Toxics Substance Control Act (TSCA) Reform - The Frank R. Lautenberg Chemical Safety for the 21st Century Act

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What is TSCA?

Prevent unreasonable risk of injury to health or the environment from chemical substances or mixtures

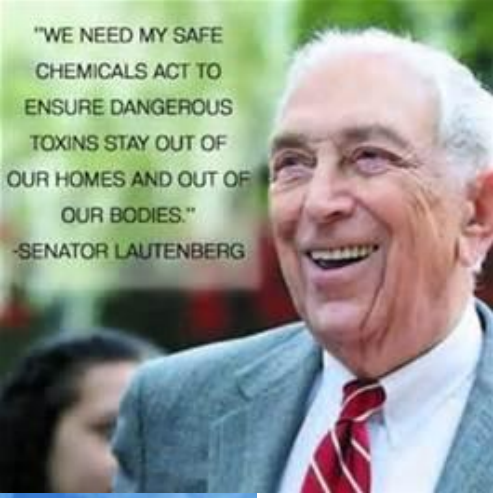
- **Control risks of Chemicals on the market**
  - **Testing of chemicals and mixtures**
  - **New chemical or significant new use**
  - **Regulation of hazardous chemicals and mixtures**
  - **Reporting and recordkeeping**

What is TSCA?

- **Control of Toxic Substances - 1976**
  - **Frank R Lautenberg Chemical Safety for the 21st Century Act, Amendment June 22, 2016**
- Asbestos Hazard Emergency Response - 1986
- Indoor Radon Abatement - 1988
- Lead Exposure Reduction - 1992
- Healthy High-Performance Schools - 2007/8
- Formaldehyde Standards for Composite Wood Products - 2010

Some Previous Challenges for old TSCA

- Focused on new chemicals/uses
- Needed more clear duties and authorities
- Difficult to require information to determine safety of existing chemicals
  - EPA tried voluntary program for high production volume chemicals
- Confidential business information claims did not require substantiation
- No timely review requirements
- Limited funding



Frank R. Lautenberg Chemical Safety for the 21st Century Act

- Signed into law June 22, 2016
- Large bipartisan support in U.S. House and Senate
- Broad stakeholder support
- Many years to get TSCA reform enacted

Major Improvements

- EPA duty to evaluate existing chemicals – clear/enforceable deadlines
  - *Previous no duty to review or deadlines*
- Chemicals assessed with risk-based standards
  - *Previous risk-benefit balancing standard*
- Unreasonable risks must be eliminated
  - *Previous cost/benefit balancing and no mandate to act*

Major Improvements

- Quickly require information/testing
  - *Previously required rulemaking*
- New chemicals need approval before marketing
  - *Previously marketed in absence of EPA action – submit premanufacturing notice*
- Some CBI claims must be substantiated
  - *Previously no substantiation required*
- New Fees - Additional Funding Source

New Chemicals/ Significant New Uses

- Premanufacturing Notice submitted >90 days before manufacturing
- EPA public notices in Federal Register
  - 5 business days from receipt
- EPA affirmative risk evaluation finding
  - 90 day review time for EPA

Risk Evaluation

- "conditions of use"
  - Intended, known, reasonably foreseen
  - Manufacturing, processing, distribution, use, disposal
- Susceptible and highly exposed populations must be considered
  - Infants, children, pregnant women, workers, or the elderly
- Determine without consideration of costs or other non-risk factors

Risk Evaluation Finding

- "presents an unreasonable risk"
  - EPA issues restrictions/limitations to address risk
- Insufficient information
  - EPA requires testing
- "not likely to present an unreasonable risk"
  - may proceed as proposed

New/Significant New Use Risk Evaluation Findings

Since enacted in June 22, 2016

- EPA completed 55 reviews
  - 37 chemical substances
  - 18 microbes
  - Determination “not likely to present an unreasonable risk” for all

Unreasonable Risk

- Risk management actions – 2-4 years
  - Prohibitions, restrictions/limits on manufacturing, processing, distribution, particular use;
  - Notifications, warnings;
  - Regulation of disposal; and/or
  - Requirements for monitoring, reporting, recordkeeping
- Costs and alternatives considered in selecting among options
- Exemption process for critical uses
  - e.g., national defense

Insufficient Information ??

- To determine prioritization or risk
- "May present an unreasonable risk"
  - based on available information,
  - requires additional information for determination, and/or
- Substantial quantities
  - Likely substantial human exposure or
  - Likely substantial release to environment

Insufficient Information - Testing Authority

- EPA may require to make prioritization or risk evaluation decisions
  - **Orders, consent agreements**, rules
- 6/2018 - strategic plan to promote alternative (non-animal) testing methods and protocols

Existing Chemicals

- Prioritized for assessment
  - **High priority** – potential unreasonable risk from hazard, route of exposure, includes consideration of susceptible subpopulations
  - **Low priority** – does not meet high priority
- EPA must establish prioritization process
  - Proposed 1/17/2017 (71 comments received);
  - Final 6/2017

Existing Chemicals

- Risk Evaluation – High priority designated chemicals
  - Must designate new high priority chemicals with each risk evaluation completed
  - 10 first year
  - 20 evaluations to be ongoing in 3.5 years
- EPA must establish risk evaluation process
  - Proposed 1/19/2017 (87 Comments)
  - Final 6/2017

Existing Chemicals

- Initial Set – 10 Work Plan Chemicals
  - Federal Register Notice 12/19/2016
  - Release scope of review for each by 6/2017

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

Existing Chemicals

- Must have 20 risk evaluations ongoing and 20 low priority ID by 12/2020
- Manufacturer Requested Assessments
  - Administrator's discretion
  - 25-50% of ongoing reviews (5-10)
    - Not part of 20 required from prioritization
  - Requestor pays 50-100% costs of risk evaluation

Persistent, Bioaccumulative, and Toxic Chemicals

- Fast-track process for PBTs already on TSCA workplan – 5 PBTs
- No risk evaluation necessary, only use and exposure assessment
  - Manufacturer requested risk evaluation for 2 PBTs
- Rules to reduce exposure proposed by 6/2019, final by 12/2020
- PBT required prioritization for risk evaluations

Updating TSCA Inventory

- Reporting requirements for chemicals manufactured or processed in last 10 years – **active** chemicals
- Chemicals will not be removed
  - Identified as active or inactive
  - Only active chemicals prioritized
  - No premanufacturing notifications for inactive ⟶ active

Ongoing Risk Management Chemicals

- Risk Assessment completed before 6/22/2016
- EPA proposed rules 1/19/2017 to prohibit:
  - Trichloroethylene
    - Use for spot cleaning and aerosol degreasing
    - Use in vapor degreasing
  - Methylene chloride use in paint removers
  - N-methylpyrrolidone use in paint removers
- Comments due by 5/19/2017

Confidential Business Information

- Manufacturers must substantiate CBI claims
  - EPA must:
    - Affirmatively review all new & past chem ID
    - Screen a subset (25%) of new non-chem ID
  - Sunset after 10 years unless reasserted
  - EPA may share CBI information with other states, medical professionals, first responders
    - May require a confidentiality agreement

Preservation of State Laws

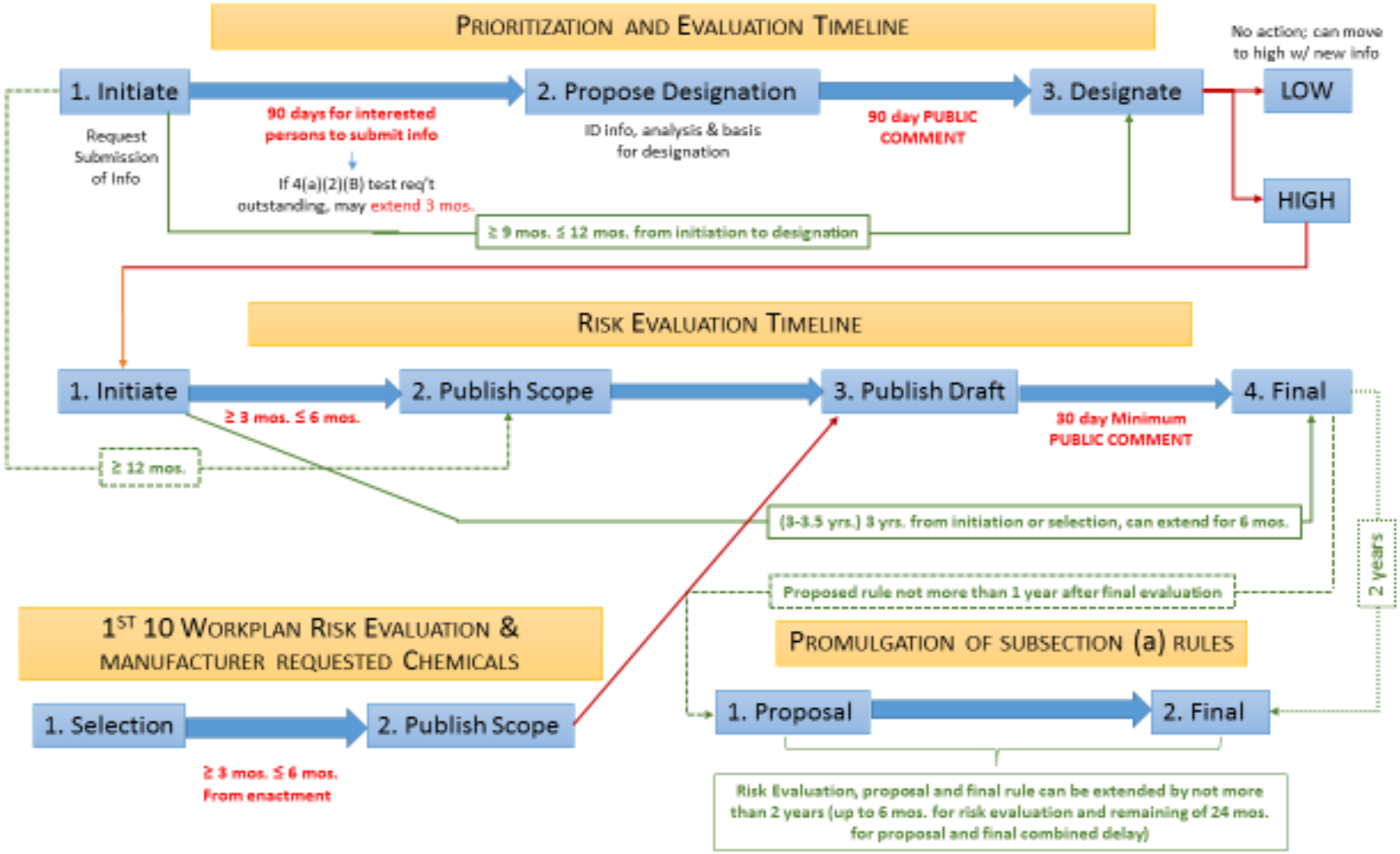
- State authority if chemical not acted on by EPA.
- If EPA acts, State actions preserved:
  - Actions taken before April 2016
  - Other environmental laws (air, water, waste treatment, disposal, reporting, monitoring, etc.)
  - Co-enforcement of identical requirements
  - Actions on chemicals identified as low-priority by EPA

Preemption of State Laws

- If EPA determines chemical is safe,
- If EPA final action to address a chemical's risks,
- If EPA imposes a comparable Significant New Use requirement,
- Unless waivers or exceptions are identified.

Existing Chemical Flowchart

≤ 1 year + ≤ 3.5 years + ≤ 4 years ≤ 8.5 years



30 chemicals every 6 years > 85,000 chemicals – may not get through existing chemicals in my grand 485x children's lifetime (assume 30 chems each 6 years and children born every 35 years)

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Pause Preemption

- New State action is “paused” during EPA’s high priority risk evaluation.
  - If deadline exceeded, pause is lifted
- If risks identified, pause is lifted temporarily until effective date of EPA’s final risk management rule (expect 2-4 years)
- If EPA determines chemical is safe, preemption continues

State Waivers for Preemption

- Pause preemption - EPA ***must*** grant if:
  - State enacted statute, proposed/finalized admin action, prohibits or restricts a chemical, or
  - State provision meets certain criteria
- General preemption - EPA ***may*** grant (rules) if:
  - "Compelling conditions" that necessitate the waiver;
  - No undue burden on interstate commerce; and
  - EPA support for the State's scientific judgment of the risk, based on best available science and weight of evidence
- 110 day review period or automatically granted
- Waivers can be challenged in court.

Chemical Substance

- **Includes**
  - **Any organic or inorganic substance of particular molecular identity,**
  - **Combination of substances from a chemical reaction or found in nature**
  - **Element or uncombined radical**
- **Excludes**
  - **Mixtures**
  - **Pesticides**
  - **Tobacco**
  - **Nuclear material**
  - **Food, food additive, drug, cosmetic or device**

Regulation of Chemicals

- Prohibitions, restrictions, limitations, notifications
  - Required least burdensome
  - Challenges through court – asbestos
- PCBs - specifically identified for rulemaking - 40 CFR 761
- Imminent hazard – serious or widespread injury likely to result before final rule would protect against such risk

Evaluation of Uses

- Intended uses are those identified in the section 5(a) notification
- “known” and “reasonably foreseen” current use of new chemical or structural analog
  - CBI EPA PMN databases
  - National Library of Medicine’s Hazardous Substances Data Bank (HSDB), the
  - Chemical Abstract Service STN Platform,
  - REACH Dossiers,
  - technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and
  - Internet searches.

Persistence

- Limited
  - half-life in water, soil or sediment of less than 2 months
- Persistent
  - half-life in water, soil or sediments of greater than 2 months but less than or equal to 6 months
- Very persistent
  - half-life in water, soil or sediments of greater than 6 months

Can use equivalent or analogous data

Bioaccumulation

- Low potential
  - BCF or BAF of <1,000
- Bioaccumulative
  - BCFs or BAFs of >1,000 and ≤ 5,000
- Very bioaccumulative
  - BCFs or BAFs of >5,000

Can use equivalent or analogous data

Human Health Hazard

- Low
  - Animal NOAEL ≥ 1,000 mg/kg/day
- Moderate
  - Animal NOAEL < 1,000 mg/kg/day
- High
  - Evidence of human adverse effects
  - Severe effect animal NOAEL ≤ 10 mg/kg/day

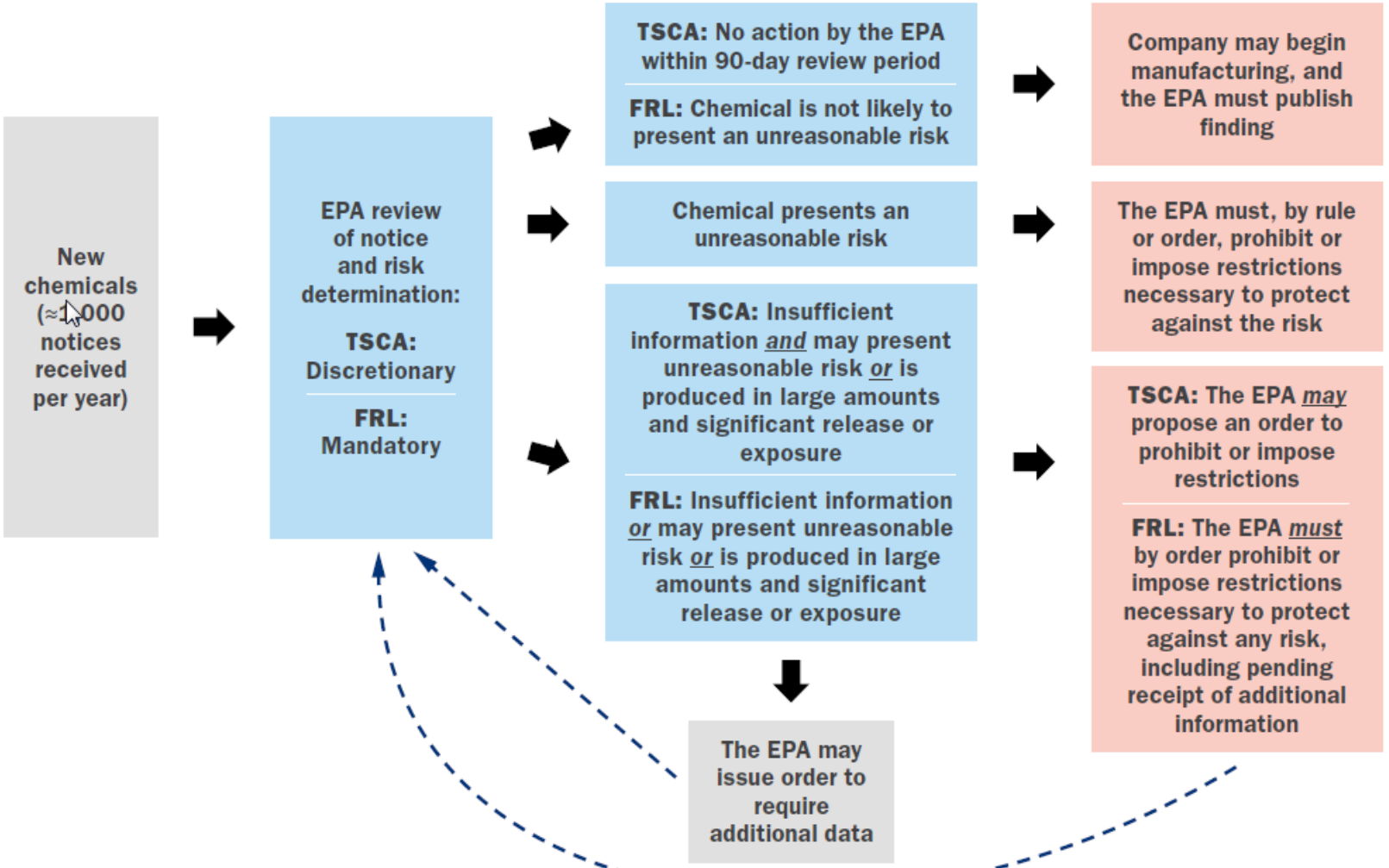
Can use analogous chemical data, in vitro, chemical categories, SAR, structural alerts to support characterization

Ecotoxicity Hazard

- Low
  - Fish, Daphnid and Algae LC50s ≥100 mg/L
  - Fish and Daphnid ChVs >10.0 mg/L
  - No effects at saturation or log Kow > QSAR
- Moderate
  - Fish, Daphnid and Algae LC50s >1 & <100 mg/L
  - Fish or Daphnid ChVs >0.1 mg/L & <10.0 mg/L
- High
  - Fish, Daphnid or Algae LC50s <1 mg/L
  - Fish or Daphnid ChVs <0.1 mg/L

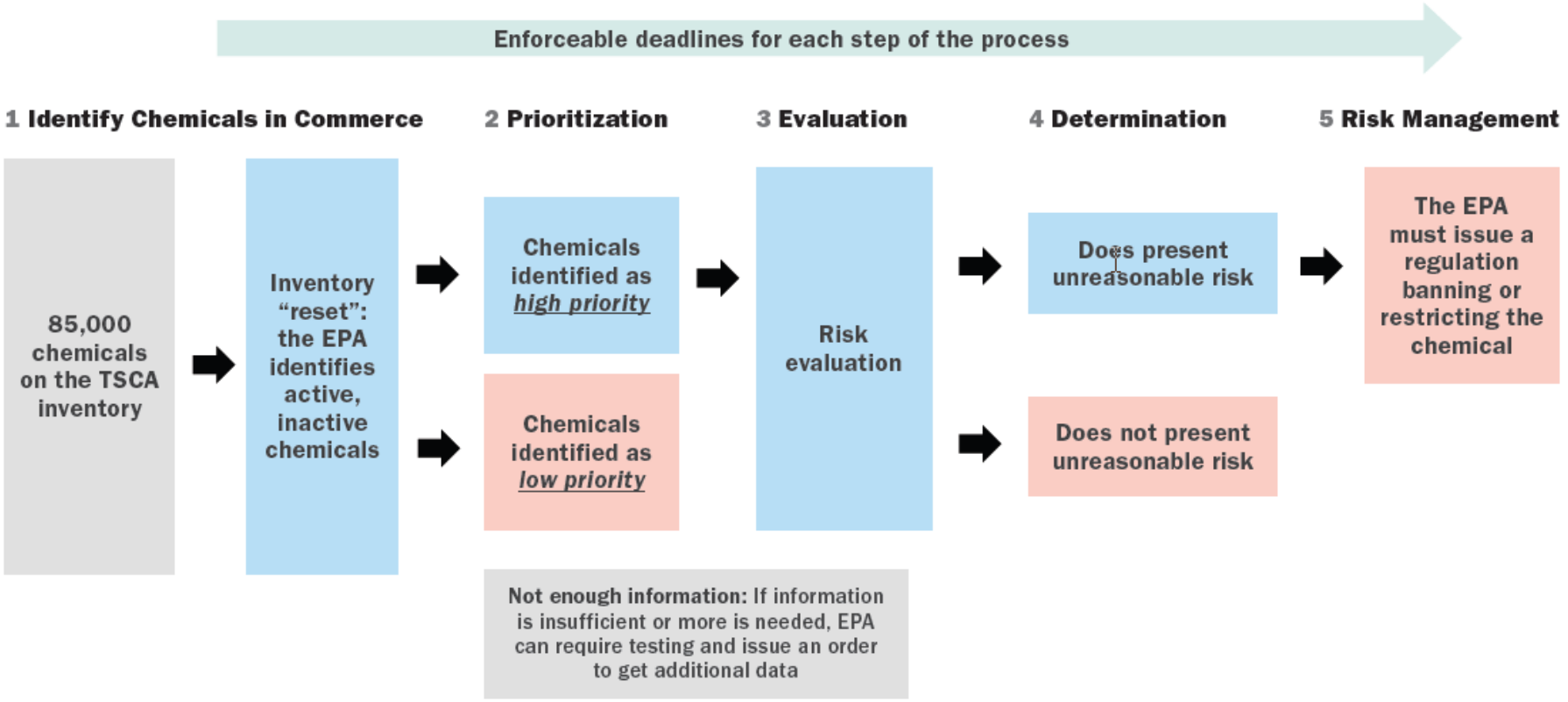
Major Improvements

- New additional funding source
  - User fees of up to 25% of costs but no more than $25M for general provisions
    - New chemical or new use
    - Required to submit test data
  - Cover costs for risk evaluations (50-100%)
  - Lower fees for small businesses
  - *Previous cap of $2500 per individual with limited collection ability*
  - Final Rule Due 6/2017



Source: Adapted from materials prepared by the Environmental Defense Fund

How the Lautenberg Act Works: Existing Chemicals



Safety standard: "No unreasonable risk to human health or the environment."

- Based solely on risks to health/environment
- The EPA cannot consider costs
- Eliminates "least burdensome" requirement

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