TOXIC SUBSTANCES CONTROL ACT: *EPA IMPLEMENTATON*

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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

TSCA Implementation Milestones

Day 1 (June 22, 2016)

- ✓ New chemicals – implement all new requirements, including affirmative determinations
- ✓ Existing Chemicals – apply new risk-based approach and scientific standards for evaluations and risk management rules
- ✓ CBI – review chem ID claims (and subset of other claims) within 90 days

By 6 months (December 2016)

- ✓ Propose TSCA Framework rules (prioritization, risk evaluation, and active/inactive inventory rules)
- ✓ Publish list of first 10 chemicals for risk evaluation
- ✓ Publish annual risk evaluation plan
- ✓ Determine whether “small business” definition warrants revision
- ✓ Report to Congress on capacity to implement

By 1 Year (June 2017)

- ✓ Finalize TSCA Framework rules
- ✓ Finalize scopes for first 10 risk evaluations
- ✓ Publish Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations
- ✓ Establish Science Advisory Committee on Chemicals

TSCA Implementation Milestones

By 2 Years (June 2018)

- ❑ Publish strategic plan for non-animal testing methodologies
- ❑ Finalize all necessary policies, procedures and guidance for TSCA implementation
- ❑ Publish guidance re: generic names for chem ID
- ❑ Receive active/inactive notices from manufacturers and processors (~Oct 2018) and update inventory listings (~Nov 2018)
- ❑ Propose rule for reviewing all chem ID claims (~Nov 2018)
- ❑ Propose rule for TSCA user fees (target date early 2018)

By 3.5 Years (late 2019)

- ❑ Finalize first 10 risk evaluations; initiate risk management if warranted
- ❑ Finalize rule for reviewing chem ID claims for active chems (~Nov 2019)
- ❑ Designate 20 High-Priority and 20 Low-Priority chemicals (~Dec 2019)
- ❑ Propose risk management rule for certain PBT chemicals (~Dec 2019)

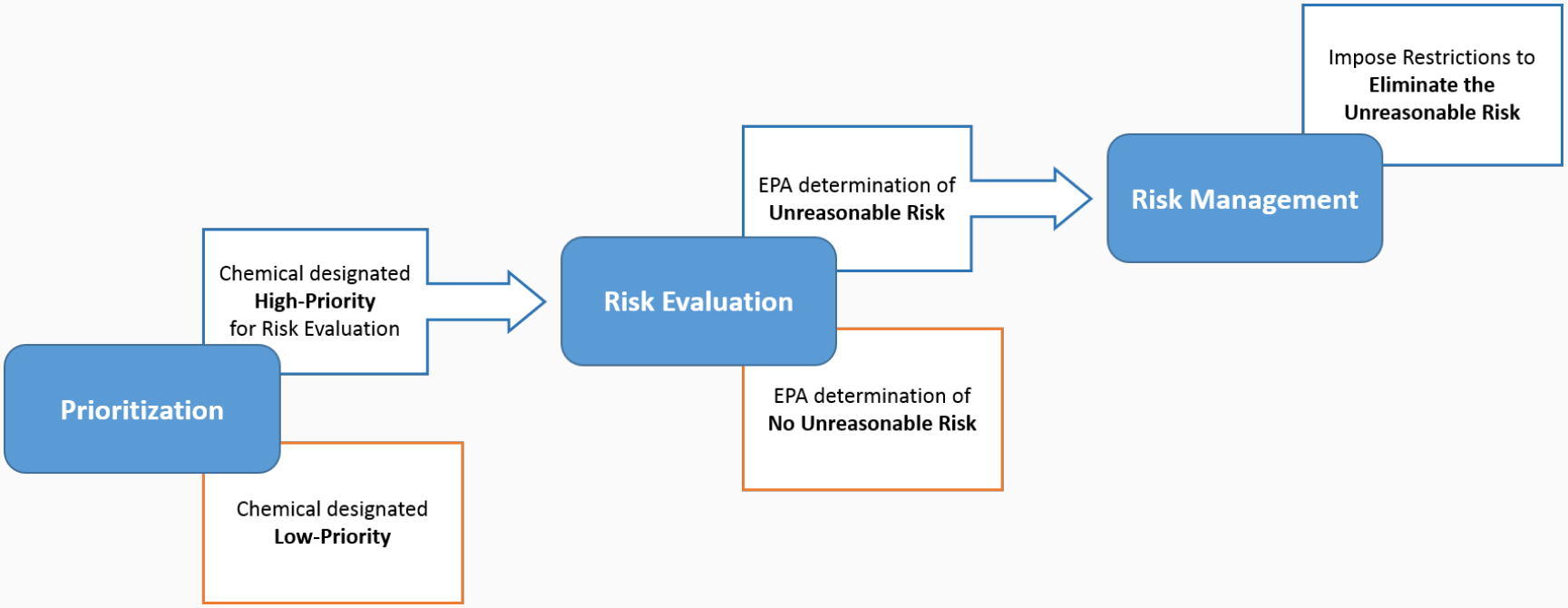
By 5 Years (June 2021)

- ❑ Complete review of CBI claims for chem ID
- ❑ Report to Congress on implementation of non-animal testing plan
- ❑ Finalize PBT rule (~December 2020)

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

The New Law

- Requires EPA to promulgate a number of rules (collectively, the "Framework Rules") to set up the procedures EPA will use to implement, and otherwise align, EPA's chemical management program with the new requirements and responsibilities in the law:
    - Fees Rule*
    - Active/Inactive Inventory Reporting Rule
    - **Prioritization Rule**
    - **Risk Evaluation Rule**
        - Signed June 22, 2017
        - Published in FR July 20, 2017
        - Effective September 18, 2017

*No statutory deadline for Fees Rule

Prioritization

Statutory Requirements

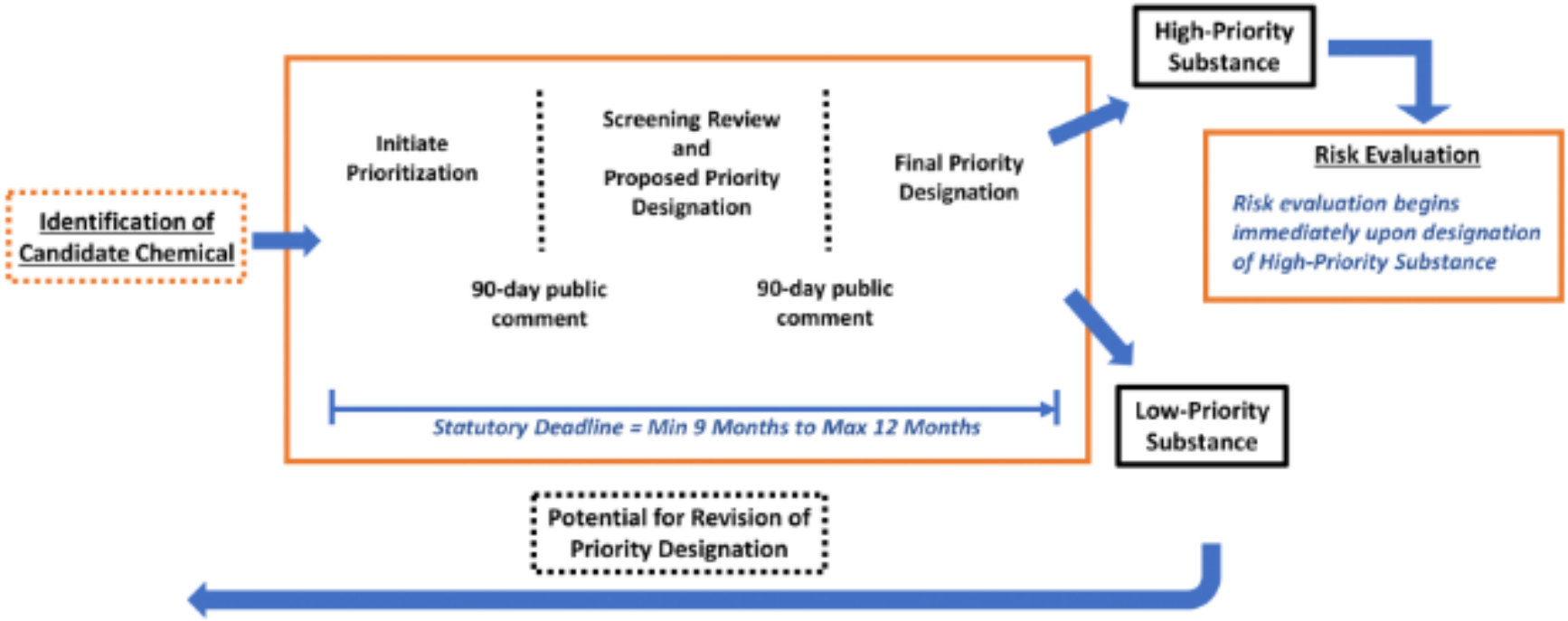
- EPA must establish a risk-based screening process and criteria for designating a chemical substance as either:
  - High-Priority Substance, OR
  - Low-Priority Substance
- Some parts of process and criteria specified in TSCA:
  - Steps and timeframes in the process
  - Definitions for High- and Low-Priority 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



Priority Designation Process

- Proposed designation announced in Federal Register
  - Accompanied by identification of information, analysis, and basis used to support the proposed designation
  - Triggers 90-day public comment period
    - Final designation, including rationale, announced in Federal Register following consideration of comments
- EPA will designate as “high-priority” if information remains insufficient after extension of public comment period following imposition of test requirements.
- TSCA prohibits consideration of costs or other non-risk factors during this process

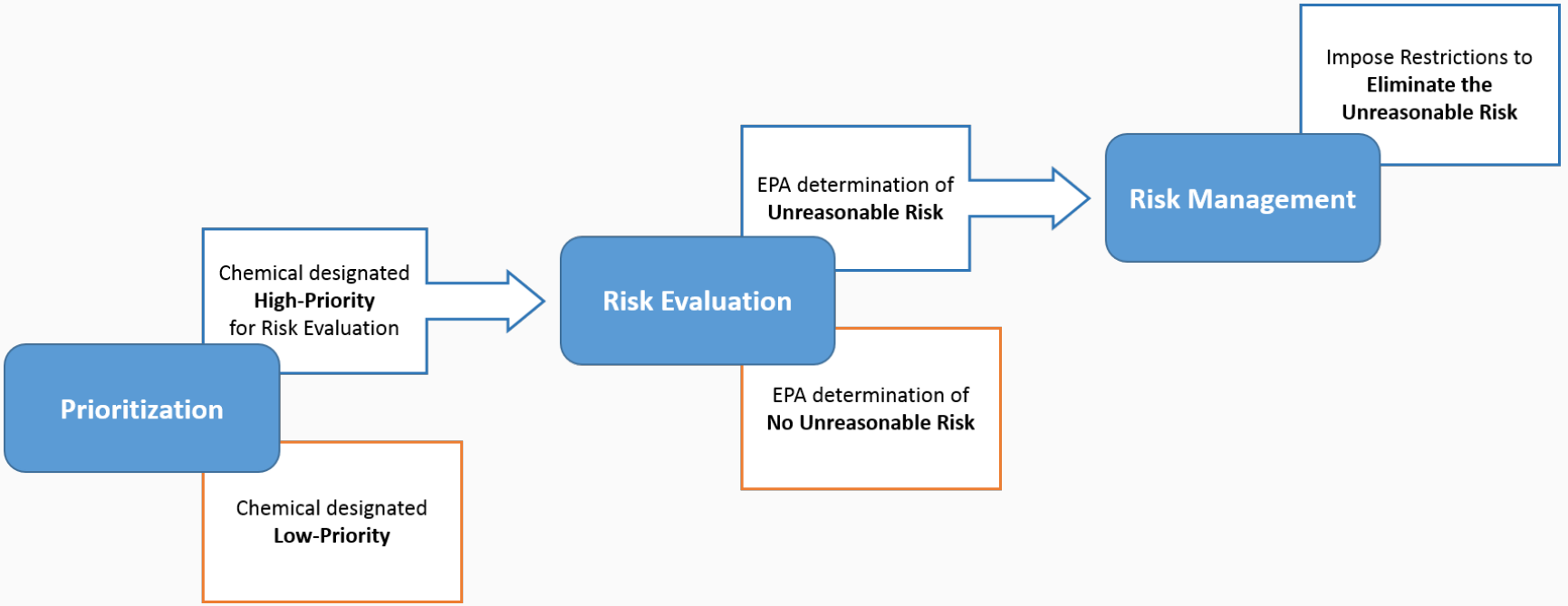
Revision/Effects of Designation

- May revise from “low” to “high” based on reasonably available information
  - Restart prioritization process and redo all steps
- “Low-Priority” means do not proceed to risk evaluation at this time
  - not a finding of “does not present an unreasonable risk”
- “High-Priority” triggers immediate initiation of risk evaluation
  - not a finding of “presents an unreasonable risk”

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.*

Evaluating Risks of Existing Chemicals



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

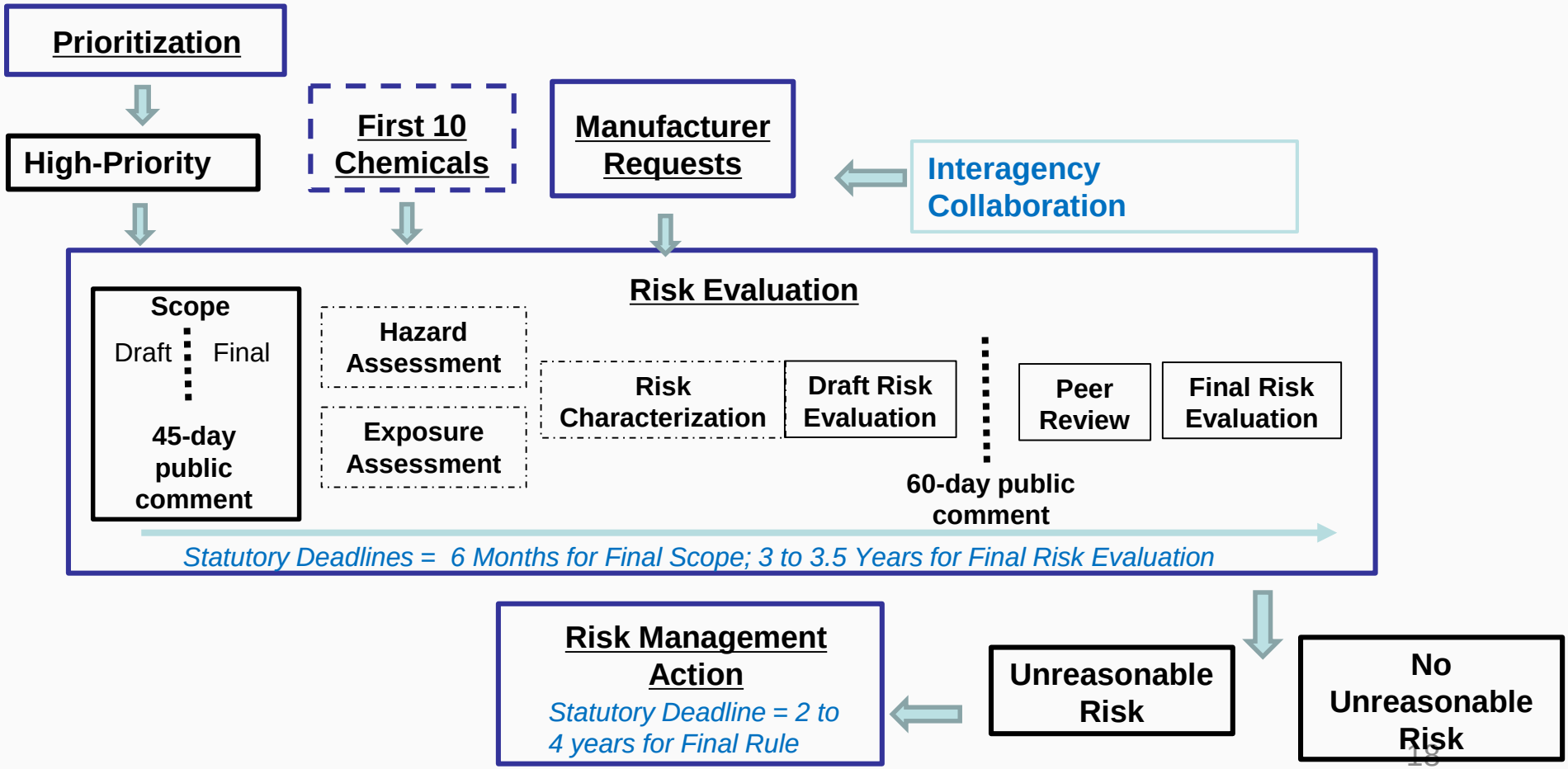
Risk Evaluation
Statutory Requirements

- **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

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

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*.

Risk Characterization Information Quality Compliance

EPA should identify:

- Each population addressed by an estimate of applicable risk effects;
- the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected;
- each appropriate upper-bound or lower-bound estimate of risk;
- each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and
- peer-reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

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 Strategy

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.

- Public and invited expert meeting Nov 2-3, 2017
- Strategic Plan by June 2018

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-Methylpyrolidone
Pigment Violet 29
Trichloroethylene
Tetrachloroethylene

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

Persistent, Bioaccumulative, and Toxic Chemicals

- Statute requires a fast-track process for certain PBT chemicals on the TSCA Work Plan, unless a manufacturer requested a risk evaluation by Sep 19, 2016
- Use and exposure assessment required; No formal risk evaluation
- Rules to reduce exposure, to the extent practicable, must be proposed by June 2019 and finalized 18 months later
- Additional requirements encourage consideration of other PBTs in overall risk evaluation process
- Status
  - 5 chemicals will get expedited action (Decabromodiphenyl ether (DecaBDE); Hexachlorobutadiene (HCBD); Pentachlorothiophenol (PCTP); Phenol, isopropylated, phosphate (3:1); 2,4,6-Tris(tert-butyl) phenol), based on use and exposure assessments for these chemicals.
  - Manufacturer requests for risk evaluations were received for 2 PBT chemicals, which are thus excluded from the expedited action requirements

New Chemicals

- New law requires EPA to make an affirmative finding on new chemicals or significant new uses of existing chemicals, before those chemicals can enter the market
- Chemicals under review at time of enactment were considered “resubmitted” and review period restarted; additional notices continued to come in, resulting in the need to re-review and “backlog”
- Backlog was eliminated in August 2017
- Current focus is to continue to improve processes to meet new requirements in law

New Chemicals

Presents an unreasonable risk

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

May present an unreasonable risk

- Section 5(e) – Regulation pending more information
- Section 5(e) order – commercialization only in compliance with order
- Testing required before or after commercialization

Is 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 required

Next-Phase of Implementation Actions
(Through Jan., 2018)

Problem Formulation

- As statutorily mandated, EPA published the Scope documents for the first 10 chemicals for risk evaluation
- In Dec-Jan we will publish Problem Formulations which will further refine these Scope documents
  - Consideration of existing regulations
  - Refinement of conditions of use and other elements of the evaluations
  - Plan for systematic review

Prioritization Candidate Identification (PCI)

- Developing a stakeholder informed process to assist the Agency in identifying potential candidate chemicals to move into the Prioritization process. Factors under consideration include:
  - Balancing high and low priority candidate chemicals
  - A chemical's readiness (information availability/sufficiency)
  - EPA's on-going work (SCIL, Work Plan chemicals, chemical data reporting)