



TOXIC SUBSTANCES CONTROL ACT: ***Section 6 Implementation***

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National Small Business Environmental Assistance Program
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Meeting Purpose and Agenda

- **Purpose:**
 - Provide background information on TSCA section 6 relevant to small businesses and technical providers
 - Describe upcoming opportunities for engagement and what you should expect
- **Agenda:**
 - Background on TSCA and 2016 Amendments
 - Existing Chemicals
 - Prioritization
 - Risk Evaluation
 - Risk Management
 - Regulatory Options and Considerations
 - Risk Management Principles and Transparency
 - Stakeholder Input and Opportunities for Engagement



Background on TSCA

- Signed into law in 1976
- “Unreasonable risk” determination involved a 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 21st 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

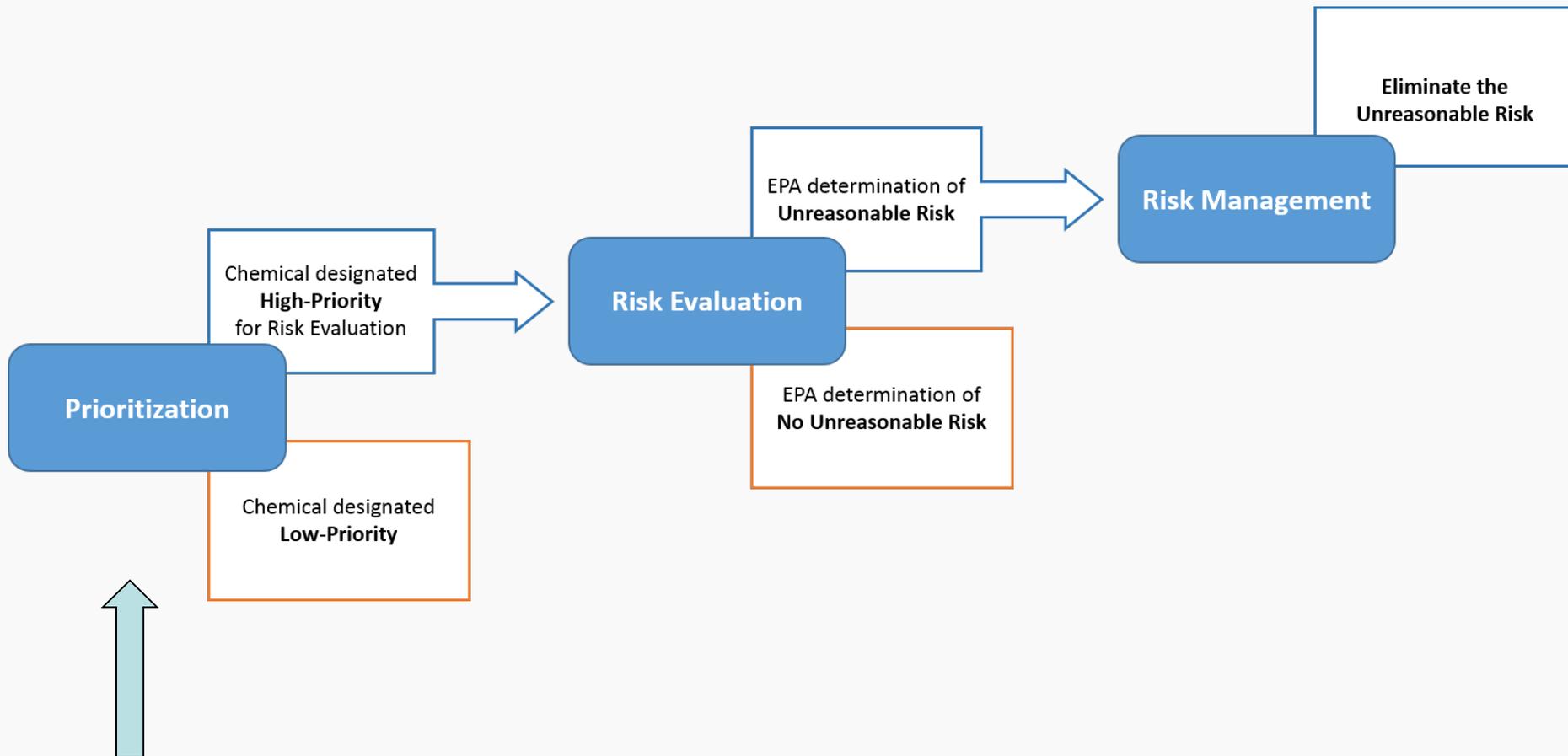


Amended TSCA: Changes Related to Existing Chemicals

- Mandatory duty on EPA to evaluate existing chemicals – clear and enforceable deadlines
- Chemical assessment is risk-based; without consideration of costs or other non-risk factors
- EPA must consider risks to potentially exposed or susceptible subpopulations determined to be relevant to the evaluation
- Unreasonable risks identified in risk evaluation must be addressed
- Expanded authority to more quickly require development of chemical information when needed



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- to 12-month process
 - 2 public comment periods (at initiation of the process, and at proposed designation of a chemical substance as high or low priority)
 - 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 Outcomes

- ***High-priority substance*** — EPA concludes, without consideration of costs or other non-risk factors, that the chemical 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”
- ***Low-priority substance*** — EPA concludes, based on information sufficient to establish, that the chemical does not meet the standard for high-priority

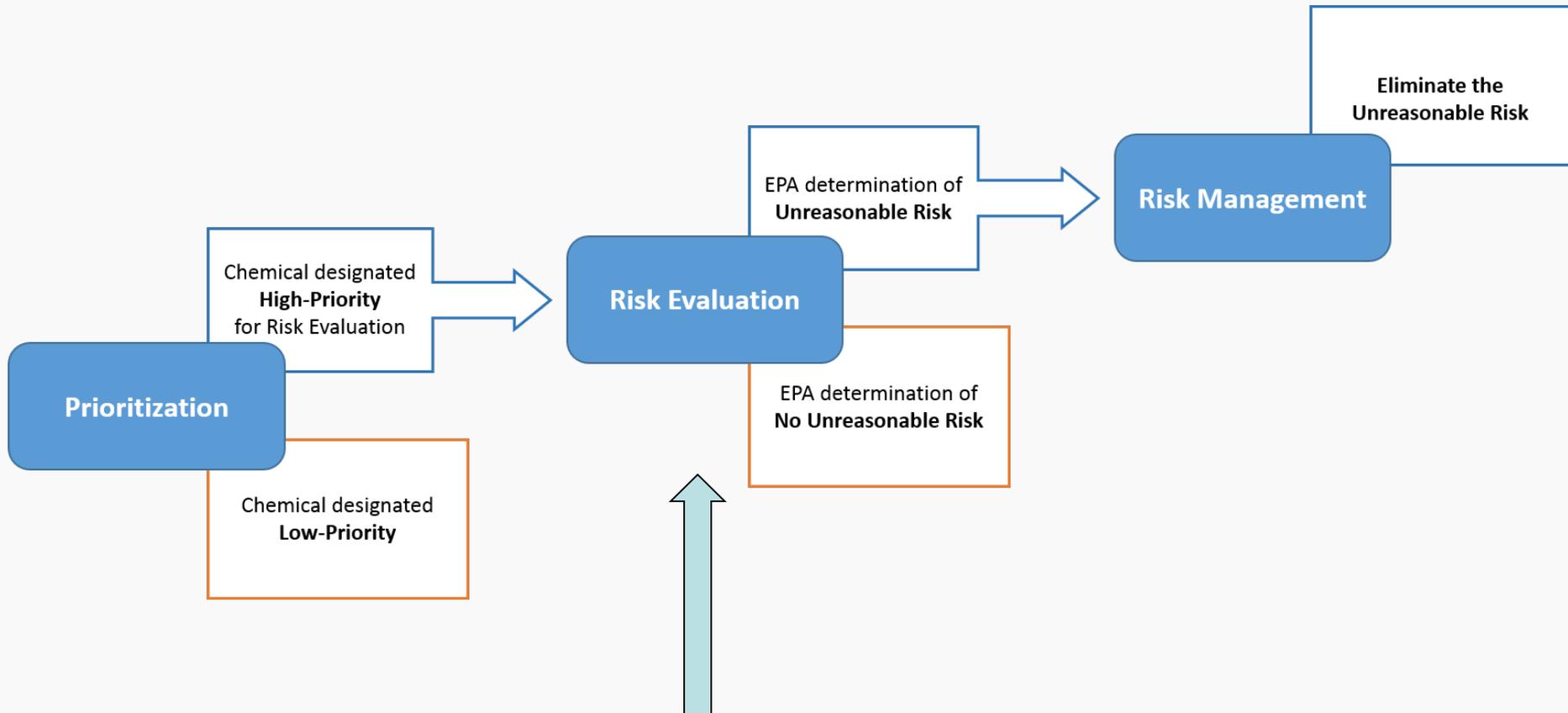


Prioritization Actions

- EPA designated 20 high-priority substances for risk evaluation in December 2019
- EPA designated 20 low-priority substances in February 2020
- Considerations for identifying high-priority candidates
 - At least 50% must come from the 2014 Update to the TSCA Work Plan, and preference must be given to chemicals on the Work Plan with certain characteristics
 - 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





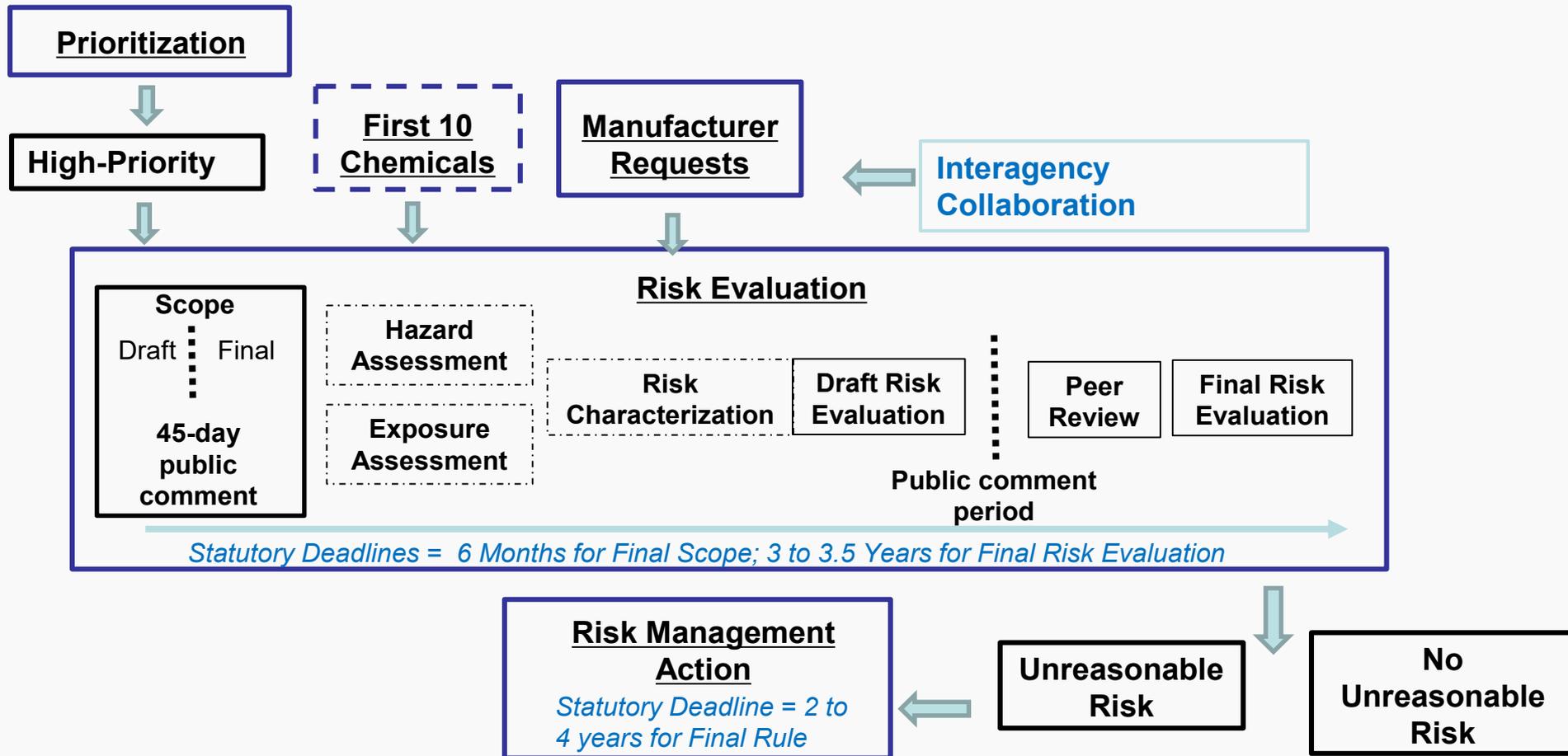
Risk Evaluation

Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the 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
- TSCA requires a risk evaluation 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





Importance of Information and Dialogue on TSCA Chemicals

- Manufacture (including import), processing, distribution, use, disposal, and release information is important for understanding conditions of use
- Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed, in commerce, used, or disposed of
- Detailed use information helps EPA understand how the chemical is used, the amounts of a chemical used, how the chemical is distributed in commerce, and the exposure scenarios for the use
- Risk evaluations require complex decisions that are best informed by complete and high-quality information



Importance of Information (continued)

- Receiving information early in the prioritization and risk evaluation processes is most helpful to ensuring an expeditious evaluation that does not require analytical rework
- Comprehensive hazard and exposure information, information on potentially exposed or susceptible subpopulations, and information that is relevant to specific risks of injury to health or the environment, improves accuracy of risk evaluations.
- See [Submitting Information to Inform Prioritization and Risk Evaluation](#)



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 of each risk evaluation – June 22, 2017
- Problem Formulation documents – June 2018
- Draft Risk Evaluations – winter 2018-2019
- Final Risk Evaluations – Jun 2020 - present

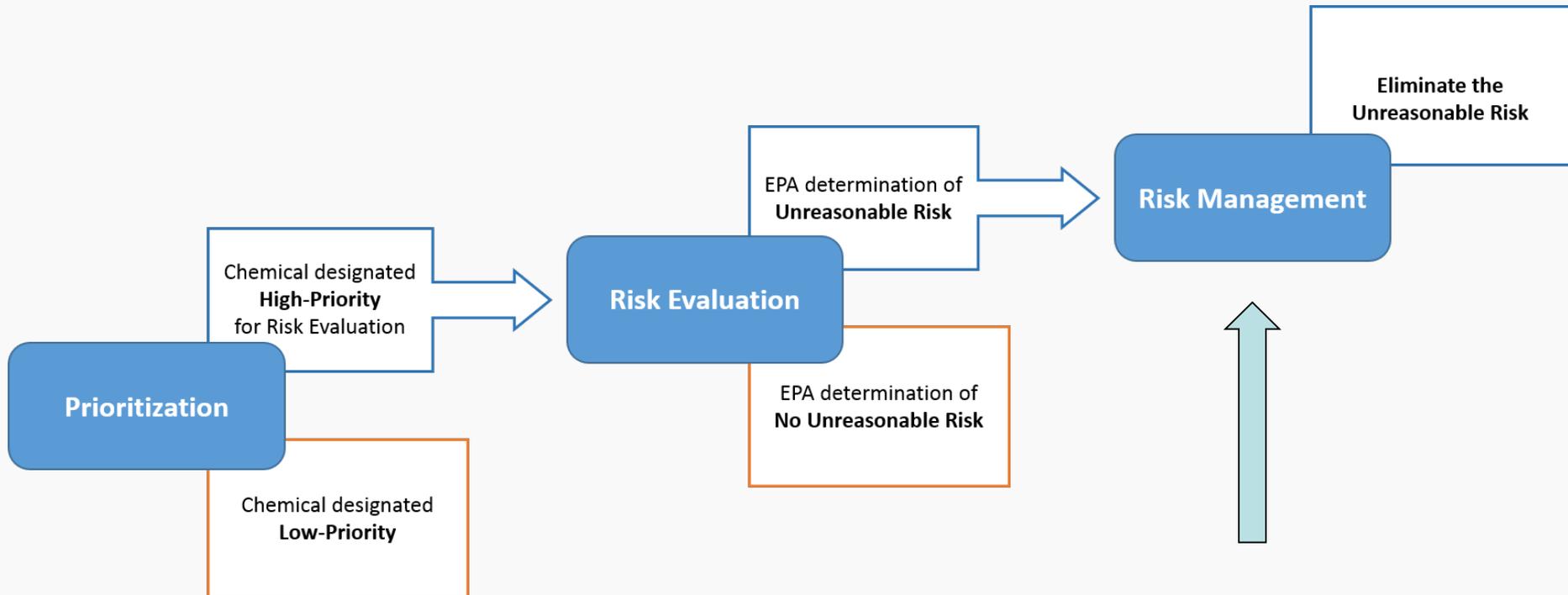


Next 20 Chemicals

- TSCA required EPA to have 20 chemicals prioritized as high-priority by December 2019
- January 2020 – Risk evaluation process began with outlining the scope of the risk evaluations for the 20 high-priority chemicals
- April 2020 – Draft scope documents published for public comment
- Summer 2020 – Publish final scope for each risk evaluation



Evaluating Risks of Existing Chemicals





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 section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
 - Proposed rule one year after risk evaluation
 - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process
- Substantial increase in regulatory activities expected due to unreasonable risk findings across diverse conditions of use



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) 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.
 - Can advise or recommend, but can regulate at the manufacturing, processing or distribution level in the supply chain for consumer use



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 PPE at occupational sites
- Require manufacturers, processors, and distributors to maintain ordinary business records



Examples of Regulatory Options

- 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 set an Existing Chemical Exposure Limit (ECEL)
- Require monitoring of exposures in occupational settings
- Require a hazard communication program to educate workers on label directions, warnings, etc.
- Prohibit or regulate manner of commercial disposal



TSCA Section 6(c)

- In promulgating any rule under 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; and
 - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives.



Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking
- EO 13771: Reducing Regulation and Controlling Regulatory Costs



Stakeholder Input to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering, and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent



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 will help people understand 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



Coordination and Engagement

- In developing risk management approaches EPA:
 - Consults with stakeholders to learn about condition of use, existing engineering, personal protection equipment (PPE), available alternatives, or other programs to tailor effective risk management solutions
 - Conducts site visits to obtain detailed information on existing practices in manufacturing and chemical use processes
 - Develops an extensive network among all stakeholders to ensure regulatory approaches are fully informed and based on current conditions



Opportunities for Engagement

- One-on-one meetings
- Webinars providing overviews of final risk evaluations and unreasonable risk determinations
 - Methylene chloride: September
 - 1-Bromopropane: September
 - Other chemicals following their final risk evaluations
- Consultations seeking targeted feedback, with:
 - States and local governments
 - Tribes
 - Small businesses
 - Environmental justice organizations and communities



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>
- *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>