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 – Significant 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
  o 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 practicable 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” chemicals may be prioritized
  – No PMN required to move from “inactive” to “active”
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

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


Contact EPA at: