EPA's RISK EVALUATION PROCESS and NEW CHEMICALS PROGRAM

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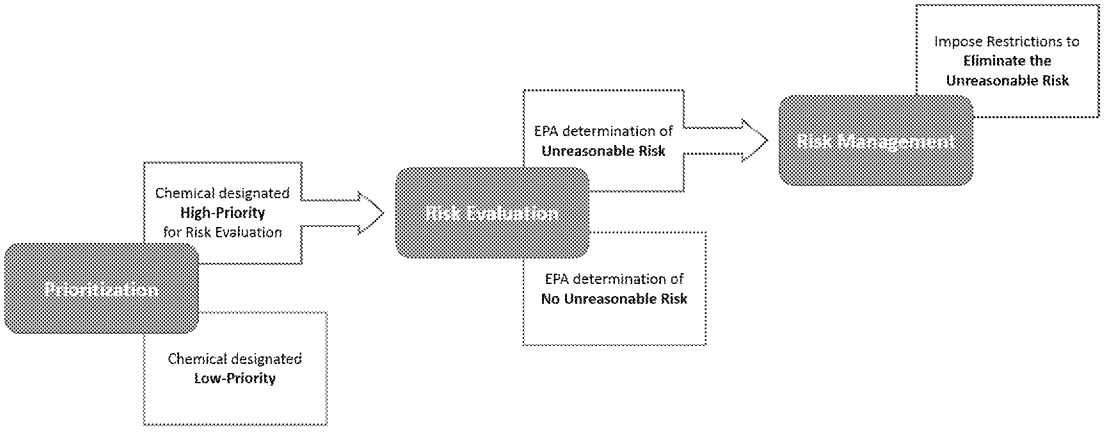
Overview

- Risk Evaluation
  - Statutory Requirements
  - First 10 chemicals
  - PBTs
- EPA's New Chemicals Program
  - Amended TSCA Determinations
  - Decision Framework
  - Implementation Tools

Evaluating Risks of Existing Chemicals



Risk Evaluation
Statutory Requirements

- EPA must establish by rule a process for risk evaluation; signed by Administrator in June 2017
  - Determine if a chemical presents an unreasonable risk of injury to health or the environment under conditions of use (i.e., 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)
  - 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 – Announced December 19, 2016

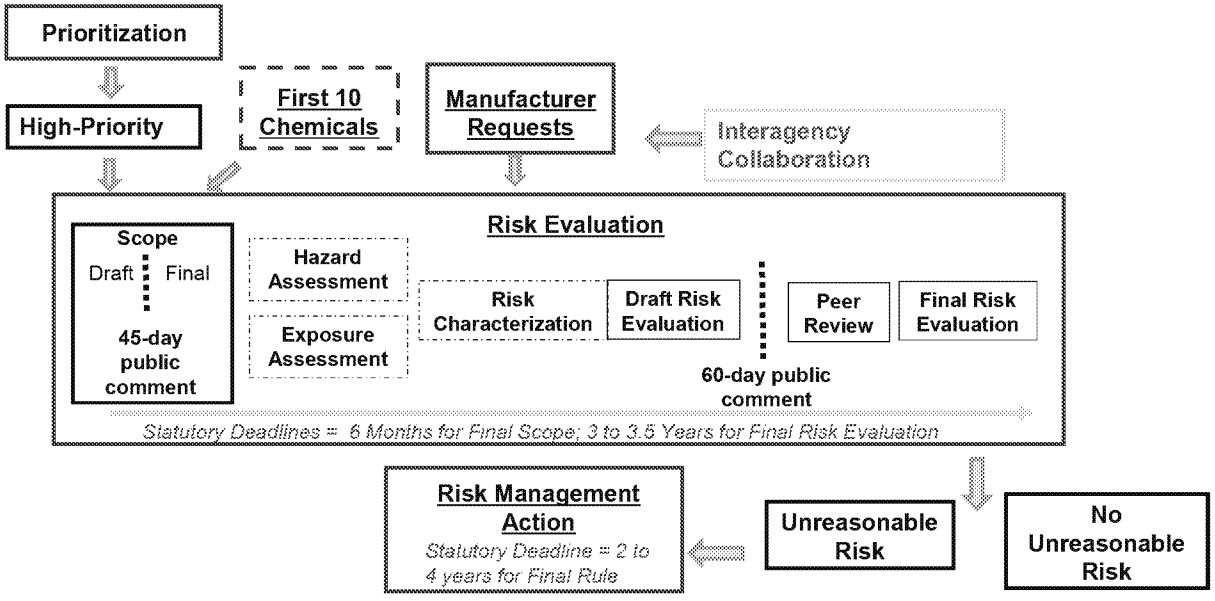
1, 4 Dioxane	Methylene Chloride
1-Bromopropane	N-Methylpyrolidone
Asbestos	Pigment Violet 29
Carbon Tetrachloride	Trichloroethylene
Cyclic Aliphatic Bromide Cluster (HBCD)	Tetrachloroethylene

- **Scope** – Publish within 6 months of initiation; must identify hazards, exposure, conditions of use, potentially exposed or susceptible subpopulation(s) EPA expects to consider
  - Scope documents published June 22, 2017
- **Problem Formulation** documents expected spring 2018

Risk Evaluation
Statutory Requirements

- **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

Risk Evaluation Process and Timeline



Persistent, Bioaccumulative and Toxic Chemicals

- Statute requires a fast-track process for certain PBT chemicals on the TSCA Work Plan and for which exposure is likely based on a use and exposure assessment, unless a manufacturer requested a risk evaluation by Sep 19, 2016
  - Rulemaking is under development for 5 chemicals
  - Manufacturer requests received for 2 PBT chemicals
- No formal risk evaluation
- Rules to address risks of injury to health or the environment and to reduce exposure to the extent practicable, must be proposed by June 2019 and finalized 18 months later
- Other PBTs are to be addressed in overall risk evaluation process

New Chemicals Background

- 2016 Amendments to TSCA
  - Required EPA to make affirmative finding on new chemicals and significant new uses of existing chemicals, before they can enter the market
  - Effective immediately
  - New chemicals determinations made using risk-based approach, considering hazard and exposure, based on 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, use, or disposed of.

New Chemicals

Presents an unreasonable risk

- Section 5(f) order
- Section 6(a) proposed rule
- Restriction/prohibition of manufacturing, processing, distribution, or disposal

Not likely to present an unreasonable risk

- Commercialization can commence after the determination is made
- Section 5(g) – Statement in the FR

Information is insufficient to permit a reasoned evaluation of the risk

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

Insufficient information to permit a reasoned evaluation **and may present** unreasonable risk

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

Current Approach

- At December 2017 public meeting, EPA presented and asked for comment on EPA's current working approach to make decisions on new chemical notices
- Intended conditions of use:
  - In general, these are the circumstances around manufacture, processing, distribution in commerce, use, or disposal as stated in the submission (original or amended).
  - In general, EPA will consider the amended conditions of use to be the intended conditions of use.

Current Approach

- Reasonably foreseen conditions of use:
  - Identification of any reasonably foreseen conditions of use will be fact- or knowledge-specific; based on evidence, knowledge, or experience leading EPA to foresee conditions of use different from those described in the submission.

Pre-Submission Support

- Two common issues with submissions
  - Information does not allow for refinement of risk assessment
  - Submitter has useful information (e.g., analog data) but it's not provided to EPA
- New *draft* Points to Consider document
  - Will provide concise guidance to strengthen PMN submissions – largely based on existing documentation
  - Will promote more robust submissions, supported by robust pre-submission consultation "program"

Pre-Submission Support

- Pre-consultation meetings
  - Understanding of information useful to EPA's review
  - Helps improve submission quality and program efficiency
- Sustainable Futures Program
  - Provides companies with risk-screening models and training to help develop safer chemicals quickly and cost-effectively.
  - Participating companies become eligible for an expedited EPA pre-manufacture review
  - Contains description of most of the risk assessment process including models and tools
  - Gives insights on what types of engineering processes and releases will be calculated

Pre-Submission Support

- New Chemicals Decision Guidelines Manual
  - Under development
  - Draft outline shared at December 2017 public meeting
  - Will provide submitters with information on how EPA conducts its new chemicals assessments
  - Will help stakeholders determine what forms of regulation and restrictions might be imposed on the manufacture, processing, distribution, use, and/or disposal of a new chemical substance
- Chemical category documents

Next Steps

- Considering public comments from December 2017 public meeting and on documents released in connection with the meeting
- Continuing to develop and revise as appropriate EPA's current approach to new chemicals, to accurately reflect OPPT's working approach as it evolves
  - Considering comments received
- Finalizing Points to Consider document and encouraging pre-submission consultation
  - Considering comments received
- Improving data systems to enhance ability to track, search and manage new chemical reviews
- Identifying opportunities to streamline processing
- Promoting transparency
- Continuing to improve overall performance

For More Information

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act

Contact EPA at

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/forms/assessing-and-managing-chemicals-under-tsca