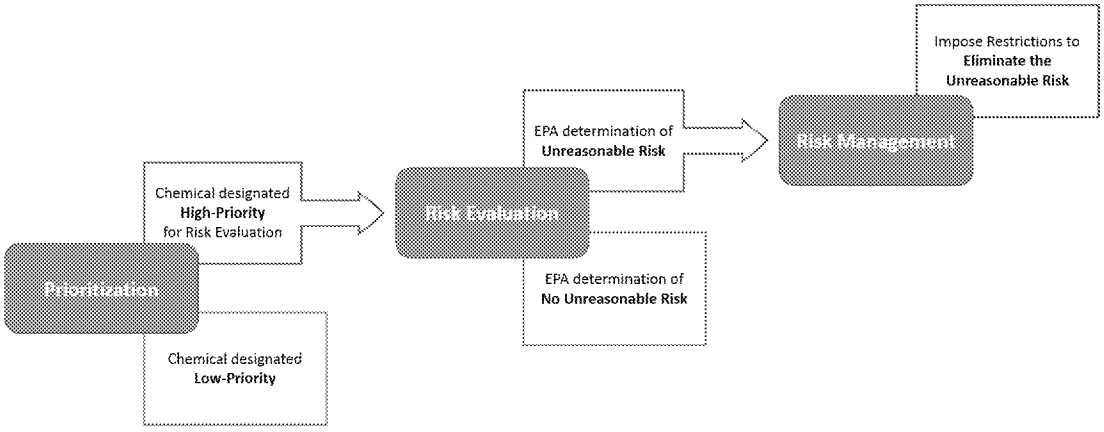
TOXIC SUBSTANCES CONTROL ACT:
Risk Evaluation Implementation

Tala R. Henry, PhD
Director, Risk Assessment Division
Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency
February 5, 2018

Evaluating Risks of Existing Chemicals



The New Law

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
- 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
- Unreasonable risks identified in risk evaluation must be addressed
- Expanded authority to more quickly require development of chemical information when needed

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
- By December of 2019, EPA must have initiated 20 high-priority chemicals for risk evaluation
  - Additional risk evaluations may come from manufacturer requests

Risk Evaluation
Statutory Requirements

- **First 10** Chemicals for Risk Evaluation – Announced December 19, 2016
- **Scope** –Publish within 6 months of initiation – Published June 22, 2017
  - Must identify hazards, exposure, conditions of use, potentially exposed or susceptible subpopulation(s) the EPA expects to consider
- **Draft Risk Evaluation**
  - Hazard Assessment – identification of types of hazards to human health and/or the environment
  - Exposure Assessment – the duration, intensity, frequency, and number of exposures under the conditions of use
  - Risk Characterization – integration of hazards and exposure into estimates of risk
  - Determination of Unreasonable Risk – does or does not present an unreasonable risk
  - Peer review – all evaluations will be peer reviewed
  - Publication and 30 day public comment period

5

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

By December of 2019, EPA must have initiated 20 high- priority chemicals for risk evaluation
Additional risk evaluations may come from manufacturer requests

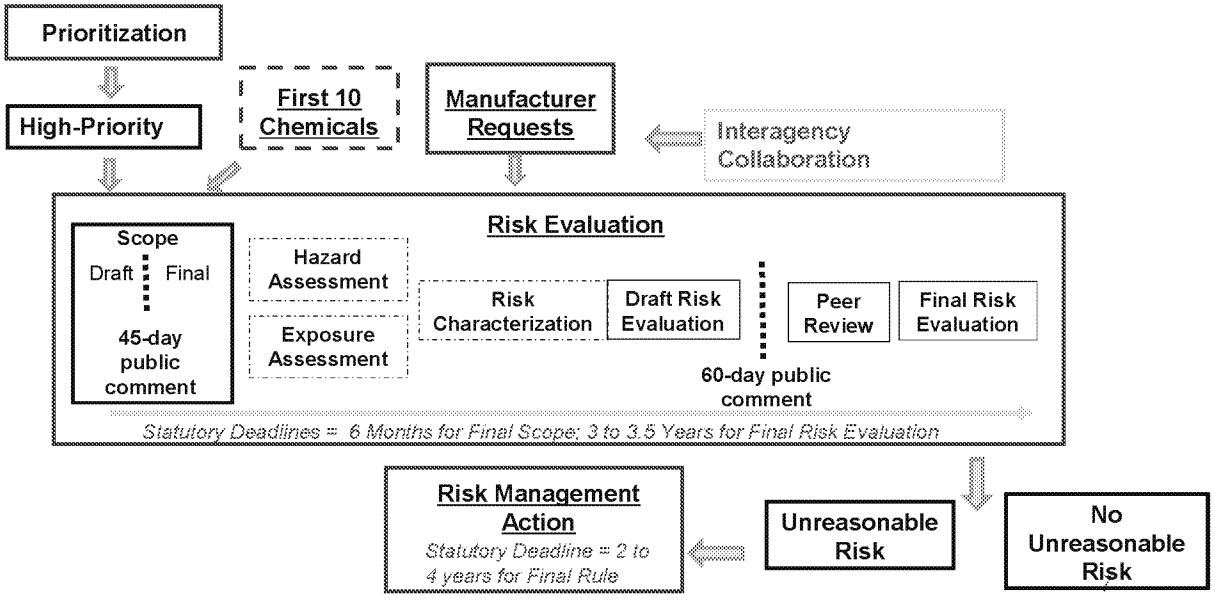
Initial 10 Risk Evaluations

- List of the initial 10 chemicals published on Dec 19, 2016

Asbestos	Methylene Chloride
1-Bromopropane	N-Methylpyrrolidone
Carbon Tetrachloride	Pigment Violet 29
Cyclic Aliphatic Bromide Cluster (HBCD)	Tetrachloroethylene
1,4-Dioxane	Trichloroethylene

- Scope documents published June 22, 2017
- Problem Formulation documents expected Spring 2018

Risk Evaluation Process and Timeline



Risk Evaluation
Statutory Requirements

- **Draft Risk Evaluation/Risk Characterization:**
  - Integrate and assess available information on hazards and exposures for the conditions of use, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations
  - Describe whether aggregate or sentinel exposures were considered, and the basis
  - Account for the likely duration, intensity, frequency & number of exposures under the conditions of use
  - Describe the weight of the scientific evidence for the identified hazard and exposure
  - Developed without consideration of cost or other non-risk factors
  - Publish in Federal Register
  - At least a 30-day public comment period

- **Final Risk Evaluation**
  - Complete within 3 years of initiation; with potential 6 month extension
  - Publish in Federal Register

Condition 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, use, or disposed of.
  - EPA generally does not view uses that are legacy uses and intentional misuse (e.g., purposeful inhalation) as conditions of use
- Statutory language for scope includes "that the Administrator expects to consider"
  - EPA may exclude from an individual risk evaluation some activities that are conditions of use (e.g., *de minimis* use that presents low risk)
- Risk determinations – A risk determination will be made for each use EPA includes in the risk evaluation
  - EPA may make early determinations on use(s) once statutory and regulatory requirements for a risk evaluation, including a peer review, are fulfilled

Best Available Science

- ***Best available science*** – science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)
  - Additionally, EPA will consider as applicable:
    - The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are **reasonable for and consistent with the intended use of the information**
    - The extent to which the information is **relevant for the Administrator's use in making a decision** about a chemical substance or mixture
    - The degree of **clarity and completeness** with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented
    - The extent to which the **variability and uncertainty** in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized
    - The extent of **independent verification or peer review** of the information or of the procedures, measures, methods, protocols, methodologies, or models

Taken from the SDWA and from TSCA section 26 requirements

Weight of the Scientific Evidence

Means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance

- Consistent with legislative history
- EPA did not codify definition of "systematic review"

Systematic Review

As defined by the Institute of Medicine systematic review "is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent"

Systematic Review

Key Elements of a systematic review:

- A clearly stated set of objectives (defining the question);
- Developing a protocol which describes the specific criteria and approaches that will be used throughout the process;
- Applying the search strategy criteria in a literature search;
- Selecting the relevant papers using predefined criteria;
- Assessing the quality of the studies using predefined criteria;
- Analyzing and synthesizing the data using the predefined methodology;
- Interpreting the results and presenting a summary of findings

Definitions (cont'd)

- ***Reasonably available information*** – information that EPA possesses or can reasonably generate, obtain, and synthesize for use, considering the [statutory] deadlines for completing the evaluation
  - includes confidential business information not available to the public

- ***Potentially exposed or susceptible subpopulation*** – group of individuals[…]who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly

Definitions (cont'd)

- ***Aggregate exposure*** – combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways
- ***Sentinel exposure*** – the exposure from a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures

Risk Characterization Summary

Consistent with 26(h), will contain:

- *Considerations regarding uncertainty and variability*.
- *Considerations of data quality*.
- *Considerations of alternative interpretations*.
- *Considerations for environmental risk evaluations*.

Manufacturer Requests

"The Administrator shall conduct and publish risk evaluations [...] that a manufacturer of the chemical substance has requested, in a **form and manner** and using the **criteria** prescribed by the Administrator"

- **Conditions of use** – Manufacturers may request a risk evaluation for only uses of interest. EPA will identify other conditions of use that warrant inclusion in the risk evaluation.
- EPA's process for granting/denying request
  - Public Notification of Receipt – within 15 days of receipt
  - EPA will identify any additional conditions of use for inclusion– 60 days
  - Public Notice and Comment (submitted request and any additional conditions of use to be considered) - open for 45 days
  - EPA's final decision – within 60 days after the end of the comment period. The manufacturer may withdraw or the risk evaluation will continue.
    - Total of 165 days from submission to grant/deny

Non-animal Testing Strategic Plan

To promote the development and timely incorporation of the new scientifically valid test methods and strategies that are not based on vertebrate animals – not later than 2 years after the day of enactment, **develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing** and provide information of equivalent or better scientific quality and relevance fro assessing risk of injury to health or the environment of chemical substances or mixtures.

Non-animal Testing Implementation

- In compliance with the statute, EPA is currently working to reduce and replace, to the extent practicable, the use of vertebrate animals in testing chemical substances as outlined in TSCA section 4(h).

- Where appropriate, to the extent practicable, and scientifically justified, EPA will require the development of information generated without the use of new testing on vertebrates in performing risk evaluation.

- Strategic Plan Development:
  - November, 2017: Public and invited expert meeting
  - Spring 2018: Draft Strategic Plan for public comment
  - Spring 2018: Public meeting on draft Strategic Plan
  - Strategic Plan by June 2018

Next Steps: Risk Evaluation Process

- **Problem Formulation:** Systematically identifies the major factors to be considered in the risk evaluation. Draws from regulatory, decision-making and policy context of the assessment and informs the evaluation's technical approach (EPA, 1998; 2014). Since Scopes, EPA has:
  - Consider existing regulations
  - Refine conditions of use, exposure pathways/routes and hazard elements of the evaluations
  - Develop further steps of systematic review process
- **Draft Risk Evaluation**
  - Public comment
  - Peer Review
- **Final Risk Evaluation**
  - By December 2019

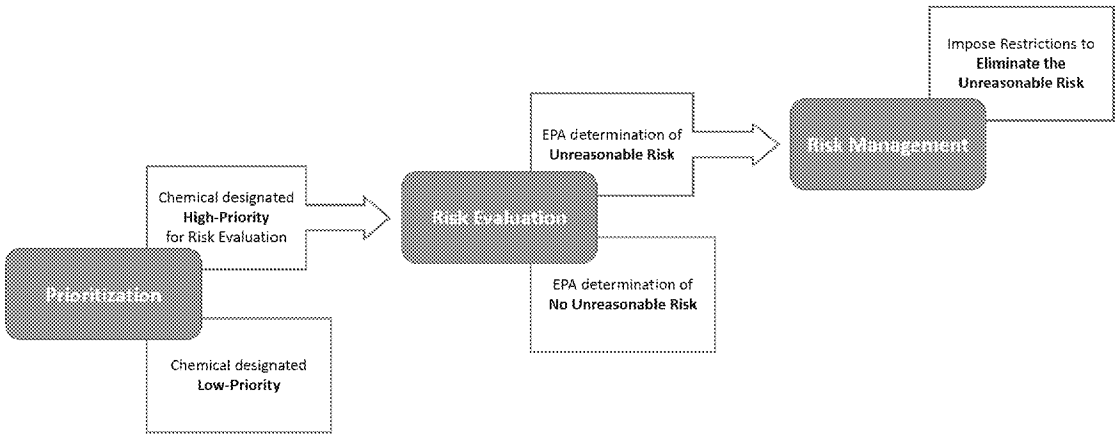
EPA 1998: Guidelines for Ecological Risk Assessment

EPA 2014: Framework for Human Health Risk Assessment to Inform Decision-Making

Toxic Substances Control Act: Prioritization Overview

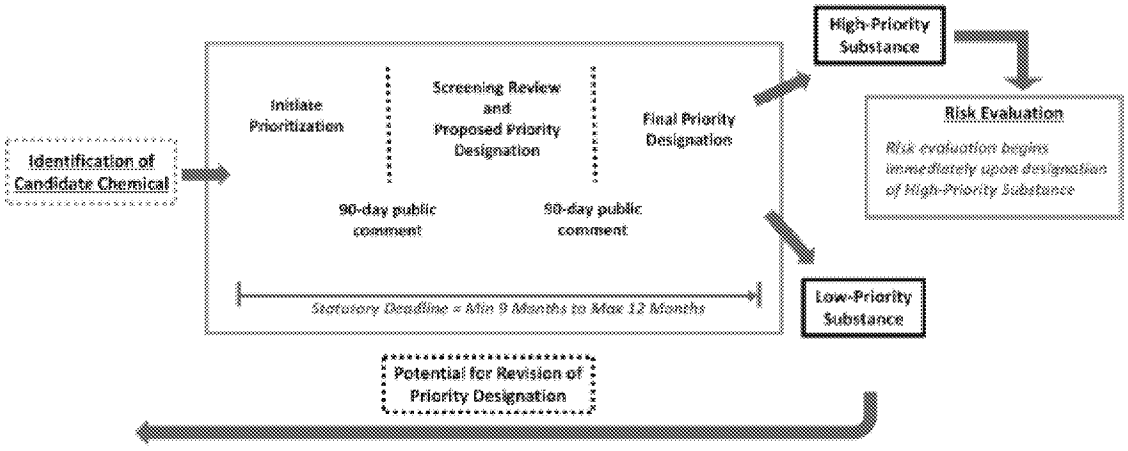
Susanna W. Blair, PhD
Office of Pollution Prevention and Toxics
EPA

Evaluating Risks of Existing Chemicals



Prioritization: Statutory Requirements

- EPA must establish a risk-based screening process and criteria for designating a chemical substance as either:
  - High-Priority Substance, OR Low-Priority Substance
- ***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
  - "High-Priority" triggers immediate initiation of risk evaluation
    - not a finding of "presents an unreasonable risk"
- ***Low-priority substance*** – EPA concludes, based on information sufficient to establish, that the chemical does not meet the standard for high-priority
  - "Low-Priority" means do not proceed to risk evaluation at this time
    - not a finding of "does not present an unreasonable risk"
  - May revise from "low" to "high" based on reasonably available information
    - Restart prioritization process and redo all steps


Identification of Candidate Chemical
Initiate Prioritization
Screening Review and Proposed Priority Designation
Final Priority Designation
90-day public comment
90-day public comment
Statutory Deadline = Min 9 Months to Max 12 Months
High-Priority Substance
Risk Evaluation
Risk evaluation begins immediately upon designation of High-Priority Substance
Low-Priority Substance
Potential for Revision of Priority Designation

Prioritization Process: Next Steps

- No 'pre-prioritization process' in final rule, as proposed.

- EPA initiated additional public comment opportunities to discuss how to identify potential candidate chemicals ready for Prioritization.

  November 2017 *– EPA initiated stakeholder engagement; released meeting materials and discussion document for public comment*

  December 2017 *- EPA held a public meeting*

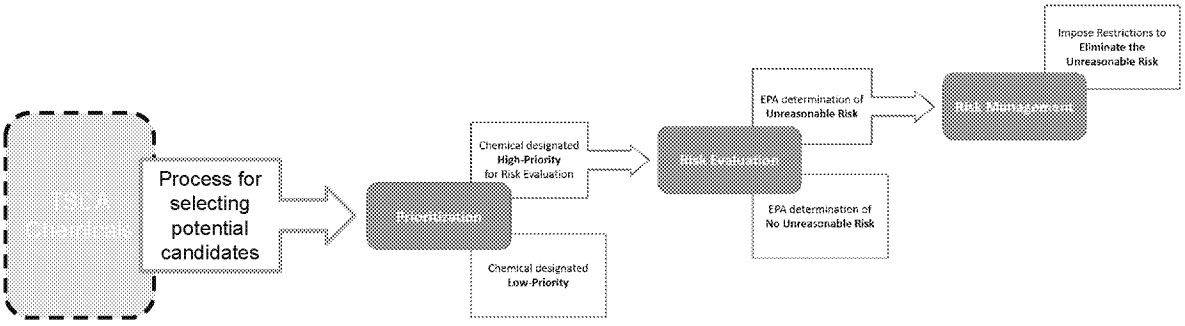
  January 25, 2018 *- Comments due to the Agency*

  June 2018 *- Conclude stakeholder engagement; identify approach/tool that will be used*

  June 2018 – March 2019 *– Implement approach/tool or set of approaches/tools*

Pre-Prioritization

- What is not required under TSCA, is a process by which the Agency identifies potential high- and low-priority candidate chemicals.



Pre-prioritization: Key statutory elements

- Of the chemicals designated as high-priority, **at least 50% must come from the 2014 Update to the TSCA Work Plan**, until that list has been exhausted. EPA must therefore be mindful to identify a sufficient number of its potential candidates for high-priority from the TSCA Work Plan
- TSCA requires that EPA prioritize **at least 20 high- and at least 20 low-priority chemicals within 3.5 years** of the law's enactment, or by the end of December 2019.
- **Risk-based** criteria must be used for Prioritization.
- Designation of a chemical as a high priority for risk evaluation begins the **three-year statutory deadline** for completing the risk evaluation.
- For each risk evaluation completed on a high-priority chemical, **EPA must designate another high-priority chemical and initiate risk evaluation**.

Pre-prioritization: Goals and Guiding Principles

- **Goal**: develop an approach, or set of approaches, with stakeholder input, that will enable EPA to identify a sufficient number of potential candidates for prioritization, initiate the prioritization process for those candidates, and finalize those priority designations within the statutory deadline.
- **Guiding Principles**:
  - Risk-based and supported by science
  - Stakeholder engagement
  - Candidate chemical's readiness for prioritization and risk evaluation
  - Mindfulness of workload and resources
  - Strive to identify more than the 20 low-priority chemicals
  - Consider high-throughput approaches
  - Strive to use the active inventory
  - Balance transparency and stakeholder concerns

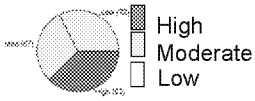
Public Meeting on Pre-Prioritization: December, 2017

- Purpose of public meeting was to initiate dialogue with stakeholders on possible approaches for identifying potential candidates for prioritization, and for EPA to describe some potential approaches under consideration.

- EPA developed a number of possible approaches and tools that could aid in this preliminary review and identification of possible candidates for prioritization.
  - EPA does not envision choosing one single approach, but rather may include a number of differing approaches and tools, or components of differing approaches and tools, that could work in tandem.
  - The Agency is committed to being transparent and communicating with the public how it evaluates existing chemicals for Prioritization.

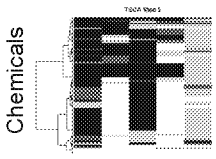
Identifying Candidates for Prioritization: Discussion Topics

- Incorporating the TSCA Work Plan Methodology
- Canada's Chemical Management Plan
- Utilizing Safer Chemicals Ingredients List as a starting point for low-priority chemicals
- Functional Category Approach based on Use and Exposure Potential
- Chemical Category Approach, based on Chemical Structure and Function
- Integration of Traditional and New Approaches



Chemical	Hazard Score	Exposure Score	Persistence Score
X	3	3	3
Y	2	3	2

Data Landscape



Pre-prioritization: Public comment summary

- 43 relevant written comments received
- Only consensus: agreement on transparency and public participation
- General support for the TSCA Work Plan methodology, with necessary updates to criteria and baseline information
- Opposing views regarding the numbers of low priority chemicals
- Calls for the Agency to define 'sufficient information' for determination of low-priority
- Very little to no support for a functional use category
- Concerns for how the Agency will fill data gaps and utilize order authority
- Concerns for the Agency's mandate to consider susceptible subpopulations

Pre-prioritization: Next-Steps

- **Spring/summer 2018** - Conclude stakeholder engagement; identify approaches/tools that will be used to identify the next chemicals for prioritization
  - 20 high-priority
  - 20 low-priority
  - 50% from the 2014 Update to the TSCA Work Plan
- **Summer 2018 – Spring 2019** – Implement approach/tool or set of approaches/tools