TSCA – Implementation of 2016 Amendments

American Chemistry Council

American® Chemistry Council

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

Principal Provisions of TSCA

- Section 4 - testing of existing chemicals
- Section 5 - screening of new chemicals or new uses of existing chemicals
- Section 6 - risk management
- Section 8 – information collection and reporting

- Section 7 – imminent hazard
- Section 9 - relationship of TSCA to other federal laws
- Section 11 – inspections
- Section 12 - chemical export
- Section 13 - chemical import
- Section 14 – CBI
- Sections 15, 16 and 17 - prohibited acts, penalties & EPA's enforcement powers.
- Section 20 and 21 - citizen actions
- Section 26 – use of categories versus specific substances

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

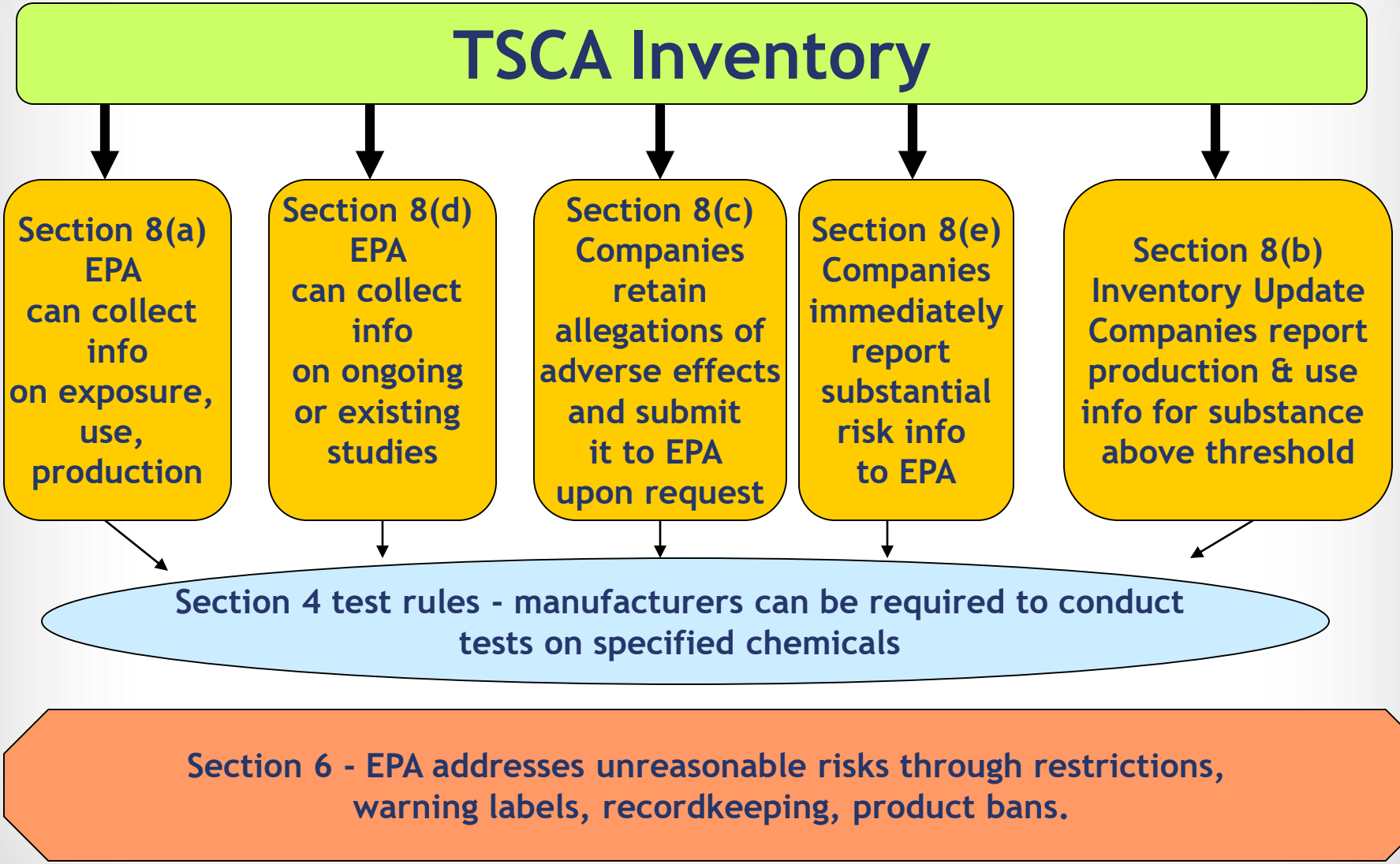
4. **EPA Develops Exposure/Release Profile**

NEW CHEMICAL REVIEW (con't)

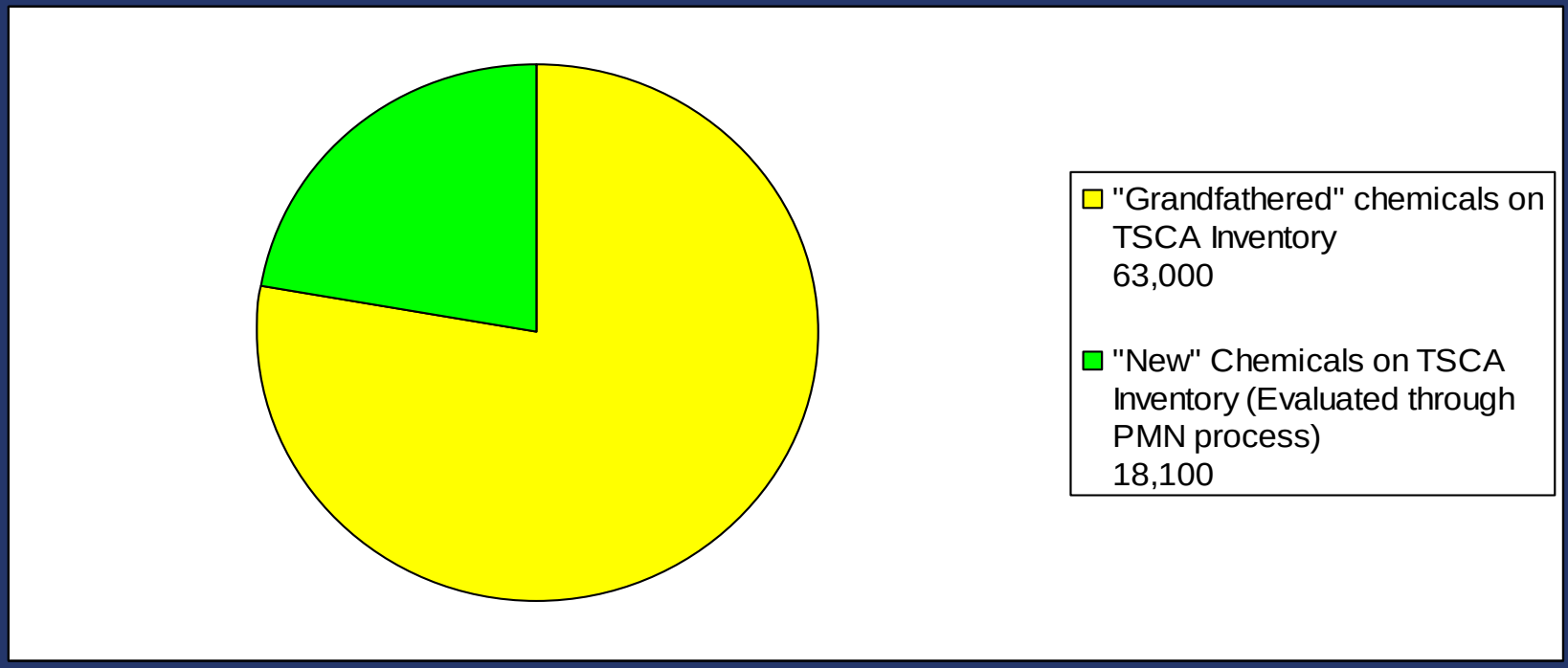
5. **EPA Holds Focus Meeting – Final Decision**
   - More testing is needed for EPA to make a decision
     - Company can produce data or withdraw PMN
   - PMN allowed after additional data provided by company
   - PMN allowed, but with use restrictions
   - PMN allowed without restrictions
   - PMN not allowed
     - Company can withdraw PMN before final decision

6. **Company submits NOC (Notice of Commencement)**
   - **New chemical added to the Inventory**

Existing Chemicals



TSCA Inventory
Grandfathered vs New Chemicals



TSCA Inventory ≠ Chemical in Commerce

- The TSCA inventory is a comprehensive list of all chemicals ever allowed by EPA to be manufactured.
  - About 84,000 chemicals; mix of "grandfathered" and "new" chemicals
- The list reported on the IUR/CDR is the best reflection of chemicals actually being used in commerce.
  - Approx. 8,400 chemicals used in commerce or about 10% percent of total TSCA Inventory
- Remaining chemicals on the Inventory are
  - Produced in small amounts (less than 10,000 lbs. annually) OR
  - Not produced at all OR
  - Inorganics (such as salts) OR
  - Polymers, which are generally viewed as low risk

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).

1976 TSCA's Unreasonable Risk Standard

Congress recognized that we do not live in a 'zero risk' world

Both the risks and benefits of chemicals needed to be considered to prudently carry out the goals of the Act.

“Unreasonable risk" is the criterion for regulating or banning chemical substances under the Act.

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

Testing under 1976 TSCA

- Testing EXISTING chemicals done under Section 4
  - EPA issues Section 4 test rule OR
  - EPA and companies work together under an enforceable consent agreement (or ECA)
- Since TSCA was enacted, data on approximately 200 chemicals were developed through Section 4 or ECAs.

Other Testing

Testing also done as part of NEW CHEMICAL review

- EPA could require testing if needed during PMN review
- 300+ chemicals tested as part of the new chemical review process

Work also done under voluntary programs

- HPV Chemical Challenge program
  - 300+ companies, 100 consortia
  - Hazard screening data sets were completed on ~ 2,200+ chemicals
- Voluntary Children's Chemical Evaluation Program (VCCEP)
  - 35 companies, 10 consortia
  - 20 chemicals
- Extended HPV program

1976 TSCA allowed innovative approaches to gathering information needed for chemical risk management.

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 is a trade secret
  - 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 wouldn't information be publicly available?

- In the old days….
  - Public databases derived from scientific journal articles
  - Journals published cutting edge research information OR highlighted studies where adverse effects were found.
  - If a safety study found no adverse effects, the journals were not interested in publishing.
    - Research information remained in the company files.

Information to public

- There was no easy mechanism to make the information readily available to the public.
- Until, that is, the advent of the Internet.
  - ACC members are using this tool to address this weakness as part of their product stewardship responsibilities.

Examples of Sources for Public Information on Chemicals

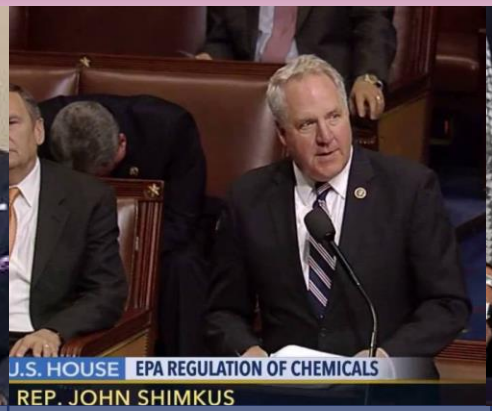
- US HPV Chemical Challenge Program: http://www.epa.gov/hpv/pubs/hpvrstp.htm
- Environmental Protection Agency (EPA)'s HPV Information System: http://www.epa.gov/hpvis/index.html
- Voluntary Children's Chemical Evaluation Program http://www.epa.gov/chemrtk/vccep/index.htm
- Toxic Substance Control Act Test Submission database http://www.syrres.com/eSc/tscats_info.htm
- Integrated Risk Information System (IRIS) http://www.epa.gov/iris/'
- European Chemical Substance Information System (ESIS) http://ecb.jrc.it/ESIS/
- United Nations Environment Program (UNEP) http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html
- INCHEM (developed by International Program on Chemical Safety) http://www.inchem.org/

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

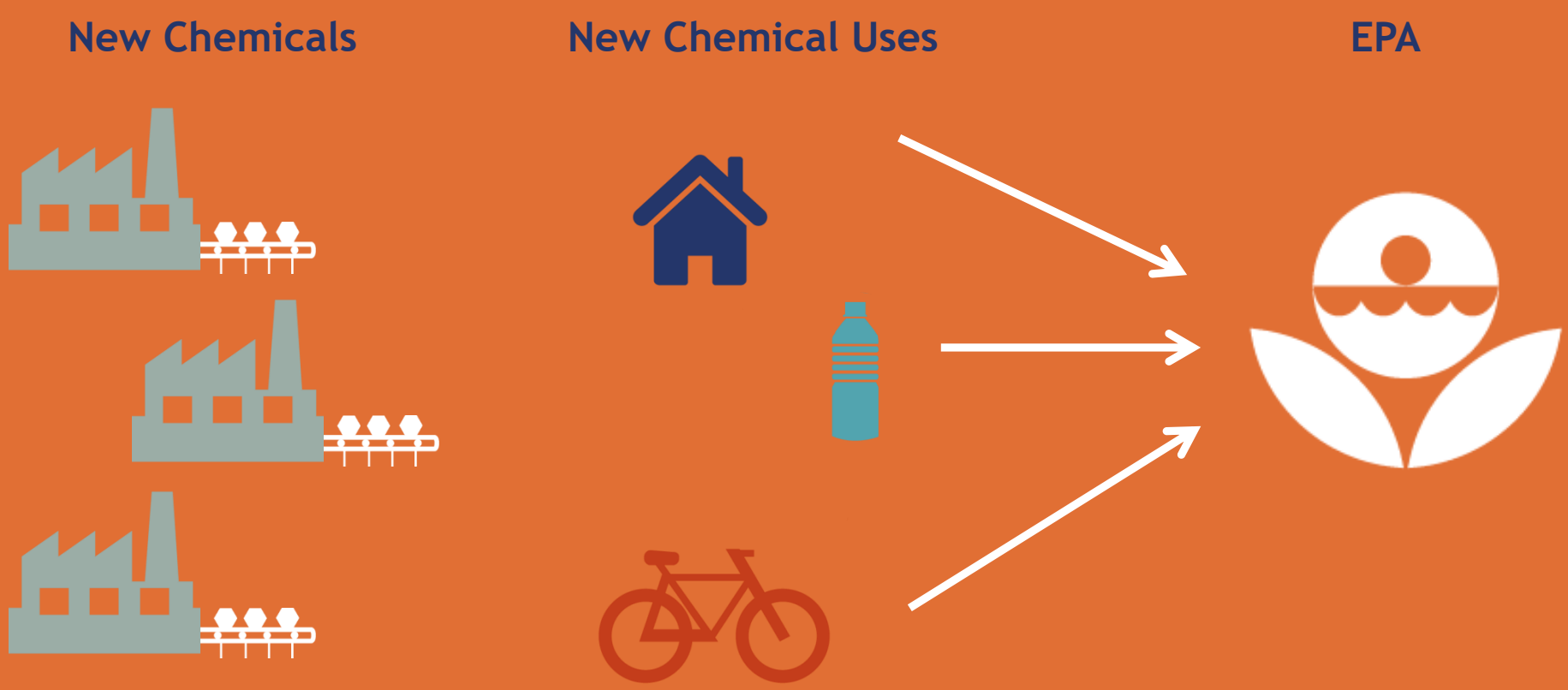
Safety Determination

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:

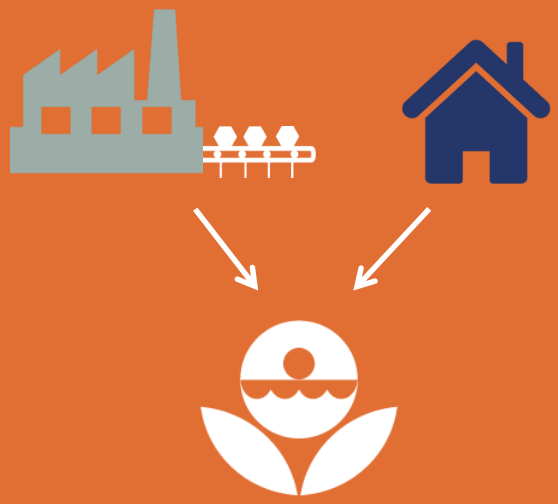
- Manufacturers provide information about new chemicals & significant new chemical uses to EPA



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

Reset Status

- More than 90,000 responses
- 86,228 chemicals on Inventory
- 40,655 (47%) active
- 19% of actives - identity withheld as CBI
- Going forward, chemicals must be active or notified as active to be manufactured or imported

Active Notification Help

- February 19, 2019 update of TSCA Inventory on https://www.epa.gov/tsca-inventory
- EPA webinar on March 13, 2019, 1-4 PM EDT
  - Will show “Notice of Activity (NOA) Form B” and
  - Show how to use EPA’s electronic reporting portal
- Next, EPA to publish “signed action” on Inventory website.
  - 90 days from this, it becomes illegal to manufacture, import, or process an inactive chemical without first submitting an NOA Form B

CBI

- Some issues still in litigation
- EPA developing rule to review claims and substantiation for all CBI claims for specific chemical identity

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

Short Term

- Next 20: Proposed March 2019
- 20 High Priority, 20 Low Priority
- TSCA Work Plan as basis

Long Term

- More sophisticated process proposed
- Binning/batching reviews
- Guidance under development

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?

First 10

- Completion due December 2019
- All 10 have scopes, problem formulations
- One (PV29) has draft risk evaluation
- EPA proposes finding of “does not present” unreasonable risk

Next 20

- Expected to be identified (proposed) March 2019
- Formal selection by December 2019
- These will be the first chemicals designated “high priority” for risk evaluation
- TSCA Work Plan selections expected

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

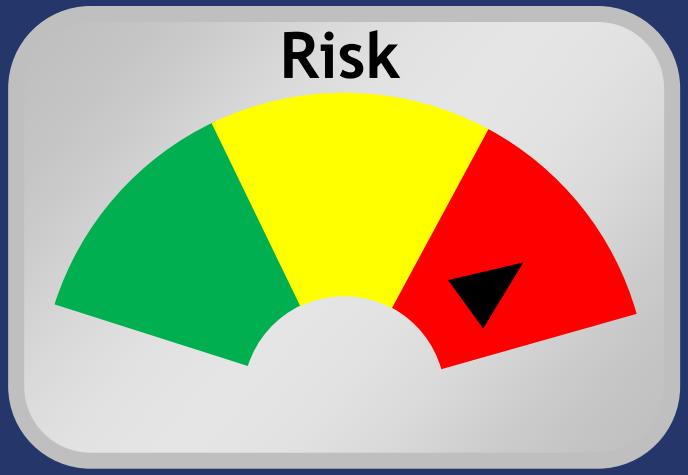
Risk Management

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



3 “Quickstart” Chemistries

- TCE
- NMP
- Methylene Chloride
  - EPA’s proposed rule Jan. 19, 2017
  - Suit filed Jan. 14, 2019 to compel final rule
  - Dec. 21, 2018, EPA sends final rule to OMB
  - Dec. 21, EPA also sends “certification and limited access program” to OMB

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
- Requires EPA to prioritize chemicals so those that need it most are reviewed first
- Makes it easier for EPA to require more safety testing of chemicals
- Gives EPA clear authority to manage risks posed by chemicals, including labeling requirements, use restrictions, phase-outs, or bans
- Sets aggressive deadlines for EPA to complete its work

LCSA Goal: Create a more efficient system with multiple deadlines to keep EPA on track

EPA to identify first 10 chemicals to undergo risk evaluations

December 2016

June 2017

EPA must have risk evaluations underway for at least 20 chemicals

December 2019

EPA establishes rules for:

- Chemical manufacturers to notify EPA of active chemicals
- Identification of low & high priority chemicals
- Risk evaluation process for high priority chemicals
- Establishment of Science Advisory Committee on Chemicals

90 days: Once Manufacturer submits info about a new chemical to EPA, within 90 days the Agency must determine safety or that information is insufficient (EPA can request more info)

3.5 Years: Once EPA begins risk evaluation of a high priority chemical, Agency must complete the evaluation within 3.5 years

2 Years: Once EPA determines chemical presents unreasonable risk, Agency must finalize risk mgmt measures within 2 years (w/ possibility for extension)

LCSA Goal: Strengthen federal oversight to ensure a robust, uniform national chemical management system that promotes the safe use of chemicals & public confidence in chemical safety.

EPA's final decisions will preempt existing & future state chemical laws and regulations…

EXCEPT in certain cases:

- *State laws enacted before Aug. 31, 2003*
- *State rules pertaining to a chemical enacted before April 22, 2016 – unless & until EPA acts on the same chemical*

As of 2016, 15 states had chem laws

*Preemption is limited to the scope of EPA's evaluation i.e., the same conditions of use

States can continue to act on chemicals EPA has not evaluated
* Including low priorities

Once EPA publishes the scope of a risk evaluation, states' ability to place new restrictions on that chemical is PAUSED while EPA conducts its work.

*States can apply for waivers from PAUSE & final preemption

CHEMICAL MEETS SAFETY STANDARD
Preemption remains in place & states can not apply new restrictions

CHEMICAL REQUIRES RISK MANAGEMENT
States can enact restrictions that are identical to EPA's requirements

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.

LCSA Solutions

Greater clarity of EPA's authority to review & regulate chemicals

Aggressive but attainable deadlines to keep EPA evaluations on track

Easier for EPA to request additional testing or safety information from manufacturers

Safety determinations will be based only on health & environmental considerations; costs & benefits now considered in risk management

EPA will conduct a risk-based review of all chemicals in commerce for the first time & all high priorities will undergo a full risk evaluation

Incorporates modern testing technology & understanding of how chemicals interact with environment & humans

EPA must make affirmative safety determination of new chemicals & significant new uses of chemicals before they can be commercialized

Snapshot of EPA Implementation Actions: 2019

- ✓ Inventory Reset published
- ✓ Prioritization Rule final
  - ✓ Short term approach selected
  - ✓ Long term approach under development
- ✓ Risk Evaluation Rule final
  - ✓ Scopes of 1st 10 Risk Evaluations (published; 1st draft risk evaluation released)
  - ✓ Risk Evaluation Guidance (published)
- ✓ New Chemicals
  - ✓ Points to Consider guidance
  - ✓ "not likely to present" website
  - ✓ Non-order SNURs
- ✓ CBI substantiation compliance
- ✓ Fees rule final; new fee schedules
- ✓ Science Advisory Committee composed
- ✓ Draft strategic plan on new alternative methodologies (NAMS) published

Notable Legal Challenges

- Prioritization & Risk Evaluation Rules
- Inventory Reset Rule
- EPA's New Chemicals Decision Framework
- Risk Management (methylene chloride)

QUESTIONS ?