

EPA Framework Rules Under Amended TSCA: *Prioritization and Risk Evaluation*

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The New Law

- “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



1st year Key Milestones

- - Final Active/Inactive **Inventory** Reporting Rule required by June 2017
 - ✓ Finalized June 22, 2017
- - Final **Prioritization** Process Rule required by June 2017
 - ✓ Finalized June 22, 2017
- - Final **Risk Evaluation** Rule required by June 2017
 - ✓ Finalized June 22, 2017
- - **Initial 10 Risk Evaluations**
 - ✓ Published First 10 Chemicals for Risk Evaluation
 - ✓ Final Scopes Published June 22, 2017
- **Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations under the Toxic Substances Control Act**
 - ✓ Guidance Published June 22, 2017
- **Science Advisory Committee** established by June 2017
 - ✓ Charter established, 18 members appointed

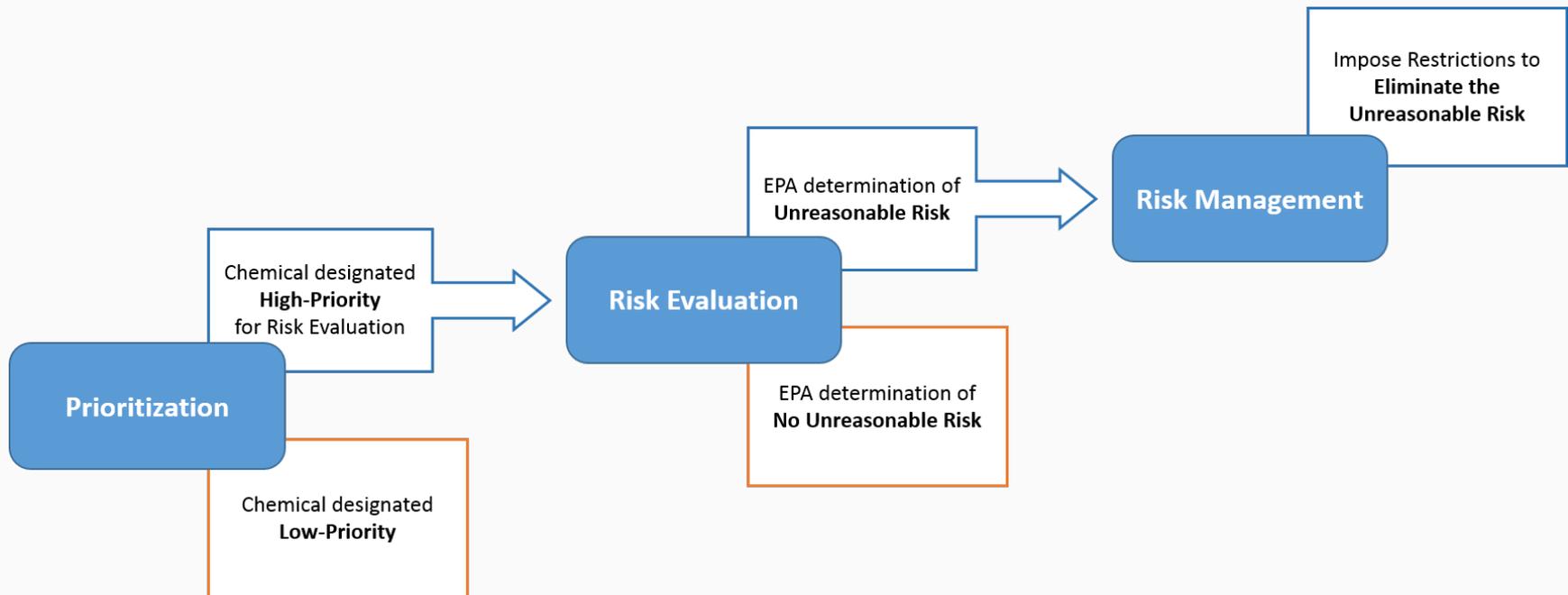


TSCA Inventory for Active/Inactive Chemicals

- Industry must report on the chemicals they manufactured, and may report on chemicals they processed, in previous 10 years
 - Chemicals will be designated as *active* or *inactive*
- Final rule signed June 22, 2017
- Currently in the 180-day reporting period (ending Feb, 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



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
- Some parts of process and criteria specified in TSCA:
 - Steps and timeframes in the process
 - Definitions for High- and Low-Priority Substances
 - Preferences for certain TSCA Work Plan chemicals
 - Criteria against which chemicals must be screened (e.g., Hazard, Exposure, Persistence, Bioaccumulation, Toxicity, Cancer)

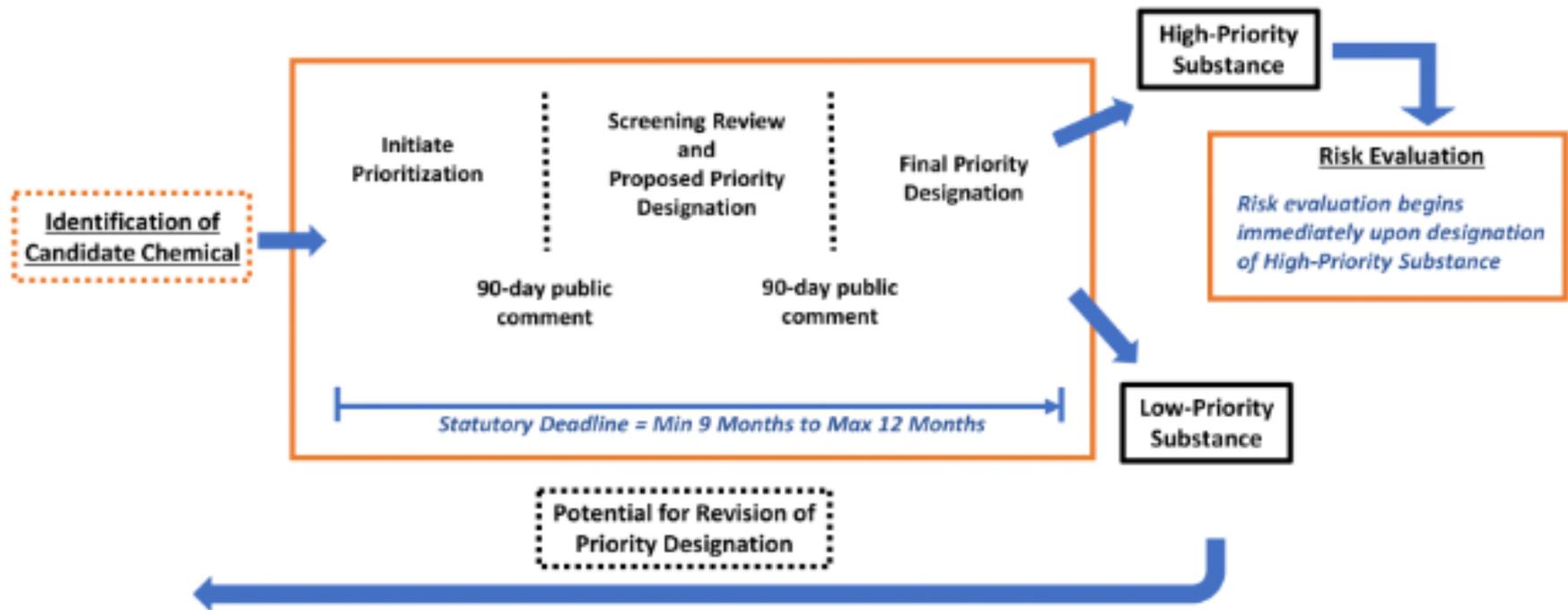


Prioritization Outcomes

- ***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 Process and Timeline



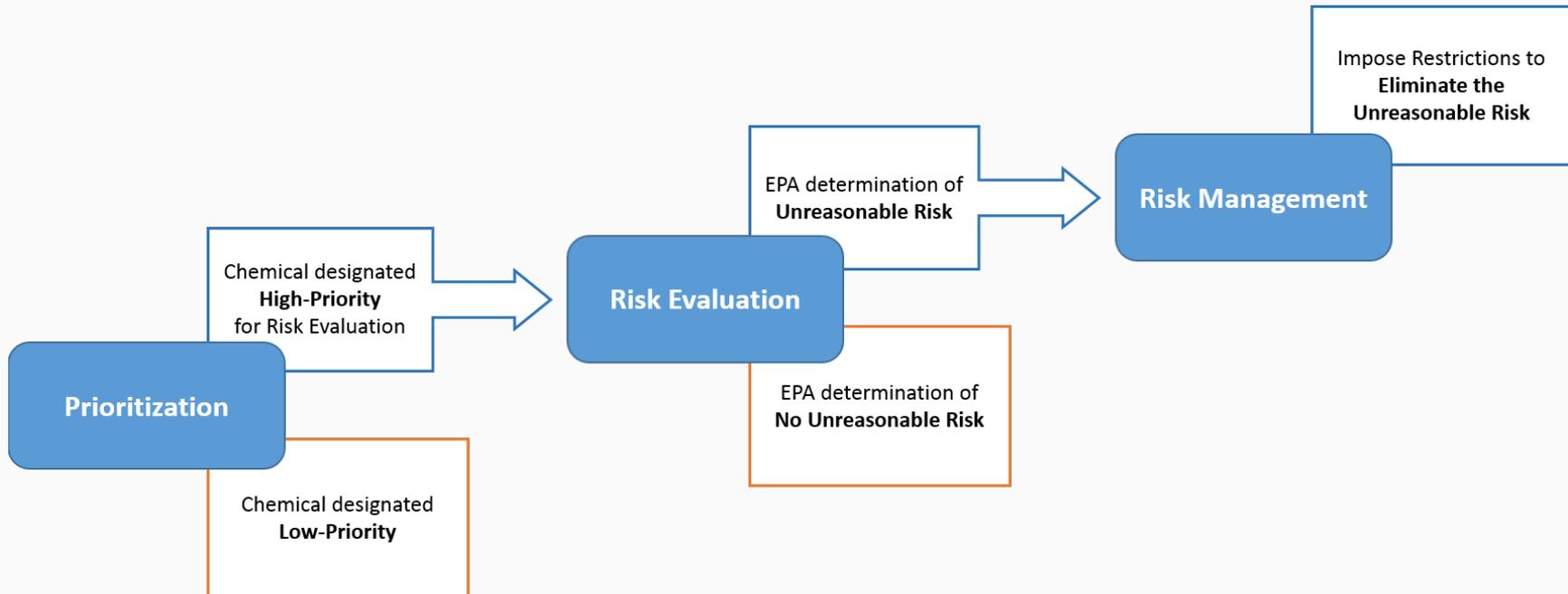


Next-steps: Prioritization Process

- The final rule does not include a ‘pre-prioritization process’ as proposed.
- EPA will be initiating additional public comment opportunities to address this step.
- This process will help the Agency identify potential candidate chemicals ready for Prioritization.
 - *EPA expects to hold a public meeting in December 2017.*

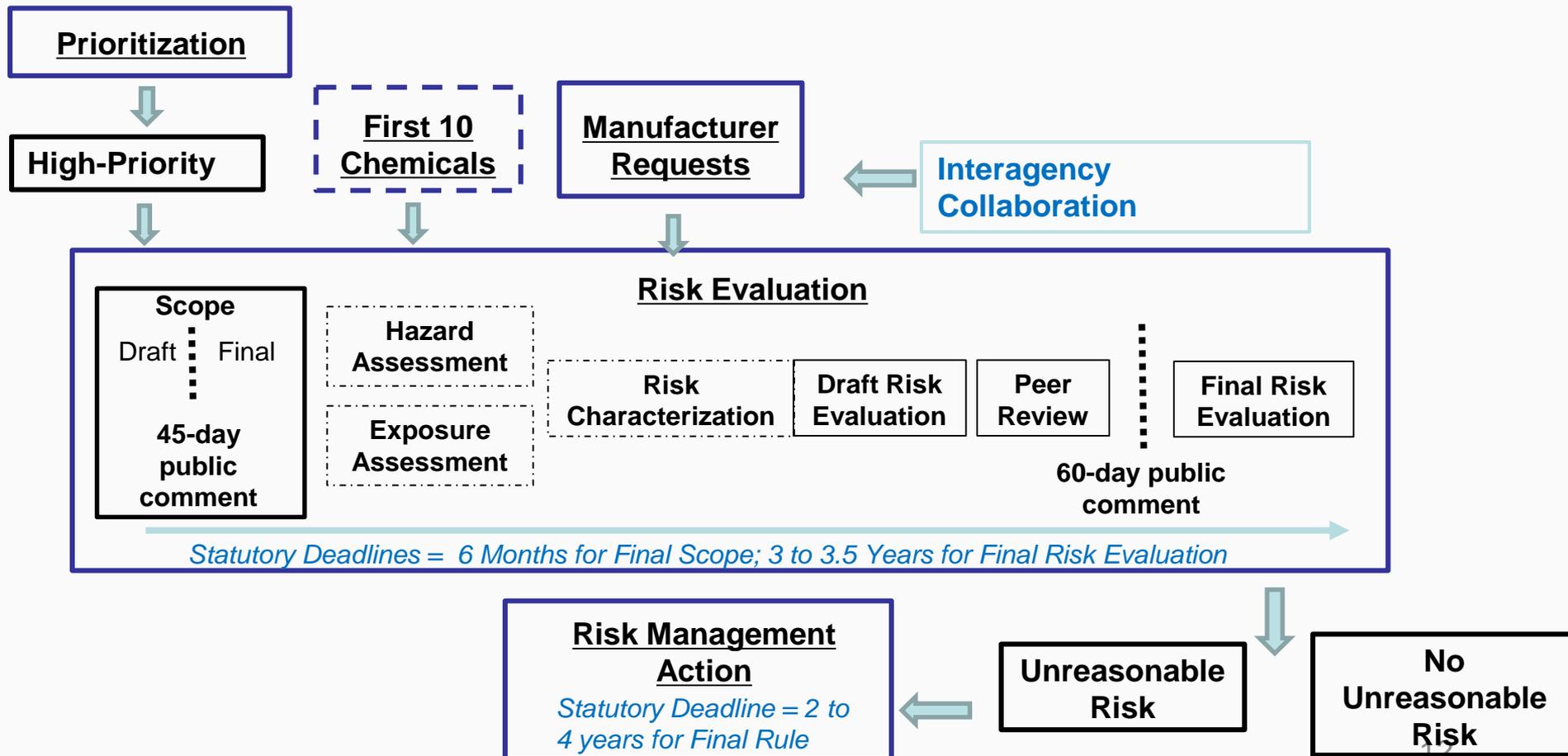


Evaluating Risks of Existing Chemicals





Risk Evaluation Process and Timeline





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

- **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



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



Use of Non-Vertebrate Data

- In compliance with the statute, EPA will work 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 by June 2018.



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 published June 22, 2017
- Problem Formulation documents expected Dec 2017-Jan 2018