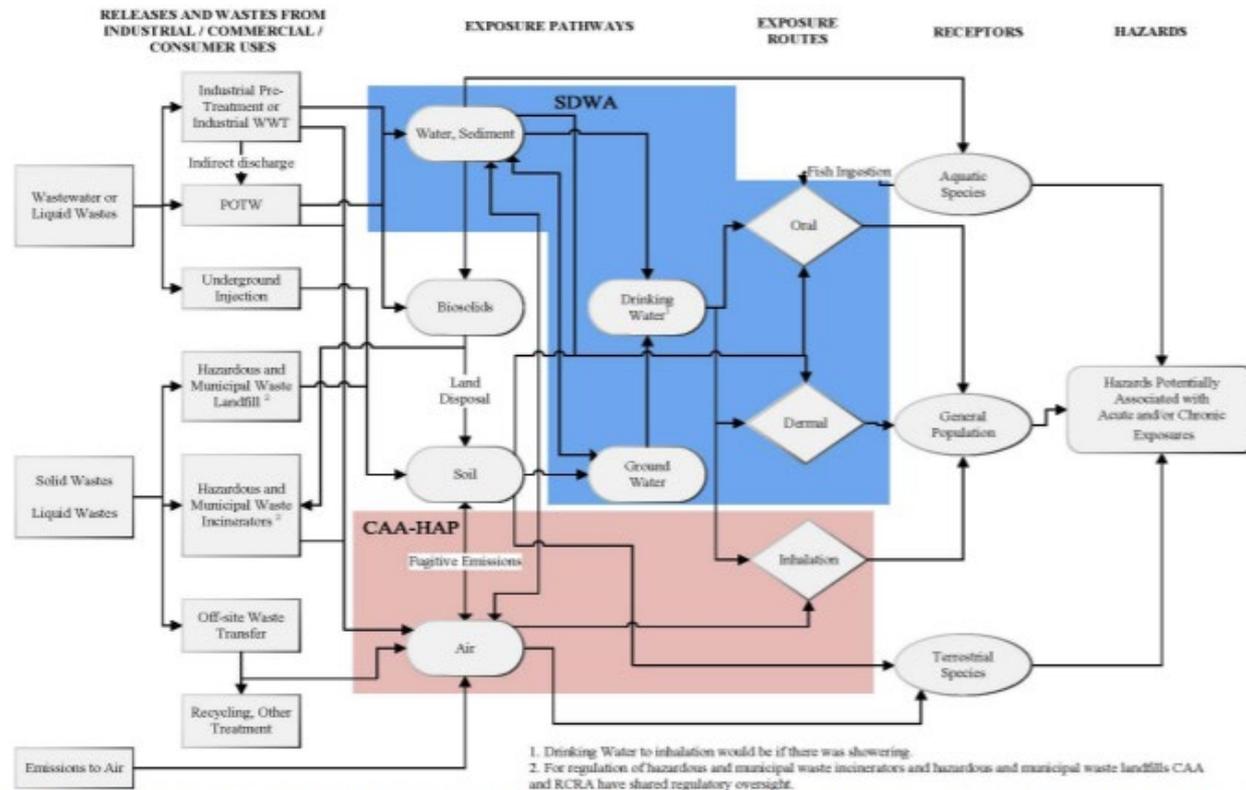
- TSCA required EPA to have 20 chemicals prioritized as high-priority by December 2019
- January 2020 – scoping began on the 20 high-priority chemicals
- April 2020 – draft scopes available
- Summer 2020 – publish final scopes



# Regulatory Nexus

- TSCA
- CAA – Clean Air Act
- SDWA – Safe Drinking Water Act
- CWA – Clean Water Act
- RCRA – Resource Conservation and Recovery Act

# Conceptual Model (1,3-Butadiene)



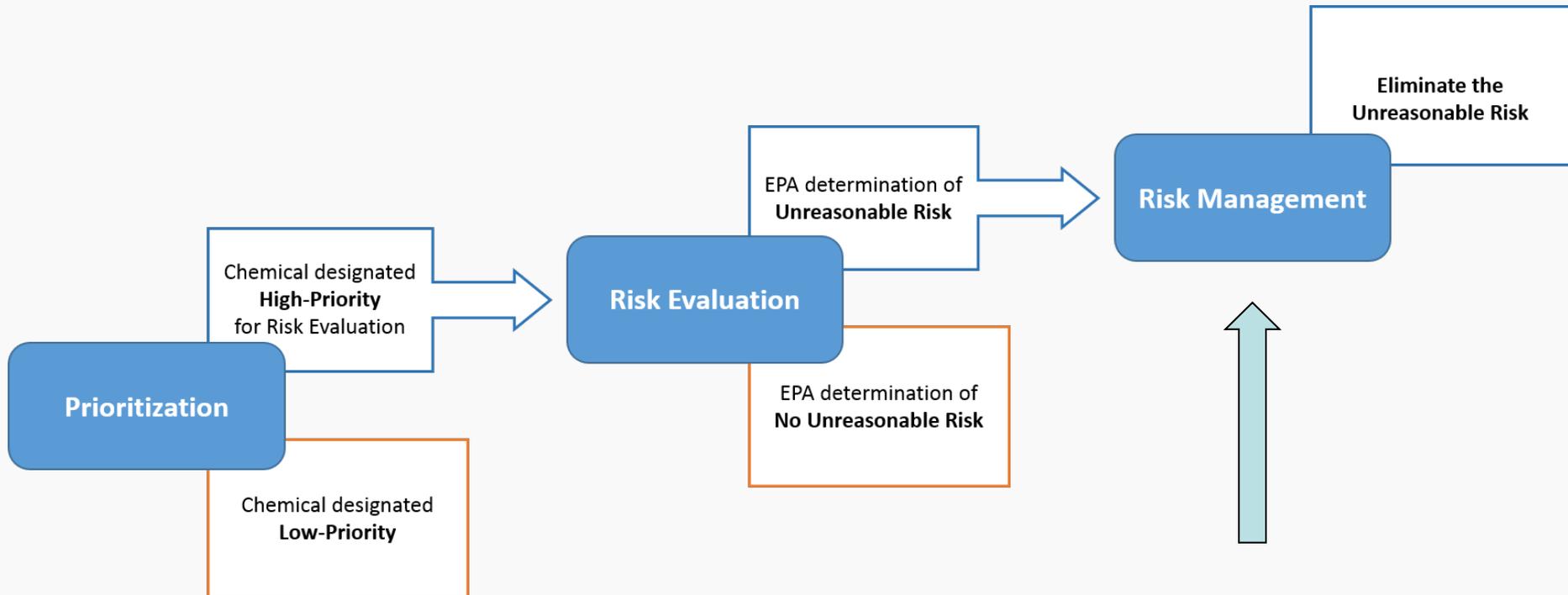
**Figure 2-10. 1,3-Butadiene Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)**

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial and commercial uses of 1,3-butadiene showing the environmental statutes covering those pathways. Notes:

- Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to a Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.
- Receptors include PESS (see Section 2.5).



# Evaluating Risks of Existing Chemicals





# TSCA Section 6(a) Regulatory Options

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



# TSCA New Chemicals Program

Program is designed to ensure that new chemicals do not present an unreasonable risk to human health and the environment

- Anyone who plans to manufacture (or import) a new chemical substance must provide EPA with notice - a Premanufacture Notice (PMN)
- EPA must review and evaluate new chemicals (or significant new uses of existing chemicals) and make a determination before those chemicals can enter the market
- Review must be completed within 90 days, with ability to extend 90 days
- Submitters may request a voluntary suspension of the review process to provide additional information and/or to mitigate any risks identified in the review process.
- If risks are identified, EPA must impose restrictions or prohibitions on the manufacturing, processing or use of the chemical to mitigate the risks



## 2016 Amendments: New Chemicals

- Determination on new chemicals or significant new uses of existing chemicals, before those chemicals can enter the market
- Assessment of chemicals under their “conditions of use”
  - Intended, known, reasonably foreseen circumstances of manufacture, processing, distribution in commerce, use and disposal



## ***TSCA 5(a)(3) Determinations***

- Presents an unreasonable risk of injury to health or the environment
- Available Information is insufficient to allow the Agency to make a reasoned evaluation of the health and environmental effects
- In the absence of sufficient information, may present an unreasonable risk of injury to health or the environment
- Produced in substantial quantities and either enters or may enter the environment in substantial quantities or significant or substantial human exposure to the chemical; or
- Not likely to present an unreasonable risk of injury to health or the environment



# Confidential Business Information

- Requirements provide greater public access to critical chemical information
  - Substantiation requirements and EPA review
  - System for assigning a unique identifier when chem ID is claimed as CBI – June 22, 2018
  - Guidance on generic names – June 22, 2018
  - Guidance on sharing of TSCA CBI with state, tribal and local governments; health and environmental professionals; and emergency personnel – June 22, 2018



## For More Information

- *General TSCA:* <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- *Evaluating Existing Chemicals:* <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals>
- *Evaluating New Chemicals:* <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epas-review-process-new-chemicals>