



Toxic Substances Control Act

A “Front-End Loaded” Environmental Program

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Where Did TSCA Come From?

- Initial major environmental statutes of the 1970s focused on “outputs”: air emissions, water discharges, waste, etc.
 - Did not regulate inputs or products
 - FIFRA (pesticides) was limited in scope
- Increased public concern about exposure to chemicals
 - E.g., publicity about PBBs (flame retardants) found in milk, PCBs, CFCs/ozone layer, etc.
- Congress enacted TSCA in 1976



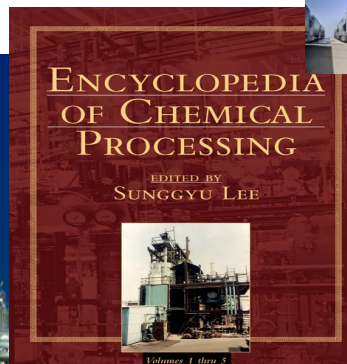
TSCA: Balancing EHS Protection & Market Access



R&D



Manufacturing



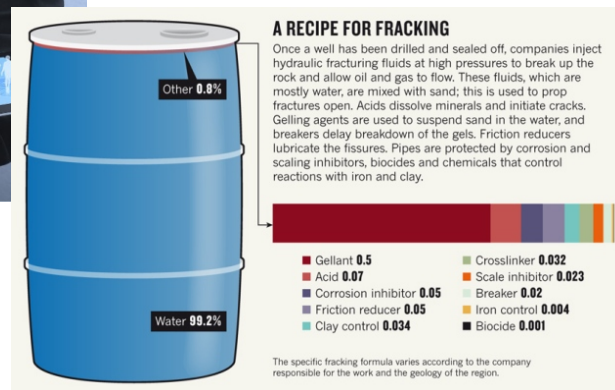
Packaging



Products



Applications



The Starting Point: “Chemical Substance”

- > Any organic or inorganic substance of a particular molecular identity, including—
 - any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
 - any element or uncombined radical.
 - This includes metals, liquids, gases, nanomaterials . . . and it does not have to be “toxic” to be regulated by TSCA.
- > Excluded:
 - pesticides (regulated by FIFRA)
 - Tobacco/tobacco products
 - nuclear materials (separately regulated)
 - Shot, shell, cartridges and their components (no gun control through TSCA)
 - any food, food additive, drug, cosmetic, or medical device (regulated by FFDCA)

TSCA – The Original Building Blocks

- > TSCA Chemical Inventory: Identify chemicals in commerce
 - If you are not on the Inventory, can't be on the market (there are a few exceptions)
 - “Grandfathered” of chemicals on market when TSCA enacted
- > EPA review of new chemicals (i.e., not on Inventory) before they go on market
 - Premanufacture Notification (“PMN”) (§5)
- > Collect information about chemicals already on market
 - Testing (§4)
 - Substantial risk information (§8(e))
 - Health and safety information (§§ 8(c) & 8(d))
 - TSCA Inventory updates (now called chemical data rules) (§8(a))
- > Chemical controls
 - Significant New Use Rules (§5(e))
 - Generic authority to regulate risky chemicals (§6)
 - Chemical-specific requirements (e.g., PCBs, lead paint)

A Few Examples of TSCA Enforcement/Litigation

- > Public interest groups have a lawsuit going against EPA right now under Section 21 of TSCA, seeking to require EPA to prohibit fluoridation of drinking water
- > DuPont was fined \$10.25 million (plus \$6.25 million in “supplemental environmental projects) by EPA for failing to disclose environmental and health risk studies regarding perfluorinated chemicals used in making Teflon
- > Aerospace company fined \$13.75 million for the unauthorized manufacture and disposal of PCBs
- > NYC Housing Authority recently entered into a consent decree regarding non-compliance with lead paint regulations, requiring over \$1 billion in expenditures

TSCA “Modernization:” Some Major Drivers

> General context:

- Agreement that there needed to be a better process to review the “existing” chemicals on the market that were “grandfathered” onto TSCA Chemical Inventory
- Perception that the EU moved ahead of the U.S. with the enactment of REACH in 2007

> NGO interests/concerns included:

- Put burden on industry to prove safety of chemicals (new and old)
- Tougher risk/safety standard
- Make it easier for EPA to demand testing data
- Precautionary approach: better safe than sorry
- Protect state “green chemistry” programs from preemption

> Industry interests/concerns included:

- Bring U.S. in line with international standards, particularly REACH
- Federal preemption: proliferation of state “green chemistry” initiatives creating “patchwork” of regulations
- More stringent regulatory framework might enhance public credibility
- Risk-based approach relying on “good science”



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

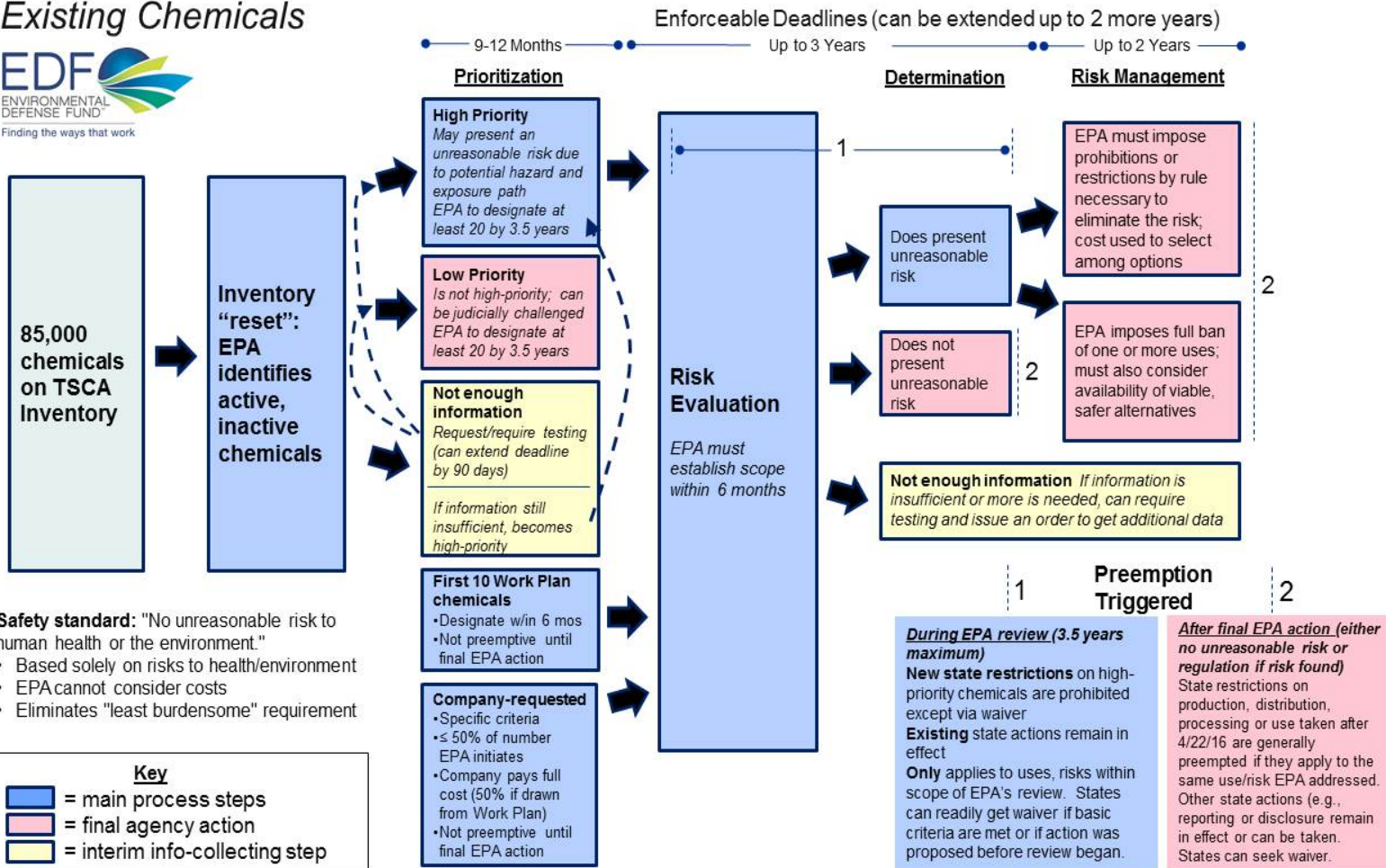
Signed by President Obama on June 22, 2016

- > Broad bi-partisan support
 - Passed by voice vote in Senate with 61 sponsors (35R, 26D); House vote 403-12
- > Selected key changes:
 - EPA must “re-set” the Inventory and begin a risk-based process of prioritizing and evaluating existing chemicals on Inventory
 - Easier path to regulate prioritized “existing” chemicals
 - More stringent new chemical review process requiring EPA to make affirmative determinations about a chemical’s risk
 - Lower threshold for requiring test data
 - Complex compromise on preemption of state laws

Review of "Existing" Chemicals -- § 6

How the Lautenberg Act works

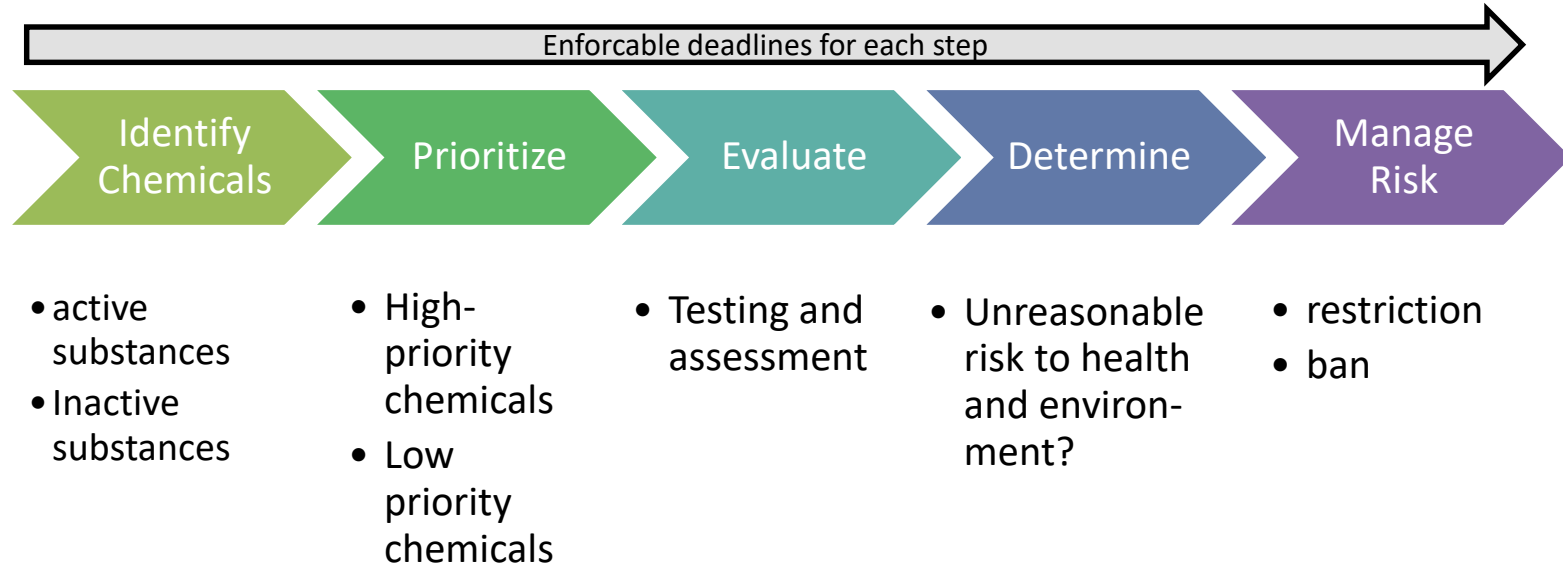
Existing Chemicals



Toxic Substance Control Act (TSCA)

How the Lautenberg Act works

Existing Chemicals



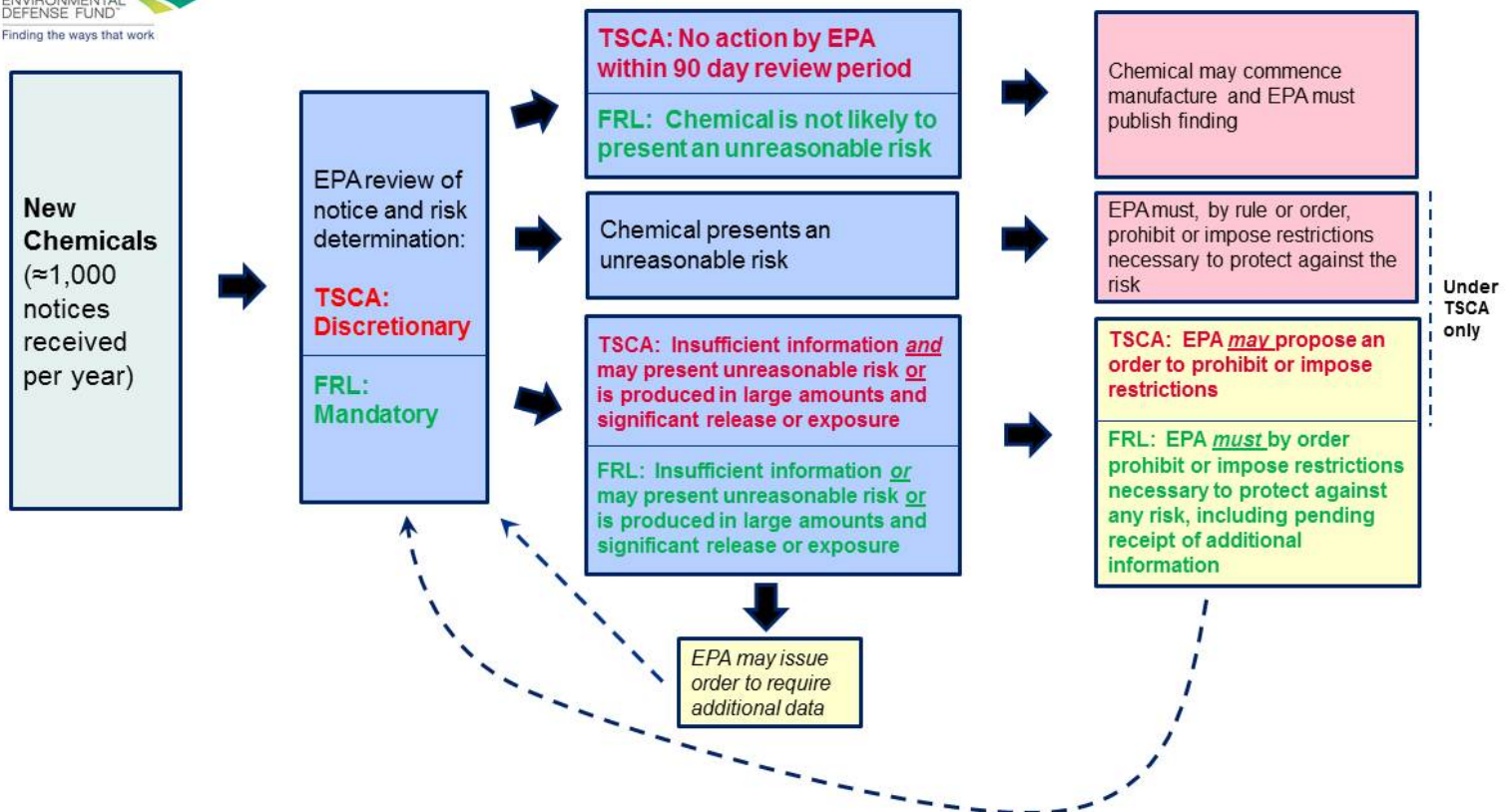
Two-Step Process From Risk To Regulation

- > The risk standard – §6(b)(4):
 - The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use
- > If a chemical has been tagged as having an “unreasonable risk,” EPA must take regulatory action to “the extent necessary so that the chemical substance or mixture no longer presents such risk.” §6(a)
 - EPA must consider effects/magnitude of exposure, benefits of chemical, reasonably ascertainable economic consequences of rule, costs/benefits and cost effectiveness of primary rule and one or more primary alternative considered by EPA. §6(c)(2)

“New” TSCA and “New” Chemicals

Toxic Substances Control Act (TSCA) vs. Lautenberg Act (FRL)

New Chemicals



Toxic Substance Control Act (TSCA)

How the Lautenberg Act works

New Chemicals



- Information about substance and uses

- Notice complete and correct?
- Produced in large amounts?
- Significant release or exposure?

- Unreasonable risk to health or environment?
- Additional data needed?

- Restriction
- Ban

The Preemption Tangle



ECOS

A Quick Guide to Preemption in the Lautenberg Act

Key Points

Scope of Preemption

The Lautenberg Act limits the scope of preemption to the “hazards, exposures, risks, and uses or conditions of use” included in the scope of the risk evaluation of final EPA action.

Certain existing laws are grandfathered from preemption:

- State laws in place before Aug. 31, 2003
- State/local chemical restrictions in place before Apr. 22, 2016

Other types of state actions not subject to preemption:

- Information obligation purposes
- Air, water, waste and related activities with limitations

Preemption under the original TSCA

While the original TSCA did include state preemption provisions, preemption had little effect on states because EPA did not take many regulatory actions under the original law.

Old preemption provisions will still apply to actions taken by EPA before the Lautenberg Act was adopted, unless EPA subjects those chemicals to a new risk evaluation and regulatory process.

This summary has been created by ECOS, drawing on materials originally developed by the Toxics Use Reduction Institute (TURI) at UMass Lowell. For more information, please see the following:

- <http://www.ecos.org/documents/ecos-key-issues-and-comments-on-toxic-substances-control-act-tasca-reform/>
- http://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/TSCA_Preemption_Provisions

Risk Evaluation...

The Lautenberg Act requires EPA to conduct a risk-based evaluation and determine whether a chemical poses an unreasonable risk to human health or environment.

triggers Pause Preemption.

New state prohibitions/restrictions are preempted, starting when EPA publishes the scope of a risk evaluation, and ending when EPA either publishes the risk evaluation or reaches the statutory deadline for publication of the risk evaluation (up to 3 years).

Duration of pause preemption depends on how quickly EPA publishes the scope of the risk evaluation and completes the risk evaluation (likely 2.5 to 3 years).

During pause preemption, states are prohibited from adopting new restrictions, even though EPA will not have taken action yet.

EPA determines that...

- There is not enough information to determine whether the chemical presents unreasonable risk.
- The chemical does or does not present unreasonable risk.

Long-Term Preemption

For a chemical that is found to **present unreasonable risk**, long-term preemption is effective on the effective date of the rule issued by EPA.

For a chemical that is found to **not present unreasonable risk**, long-term preemption is effective on the date of the EPA determination.

Note: Long-term preemption can apply to both new and existing state restrictions. Also, if EPA requires notification of a chemical use under a significant new use rule, states are preempted from issuing similar notification requirements for the same uses.

Waiver from Pause Preemption “Required Exemptions”

Considerations on a waiver application from pause preemption include an EPA determination that the state “has a concern” about the chemical “based in peer-reviewed science.”

Note: EPA must provide a waiver if the state “has enacted a statute or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance” by either 18 months after the date EPA initiated the prioritization process or the date when EPA publishes the scope of its risk evaluation, whichever comes first.

Note: If EPA fails to make a waiver determination within the required time period, the waiver is automatically granted.

Exceptions to Pause Preemption

- Chemicals for which EPA grants a manufacturer-requested risk evaluation
- First 10 Work Plan chemicals for which EPA undertakes a risk evaluation.

Waiver from Long-Term Preemption “Discretionary Exemptions”

Considerations on a waiver application from long-term preemption include “compelling conditions” related to health or environment, and an EPA evaluation of the state’s use of science in decision making.

This chart is provided strictly as an educational resource. It is not comprehensive and does not constitute a formal legal analysis. If you need legal information or opinions, please consult appropriate experts.

The Initial Returns

> The Big Picture

- Bi-partisan support for implementing the new TSCA continues
 - Some partisan divides have re-emerged: post-enactment competing “legislative history” issued by both parties; Democrats are calling for hearings on certain issues
- Most industry and NGO stakeholders not looking to dismantle or obstruct new TSCA
- Current EPA appears to be putting credible effort into implementing the revised requirements.

- ## > Many rulemakings have been launched, including rules on Inventory update, fees, framework for risk evaluation of existing chemicals, etc.
- Some court challenges have already been filed, though it is still early days, with no decisions
 - DC Circuit heard oral argument in early October on a challenge to EPA’s rule regarding the existing chemicals Inventory

How Is It Working – New Chemicals

- > Interpretation of “foreseeable use”
 - Critical issue for determining scope of risk evaluation
 - EPA initially took a very broad view, but in a recent SNUR, adopted a narrower interpretation based solely on the uses identified by the PMN submitter
- > Some conflation of “hazard” with “unreasonable risk”
 - “Unreasonable” is a judgment call
- > Cost not part of “unreasonable risk” determination
- > Use of very conservative exposure assumptions
- > Apparent hesitation to make “not likely” to pose an “unreasonable risk” determinations
 - Big shift from “old” TSCA, where EPA did not have to make affirmative decisions

How Is It Working – New Chemicals

- > Significant drop-off in pace of new chemicals coming to market
 - Under the “old” TSCA, generally completed < 90 days; now some submissions backed up over a year
 - Far higher percentage of PMNs resulting in regulatory action
 - Approx. 57% of PMNs post-Lautenberg have resulted in SNURs, vs. approx. 6% 1979 – 2015.
 - Much higher percentage of withdrawn PMNs
 - Approx. 26% post-Lautenberg vs. approx. 5% 1979-2015
- > Mixed response
 - Industry advocates worry about “stifled innovation”
 - Others applaud caution, saying that was the point of the amendments
 - Unexpected by some, since new chemicals program did not get a lot of attention during Lautenberg negotiations

How Is It Working – Existing Chemicals

- > 11/29/16: EPA announces list of first 10 priority chemicals to undergo risk reviews under TSCA §6
 - Includes asbestos, trichloroethylene, carbon tetrachloride, and methyl chloride
 - EPA has selected 5 PBT chemicals (including some flame retardants) for “expedited” review and control to reduce “well-documented threats”
 - The “Obama EPA” was working on §6 rules that would impose restrictions on three of the “top ten” chemicals
- > Concern being expressed at the speed and diligence of these reviews under new administration
- > EPA has initiated “re-setting” the TSCA Chemical Inventory
 - This is an important step, because if it is not on the Inventory, you can’t use it.
 - Expected that thousands of chemicals will drop off.

How Is It Working – Other Issues

- > Confidential business information
 - Long-standing dispute: protecting intellectual property vs. transparency and public right-to-know
 - Lautenberg imposes more requirements on organizations claiming CBI, but the disputes continue
- > “Good science”
 - Another long-running dispute, critical to effective and credible risk assessment
 - Current debate largely centered around EPA’s initiative to not use so-called “secret science”
 - Define “best available science” as studies that can be made publicly available such that the data can be evaluated and results reproduced
 - Critics argue this will bar use of good science that depended upon keeping confidentiality of study participants (e.g., human health data), many good studies are not published because there is no market for them, etc.

“Non-TSCA” Pressure On Chemicals Will Continue

PROP. 65 WARNING
 The State of California contains one or more chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm.

State Initiatives

(even with new TSCA preemption provisions)

Walmart ✨ Policy on Sustainable Chemistry

“Customers should not have to choose between products that they can afford and products that are better for them and the environment.”

Transparency

- Online ingredient disclosure beginning 2015
- Priority chemicals on pack beginning 2018

Safer Formulation

- Reduce, restrict and eliminate use of priority chemicals using informed substitution

DfE in Private Brands

- Strive for Design for the Environment certification of private brands to the extent possible

Commitment to Every Day Low Cost (EDLC) and performance

Sustainability Will Change the Way We Do Business Around the World

Be Part of What's Next...

Private Sector Initiatives

How retailers rank on tackling toxic chemicals

	15 Oversight	20 Policy	10 Database	10 Action	10 Safer Alternatives	15 Transparency	10 Chemical Footprint	10 Third Party Standards	5 Engage	5 Joint Announcements	10 Continuous Improvement	5 Safer Products	5 Collaborator	Final Score
Walmart	12	12	5	10	5	12	5	7.5	5	0	0	0	5	78.5 (B)
Target	12	8	6	8	2.5	10	0	5	5	0	10	5	5	76.5 (B)
CVS Health	12	8	5	8	2.5	3.5	2.5	0	5	1.5	0	0	5	53 (C)
Walgreens	8	3	0	8	0	3.5	0	2.5	5	1	0	5	5	41 (C-)
The Home Depot	8	0	0	6	0	0	0	2.5	4	5	0	5	5	35.5 (D+)
Lowes	8	0	0	5	0	1.5	0	2.5	5	2.5	0	0	5	29.5 (D)
Walgreens	8	2	0	8	0	1.5	0	0	5	0	0	0	5	29.5 (D)
Kroger	4	0	0	8	0	1.5	0	0	2	0	0	0	0	15.5 (D-)
Albertsons	4	0	0	4	0	0	0	2.5	2	0	0	0	0	12.5 (F)
Costco	4	0	0	0	0	0	0	2.5	3	0	0	0	0	9.5 (F)
Amazon	4	0	0	2	0	1.5	0	0	0	0	0	0	0	7.5 (F)

From Safer Chemicals, Safer Families NGO Initiatives



Litigation

Looking Ahead

- > Broad bi-partisan, industry and NGO support signals that TSCA is an unlikely target for major “roll-backs”
- > TSCA has comprehensive deadlines/obligations that will subject EPA to litigation if EPA lets them slide
- > Delays/inaction by EPA might decrease effectiveness of preemption provisions, leaving door open for expansion of State “green chemistry” programs
- > This administration appears to be less aggressive on a number of TSCA interpretation issues
- > The devil is in the details: plenty of skirmishing ahead in the various rulemakings, risk assessments, etc.
- > Private sector and consumer-driven chemical content initiatives will continue to grow
- > Chemical regulatory regimes outside the U.S. will also drive harmonized approaches