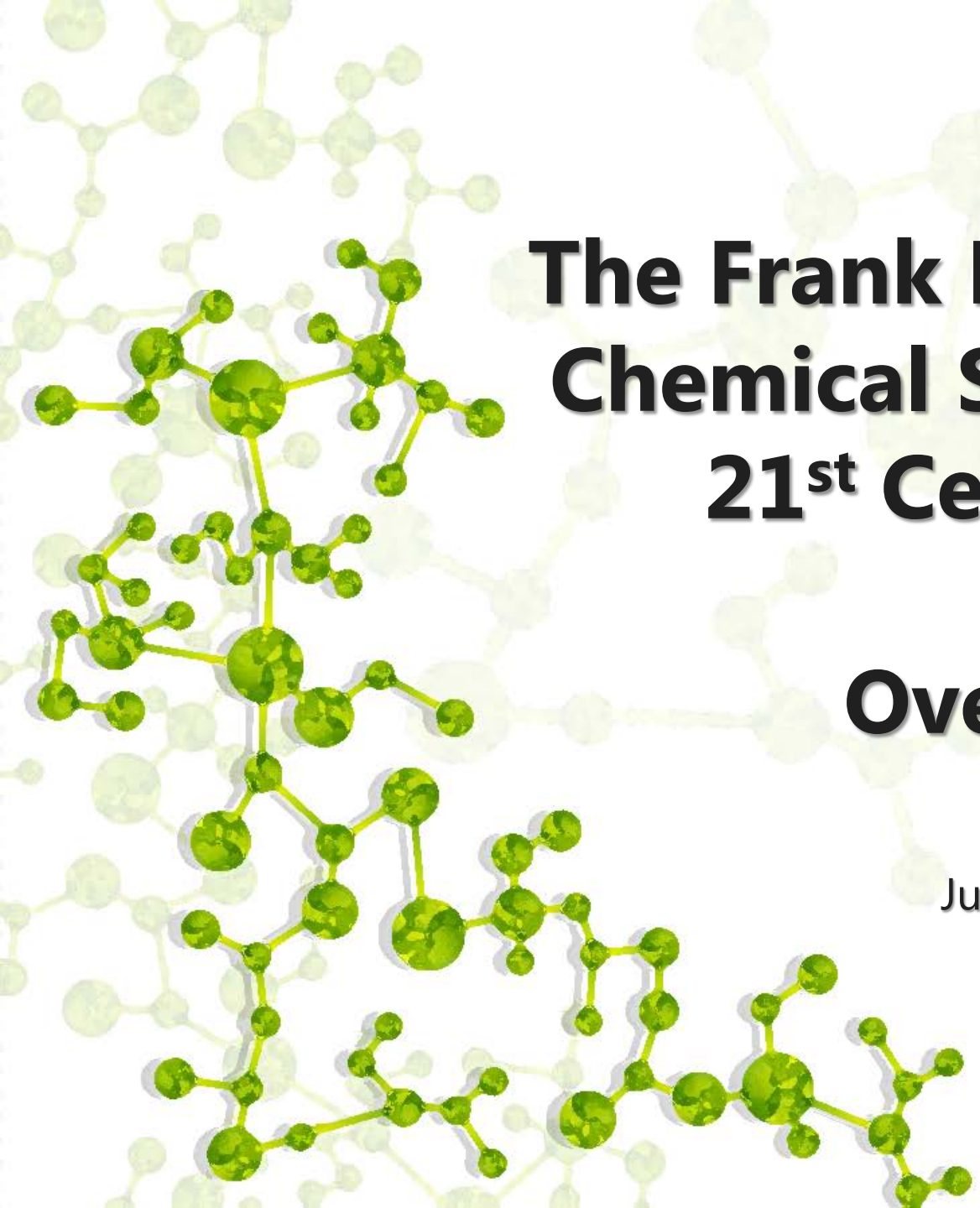


The Frank R. Lautenberg Chemical Safety for the 21st Century Act

Overview

June 2016

The New Law

- The "Frank R. Lautenberg Chemical Safety for the 21st Century Act" was signed by the President and went into effect on June 22, 2016
- Amends and updates the Toxic Substances Control Act of 1976
- Passed by large bipartisan margins in the U.S. House and Senate
- Received broad stakeholder support

Major Improvements Over Current Law

- Mandatory duty on EPA to evaluate existing chemicals with clear and enforceable deadlines
  - *Old TSCA – no duty to review; no deadlines for action*
- Chemicals assessed against a risk-based safety standard
  - *Old TSCA – risk-benefit balancing standard*
- Unreasonable risks identified in the risk evaluation must be eliminated
  - *Old TSCA – Signficant risks might not be addressed due to cost/benefit balancing and no mandate to act*
- Expanded authority to more quickly require development of chemical information when needed
  - *Old TSCA – Required lengthy rulemaking*

Major Improvements Over Current Law

- Requires EPA to make an affirmative determination on new chemicals before entry into the marketplace
  - *Old TSCA – new chemicals enter the market in the absence of EPA action*
- Requires substantiation of certain CBI claims
  - *Old TSCA – no statutory substantiation requirements for CBI claims*
- New funding source (up to $25 million total in annual user fees), to be supplemented by Congressional appropriations
  - *Old TSCA – Cap on individual user fees at $2,500, and limited fee collection authority*

New Chemicals

- New law requires EPA to make affirmative finding on new chemicals or significant new uses of existing chemicals
- Before the chemical can enter the market, EPA must find that the chemical:
  - "presents an unreasonable risk" and issue a 5(f) order to address such risk;
  - "information…is insufficient to permit a reasoned evaluation…" and issue a 5(e) order;
  - "may present an unreasonable risk" and issue a 5(e) order; or
  - is "not likely to present an unreasonable risk" and publish the determination
- New law effectively resets 90-day clock for reviews underway but EPA is working to complete reviews & make determinations within the original review period.

Specific Requirements Existing Chemicals

- Prioritizing Chemicals for Assessment
  - Establish a risk-based process to identify "high" and "low" priority substances
  - High priority – the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including to susceptible subpopulations
  - Low priority – the chemical use does not meet the standard for high-priority

❖ Procedural rule required by June 2017 to establish process for prioritizing chemicals

- Interim milestone – proposed rule mid-December 2016

Specific Requirements Existing Chemicals

- Risk Evaluation
  - "High priority" designation triggers mandatory risk evaluation to be completed in 3 years, with possible 6 month extension
  - For each risk evaluation completed, EPA must designate a new high priority chemical
  - Within 3.5 years, EPA must have 20 ongoing chemical risk evaluations

❖ Procedural rule required by June 2017 to establish process for evaluating the risks of high priority chemicals

- Interim Milestone – Proposed rule mid-December 2016

Specific Requirements Existing Chemicals

- Initial Set of Work Plan Chemical Assessments
  - Identify a list of 10 TSCA Work Plan chemicals and formally initiate risk evaluations by mid-December 2016
  - Release the scope of each assessment by mid-June 2017

Specific Requirements Existing Chemicals

- Risk-Based Safety Standard
  - Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an "unreasonable risk"
    - The risk determination is to be made without consideration of costs or other non-risk factors
  - Risks to susceptible and highly exposed populations must be considered
  - EPA must take risk management action to address unreasonable risks
    - Costs and availability of alternatives to be considered when selecting among risk management options
    - Exemption process for critical uses
    - Risk management actions must be promulgated within 2 years of completing risk evaluation, with extension of up to two additional years

Specific Requirements Existing Chemicals

- Manufacturer-Requested Assessment
  - Establishes a process for manufacturers to request that EPA evaluate specific chemicals, and pay costs as follows:
    - For chemicals on the TSCA Workplan, manufacturers pay 50% of costs; and
    - For all other chemicals, manufacturers pay 100% of costs
- Manufacturer requests subject to the following limitations:
  - Granted at the Administrator's discretion
  - Do not count toward the 20 risk evaluations EPA must have underway
  - Must be a minimum of 25% of ongoing reviews but no more than 50%
    - E.g., if EPA is evaluating 20 high priority chemicals, there could be an additional 5 to 10 industry petitioned evaluations proceeding in parallel

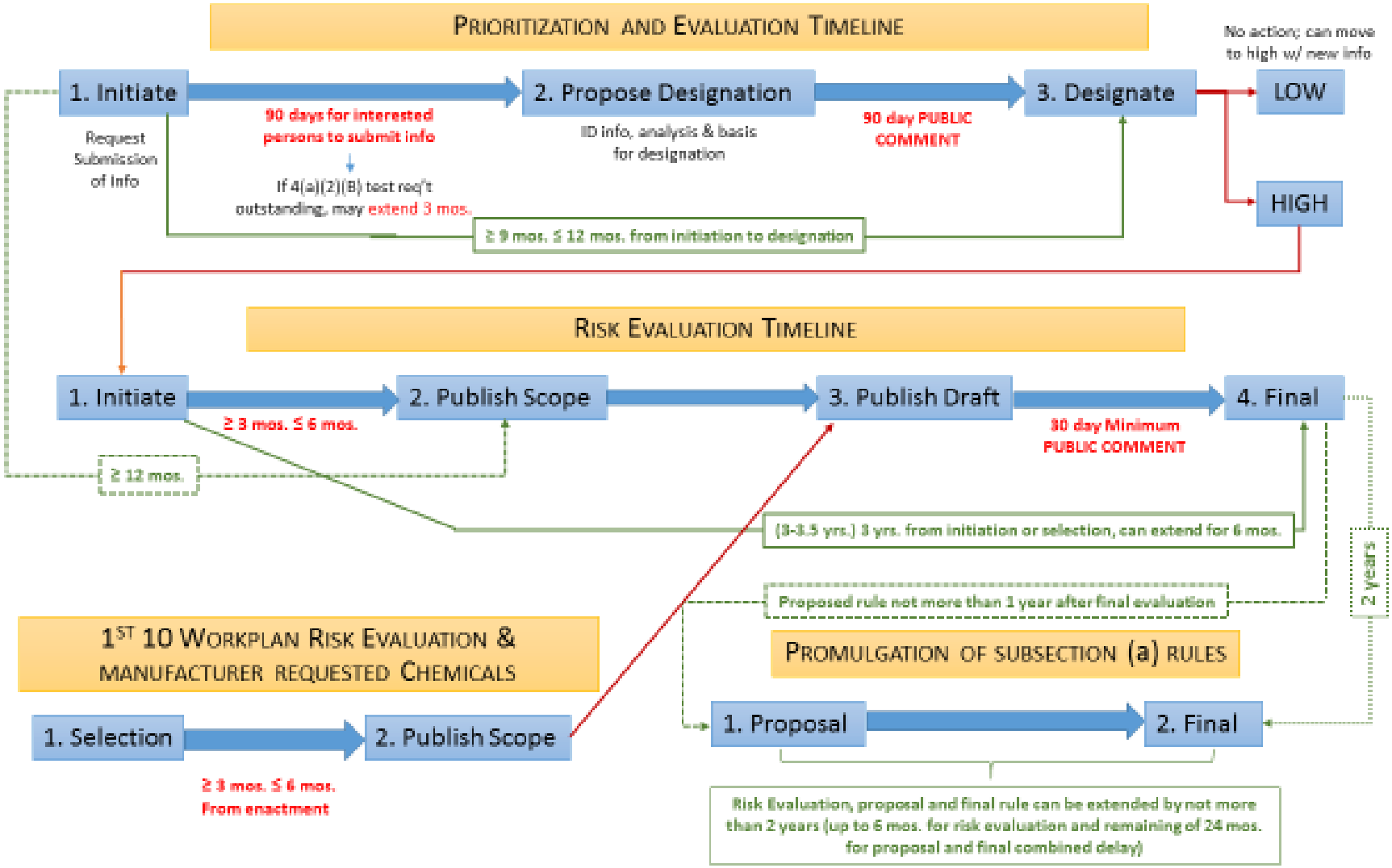
Specific Requirements Existing Chemicals

- Persistent, Bioaccumulative and Toxic Chemicals
  - The new law establishes fast-track process to address certain PBT chemicals already on TSCA Workplan
  - No risk evaluation; only a use and exposure assessment
  - Rules to reduce exposure to the extent practable must be proposed within 3 years of enactment and finalized 18 months later, unless a manufacturer requests a risk evaluation by Sept. 22, 2016
  - Additional requirements encourage prioritization of PBTs in overall risk evaluation process

Existing Chemicals

- TSCA Inventory
  - Requires industry to report on the chemicals they manufactured or processed in previous 10 years to determine if chemicals are currently “active” in the marketplace
  - The chemicals on the TSCA Inventory will not change
  - Chemicals will be designated as “active” or “inactive”
  - Only “active” chemcials may be prioritized
  - No PMN required to move from “inactive” to “active”

Existing Chemicals FlowChart



Specific Requirements Existing Chemicals

- Ongoing Risk Management Rulemakings
  - For chemical uses with completed risk assessments showing unreasonable risk before June 22, 2016, Section 26 allows EPA to propose and issue final Section 6 rules consistent with those assessments
  - EPA anticipates issuing the following rules:
    - TCE use in spot cleaning and aerosol degreasing
    - TCE use in vapor degreasing
    - Methylene chloride (MC) and N-methylpyrrolidone (NMP) in paint removers

Testing Authority

- Provides authority to issue orders to require testing when necessary for prioritizing a chemical or conducting a risk evaluation, in addition to rulemaking
- Requires development of strategic plan for promoting the development and implementation of alternative (non-animal) testing methodologies and protocols

Confidential Business Information

- New requirements for Confidential Business Information (CBI) will provide greater public access to critical chemical information
  - Manufacturers must substantiate certain CBI claims including those for chemical identity (Chem ID) for existing chemicals
    - All CBI claims sunset after ten years unless reasserted by the company
  - For new CBI claims, EPA must:
    - Affirmatively review all chem ID CBI claims
    - Screen a subset of non-chem ID CBI claims (25%)
  - For past CBI claims, EPA must:
    - Retrospectively review past chem ID claims to determine if claims are adequately substantiated.

Source of Funding

- Provides authority to collect fees from manufacturers and processors who:
  - Are required to submit test data;
  - Submit notification of intent to manufacture a new chemical or new use of a chemical;
  - Manufacture or process a chemical substance that is subject to a risk evaluation; or
  - Request EPA to conduct risk evaluation on an existing chemical;
- General fee amounts:
  - EPA can set fees amounts to defray 25% of program implementation costs
  - Subject to annual cap of $25 million

❖ Goal – Engage stakeholders and publish proposed rule by mid-December and final rule mid-June 2017

State-Federal Partnership

- Preservation of State Laws
  - Bill preserves state authority to act on chemical risks not acted on by EPA.
  - If EPA does act, the following State actions are preserved:
    - Actions taken before April 2016
    - The implementation of other environmental laws (air, water, waste treatment, disposal, reporting, monitoring, etc.)
    - Co-enforcement of identical requirements and penalties that do not exceed the federal maximum
    - Actions on chemicals identified as low-priority by EPA

State-Federal Partnership

- Preemption of State Laws
  - If EPA's assessment indicates that a chemical is safe, State provisions are preempted
  - If EPA takes final action to address a chemical's risks, State provisions are preempted,
  - State Significant New Use Rules preempted if EPA imposes a comparable requirement, unless waivers or exceptions are identified.
- New State action is "paused" during EPA's risk evaluation of high priority chemicals
  - If EPA misses deadline for the risk evaluation, pause is lifted
  - If risks identified, pause is lifted and states could put new provisions in place but would be preempted on effective date of EPA's final risk management rule
  - If EPA determines chemical is safe, preemption continues

State-Federal Partnership

- State Waivers for Preemption
  - States can apply to EPA for a waiver from general or pause preemption.
  - EPA must grant an exemption from pause preemption if:
    - State has enacted a statute, or proposed or finalized an administrative action, to prohibit or restrict a chemical, or
    - State provision meets certain criteria
  - EPA may grant an exemption from general preemption, through rulemaking, if specific criteria are met, including:
    - "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
  - If EPA fails to make a decision on a state waiver within 110 day review period, the waiver is automatically granted
  - EPA's grant of an exemption can be challenged in court.

Other Actions

- Mercury
  - Adds mercury compounds to export ban of elemental mercury
    - Publish initial list of prohibited compounds by mid-Sep
  - Requires that EPA publish an inventory of mercury supply, use and trade in the US
    - Publish by April 1, 2017 and update every 3 years
- Annual Report to Congress
- Review Small Business definition within 180 days
- Establish a Scientific Advisory Committee by June 2017

Key Milestones

	New Chemicals	Existing Chemicals	Inventory / Nomenclature	CBI	Other	Fees
Day 1	Implement for all	- §6 rules under development will address new standards - Risk Assessments – will address new standards		- Review CBI claims for chem ID w/in 90 days		
6 Months		-Publish List of 10 Risk Assessments underway for WP Chemicals -January 1st of each year – updated plan for Risk Evaluations ** Proposed rule – prioritization and evaluation	Proposed rule – Active/Inactive		-Determine whether review small business definition warranted -Report to Congress on Capacity to Implement	**Proposed Rule
1 Year		-Final Rule: Prioritization Process -Final Rule: Risk Evaluation Process (including guidance for manufacturer requests) - Publish scope of first 10 risk evaluations	-Final Rule: Active/Inactive		--Establish SACC	**Final Rule
2 Year		-Negotiated Proposed Rule – Byproduct Reporting	-2½ years: Get active/inactive reports	-Rules re: CBI substantiation – 2.5 years -Guidance re: generic names	-Strategic Plan: Promote Alternative Test Methods -All policies, procedures, guidance needed	
3 Year		-3½ years -- 20 Risk Assessments underway (1/2 from WP, min) -20 Low Priorities identified -Proposed Rule – WorkPlan PBTs -Final Rule: Byproducts		-3½ years: Rule to establish plan for reviewing all CBI claims for active chemical IDs		
5 Year		-4 ½ years – Final Rule: PBTs		-Complete review of CBI claims for all active ChemIDs	-Report to Congress re: implementation of plan re: Alternative Methods	**Not a statutory deadline

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