Identifying Potential Candidates for Prioritization: Background, Goal, Guiding Principles, and Milestones

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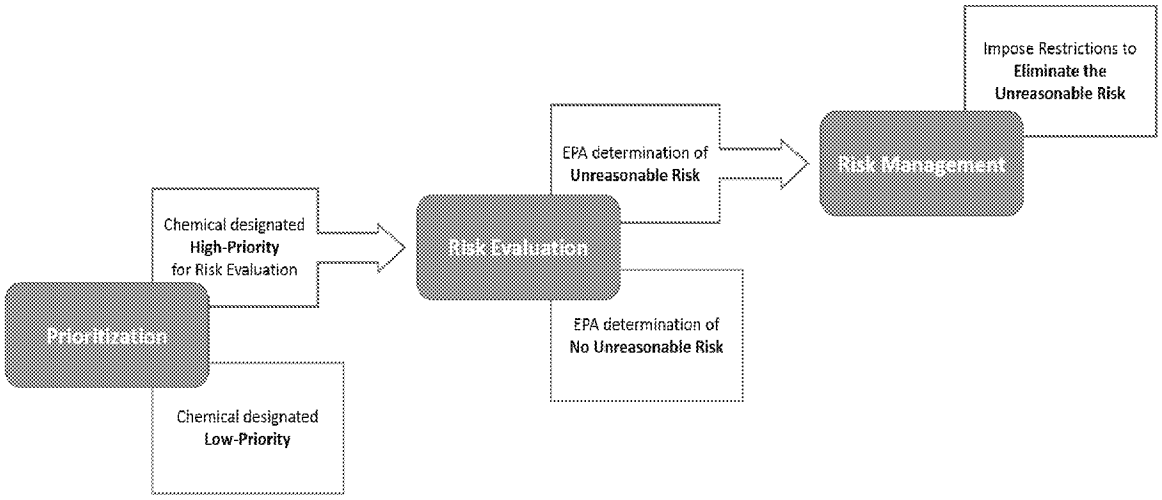
Introduction

- "The Frank R. Lautenberg Chemical Safety for the 21st Century Act"
  - Amends and updates the Toxic Substances Control Act (TSCA); signed into law June 22, 2016
  - First major update to TSCA in 40 years (1976)

- TSCA now mandates new risk-based processes, criteria and deadlines for:
  - Prioritizing existing chemical substances for review
  - Conducting chemical risk evaluations, and
  - Managing unreasonable risks, where identified

New Process for Reviewing Existing Chemicals



Prioritization Framework Rule

- Prioritization Final Rule – June 22, 2017
  - 9-12 month process to determine whether or not a particular chemical should undergo further risk evaluation
  - Begins with identification of a chemical candidate for prioritization
  - Multiple opportunities for public comment
  - Two possible outcomes:
    - High Priority Designation – immediately advances to risk evaluation
    - Low Priority Designation - does not advance to risk evaluation
- "Pre-Prioritization" Phase
  - Activities leading up to the start of prioritization
    - Identification of *potential* chemical candidates for prioritization
    - Review of available information; identification of additional information needs
  - EPA deferred final action on these provisions in the final rule, and committed to further dialogue with interested stakeholders

Purpose and Goal

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

- Goal is to develop an approach, or set of approaches, that enables the identification of at least 20 potential high-priority and 20 potential low-priority candidates, such that EPA can meet upcoming statutory deadlines for prioritization
  - EPA must identify these 40 potential candidates and begin the prioritization process by no later than March 2019
  - One potential outcome of stakeholder engagement is that no approach will be identified

Statutory Requirements

- EPA must prioritize at least 20 high-priority and low-priority chemicals within 3.5 years of the law's enactment (December 2019)
  - Because prioritization is a 9-12 month process, the candidates must be identified by no later than March 2019
- 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
- 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

Guiding Principles

- EPA's approach to identifying potential candidates for prioritization should be risk-based and supported by science, just as the processes for prioritization and risk evaluation
- EPA's approach to identifying potential candidates should be guided by input from stakeholders, including state and federal agencies
- EPA should factor in the need for analyses of candidate's readiness for both prioritization and risk evaluation in order to ensure responsible implementation of TSCA
  - Identify data needs and actively address those needs before initiating prioritization
- EPA should be mindful of its workload and resource constraints
  - For example, incorrectly identified potential low-priority candidates that are subsequently designated as high-priority could permanently increase the number of ongoing risk evaluations

Guiding Principles (cont.)

- EPA should consider whether high-throughput approaches offer a rapid and cost-effective approach to conducting an initial screen for hazard and exposure
- EPA should focus its efforts to identify potential candidates for prioritization from the active inventory, once it has been updated, given that active chemicals may have a greater potential for exposure
- EPA should balance transparency and stakeholder concerns over stigmatization associated with candidate lists. EPA should avoid approaches that could lead to public misperception on risks, while also striving for transparency on how potential high-priority and low-priority candidates are identified

Milestones

- November 2017
  - Initiate stakeholder engagement; release meeting materials and discussion document for public comment
- December 11, 2017
  - Public Meeting
- January 25, 2018
  - Comment period closes; EPA to begin reviewing comments received
- June 2018
  - Conclude stakeholder engagement; identify approach/tool that will be used*
- June 2018 – March 2019
  - Implement approach/tool or set of approaches/tools*

**Note: One potential outcome of stakeholder engagement is that no approach will be identified*