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The Lautenberg Act: TSCA Reform Implications

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Higher Bar for New Chemicals

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- **Old TSCA:**
  - No affirmative decision by EPA is required.
  - A company can make and sell a new chemical at end of a 90-day review period unless EPA finds that the chemical presents an unreasonable risk.
  - "Unreasonable risk" requires cost benefit analysis and balancing.
- **New TSCA:**
  - EPA must make an *affirmative determination* that a new chemical substance (or significant new use) is "*not likely to present an unreasonable risk of injury*" to health or the environment "under the conditions of use" before it can be manufactured, imported, or processed in the U.S.
  - EPA cannot consider costs or "other non-risk factors."
  - EPA can issue orders to prohibit or restrict the manufacture, processing, use, distribution, or disposal of chemicals that present unreasonable risk.
  - EPA can issue administrative orders requiring testing of new chemicals.

The “Inventory Reset”

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- **Old TSCA:**
  - Chemicals on the TSCA inventory stay there, whether being manufactured or not.
- **New TSCA:**
  - Within one year of enactment, EPA must issue a rule that “shall require manufacturers” and “may require processors” to notify EPA which chemicals on the TSCA Inventory they have manufactured or processed within the previous 10 years.
  - Proposed rule by mid-December 2016; final rule by mid-June 2017.
  - Manufacturers and processors must provide the information to EPA no later than 180 days after the final rule is published (i.e., by December 2017).
  - Chemicals with notices will be designated as “active” on the TSCA Inventory. Chemicals without notices will be designated as “inactive.”

Prioritization of Existing Chemicals

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- **Old TSCA:**
  - No deadlines for completing chemical assessments or imposing restrictions.
- **New TSCA:**
  - EPA must designate existing active chemicals as “high” or “low” priority based on risk- and conduct risk evaluations on the high-priority chemicals.
  - All listing decisions must have 90 days public comment.
  - Within 180 days of enactment (i.e., by mid-December 2016), EPA must initiate risk evaluations on 10 chemicals.
  - Within 3½ years, EPA must initiate risk evaluations on at least 20 high--priority chemicals and designate 20 chemicals as low -priority.

Risk Evaluations for Existing Chemicals

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- **Old TSCA:**
  - No deadlines for completing chemical assessments or imposing restrictions.
- **New TSCA:**
  - Within one year of enactment, EPA must issue a rule establishing the process for conducting risk evaluations.
  - EPA must also define the scope of the risk evaluation within 6 months of initiation. It must include the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that EPA expects to consider.
  - EPA must complete the risk evaluation within 3 years after its initiation.
  - EPA must either ***ban, phase out or impose restrictions*** for any high-priority chemical presenting an unreasonable risk.
  - EPA's determination that a chemical substance does not present a risk must be made by an order and is ***subject to judicial review***.
  - Manufacturers can (strategically) request risk evaluations of substances if not yet started by EPA.

More Scrutiny of Confidentiality Claims

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- **Old TSCA:**
  - Stringent provisions for protecting trade secrets shared with EPA. Once claimed, CBI remained protected until EPA finds it does not meet legal requirements for protection. EPA rarely challenged CBI claims.

- **New TSCA:**
  - CBI claims must be substantiated and then reviewed and approved by EPA. They generally expire after 10 years unless renewed and re-substantiated.
  - EPA may review and require re-substantiation of any CBI claim at any time for high--priority priority chemicals or inactive chemical substances.
  - EPA can share CBI with state and local governments, health care professionals, first responders, and others under certain conditions.

Broader Testing Authority

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- **Old TSCA:**
  - EPA must have evidence of risk and issue a rule before requiring testing.
- **New TSCA:**
  - EPA can issue ***administrative orders*** to require testing – not just rules. Testing can be required to:
    - Review a PMN or Significant New Use Notice
    - 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
  - EPA must employ a "tiered screening and testing process" when deciding what testing will be required.
  - Requires reduction in animal testing "to the extent practicable."

Preemption of State Chemical Regulations

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- States may not impose new restrictions on a chemical that EPA has found does not 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) (“Pause Preemption”).
  - Preemption applies only to the specific hazards, exposures, risks, uses or conditions of use included the scope of the risk evaluation or the Section 6 rule.
- Preemption does not apply to:
  - Any action taken pursuant to a state law that was in effect on August 31, 2003.
  - Requirements for reporting, monitoring, disclosure or restrictions imposed by states pertaining to air or water quality or waste treatment or disposal.
  - Enforcement of 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.
- States can request preemption waivers from EPA.

Wave of New Rulemakings

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- EPA is now “on the clock” to promulgate several key rules:
  - “Inventory reset” reporting for “active” chemical substances by manufacturers and processors (by June 2017).
  - Setting a risk-based screening process for prioritizing chemicals (by June 2017).
  - Establishing how to conduct risk evaluations (including criteria for manufacturers to propose chemicals for risk evaluations) (by June 2017).
  - Determining how to review confidential business information claims for active substances (within one year after the list of active chemicals is established).
  - Payment of fees by industry (no deadline, but promised by June 2017).
  - Reporting by manufacturers and users of mercury and mercury-added products (by June 2018).
- These rulemakings are in addition to rulemakings generally required for actions under Sections 5, 6, and 8 and other sections.
- There is also a substantial list of required guidance documents and policies that must be developed and issued during the next two years.

EPA First-Year Implementation Plan

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- New Chemicals (and New Uses)
  - EPA now must make an affirmative determination on all PMNs and SNUNs (including “trapped” filings). Serious backlog and transition issues.
  - Meet the 90-day deadline for incoming CBI claims for chemical identity.
- Initial Risk Evaluations on Work Plan Chemicals
  - Mid-December 2016: EPA must publish a list of 10 chemicals and formally initiate risk evaluations on them.
  - Mid-June 2017: EPA must publish the scope of each risk evaluation.
- Ongoing Section 6 Rulemakings for Trichloroethylene (TCE) use in spot cleaning and aerosol degreasing; TCE use in vapor degreasing; and Methylene chloride (MC) and N-methylpyrrolidone (NMP) use in paint removers
  - Proposed rules in December 2016
  - Final rules in December 2017
- Major rulemaking push (before Obama administration ends)

What Should Companies Be Doing Now?

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- **Build and Educate Your Team**
  - Designate technical, operational, and legal leads
  - Identify key trade group and agency touchpoints
  - Monitor developments and identify key advocacy needs/opportunities
  - Communicate early and often

- **Think About Your Planned New Products (and New Uses)**
  - Decide whether you really need/want to file a PMN (or SNUN) now or can wait until the process for review and safety determinations, including information needs and testing orders has matured
  - Alternatively, think about an exemption (LVE, R&D, TME, LoREX, Polymers)

- **Review Your Current Products**
  - Know what you are making, importing, and/or processing
  - Active vs. Inactive Chemicals: notification to EPA by December 2017
  - Be sure that what you are making, importing, or processing is on the TSCA Inventory
  - Discrepancies may cause problems as EPA reviews chemical notifications

What Should Companies Be Doing Now?

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- **Know Your Uses**
  - EPA will consider the full range of current and foreseeable uses in a risk evaluation
  - Know (i) the uses of the chemicals your make, (ii) the chemicals you process and what you use them for, and (iii) the chemicals in any articles you import or use
  - Also be sure you know what your sales and marketing people are saying

- **Review EPA's TSCA Work Plan**
  - Are you making, importing, or processing a Work Plan chemical, or is it in an article you are importing or using?
  - Will the chemical substance be up for early risk evaluation?

- **Risk Evaluations**
  - Should you ask EPA to evaluate your chemical substance and its uses?
  - Will a competitor ask EPA to evaluate the chemical substance and uses?
  - Are changes likely to impact your suppliers or customers?

What Should Companies Be Doing Now?

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- **Test Data**
  - What data do you already have on the chemicals you make and process?
  - How will you respond/react to a testing order?

- **Confidential Business Information**
  - For new chemicals, think about what you really need to keep confidential and whether you can substantiate your claim
  - Review your current chemicals and know what you claimed as CBI and why.
- **SNUR Issues**
  - More SNURs are coming – will your customers want to use a SNUR'ed chemical or an article with a SNUR'ed chemical?
  - Be sure that you can comply with SNUR restrictions and notification requirements
- **Import & Export Issues**
  - Pay attention to the Section 12(b) export notification list: more chemical substances will go on the list as more rules and orders are issued for chemicals
  - Section 13 import certifications: more attention is warranted as EPA puts more restrictions on chemical substances

Questions?

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