



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

Amendment to Toxic Substance
Control Act (TSCA)

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Objectives

- Have a working understanding of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA 2.0) and the significance of the recent amendment
 - Know the intent of the Act
 - Know why the original Act was amended
- What is new
 - Major changes
- Timelines
- Know how this amendment affect you or your clients

Overview of the Amendment

- The Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576)
- Nicknamed TSCA 2.0
- Signed into law June 22, 2016 by President Obama
- The U.S. House of Representatives voted 403 to 12
- 'The first major update to an environmental statute in 20 years' – Gina McCarthy, head of the EPA
- Strengthens an Act that was meant to be as powerful as the Clean Water Act, Clean Air Act and Endangered Species Act

Principles of TSCA 2.0

- Chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment
- Manufacturer's should provide EPA with the necessary information to conclude that new and existing chemicals introduced into commerce are safe and do not endanger public health or the environment
- Risk management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations
- Manufacturer's and EPA should assess and act on priority chemicals, both existing and new, in a timely manner
- Green chemistry should be encouraged, transparency and public access to information should be strengthened
- EPA should be given a sustained source of funding for implementation

About the Original TSCA

- Background
 - First passed in 1976
 - Federal law the EPA uses to regulate the manufacturing and commerce of chemical substances that are not regulated by other federal laws
 - Intent was to protect the public from the health effects of toxic chemicals found in household and industrial compounds in commerce
 - Does not cover drugs, cosmetics or pesticides

The Original TSCA

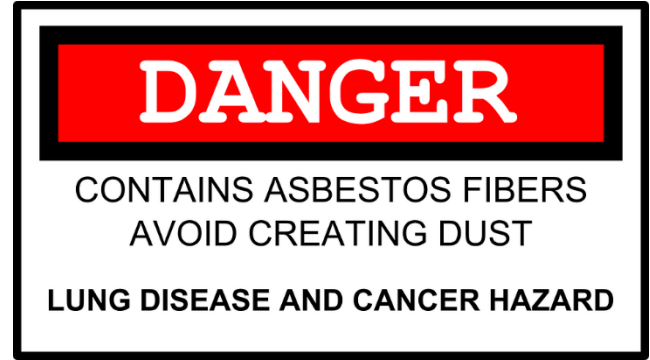
- Manufacturer's submit a Pre-Manufacturing Notice ("PMN")
 - Not all chemicals are reviewed unless they are suspected of posing an unreasonable risk
 - In the absence of toxicity data, the EPA makes some worst-case assumptions and restricts use accordingly
 - Only a fraction of chemicals subject to TSCA have been banned or restricted
 - EPA reviewed chemicals based on risk-benefit

About the Original TSCA

- Shortcomings
 - EPA could not enforce it without lengthy rulemaking
 - Only 5 chemicals or chemical groups of the 60,000+ chemicals that were on the market at the time the original act was passed have been banned
 - Inadequate premarket safety testing standards-the biggest problem was that toxicity data was not required to be generated
 - Risk/benefit analysis made it difficult to ban any material

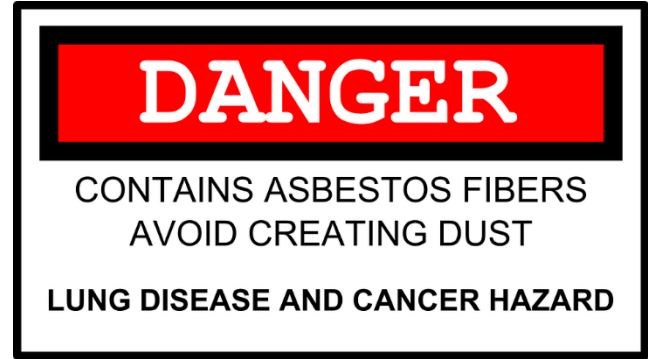
Case Study: Asbestos

- Asbestos
 - Known Carcinogen
 - » Scientists have been well aware of this for years
 - Chronic exposure can lead to significant health effects
 - » Lung cancer
 - » Mesothelioma



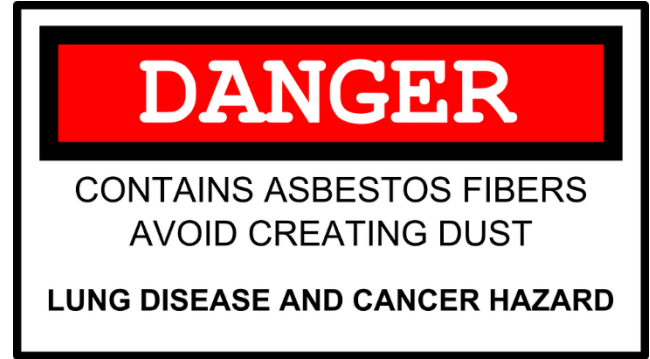
Case Study: Asbestos

- EPA's Strategy
 - In the 1980's soon after the first TSCA was passed, the EPA attempted to use their evaluation of asbestos to set the precedent for how other chemical substances were assessed. As a result they spent 10 years building a case against asbestos.



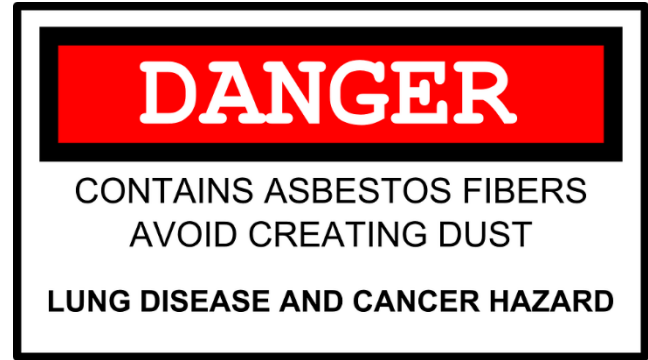
Case Study: Asbestos

- EPA's Conclusion
 - A total ban was necessary
 - 202 lives would be saved
 - Cost to ban asbestos: 459 million (3.1 million per life saved)



Case Study: Asbestos

- Court's Ruling
 - EPA's methodology incomplete and inadequate
 - Did not assess the impact of incremental restrictions only looked at complete ban or unregulated
 - Did not assess the risk-benefit of asbestos substitutes
 - Should have looked at the risk benefits over a longer period of time
 - ❖ *As a result, you can still purchase products that contain asbestos*





What's New

Amendment vs Original Act

Frank R. Lautenberg Chemical Safety for the 21st Century Act 2016 Act	Toxic Substance Control Act 1976 Act
Mandatory review of existing chemicals	Review not required
Aggressive deadlines and a prioritized review schedule	No deadline for action
Risk-based safety standard with special considerations for vulnerable populations	Risk-benefit balancing standard with no special considerations for vulnerable populations
Elimination of unreasonable risk	Significant risks not addressed due to cost/benefit balancing
EPA has new authority to require additional information such as health and safety testing on chemicals when necessary	Lengthy rulemaking that made it onerous to assess chemicals and/or impose restrictions

Amendment vs Original Act

Frank R. Lautenberg Chemical Safety for the 21st Century Act 2016 Act	Toxic Substance Control Act 1976 Act
Mandated safety tests	Safety tests not mandated
New chemicals or a significant new use of an existing chemical must be approved by the EPA before reaching the market	Chemicals were not deemed safe by the EPA before being made available to the public
Must substantiate Confidential Business Information (CBI) claims	No legal requirement to prove CBI claims

Amendment vs Original Act

Frank R. Lautenberg Chemical Safety for the 21st Century Act 2016 Act	Toxic Substance Control Act 1976 Act
Funding from user fees up to \$25 million total and Congressional appropriations	Funding from capped individual user fee up to \$2,500 and limited authority to collect fees
Requires review of all chemicals actively used in commerce as well as new chemicals	Existing chemicals at the time the law was passed were grandfathered in and did not require review
Greater transparency: States and health and environmental professionals have access to confidential information	--



Key Features of the New Act

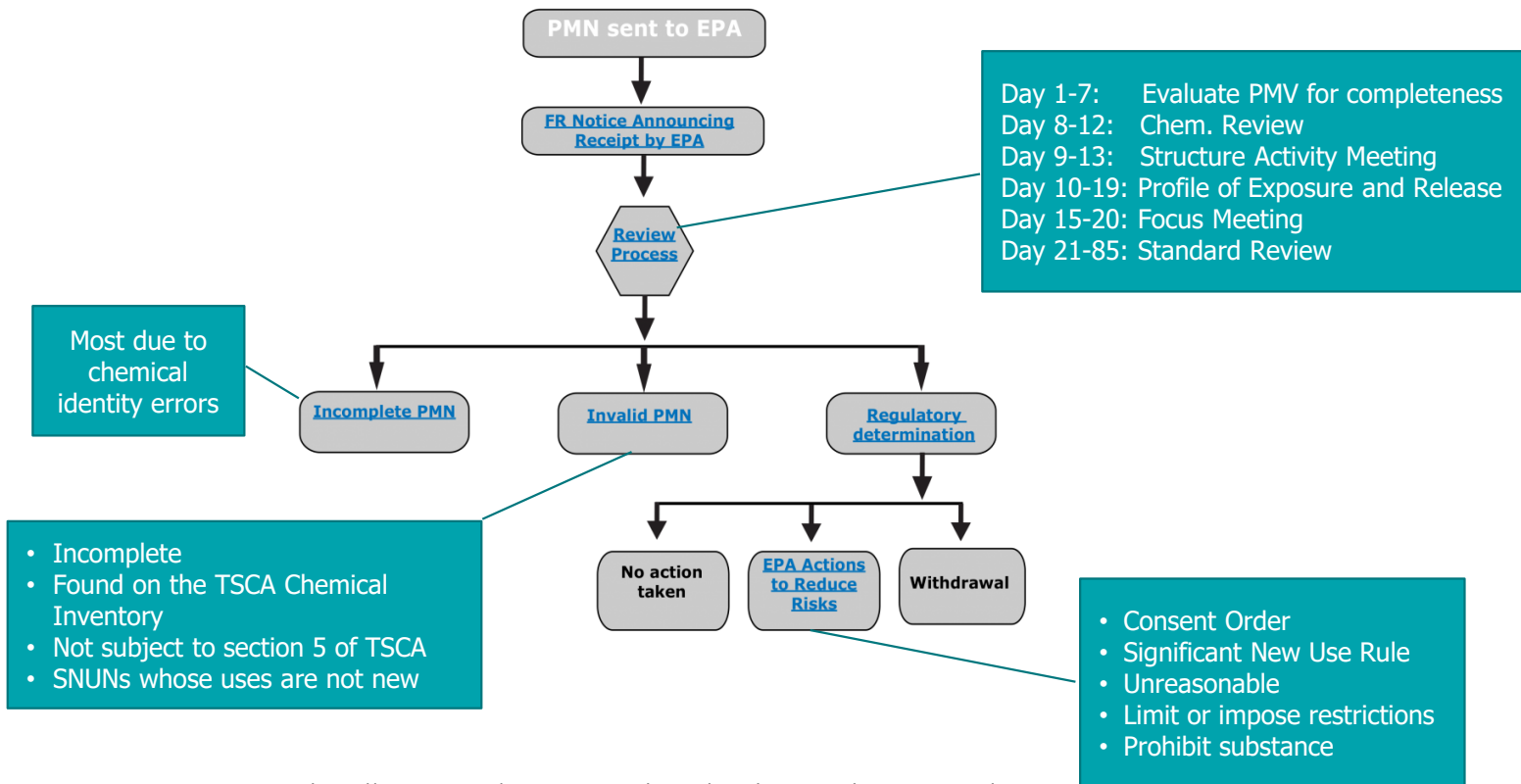
Risk Assessment Process

- Revises the threshold for regulating chemical substances and separates consideration of costs and other non-risk factors from the process
 - EPA will be limited to considering human health and environmental effects including risks to vulnerable population subgroups
 - If EPA determines a unreasonable risk, the agency must issue a regulation to manage
 - EPA's decisions will be based on the 'best available' science and the 'weight of the evidence'

Determination for New Chemicals

- New chemicals cannot enter commerce until EPA makes an affirmative determination whether the new chemical may present an unreasonable risk to human health or the environment
- The same standard will apply to Premanufacture Notices (PMNs) and Significant New Use (SNU)s

What Happens to My PMN?



Chemical Testing

- Expands EPA's authority to require chemical testing on certain substances
- Provides additional, more flexible authority to allow EPA to require development of new hazard or exposure information
- Requires EPA to take expedited action when new information indicates that a chemical presents a significant risk to humans
- Requires EPA to:
 - Reduce and replace vertebrate animal testing when this can be scientifically justified
 - Develop and implement a strategic plan to promote the use of alternative test methods that are not based on vertebrate animals

Prioritize Chemical Substances

- EPA must prioritize chemical substances already in commerce for risk assessment and risk management determination
- EPA must establish its risk evaluation process by rule. Timelines set for creating the 'high priority' and 'low-priority' substances
- EPA is expected to give preference to chemicals listed on its *Work Plan*
- EPA must implement a risk-based screening process that includes considerations such as hazard and exposure potential, persistence and bioaccumulation, and storage near significant sources of drinking water

TSCA Work Plan

- EPA has identified a work plan of chemicals for further assessment. The criteria focused on chemicals that meet one or more of the following factors:
 - Potentially of concern to children's health (for example, because of reproductive or developmental effects)
 - Neurotoxic effects
 - Persistent, Bioaccumulative, and Toxic (PBT)
 - Probable or known carcinogens
 - Used in children's products
 - Detected in biomonitoring programs
- Originally released in March 2012, updated in October 2014, EPA's TSCA Work Plan helps focus and direct the activities of its Existing Chemicals Program

Updates the TSCA Inventory (Inventory Reset)

- EPA maintains an inventory of chemicals that are 'existing' and 'new'
- EPA must issue a new rule within 1 year to require reports to update the inventory
 - Requires manufacturers and possibly processors to notify EPA within 6 months that a chemical has been manufactured or processed during the 10 year period prior to enactment
- EPA is to retain the chemical nomenclature conventions made for the initial inventory

Confidential Business Information (CBI) Changes

- New act revises and completely replaces existing Section 14
- EPA must review existing CBI claims
- Substantiated claims will be protected for an initial 10-year period
- EPA has authority to share CBI with state and tribal governments, health and environmental professionals and first responders

Fee Adjustment

- EPA is authorized to collect considerably higher fees
- For risk evaluations requested by manufacturers, establish the fee at a level sufficient to defray the full costs (or 50 percent of the cost in the case of chemicals in the 2014 update of the TSCA Work Plan)
- Refund fees (or a portion thereof) if a PMN/SNUN is not reviewed or is withdrawn, if no substantial work was performed on the notice

Preemption of State Regulations

- Final EPA actions on chemicals will preempt state regulation (subject to exceptions and state waivers)
- States can adopt regulations identical to federal standards issued pursuant to TSCA
- Penalties will be capped at the federal statutory maximum
- If EPA issues a final risk management rule which limits or prohibits a chemical substance, state actions would be preempted
- Two significant grandfathering provisions:
 1. States may continue to enforce any actions taken or requirements imposed regarding specific chemicals prior to April 22, 2016; and
 2. States may continue to enforce and take new regulatory actions regarding chemicals pursuant to state laws that were in effect on August 31, 2003

Identification of Hot Spots

- Act amends the Public Health Service Act to encourage the identification and investigation of potential cancer clusters

Important Timelines

September 2016

- EPA must publish list of mercury compounds prohibited from export

December 2016

- EPA must conduct risk evaluations on 10 chemicals identified in the 2014 update to the TSCA Work Plan
- EPA must decide if they are going to revise what constitutes a 'small business'

April 2017

- EPA must publish an inventory of mercury supply, use and trade in the U.S.

Important Timelines

June 2017

- EPA must establish a risk-based screening process and criteria for designating chemicals as high or low priority
- EPA must develop guidance to help manufacturers conduct and submit draft risk evaluations for EPA consideration
- The TSCA Work Plan is likely to serve as the initial basis for both

June 2018

- EPA must develop any policies, procedures, and guidance that it determines necessary to carry out legislation
- EPA must develop a strategic plan to promote development of alternative test methods to reduce or replace vertebrate animal testing

Early Requirements

- EPA must set fees
- EPA must begin making affirmative findings based on review of PMNs and SNUNs
- Establishment of a Science Advisory Committee on Chemicals (SACC)

Mercury Export

- Published August 26, 2016
- 5 mercury compounds cannot be exported starting June 1, 2020
 - Mercury (I) chloride or calomel
 - Mercury (II) oxide
 - Mercury (II) sulfate
 - Mercury (II) nitrate
 - Cinnabar or mercury sulphide
- The purpose of this ban is to prevent the conversion of the compounds to elemental mercury once they have been exported outside of the U.S.
- Who's affected?
 - Manufacturers of basic inorganic chemicals
 - Manufacturers of chemical products
 - Manufacturers of instruments and instrumentation systems for laboratory analysis
 - Other Chemical and Allied Products Merchant Wholesalers

Persistent, Bioaccumulative, and Toxic Chemicals Covered Under TSCA Section 6(h)

- The new Act requires that EPA take expedited action on certain PBT chemicals listed on the Agency's 2014 update of the TSCA Chemicals Work Plan for Chemical Assessment (2014 Work Plan)

PBT Chemicals Subject to Section 6(h)

Decabromodiphenyl ethers (DecaBDE) (CASRN 1163-19-5)

Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl)- (CASRN 54464-59-4)

Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)- (CASRN 54464-57-2)

Hexachlorobutadiene (CASRN 87-68-3)

Pentachlorothio-phenol (CASRN 133-49-3)

Phenol, isopropylated, phosphate (3:1) (iPTPP) (CASRN 68937-41-7)

2,4,6-Tris(-tert-butyl)phenol (CASRN 732-26-3)



Impact

Who's impacted?

- Chemical manufacturers, processors, and importers
- Innovators of chemicals and products
- Entities engaged in mergers and acquisitions
- Investors in chemical, manufacturing, and retail sector entities
- Importers
- Corporate entities subject to US Securities and Exchange Commission (SEC) risk disclosures

Challenges for Industry

- Manufacturers should participate in rulemaking process for fees
- Inventory Reset Rule will require manufacturers and processors to report to the EPA all chemicals they have manufactured or processes within the preceding 10 years
- Manufacturers must provide confidentiality claims for chemicals manufactured during the preceding 10 years
- If submitting PMNs and SNUs, be aware of EPA's obligation to make an affirmative finding about risk-consider developing additional information that will allow EPA to find that they are not likely to present an unreasonable risk
- Manufacturer can request that EPA designate a chemical as high-priority

Challenges for Industry (Cont.)

- Suppliers may submit requests on behalf of processors (who are not authorized to make requests)
- Companies should review the TSCA Work Plan list for chemicals relevant to their business and plan accordingly
- As EPA prioritizes, conducts a risk evaluation for, and possibly regulates individual chemicals, affected companies or trade association should participate in the process

Preparing for Impact

- Review Product Lines Now
 - Determine which ones are likely to become 'high priority' targets for EPA risk evaluations
 - Flag chemicals that are persistent, bioaccumulate and carcinogenic. Collect and review all health, safety and environmental fate and effects data
 - Evaluate potential business impact if EPA decides to do a risk evaluation and customers may discontinue use
- Confirm the chemical nomenclature for all chemicals in the product lines to avoid a substance being treated as 'new'
- Monitor state chemical-regulator actions
- Review existing claims of confidentiality
- Supply Chain-Communicate with supply chain and downstream users regarding substances or products that might be subject to this act

Thank You

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