The New TSCA

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

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What has Changed

▶ On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R.2576) which amends the Toxic Substances Control Act (TSCA).

▶ The Act became effective immediately! (June 22, 2016)

▶ First significant amendment to TSCA in its 40 year life!

▶ Reform under Lautenberg & Vitter started in 2011–2013
The Frank R. Lautenberg Chemical Safety for the 21st Century Act

SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.

(a) SCOPE OF REGULATION.—If the Administrator finds that there is a reasonable basis to conclude determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical...
A Brief History of TSCA

15 USC 2601-2692

- Originally enacted October 11, 1976
- Designed to regulate chemicals that pose an “unreasonable risk” of harm to human health or the environment
- It was designed to fill a gap in national safety due to chemicals
- The EPA is tasked with managing the assessment and restriction of all chemicals in “commerce” in the United States
- Largely seen in its management of the TSCA Inventory
The Era of Regulation

FDA and food safety regulations – 1969
FDA and over-the-counter drug review – 1972

OSHA and worker safety – 1970

CPSC and consumer safety – 1972

EPA and pesticides – 1972
Clean Air Act – 1963
Clean Water Act – 1972
RCRA – 1976

There was no existing regulation which could control the hazardous chemicals PRIOR to their production.
What was TSCA Intended to Do?

▶ TSCA would approach risks from chemicals in a holistic rather than fragmented way.

▶ TSCA would develop information in order to increase understanding about the toxicity of chemicals and the risks they posed.

▶ EPA would maintain an inventory that would dictate what could be sold into commerce and what was new and needed to be evaluated.

▶ TSCA would apply to “existing” (62,000) chemical substances grandfathered onto the list and to “new” chemical substances.
Who does TSCA Effect?

Anyone in the very broad chemical industry who is a:

- Manufacturers
- Processors
- Distributors
- Exporters
- Importers
- End Users
The Details of TSCA

▶ Let's look at the individual Sections within the Lautenberg Act and how it changes the rules.

▶ I will summarize these changes in the end of the presentation and give a rundown of how these changes may effect you.
Sec. 1. Short title and table of contents.
Sec. 2. Findings, policy and intent.
Sec. 3. Definitions.
Sec. 4. Testing of chemical substances and mixtures.
Sec. 5. Manufacturing and processing notices.
Sec. 6. Regulation of hazardous chemical substances and mixtures.
Sec. 7. Imminent hazards.
Sec. 8. Reporting and retention of information.
Sec. 9. Relationship to other Federal laws.
Sec. 10. Research, development, collection, dissemination, and utilization of data.
Sec. 11. Inspections and subpoenas.
Sec. 12. Exports.
Sec. 13. Entry into customs territory of the United States.
Sec. 15. Prohibited acts.
Sec. 16. Penalties.
Sec. 17. Specific enforcement and seizure.
Sec. 18. Preemption.
Sec. 20. Citizens’ civil actions.
Sec. 21. Citizens’ petitions.
Sec. 22. National defense waiver.
Sec. 23. Employee protection.
Sec. 24. Employment effects.
Sec. 25. Studies.
Sec. 27. Development and evaluation of test methods.
Sec. 28. State programs.
Sec. 29. Authorization for appropriations.
Sec. 30. Annual report.
Sec. 31. Effective date.
Why Amend TSCA

(the short list)

- **Section 4–Test Rules:** Ineffective due to required formal rule making

- **Section 5–New Chemicals:** No health or exposure data. No clear responses from EPA.

- **Section 6–Regulation of Existing Chemicals:** Had failed due to resource intensive process and “least burdensome” requirement (*Corrosion Proof Fittings vs EPA, 1991*)

- **Section 8(b) –Inventory:** Unknown status of many of the substances on the list –
  - volumes below CDR,
  - pertinent to section 6 review

- **Section 14–Confidential Information:** Low justification requirements for information allow great amounts of information to be withheld from the public nearly indefinitely
What Lautenberg Act Effected

- Stronger testing authority for EPA
- Greater emphasis on the “existing” chemicals
- No “REACH –like” data requirements
- Prioritization process for existing chemicals into “High” and “Low” priority
- Agency required to use science-based risk assessments
- Cost sharing
- Kept CBI
  - but rewriting substantiation
- Added preemption provisions
Section 4 – Test Rules

- Changes in the Lautenberg Act remove the restrictions to issue a **rule**, to “by rule, order or consent agreement”

- This impacts sections 5 (new chemicals) and Section 6 (prioritization and hazard assessments)

- Orders and consent agreements are significantly less effort and time for the Agency (weeks to months instead of years)

- Also requires tiered testing approach

- New requirement to implement non-vertebrate animal methods for testing
Section 5: MANUFACTURING AND PROCESSING NOTICES (PMN)

Most of the existing language of Section 5 was retained

- However, now EPA is required to give a public determination on all new chemicals (and SNUNS)

- There are three possible determinations:

  A. Substance “presents” an unreasonable risk —5(f) Protection against unreasonable risk rule

  B. Information is “insufficient” or substance “may present” unreasonable risk or it has “substantial production and exposure” —5(e) order to prohibit or limit the manufacture, processing, distribution

  C. Substance “not likely” to present unreasonable risk — added to inventory
Section 6: Prioritization –What is it?

EPA must *create a process* to screen new and existing chemicals on the inventory, as either “HIGH” or “LOW” priority within 9–12 months from initiation.

▶ **HIGH–PRIORITY SUBSTANCES.** — *...a chemical substance that may present an “unreasonable risk” of injury to health or the environment because of a*
  
  ▶ potential hazard
  ▶ a potential route of exposure under the conditions of use
  ▶ an unreasonable risk to a potentially exposed or susceptible subpopulation

▶ **LOW–PRIORITY SUBSTANCES.** — *...that such substance does not meet the standard for a high–priority substance.*
  
  ▶ based on information “sufficient to establish” no unreasonable risk
Section 6: Prioritization

What is prioritization based on?
- The TSCA Safety Standard – “unreasonable risk of injury to health or the environment”
- Must consider Hazard and Exposure potential
  - Bioaccumulation and persistence
  - Potentially exposed or susceptible subpopulations
  - Storage near significant sources of drinking water

- Designed to be a health-based safety standard—replaces cost-benefit safety standard
- Gives EPA enhanced authority to require testing of both new and existing chemicals under Sec.4
Section 6: Prioritization

- Issues to yet be addressed:
  - What will be the *process* for nominating existing chemicals? (TSCA Work Plan Chemicals, CDR, then???)
  - What will be the process for nominating new chemicals?
  - Will anyone be notified if the substance is under review?
  - High priority default– standard of "*sufficient to establish*" will dictate a bias to high priority
  - Resources
Section 6: Risk Evaluation

► “Upon designating a chemical substance as a High-Priority substance, the EPA shall initiate a risk evaluation on the substance.”

► Within 1 year of June 22, 2016 the EPA must establish, by rule, a process to conduct risk evaluations.

► Initial rule to be released for comment in December.
Section 6: Risk Evaluation

What are the known of the requirements of the process?

Congress states it must:

- Integrate and assess available information on hazards and exposures for the conditions of use including “potentially exposed susceptible subpopulations”
- Take into account the likely duration, intensity, frequency, and number of exposures under the conditions of use
- Use and describe aggregate or sentinel exposures
- Costs or other factors are not to be considered
- Publish a scope of the risk evaluation for each chemical within 6 months of initiating
- Complete evaluation within 3 years
- If material has a negative determination from the evaluation the EPA must issue a rule to control the chemical such that it no longer will present a risk (bans, restrictions, use restrictions, warnings, record keeping, disposal options, testing etc.)
Section 6: Risk Evaluation

Issues to yet be addressed:

- 2012 Work Plan Chemicals highly prioritized
- Conditions of use
- Aggregate vs sentinel exposure
- Best Available Science
  - what does that mean, what is the role of the Science Advisory Committee on Chemicals and third parties
- Weight of Scientific Evidence
  - must be used in section 4, 5 and 6
- Does the EPA have the resources to complete a risk evaluation in 3 years
  - Does EPA have to evaluate 85,000 chemicals or only 10,000?
This chemical was on the 2012 Work Plan. The final assessment published March 2015. It is one of 5–8 final assessments of the original 345.
The 2017 List

- EPA was required to publish a list by Dec. 19th 2016 of the first 10 chemicals to undergo prioritization and risk evaluation:

- The first ten chemicals to be evaluated were released Nov 29 2016:
  - 1,4-Dioxane
  - 1-Bromopropane
  - Asbestos
  - Carbon Tetrachloride
  - Cyclic Aliphatic Bromide Cluster
  - Methylene Chloride
  - N-methylpyrrolidone
  - Pigment Violet 29
  - Tetrachloroethylene, also known as perchloroethylene
  - Trichloroethylene

- These chemicals were drawn from EPA’s 2014 TSCA Work Plan, a list of 90 chemicals selected based on their potential for high hazard and exposure as well as other considerations.

- OPPT Acting Director, Jeffery Morris, had indicated the first materials would be from the 2014 TSCA Work Plan primarily because EPA had existing data on these materials which would allow EPA to meet the 3 year deadline.
Section 8: REPORTING AND RETENTION OF INFORMATION. (AKA Inventory Reset)

▶ Under TSCA 8(b) the EPA is required to “compile, keep current and publish a list of each chemical substance which is manufactured or processed in the US”
▶ This is the so called TSCA inventory
▶ Of the ~85,000 chemicals on the list, 63,000 were grandfathered onto the list without any review
Section 8: REPORTING AND RETENTION OF INFORMATION. (AKA Inventory Reset)

- Lautenberg Act requires manufacturers, and may require processors to notify/respond to request for notification from the EPA of each chemical substance on the list that the manufacturer or processor has manufactured or processed during the last 10-year period.

- CBI claims must be re-asserted and substantiated in active substance notices. If EPA receives no substantiated CBI claims for an active substance, substance is not kept confidential.

- EPA will establish an Active list and an Inactive list based on notification responses.

- Inactive substances cannot be sold in commerce without notifying EPA.
  - What will that require??? Not a PMN.

- SNUR???
Section 8: REPORTING AND RETENTION OF INFORMATION. (AKA Inventory Reset)

Issues to yet be addressed:

- By **December 22, 2016** EPA must publish a rule for this reset process to meet the 1 year deadline
- The process is yet to be determined. EPA indicates it will be simple with very simple requirements (not a CDR) but possible data required?
- Problematic for the 62,000 grandfathered substances – who will notify? How will joint notification work?
- Problematic for low volume manufacturers
- Orphaned substances – no notifier but users
- Problematic for foreign importers (US PMN submitters may no longer exist) How will EPA notify?
Section 8: The Mercury Inventory

“Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall carry out and publish in the Federal Register an inventory of mercury supply, use, and trade…”

In this paragraph, notwithstanding section 3(2)(B), the term ‘mercury’ means—

(i) elemental mercury; and
(ii) a mercury compound.

Section 3(2)(B) is the definition of chemicals excluded from TSCA, i.e. drugs, pesticides, tobacco, and food or food additives

So substances usually excluded from TSCA will be included in this inventory!

This will impact the 2020 CDR
Section 14: Disclosure of Data (CBI)

Under the Act, section 14 regarding Confidential Information has been completely rewritten.

4 certifying statements of support for claiming CBI on the PMN. These require the submitter certify

1) his or her company has taken reasonable measures to protect the confidential information,
2) his or her company has determined the information is not required to be disclosed to the public under any other Federal law,
3) he or she has a reasonable basis to conclude disclosure of the information will cause substantial harm to the competitive position of his or her company and,
4) he or she have a reasonable basis to believe the information in not readily discoverable through reverse engineering

→ Reverse engineering generally NOT requiring extensive unit operations (distillation, filtering, CE...) and then analysis
Section 14: Disclosure of Data (CBI)

▶ Section 14(b)(2) -- Health and safety studies are not protected CBI

▶ Section 14(b)(3): CBI protection does not apply to:
  ▷ General information describing the manufacture
  ▷ Aggregate volumes or ranges of aggregate volumes
  ▷ General descriptions of processes used in manufacture or processing, functions, and use
  ▷ Information specific to a certain sector that would not customarily be shared with the general public

▶ Any substances currently on the TSCA inventory confidential list must submit or re-submit substantiation

▶ 10 year limit on CBI claims

▶ EPA must evaluate 25% of received CBI claims
Section 18: Preemption

▶ Preemption – When federal law overrules state law
▶ States with strong chemical control laws fought this issue fiercely
  ▶ States like CA felt they had already created “better" regulations for chemical control – Prop65, Safer Consumer Products
  ▶ TSCA cannot preempt any state action taken prior to April 22, 2016 that restricts chemical substances (any action taken under a state law prior to Aug 2003 is not effected)

▶ General preemption clauses:
▶ States cannot create new or enforce existing state regulations if they are likely to produce the same information required under TSCA Section 4, 5, or 6
▶ States can not regulate a chemical after EPA performs a risk evaluation and finds the chemical does not present an unreasonable risk. Nor can states add additional regulations about a specific risks after EPA promulgates a rule addressing the identified risks
Section 18: Preemption

► Pause Preemption:
► A possibly temporary time period within which states are preempted
  ▶ Starts once EPA begins a risk evaluation under TSCA Section 6
  ▶ Ends on earlier date when:
    ▶ Date when EPA publishes risk evaluation
    ▶ Expiration of the time deadline established under section 6
  ▶ Pause Preemption Only Applies to high-priority substances
    ▶ NOT Low-priority substances, new chemical substances, first ten Work Plan chemicals or chemicals undergoing self-requested risk evaluations

► States can request a waiver from pause preemption

The lawyers and politicians are going to have the most to say about this change in TSCA law!
Section 26: Fees

- Lautenberg Act re-writes the way EPA can and will collect fees for section 4, 5, 6, and 14 activities.

- Total annual fees may be:
  - 25% of EPA’s costs for operating TSCA Sections 4, 5, 6, and 14
  - Up to a MAXIMUM of $25 million (TSCA Service Fee Fund)

- Proposed rule by December 2016; Final rule by June 2017

- The Act requires EPA to:
  - Set lower fees for small business (define??)
  - Consider how to charge manufacturers vs. processors
  - Consult with the regulated community
Section 26: Other Items

- Science Advisory Committee on Chemicals (SACC)

- Scientific Standards – Requires the EPA science decisions to be done in manner “consistent with the best available science”

- Weight of Scientific Evidence – Requires EPA decisions for Sections 4, 5, and 6 must be “based on the weight of the scientific evidence”
Interplay with Other Agencies

- EPA actions to risk assessments may have substantial overlap with other agencies
  - OSHA – EPA required inhalation studies vs PEL’s
  - CPSC – consumer uses may vastly expand EPA’s required exposure assessments
  - FDA – EPA assessments may impact drug active ingredients or their inactive ingredients
  - FIFRA – EPA regulation of pesticides
- OSHA deferred EPA to regulate methylene chloride due to “limitations on OSHA authority”
## Proposed Rules and efforts Required of EPA by Dec 22 2016

1) Establish, by **rule**, “a risk-based screening process”

2) Establish, by **rule**, “a process to conduct risk evaluations”

3) Establish, by **rule**, the process for the inventory reset

4) Establish, by **rule**, a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion of the list

5) Establish, by **rule**, a fee structure system to meet the needs of EPA and the requirements of the Act (rule due in 3 years, but all fees needed sooner)

6) Establish SACC

7) Publish Guidance on 3rd party risk evaluations

8) Make a determination with Small Business Administration on adequacy of small manufacturers standards – i.e. definition of a small business <$4mill

9) Report to Congress on capacity to perform evaluations and promote rules under section 6

10) At the beginning of each calendar year, the EPA shall publish an **annual plan** that details which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion
The Frank R. Lautenberg Chemical Safety for the 21st Century Act will have profound and far reaching impact to the entire chemical industry, the most significant (in my opinion) being:

- **Inventory reset** – potential market restriction – need to reevaluate all RM’s for US legal status
- **Increased requirement for testing** – increased testing costs without clear pre-market test plans
- **Prioritization** – planning for prioritization
- **Risk evaluations** – far more common in the future, going to need to be faster, EPA will have to use 3rd parties, what will be the assessed costs
- **Preemption** – mostly political
- **Fees** – it’s could get expensive (i.e. market restriction)
- **EPA capabilities** – can they do the job?

There are no experts anymore—even EPA!
Implementation of TSCA– Who and Where in EPA
Is TSCA Actually administrated

Exposure Assessment Coordination and Policy Division

Chemical Control Division

Chemistry, Economics and Sustainable Strategies Division

Environmental Assistance Division

Information Management Division

National Program Chemicals Division

Risk Assessment Division

Toxic Release Inventory Program Division

TSCA Interagency Testing Division

Office of Science Coordination and Policy

Office of Chemical Safety and Pollution Prevention

Office of Pollution Prevention and Toxics

EPA Office of Administrator

1 of 12 EPA Offices--
Office of Water
Office of Research and Development
Office of Land and Emergency Management
Office of International and Tribal Affairs
Office of Inspector General
Office of General Counsel
Office of Environmental Information
Office of Enforcement and Compliance Assurance
Office of the Chief Financial Officer
Office of Air and Radiation
Office of Administration and Resource Management