An Overview of TSCA, TSCA Reform, and LCSA Implementation

American Chemistry Council

American® Chemistry Council

American Chemistry Council

- **Primary trade association for the chemical industry in the US.**
- **160 members representing ~85% of US chemical production by volume.**
- **Approximately 185 full-time and part-time staff at HQ and four small regional offices**

The leading voice of the business of chemistry

Responsible Care®

Our commitment to:

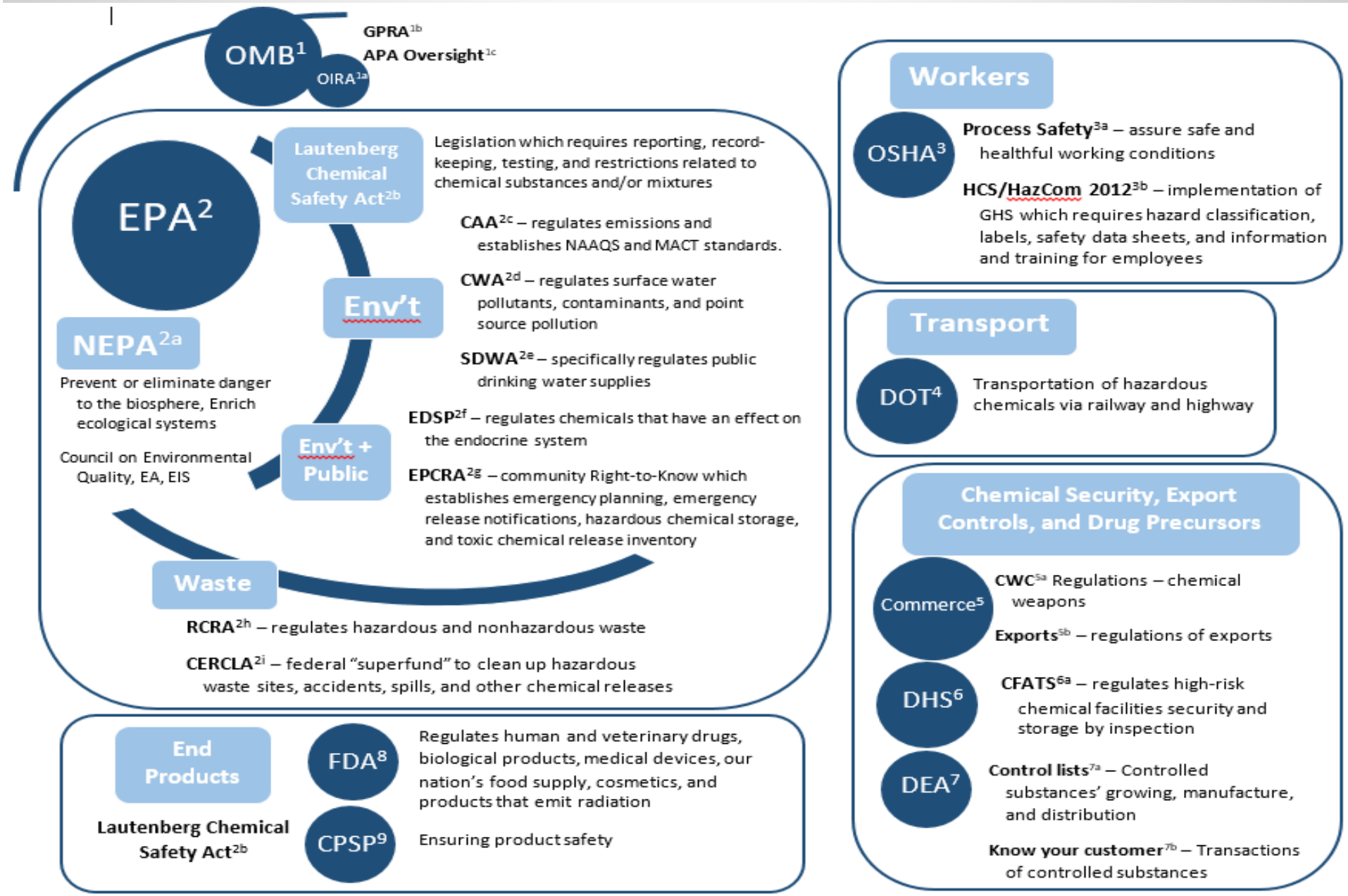
- Improve EHS&S performance and chemical management
- Use resources efficiently
- Build stakeholder relationships
- Report openly and transparently
- Improved efficiencies, lower operating costs
- Share ethical and operational philosophies, linking suppliers and customers
- Provide a performance foundation for ACC advocacy

Responsible Care®

OUR COMMITMENT TO SUSTAINABILITY

- Responsible Care provides a robust **foundation** for addressing common sustainability impacts across the chemical industry

- The common impact areas addressed by Responsible Care Codes: *occupational-, process- and product safety, environmental protection, emergency preparedness, community engagement, chemical distribution safety, security*


OMB[1]
OIRA[1a]
GPRA[1b]
APA Oversight[1c]
EPA[2]
Lautenberg Chemical Safety Act[2b]
Legislation which requires reporting, record-keeping, testing, and restrictions related to chemical substances and/or mixtures
Env't
CAA[2c] – regulates emissions and establishes NAAQS and MACT standards.
CWA[2d] – regulates surface water pollutants, contaminants, and point source pollution
SDWA[2e] – specifically regulates public drinking water supplies
NEPA[2a]
Prevent or eliminate danger to the biosphere, Enrich ecological systems
Council on Environmental Quality, EA, EIS
Env't + Public
EDSP[2f] – regulates chemicals that have an effect on the endocrine system
EPCRA[2g] – community Right-to-Know which establishes emergency planning, emergency release notifications, hazardous chemical storage, and toxic chemical release inventory
Waste
RCRA[2h] – regulates hazardous and nonhazardous waste
CERCLA[2i] – federal "superfund" to clean up hazardous waste sites, accidents, spills, and other chemical releases
Workers
OSHA[3]
Process Safety[3a] – assure safe and healthful working conditions
HCS/HazCom 2012[3b] – implementation of GHS which requires hazard classification, labels, safety data sheets, and information and training for employees
Transport
DOT[4]
Transportation of hazardous chemicals via railway and highway
Chemical Security, Export Controls, and Drug Precursors
Commerce[5]
CWC[5a] Regulations – chemical weapons
Exports[5b] – regulations of exports
DHS[6]
CFATS[6a] – regulates high-risk chemical facilities security and storage by inspection
DEA[7]
Control lists[7a] – Controlled substances' growing, manufacture, and distribution
Know your customer[7b] – Transactions of controlled substances
End Products
Lautenberg Chemical Safety Act[2b]
FDA[8]
Regulates human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation
CPSP[9]
Ensuring product safety

Toxic Substances Control Act (TSCA)

The 1976 Toxic Substances Control Act regulated the production & use of industrial chemicals in commerce

New Chemicals:

Any chemical introduced or a significant new use of an existing chemical required notice and/or EPA review before commercialization. Generally viewed as effective.

Existing Chemicals:

All chemicals in commerce when TSCA was enacted were "grandfathered" - no EPA review was required for the chemicals to remain in use. Became a greater source of debate.

Toxic Substances Control Act (TSCA)

Gave EPA authority to

- Review new chemicals before they are manufactured
- Gather information on existing chemicals in commerce
- Require manufacturers to test chemicals
- Regulate chemicals

Chemical Safety Net

- TSCA is one of many statutes that regulate chemicals
- Other statutes cover pesticides; food, drug & cosmetics; pollutants; and worker safety
- TSCA's unique focus is on chemicals in commerce

In the beginning...

- When TSCA was first enacted, companies informed EPA which chemicals were produced at that time.
- That list of chemicals resulted in the initial TSCA inventory (1979).
  - Also referred to as “grandfathered” chemicals
- Any chemical developed and marketed AFTER 1979 has gone through New Chemical Review

NEW CHEMICAL REVIEW
TSCA Section 5

1. **Company submits PMN (pre-manufacture notice)**
   - Chemical identity information
   - Production volumes
   - Intended categories of use
   - Description of by-products
   - Molecular formula
   - Available information

2. **EPA conducts initial review**

3. **EPA Develops Hazard Profile**
   - Structure Activity Team uses analogs
   - Evaluates health effects, environmental effects, environmental fate
   - Establishes health and environmental hazard potential

4. **EPA Develops Exposure/Release Profile**

Chemical industry one of the MOST regulated industries

In addition to the Toxic Substances Control Act (TSCA), we have…

- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),
- Federal Food, Drug and Cosmetics Act (FFDCA),
- Clean Air Act (CAA),
- Clean Water Act (CWA),
- Resource Conservation and Recovery Act (RCRA),
- Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA)
- Emergency Planning and Community Right-to-Know Act (EPCRA),
- Occupational Safety and Health Act (OSHA)
- Hazardous Materials Transportation Act (HMTA)
- Consumer Product Safety Act (CPSA)
- Federal Hazardous Substances Act (FHSA)
- Food Quality Protection Act (FQPA).

Evaluation of New Chemicals under 1976 TSCA

Companies required to submit:

- any available health or environmental test information
- information on the chemical identity and structure
- anticipated uses, production volume
- by-products
- human exposures
- disposal practices

EPA scientists used the information submitted to:

- Reach scientific conclusions based on chemical size & structure
- Identify structural analogs and use the analog data in evaluation
- Conduct computer modeling
  - If the above not sufficient, EPA would require testing

Innovation under 1976 TSCA's New Chemicals Program

Compared to Europe, US industry has

- Higher economic performance
- Higher R&D productivity
- Higher patent productivity
- Higher polymer patent
- Higher numbers of new chemical notifications.

TSCA allowed US companies to remain innovative while still appropriately evaluating the new chemicals for risk.

Restrictions on Chemicals

Only five substances were restricted under TSCA Section 6

BUT over 1,000 substances were restricted under Sect. 5

- EXAMPLE: A chemical does not show unusual toxicity except to certain aquatic organisms. EPA uses Section 5 to prevent waste disposal to water or sewers, and compel disposal methods that do not present environmental risks.

Voluntary Controls: chemicals voluntarily controlled through industry's product stewardship programs.

Confidential Business Information

- The issue of Confidential Business Information (CBI) is very important in TSCA.
- Congress clearly understood the need to build in strong protections for CBI.
- TSCA compels industry to provide a wealth of sensitive data
  - Chemical identity for a new substance which may not yet have received patent protection
  - Volume produced, which would signal to competitors the potential market size for the chemical
  - Molecular weight range for a new commercially valuable polymer
  - Impurities, which can signal key information on process or precursor substances

Health and Safety Information Cannot Be Claimed as CBI

Some groups argued that the general public needed access to CBI to understand potential risks, but

- Presumably, the general public would be most interested in health and safety information, and
- **Companies were NOT entitled to claim health & safety information as confidential under TSCA.**
- Specific chemical names and chemical structures are normally claimed confidential
  - Generic descriptions of chemicals are not.
- Generic name descriptions, along with the health and safety information, is suitable for most purposes.

Information about Chemicals

- Companies have conducted testing and evaluations of existing chemicals for many, many years.
  - The problem is not that the information doesn't exist.
  - It's that, until recently, it has not been publicly available.

Why TSCA Reform?

Over time TSCA implementation became a source of frustration for regulators, industry & the interested public

- Lawsuits challenged EPA's authority
- Delays plagued EPA chemical reviews & determination
- Requiring safety testing & data from chemical producers was difficult
- EPA believed it had to consider costs & benefits when determining a chemical's safety, which complicated reviews
- EPA regulated relatively few existing chemicals
- Advances in testing technology & scientific understanding of chemicals not reflected in TSCA's policies & procedures
- Despite new chemicals program's success, there were calls for additional safeguards

Republicans & Democrats; industry, environmentalists, EPA, public health groups & organized labor agreed it was time for reform

2009	2013	2015	2016
			
ACC called for TSCA reform	First bipartisan reform bill introduced by Lautenberg & Vitter with support of ACC & EDF	Both the Senate & the House pass TSCA reform by overwhelming margins	President Obama signs the Frank R. Lautenberg Chemical Safety for the 21st Century Act into law

Lautenberg Chemical Safety Act

A More Effective Way to Regulate Chemicals

EXISTING CHEMICALS

EPA will conduct risk-based reviews of chemicals in commerce

Inventory Reset

EPA maintains an inventory of chemicals, but it is difficult to tell which are used today and which are no longer in use

LCSA requires the inventory be updated so EPA can focus on chemicals actually in use today

Prioritization

EPA will screen all chemicals in active use to identify low and high priorities for risk evaluation. Prioritization will be based on factors including hazards, uses and exposures to people and the environment, including vulnerable groups like infants, children, pregnant women and the elderly

Low Priority Chemicals ✓

Chemicals can remain in use but can be reprioritized based on new information

High Priority Chemicals

EPA will conduct a thorough risk evaluation

The first 10 high priorities must be drawn from EPA's existing TSCA Chemical Work Plan list

Risk Evaluation

EPA Risk Evaluations will:

- Be based solely on health and environmental information
- Consider a chemical's conditions of use
- Rely on the best available studies and weight of scientific evidence
- Consider risks to vulnerable groups

LCSA makes it easier for EPA to request more testing and data from producers when needed

20 risk evaluations must be underway within 3.5 years

Safety Determination

EPA will determine if a chemical meets the law's safety standard or requires risk management

Chemical Meets Safety Standard ✓

Chemical may be used for its intended uses

Chemical Needs Risk Management

EPA's options include:

- Labeling Requirements
- Use Restrictions
- Phase Outs
- Bans

NEW CHEMICALS

EPA must conduct a risk-based review and make an affirmative safety determination before a new chemical can come to market

Information Submitted to EPA

Manufacturers provide information about new chemicals and new chemical uses to EPA

Risk-Based Review

EPA reviews information including chemical characteristics, available testing and exposure data and intended uses

EPA can request more information if needed

Safety Determination

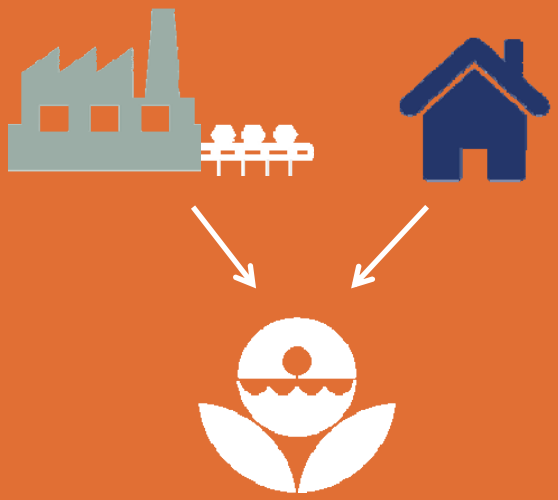
If EPA finds the chemical is not likely to present an unreasonable risk, it proceeds to market

If the chemical presents an unreasonable risk, EPA may apply risk management measures

EPA must review & make an affirmative safety determination before a new chemical can be manufactured

Information submitted to EPA:

Manufacturers provide information about new chemicals & significant new chemical uses to EPA



Risk-Based Review:

EPA reviews info. including chemical characteristics, available testing & exposure data & intended uses

* EPA can request more information, if needed

Safety Determination:

If no unreasonable risk, chemical can proceed to manufacturing.

Unreasonable risk, EPA may apply a range of risk management measures.

Inventory Reset

- EPA's TSCA chemical inventory did not distinguish between chemicals in use and those no longer produced
- LCSA's inventory reset will clarify which chemicals are in use today
- All active chemicals must undergo screening for prioritization & possible risk evaluation

Heard the myth that there are 84,000 chemicals in commerce?

Learn more

Prioritization

- EPA will conduct a risk-based screening of all active chemicals from the inventory to identify those in need of a full evaluation
- If more information is needed, EPA can request additional testing and data

Low Priority Chemicals:

- Remain in use without further action
- Can be reprioritized based on new information at any time

High Priority Chemicals:

- Require a risk evaluation
- First 10 must be from TSCA Work Plan
- For each risk evaluation completed, EPA must designate a new high priority chemical

Risk Evaluation

High Priority chemicals will undergo a full evaluation of *hazards*, *uses*, *exposure*, to determine *risk*

Risk Evaluations must:

- Consider groups like pregnant women, children, the elderly & workers
- Be based solely on health & environmental considerations
- Employ clear scientific standards for scientific quality & reliability & the most relevant studies to ensure the most credible studies carry the most weight

***EPA can again request more information & data if needed.**

Do you know the difference between hazard & risk?

Safety Determination

EPA will determine if a chemical meets LCSA's safety standard, meaning it does not pose an unreasonable risk

Chemicals that meet the safety standard are cleared for use

Chemicals uses that do not meet safety standard require risk management

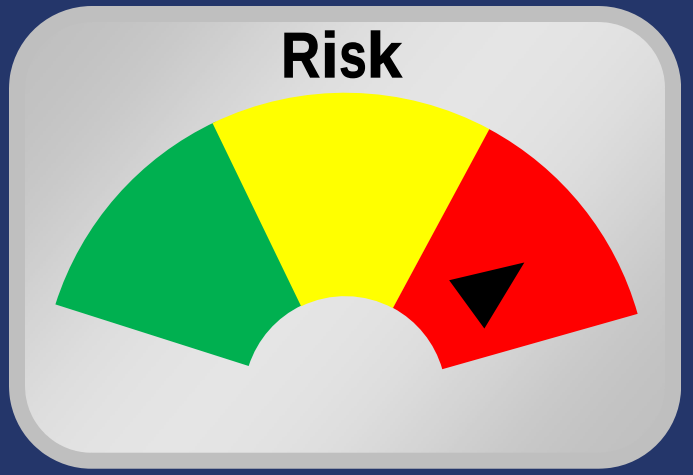
Risk Management

Chemical uses that do not meet the LCSA's safety standard are subject to risk management

Risk management requirements must consider costs & benefits

EPA options include:

- Labeling requirements
- Handling instructions
- Use restrictions
- Phase Outs
- Bans



LCSA Goal: Protect Americans' health and the environment

- Subjects all chemicals in commerce to an EPA review for the first time
- EPA must review and make an affirmative safety determination before a new chemical can come to market
- Requires EPA to consider vulnerable groups like infants, pregnant women, and the elderly when reviewing chemicals for safety

LCSA Goal: Provide more transparency about chemicals, while also protecting legitimate intellectual property

- Companies must substantiate confidentiality claims.
- EPA will apply greater scrutiny to confidentiality requests.
- CBI claims will expire after 10 years unless the company renews the claim.
- State officials, medical professionals & first responders will have greater access to CBI when necessary.

*Sales and manufacturing data is always CBI and always protected

LCSA Goal: Enhance consumer confidence in chemical safety & provide greater regulatory certainty for businesses to foster innovation & growth of the manufacturing sector

The LCSA will:

- **Stop the growth of the conflicting patchwork of state chemical regulations;**
- **Reduce calls for unnecessary product deselection thanks to greater consumer confidence in the safety of chemistry & EPA oversight;**
- **Ensure timely approval of new chemicals so U.S. companies can bring innovations to market in a timeframe that will allow them to compete globally;**
- **Safeguard intellectual property;**
- **Consider small businesses needs.**

LCSA Goal: Ensure EPA has adequate resources to implement the new law & meet deadlines

- The LCSA directs that Congressional appropriations will not fall below FY 2014 levels or $56 million.
- EPA can collect user fees from the regulated community to help cover the costs of implementation.
- Fees can be adjusted over time to ensure they are sufficient to defray the lesser of $25 million or up to 25% of relevant EPA costs.

Consumer Product Safety Act (CPSA)

CPSA Overview

- Protects consumers against unreasonable risk of injury from potentially hazardous products
- Implemented by Consumer Product Safety Commission (CPSC)
  - CPSC can set new acceptable levels of substances to be used in products; develop new testing and documentation requirements; ban substances as necessary
- Example: Children's Product Safety
  - Bans any children's product (a consumer product designed or intended primarily for children 12 years of age or younger) containing more than a specified amount of lead.
  - Manufactures of a product must have the product tested by an accredited third party for compliance

Questions / Discussion?

Thank you!

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