

Regulating Chemicals Toxic Substances Control Act

September 28, 2016



Agenda

- > TSCA -- Overview
- > “Old” TSCA – Key Hot Buttons
- > Drivers for Change
- > The “New TSCA”

Throughout: Discussion

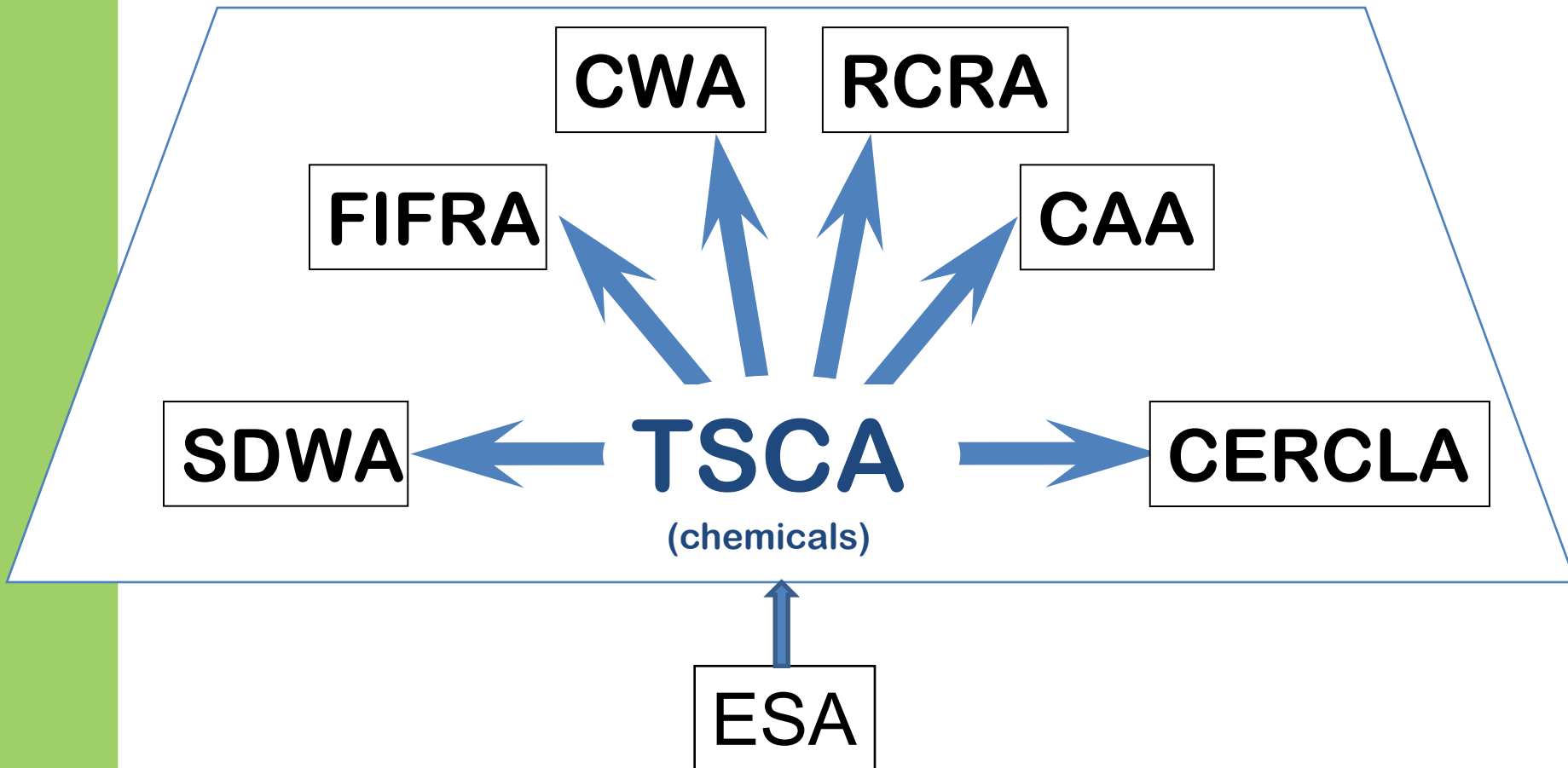
TSCA -- OVERVIEW

Where Did TSCA Come From?

- Environmental statutes of the 1970s regulating waste, air emissions, water discharges, etc., did not control inputs or products
- FIFRA (pesticides) and FFDCA (drugs, devices, cosmetics, food) were limited in scope
- Increased public concern about exposure to chemicals
 - E.g., publicity about PBBs (flame retardants) found in milk, CFCs/ozone layer, etc.
- Congressional debate on legislation to close this gap began in 1971
- Congress enacted TSCA in 1976



Where Does TSCA Fit In Environmental Law?



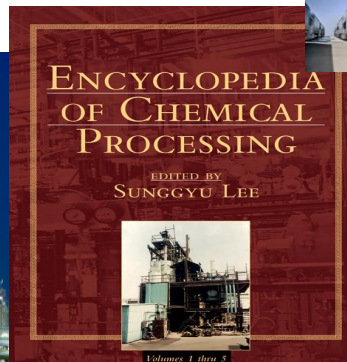
Where Does TSCA Fit In The Economy?



R&D



Manufacturing



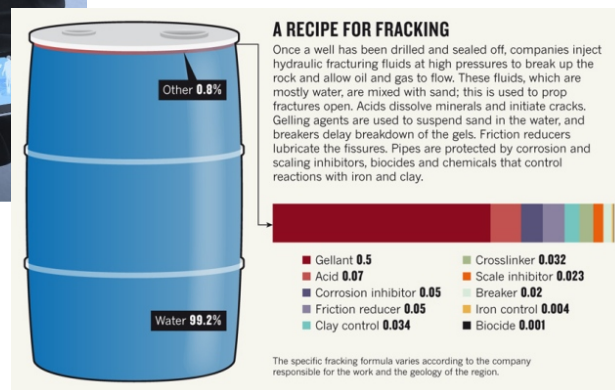
Packaging



Products



Applications



How Does TSCA Try To Protect The Environment?

- > Identify chemicals in commerce
 - Initial “TSCA Chemical Inventory”
- > EPA review of new chemicals
 - Premanufacture Notification (“PMN”) (§5)
- > Collect information about chemicals
 - 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 under §6(e))

“OLD” TSCA

TSCA – What The Critics Said

- > Most chemicals on the TSCA Inventory, and thus on the market, were “grandfathered” and have not been subject to any meaningful risk review by regulators
- > Companies are not required to prove that their chemicals are “safe”
- > It is too difficult for EPA to:
 - Require testing for toxicity or exposure
 - Restrict or prohibit the manufacture, processing or use of risky chemicals
- > EPA and the public have insufficient access to chemical risk data

Broad Scope: TSCA Regulates “Chemical Substances”

➤ Broad definition: “any organic or inorganic substance of a particular molecular identity”

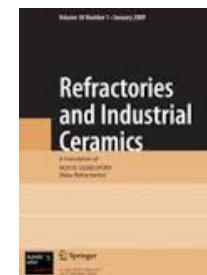
- Not limited to “toxic” chemicals
- Solids, liquids, gases
- Natural and synthetic

➤ Selected exemptions to avoid double-regulation

- Any “drug” as defined by the Federal Food, Drug and Cosmetic Act
- Any “pesticide” as defined by FIFRA
- Nuclear materials

➤ Selected exemptions based on policy considerations

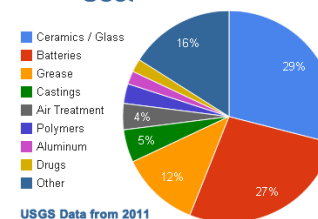
- Tobacco
- Ammunition/firearms



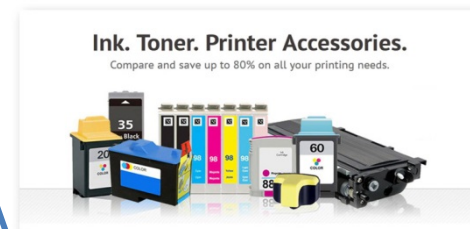
What are nanomaterials?

Nanomaterials are materials, are materials possessing grain sizes on the order of a billionth of a meter (10⁻⁹ m).
Nanotechnology literally exploded in mid-1980's

Use:



USGS Data from 2011

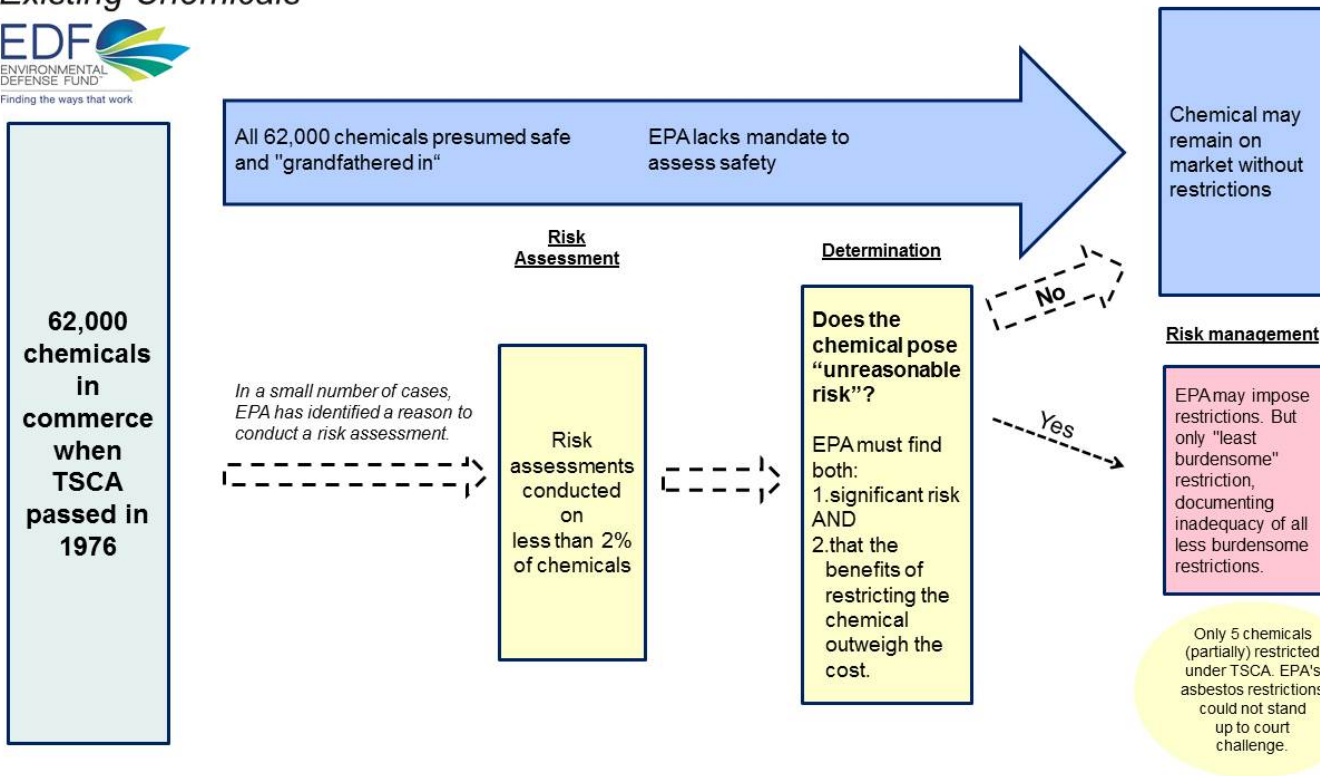


Starting Point: The TSCA Inventory

- > Cannot manufacture, import or distribute in commerce chemicals that are not on the “TSCA Inventory”
 - Several exemptions, including for R&D, low-volume chemicals, test-marketing, etc., so long as certain conditions are met
- > Distinction between “existing” and “new” chemicals
 - Approximately 60,000 “existing” chemicals were “grandfathered” into the Inventory in 1976-77 without risk review
 - “New” chemicals coming onto the market after the initial Inventory was created have to go through the premanufacture (“PMN”) review process
 - Over 40,000 PMNs have been filed, not all resulting in chemicals being placed on the market
- > Currently over 80,000 chemicals on the Inventory
 - > We do not know how many are actually in commerce or being used
 - > Fewer than 10,000 chemicals are manufactured/imported in volumes of > 25,000 pounds/yr

“Grandfathered” Chemicals A Key Issue In TSCA “Reform”

How the original Toxic Substances Control Act worked *Existing Chemicals*



“Existing” chemicals under the “Old” TSCA

- > EPA made one serious attempt to use its § 6 authority to restrict/ban a chemical, asbestos, was rejected in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991)
 - Corrosion Proof Fittings became the critic’s symbol for everything wrong about TSCA . . . though not clear how many people have read it!
- > In the absence of formal regulations, EPA used its bully pulpit to obtain “voluntary” agreements to remove some chemicals from the market
 - E.g., widely used category of flame retardants, family of perfluorinated chemicals used in flame retardants, non-stick and stain resistant coatings, etc.
- > Limited number of § 4 test rules (covering several hundred chemicals) supplemented by EPA “voluntary” initiatives, such as the joint EPA-industry program for testing well over 2,000 high-volume chemicals
 - TSCA not the only source of toxicity data on chemicals (e.g., IRIS, OECD, etc.)

General Consensus That Absence Of Systemic Review Of “Old” Chemicals The Primary Weakness of TSCA

Detour: Corrosion Proof Fittings v. EPA (5th Cir. (1991))

- > “The system was so complex, it was so burdensome that our country hasn’t even been able to uphold a ban on asbestos - a known carcinogen that kills as many as 10,000 Americans every year. I think a lot of Americans would be shocked by all that.” President Obama, 6/22/16 signing ceremony for “new” TSCA
- > Critics have variously called the decision a “tragedy” that was effectively the “death knell” of any serious chemical regulation under TSCA
- > Frequently used as short-hand for everything wrong with TSCA (“If you can’t ban asbestos, what can you do?”)

What Did The Court Actually Say?

“New” Chemicals Under The “Old” TSCA (ACC’s View)



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“New” Chemicals Under The “Old” TSCA – The Critics

- > EPA does not have to make an affirmative finding of safety for a new chemical to clear the PMN process
- > If EPA does raise questions about or object to a PMN, the chemical will automatically get a green light in 90 days (unless EPA asks for an extension)
- > Companies only required to submit the data they have, and are not required to generate and submit a minimum data set on risk
- > EPA uses its § 5(e) authority sparingly

Observation: Most Of The Big Chemical Controversies Have Involved “Existing,” Not “New” Chemicals

TSCA Enforcement

- > Despite the criticisms, TSCA is not without enforcement teeth
- > Some examples:
 - DuPont assessed \$16.5 million for failure to report “substantial risk” information under §8(e)
 - Dover assessed \$1.4 million for manufacturing a “new” chemical without filing a PMN (and agrees to stop manufacturing an entire class of chemicals)
 - Importer of ink cartridges paid \$1 million for failure to file import certification and presence of chemicals not on Inventory
 - In 2012, EPA collected over \$2 million in penalties from several companies for failure to comply with the Inventory update rule
 - Titanium Metals paid \$13.75 million for the unauthorized manufacture and management of PCBs

DRIVERS FOR TSCA “MODERNIZATION”

TSCA “Modernization:” Some Major Drivers

> General context:

- Agreement that there needed to be a process to review the “existing” chemicals on the market
- 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 (States weighed in heavily on this)

> Industry interests/concerns included:

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

A Short Detour: The EU's REACH Regulation

- > *Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation* entered into force in 2007 and has been implemented in phases since then
- > Selected key features that got attention in the U.S.:
 - Required the submission of “dossiers” with minimum data requirements for all chemicals on EU market, including all “grandfathered” chemicals
 - Established an “authorisation” process for nominated higher risk chemicals
 - Companies have the burden of demonstrating that these chemicals deserve to be on the market, taking risk, social and economic benefits into account
- > Stringency of REACH somewhat exaggerated in the U.S.
 - REACH does not require industry to prove all chemicals safe (“no data-no market” is not the same thing)
 - New chemical review in REACH arguably less stringent than even “old” TSCA
 - Consequences of non-compliance under REACH not even close to enforcement in the U.S.

THE “NEW” TSCA

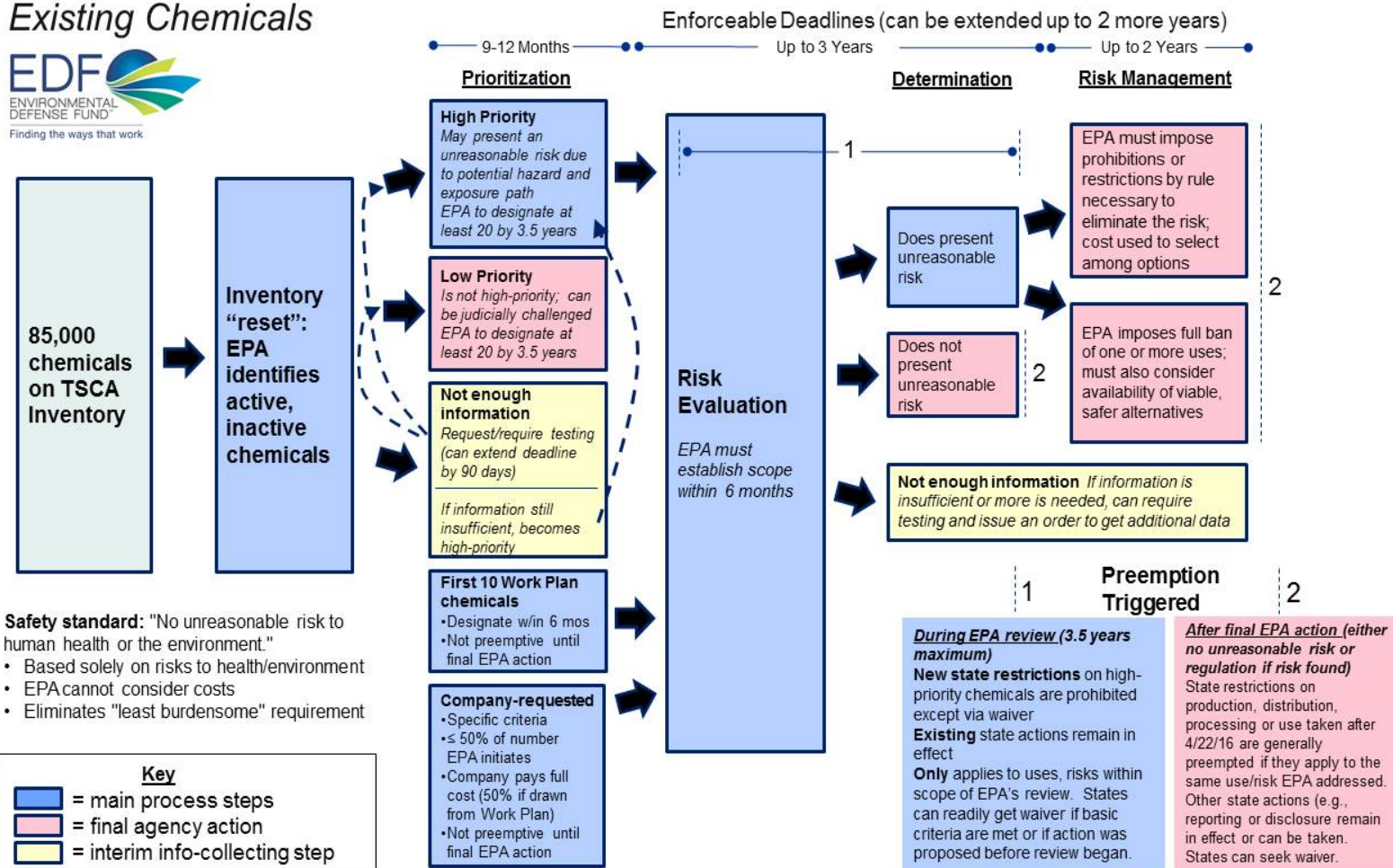
Frank R. Lautenberg Chemical Safety for the 21st Century Act

- > Signed by President Obama on June 22, 2016
- > Broad bi-partisan support
 - 61 Senate sponsors (35R, 26D); House vote 403-12
- > Selected key changes:
 - EPA must “re-set” the Inventory and begin a risk-based process of prioritizing “existing” chemicals on Inventory
 - Easier path to regulate prioritized “existing” chemicals; EPA not bound to least burdensome option (though cost still in equation)
 - More stringent new chemical review process requiring EPA to make affirmative determinations about a chemical’s risk
 - Lower threshold for requiring test data
 - Rather complex compromise on preemption

“New” TSCA and “Existing” Chemicals -- § 6

How the Lautenberg Act works

Existing Chemicals



Risk and Chemical 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
- > Once 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)

Compare to Corrosion Proof Fittings: How Would The Asbestos Rule Do?

“New” TSCA and “New” Chemicals

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

New Chemicals



New Chemicals
(≈1,000 notices received per year)



EPA review of notice and risk determination:
TSCA: Discretionary
FRL: Mandatory



TSCA: No action by EPA within 90 day review period
FRL: Chemical is not likely to present an unreasonable risk



Chemical presents an unreasonable risk



TSCA: Insufficient information and may present unreasonable risk or is produced in large amounts and significant release or exposure
FRL: Insufficient information or may present unreasonable risk or is produced in large amounts and significant release or exposure



Chemical may commence manufacture and EPA must publish finding



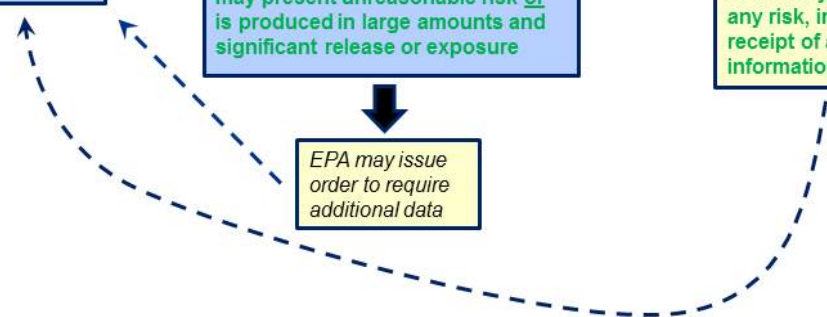
EPA must, by rule or order, prohibit or impose restrictions necessary to protect against the risk



TSCA: EPA may propose an order to prohibit or impose restrictions
FRL: EPA must by order prohibit or impose restrictions necessary to protect against any risk, including pending receipt of additional information

Under TSCA only

EPA may issue order to require additional data



Chemical Testing -- §4

- > EPA no longer has to make risk determinations to justify testing requirements
- > EPA can require testing for a broad range of regulatory reasons, including to collect data for purposes of prioritizing among “old” chemicals
- > Authorizes EPA to require testing through orders, not just lengthy rulemaking
- > Explicitly allows EPA to require testing for exposure, not just toxicity
- > Includes provisions encouraging alternatives to animal testing, including use of modeling

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.

3 Months Later – Initial Returns

- > The partisan divide re-emerges: post-enactment competing “legislative history” documents issued by both parties
- > Absence of an explicit transition period for the new chemicals program has caused turbulence, as EPA applied new statute to “in process” PMNs
 - EPA has made affirmative “not likely to pose an unreasonable risk” determinations for a handful of new chemicals; has also been asking for more information and extensions of time on many PMNs
 - EPA taking a harder line on substantiation of confidential business information claims
- > Preliminary indications of §6 rulemaking includes restrictions aimed at occupational and consumer exposures
- > Several “implementing” rulemakings already launched, with industry and NGO skirmishing in initial comments
 - Issues include the extent to which “sound science” should be baked into implementing regulations on prioritization, risk evaluation, etc.
- > EPA doing this with no extra budget or staff

Back To The Big Picture

- > TSCA provides EPA with a regulatory tool to adopt a life cycle approach to materials management and regulation
- > Not just a “chemical company” statute
- > Effective compliance with TSCA calls for a cross-functional and life cycle approach that includes research, manufacturing, marketing, EHS professionals, lawyers, etc.
- > Implementation of the “new” TSCA will enhance public and NGO awareness of chemical risk issues, and State “green chemistry” initiatives are likely to continue
- > There will surely be turbulence, delays and detours in the implementation of the “new TSCA