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

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TSCA Reform: Background

- US House of Representatives passed HR 2576, the “TSCA Modernization Act of 2015,” on June 23, 2015, by a 398-1 vote.
- US Senate approved S.697, the “Frank R. Lautenberg Chemical Safety for the 21st Century Act,” by voice vote on December 17, 2015.
- US House approved a compromise version of the Lautenberg Act (now HR 2576) by a 403-12 vote on May 24, 2016.
- US Senate approved the compromise bill by voice vote on June 7, 2016.
- President Obama signed the bill on June 22, 2016.
- Now Public Law No.114-182.

Key Aspects of the Lautenberg Act

- Requires EPA to evaluate new and existing chemicals to determine whether they present an unreasonable risk of injury to health or the environment under the conditions of use.
- Prohibits consideration of costs or other non-risks factors in chemical evaluations.
- Requires EPA to consider potentially exposed or susceptible subpopulations in evaluating chemicals.
- Requires EPA to develops a list of “active” and “inactive” chemicals.
- Allows companies to ask EPA to evaluate an existing chemical.
- Authorizes EPA to issue administrative orders to require testing of chemicals.
- Eliminates the “least burdensome” requirement for chemical restrictions.
- Puts limits on confidential business information (CBI) claims and allows EPA to share CBI with states.
- Preempts state chemical regulations under certain conditions.
- Allows EPA to charge higher fees for chemical reviews.

Rulemakings Required

- EPA must promulgate several rules soon after enactment:
  - Rulemaking to require reporting for “active” substances by manufacturers and processors (within one year).
  - Rulemaking to establish a risk-based screening process for prioritizing chemicals (within one year).
  - Rulemaking to establish a process for conducting risk evaluations (including criterial for manufacturers to propose chemicals for risk evaluations) (within one year).
  - Rulemaking to establish a plan for reviewing confidential business information claims for active substances (including on the confidential TSCA Inventory) (within one year).
  - Rulemaking to require payment of fees by industry (no actual deadline for this rule, but EPA likely will issue it quickly).
  - Rulemaking for reporting by manufacturers and users of mercury and mercury-added products (within two years).
- These are in addition to rulemakings generally required for actions under Sections 5, 6 and 8 and other sections.

Policies, Procedures & Guidance Documents

- Within one year after enactment, EPA must develop guidance to assist interested persons in preparing and submitting draft risk evaluations.
- Other policies, etc. must be developed within two years:
  - Policies and guidance for testing chemical substances and mixtures.
  - Policies and guidance describing "the manner in which EPA will determine that additional information is necessary to carry out" TSCA's requirements (including information relating to potentially exposed or susceptible populations).
  - Guidance on the development of generic names for CBI substances.
  - Guidance on the content and form of the statement of need and agreements for sharing CBI with states and other parties.
  - Guidance regarding animal, non-animal and epidemiological test methods and procedures for assessing and determining risk.
  - Plan to reduce testing on vertebrate animals.
  - Guidance establishing procedures and standards for the management and short-term storage of elemental mercury by generators.

EPA First Year Implementation Plan

- New Chemicals (and New Uses)
  - EPA now must make an affirmative determination on all PMNs and SNUNs before manufacturing can commence.
  - 90-day review period “reset” on June 22, 2016.
  - For PMNs submitted prior to June 22, “EPA will make every effort to complete its review and make a determination within the remaining time under the original deadline.”
  - Confidential Business Information
  - Meet the 90-day deadline for incoming CBI claims for chemical identity and create a plan to link associated information by mid-July 2016.
  - Routine review of and determination on (within 90 days) at least 25% of new confidentiality claims for other types of information

EPA First Year Implementation Plan

- Initial Work Plan Chemicals Risk Evaluations
  - December 2016: publish list of 10 Work Plan chemicals & formally initiate risk evaluation on those chemicals
  - June 2017: publish the scope of each assessment
- Ongoing Section 6 Rulemakings
  - Trichloroethylene (TCE) use in spot cleaning and aerosol degreasing
    - Proposed rule: October 2016.
    - Final rule: October 2017.
  - Trichloroethylene (TCE) use in vapor degreasing
    - Proposed rule: December 2016.
    - Final rule: December 2017.
  - Methylene chloride (MC) and N-methylpyrrolidone (NMP) use in paint removers
    - Proposed rule: December 2016.
    - Final rule: December 2017.

EPA First Year Implementation Plan

- Early Rulemakings
- Prioritization Process Rule:
  - Proposed rule: December 2016.
  - Final rule: June 2017.
- Risk Evaluation Process Rule:
  - Proposed rule: December 2016.
  - Final rule: June 2017.
- Inventory Rule:
  - Proposed rule: December 2016.
  - Final rule: June 2017.
- Fees Rule:
  - Proposed rule: December 2016.
  - Final rule: June 2017.

Review of New Chemicals

- EPA has to make an affirmative determination that a new chemical (or significant new use) is “not likely to present an unreasonable risk of injury ... under the conditions of use” before it can be manufactured, imported, or processed in the US.
  - “Conditions of use” are “the circumstances, as defined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.”
  - EPA may not consider costs or “other non-risk factors” in determining whether there is an unreasonable risk.
- EPA can issue an order to prohibit or restrict the manufacture, processing, use, distribution or disposal of a chemical that presents an unreasonable risk.
- EPA can require testing of new chemicals, including by issuing administrative orders.

Active and Inactive Chemicals

- Within one year after enactment, EPA must issue a rule requiring manufacturers and processors to tell EPA which chemicals they have manufactured or processed within the previous 10 years.
  - Manufacturers and processors must provide the information no later than 180 days after rule the rule is published.
- EPA will develop a list of “active” chemicals and a list of “inactive” chemicals based on these notifications.
  - Chemicals on the “active” list will be prioritized for purposes of risk evaluations.
  - EPA must develop an “interim” list of active chemicals based on the CDR reporting.
- If a chemical is designated as “inactive,” a company must notify EPA before it can manufacture or process the chemical.
  - Once a chemical is moved from the “inactive” list to the “active” list, it is subject to prioritization.

Prioritization of Existing Chemicals

- EPA must designate existing “active” chemicals as “high” or “low” priority through on a risk-based prioritization process and then conduct risk evaluations on the high-priority chemicals.
  - The time required to make a priority designation can be no shorter than 9 months and no longer than one year.
  - All listing decisions (high- and low- priority) must have 90 days public comment before they are finalized.
  - Low-priority designation is subject to judicial review.
  - EPA must give preference to Work Plan PBT chemicals and Work Plan chemicals that are known carcinogens and have high toxicity.
- Within 180 days of enactment, EPA must initiate risk evaluations on 10 Work Plan chemicals.
  - Within 3 ½ years, EPA must initiate risk evaluations on at least 20 high-priority chemicals and designate 20 chemicals as low-priority.
  - At least half of the 20 risk evaluations must be on Work Plan chemicals.

Risk Evaluations for Existing Chemicals

- Within one year after enactment, EPA must issue a rule establishing a process for conducting risk evaluations.
- EPA must define the scope of the risk evaluation not later than 6 months after initiating the risk evaluation.
  - For a high-priority chemical, there must be at least 12 months between initiation of the prioritization process and publication of the scope of the risk evaluation.
  - Scope must include the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that will be considered.
- EPA must complete the risk evaluation within 3 years.
  - 6 month extension possible if EPA needs additional data or testing.
  - Draft risk evaluation subject to at least 30 days notice and comment.
  - Must consider a draft evaluation submitted by an “interested person.”
- EPA’s determination that a chemical does not present a risk must be done by an order and is subject to judicial review.
  - If chemical does present a risk, EPA must issue a Section 6 rule.

Company Requests for Risk Evaluations

- A manufacturer can ask EPA to conduct a risk evaluation on a chemical if EPA has not yet prioritized it.
  - The company must pay the cost of the risk evaluation.
    - Must pay 50% of the cost if evaluating a Work Plan chemical.
    - Must pay the full cost for all other chemicals.
  - Not less than 25% nor more than 50% of the chemicals designated to undergo risk evaluations may be ones requested by companies (but the 50% limit does not apply to evaluations of Work Plan chemicals requested by companies).
  - EPA cannot “expedite or otherwise provide special treatment” to company-requested risk evaluations.
- Initiation of a company-requested risk evaluation does not trigger preemption.

Testing

- EPA may issue an administrative order to require testing on a chemical if the information is necessary:
  - To review a PMN or SNUN or perform a risk evaluation.
  - Implement a requirement imposed in a rule, order or consent agreement under Sections 5(f) or 6.
  - Meet the regulatory needs of another federal agency regarding toxicity and exposure.
  - To determine whether a chemical presents an unreasonable risk for purposes of the Section 12 “export only” exemption.
- This administrative order authority is in addition to the authority to promulgate a formal rule or enter into a consent agreement.
- EPA must employ a “tiered screening and testing process” when deciding what testing will be required for a chemical.
- EPA must “reduce and replace” the use of vertebrate animals in testing.

Regulatory Action on Chemicals

- EPA must issue a Section 6 rule if it determines that an existing chemical presents an unreasonable risk.
  - EPA must propose the rule within one year after publishing the final risk evaluation and issue the final rule within two years.
  - EPA must consider several factors, including the costs and benefits of the proposed and final regulatory action and one or more "primary" alternative actions considered, as well as the "cost effectiveness" of the proposed action and one or more primary alternative actions.
  - Replacement parts for "complex durable goods" and "complex consumer goods" designed prior to the publication date of the final rule are exempt unless they "contribute significantly" to the risk.
  - Articles may be restricted "only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles".
  - EPA must issue Section 6 rules for certain Work Plan PBT chemicals (with no risk evaluation needed).
- No requirement that EPA select the "least burdensome" option.
- A Section 6 rule is subject to judicial review.

Preemption of State Chemical Regulations

- States and political subdivisions may not impose new restrictions on a chemical found not to present an unreasonable risk or that has been regulated by a Section 6 rule.
  - Preemption starts when EPA publishes the scope of a risk evaluation for a high-priority chemical and ends when the final risk evaluation is issued (or when the deadline for the final risk evaluation has passed).
  - Preemption applies only to hazards, exposures, risks, uses or conditions of use in the scope of the evaluation or the Section 6 rule.
- Preemption does not apply to:
  - Requirements for reporting, monitoring or disclosure or restrictions imposed by states pursuant to a federal law or a state law pertaining to air or water quality or waste treatment or disposal.
  - The authority to continue to enforce any action taken before April 22, 2016 under a state or local law that prohibits or otherwise restricts the manufacturing, processing, distribution in commerce, use or disposal of a chemical substance.
  - Any action taken pursuant to a state law that was in effect on August 31, 2003.

State Waivers from Preemption

- EPA *may* grant a waiver request if warranted by "compelling circumstances" and other factors.
  - EPA must issue a formal rule when granting a "discretionary" waiver, with the rule subject to judicial review.
- EPA *must* grant a waiver if a state has a concern that is "based in peer-reviewed science" (and other factors exist).
- EPA also *mus*t grant a waiver for a state statute enacted -- or administrative action proposed or finalized -- no later than (i) 18 months after the date on which EPA has initiated the prioritization process or (ii) the date on which EPA publishes the scope of the risk evaluation, whichever is sooner.
- If EPA fails to make a decision on a "required" waiver within 110 days, it is automatically granted on the date that is 10 days after the deadline.
- A "required waiver will remain in effect until EPA publishes the final risk evaluation.
- EPA's decision on a waiver is subject to judicial review.

Confidential Business Information

- New CBI claims must be substantiated and approved by EPA.
  - CBI claims will expire after 10 years unless renewed.
- Within one year after enactment, EPA must establish by rule a plan to review all active chemicals on the confidential portion of the TSCA Inventory within 5 years after compiling the active list.
  - CBI claims for chemical identity will have to be re-substantiated and subject to the 10-year time limit if approved.
- EPA may review and require re-substantiation of any CBI claim at any time for high-priority priority chemicals or inactive chemicals.
  - CBI claims made before enactment that are reviewed by EPA would be subject to the 10-year time limit unless renewed.
  - CBI claims for chemical identity of inactive substances must be re-substantiated if they are moved to the active list.
- EPA can share CBI with state and local governments, health care professionals, first responders and others under certain conditions.

Nomenclature

- For purposes of the TSCA Inventory, EPA must:
  - Maintain the use of Class 2 nomenclature (UVCBs) in use on the date of enactment.
  - Maintain the use of the Soap and Detergent Association Nomenclature System (as published in March 1978 by EPA and used to develop the initial Inventory).
  - Treat all components of categories that are considered to be statutory mixtures as being on the Inventory under the CAS numbers for the categories.
- If a manufacturer or processor demonstrates to EPA that a substance appears multiple times on the Inventory under different CAS numbers, EPA may recognize the multiple listings as a single chemical substance.

Mercury

- By April 1, 2017, EPA must publish an inventory of mercury "supply, use and trade" in the US (and update the list every 3 years thereafter).
  - Within 2 years after enactment, EPA must promulgate a rule requiring reporting by manufacturers of mercury and mercury-added products, as well as by anyone who "otherwise intentionally uses mercury in a manufacturing process."
- Effective January 1, 2020, exports of several specific mercury compounds are banned.
  - EPA can add other mercury compounds to the list of banned exports, and parties may petition EPA to do so.
  - Within 90 days after enactment, EPA must publish in the Federal Register the list of mercury compounds banned from export.
  - Within 5 years after enactment, EPA must submit a report to Congress on exports of mercury for disposal, including the receiving countries, disposal methods and management options in the US.
  - New requirements also are imposed on the accumulation, storage and disposal of mercury.