

TSCA Reform: An Overview

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Why Did TSCA Need Reform?

- **Grandfathered** in 60,000+ existing chemicals without testing and without a process for reviewing safety
- Allowed new chemicals to enter the market without providing a minimum data set and **without a safety finding** by EPA
- “Unreasonable risk” determination **not based on health**, included cost considerations
- In selecting risk management options, EPA was limited to the **“least burdensome” regulatory option**
- Imposed **major hurdles** before EPA could require chemical safety testing

Core Mandate of Reformed TSCA

EPA must ensure that the manufacture (includes importation), processing, distribution in commerce, use, or disposal of a chemical substance or mixture – *or any combination of such activities* -- does not present 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 reasonably foreseeable conditions of use

Substances Covered By TSCA

- TSCA applies to “chemical substances” and mixtures of chemical substances
- Many provisions of TSCA apply to “articles” containing “chemical substances”
- TSCA does not cover:
 - pesticides
 - tobacco
 - nuclear material
 - food, drugs, cosmetics and devices regulated by FDA
 - items taxed under section 4181 of the IRS Code, including lead shells and cartridges

Prioritization, Risk Evaluation & Risk Management

- EPA must review all 80,000+ existing chemicals to decide whether they are high or low priority
- EPA must conduct a risk evaluation for all high priority chemicals
- EPA must order “risk management” for all chemicals that present an “unreasonable risk” under the reasonably foreseeable conditions of use
 - This includes an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA

Prioritization

- High priority = **may** present an unreasonable risk to health or the environment (without cost consideration) including to a vulnerable subpopulation. Can order testing to determine.
 - Low priority = not “high priority”
 - Once the prioritization process has been initiated for a chemical, EPA must seek information about the chemical from the public (90 days minimum time for response)
 - EPA must publish proposed designations for public comment
- ❖ Procedural rule required by June 2017 to establish a risk-based screening process for prioritizing existing chemicals

Criteria for Prioritization

- In deciding which chemicals to prioritize, EPA must give preference to chemicals on the EPA Work Plan that score high for persistence & bioaccumulation OR are known human carcinogens
- Each proposed prioritization (high or low) must be published and the public must have at least 90 days to comment
- A decision to designate a chemical as “low priority” is judicially reviewable



Which Chemicals Will Undergo Risk Evaluation?

- 4 “buckets” of chemicals must go through the new risk evaluation / risk management process:
 - 10 chemicals from the TSCA Work Plan, which must be named by **December 19, 2016**.
 - All chemicals designated as high priority in the ongoing prioritization process.
 - A somewhat limited number of chemicals nominated for risk evaluation by manufacturers. [discussed below]
 - Non-metal PBTs on the TSCA Work Plan. [discussed below]



The Risk Evaluation Process

- EPA must publish the scope of a risk evaluation within 6 months of its initiation, including “the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider”
- EPA must open comment period of at least 30 days on draft risk evaluations
- EPA must complete each risk evaluation within 3 years, which can be extended up to 6 months
- ❖ Procedural rule required by June 2017 to establish risk evaluation process

Manufacturer-Requested Evaluations

- Manufacturers can ask EPA to evaluate specific chemicals, and pay costs
 - For chemicals on TSCA Work Plan, manufacturers pay 50% of costs
 - For all other chemicals, manufacturers pay 100% of costs
- Manufacturer requests are limited
 - Granted at the Administrator's discretion
 - Don't count toward the 20 risk evaluations EPA must have underway in 3.5 years
 - Must be a minimum of 25% of ongoing reviews (if enough requests) but no more than 50% [e.g., if EPA is evaluating 20 high priority chemicals, there could be an additional 5 to 10 industry petitioned evaluations proceeding in parallel]

Persistent, Bioaccumulative and Toxic Chemicals

- Nine (9) non-metal PBT chemicals that are on the TSCA Work Plan are fast tracked
- Within 3 years, EPA must propose final risk management rules for these chemicals
- Risk management rules must reduce exposure to the extent practicable (stronger than to prevent unreasonable risk)
- No risk evaluation is required; EPA goes straight to a use and exposure assessment
- BUT: manufacturers had until Sept. 20, 2016 to place any of the 9 PBTs on the “off-ramp,” meaning they go through regular risk evaluation – paid for by the manufacturers. Risk management rules must still reduce exposure to the extent practicable. *[We don't know if this happened.]*

Risk Evaluation Volume

- By December 22, 2019, EPA must be conducting risk evaluations of at least 20 high priority chemicals
 - 50% of all chemicals being evaluated must be from the Work Plan until it is exhausted
- This is in addition to
 - the first 10 chemicals taken from the Work Plan list
 - the 9 PBTs
 - manufacturer recommended chemicals

Upcoming Risk Management Rules

- EPA has already finalized risk assessments for some chemicals and has announced plans to issue risk management rules before the end of the year for these chemicals:
 - TCE use in spot cleaning and aerosol degreasing
 - TCE use in vapor degreasing
 - Methylene chloride (MC) and N-methylpyrrolidone (NMP) in paint removers
- Legal challenges will likely follow.



Testing Authority

- EPA can require manufacturers to test chemicals by issuing an **order** [under old TSCA, EPA had to go thru notice and comment rulemaking]
- Under **any** circumstance, EPA can require testing if it finds the chemical “may present an unreasonable risk”
- Under **certain** specified circumstances, EPA can require testing **without** the “may present” finding
- Test rules and orders are final agency actions subject to judicial review

Judicial review

- Citizens can bring legal challenges to EPA decisions on low priority designations
- After a final risk management rule is issued, citizens (and chemical manufacturers) can challenge the “unreasonable risk” finding as well as the risk management measures.

Citizens' Petitions

- Citizens may petition EPA to adopt rules and orders including to require health and safety testing or to evaluate and regulate a chemical
- EPA must grant or deny a citizen petition within 90 days
- If EPA denies a citizen petition, it must publish an explanation in the Federal Register
- If EPA denies, or fails to grant, a citizen petition, the citizen may commence a lawsuit to compel the requested action in a *de novo* proceeding



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Vulnerable Populations and Legacy Exposures in Revised TSCA

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Vulnerable (i.e. Potentially Exposed or Susceptible) Populations

- Defined as populations that the EPA Administrator determines are:
 - Differently exposed to chemicals under reasonably foreseeable circumstances during manufacture, processing, distribution in commerce, use, or disposal
 - Susceptible to greater adverse health consequences from chemical exposures than the general population
- May include infants, children, pregnant women, workers, and the elderly

Health and Safety Standard

- Big win that new and existing chemicals must be safe for vulnerable populations, however:
 - The EPA Administrator will decide which vulnerable populations will be considered for each chemical
 - No explicit mention of vulnerable communities
 - The details of how, how quickly, and which chemicals are evaluated first in updated TSCA will be very important to health

Prioritization Screening Process

- Within the first year, EPA must establish a process and criteria for identifying high priority and low priority chemicals for evaluating and determining their safety
 - EPA will publish a list of chemicals being considered for prioritization
 - Consideration based on recommendation of Governors or state agencies, hazard and exposure data, PBT's, exposure to vulnerable populations, storage near drinking water, and volume of production of the chemical
 - EPA will request information on these chemicals from interested parties
 - EPA will use information to determine high or low priority for review and regulation

High Priority Chemicals

- For High Priority chemicals, EPA:
 - Conducts a Safety Assessment-risk assessment integrating toxicity, use, and exposure information
 - Scope out the uses, toxicities, and vulnerable population exposures it is considering regulating within 6 months of listing as High Priority
 - Makes a Safety Determination-determination what restrictions are needed for the chemical to meet the safety standard
- Risk Assessment (Safety Assessment) has often been used against EJ and tribal communities
 - Anecdotal evidence of observed exposures and disease is often declared insufficient and assumed to be false
 - Theoretical assumptions are accepted as true



Legacy Exposures

- EJ and Indigenous communities are often exposed to toxics from legacy chemicals
- Legacy chemicals are chemicals no longer in use that have not been disposed of properly
 - Contaminated soil in Brownfields
 - Underground storage tanks at abandoned industrial sites
 - Lead pipes
- Reformed TSCA does not directly address these exposures



9/21/16

State Actions & Priority Chemicals in New TSCA

Presentation to Alaska CHE:

Will the New Federal Chemicals Policy Adequately Protect Public Health? Understanding the Strengths, Limitations, and Implications of the Lautenberg Act



Some State Actions Protected

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When EPA takes steps to regulate a chemical, the following State actions are **preserved**:

- ▣ **Actions** taken before April 22, 2016
- ▣ Actions taken at any time pursuant to a state **law** that was in effect on August 31, 2003 (e.g., CA Proposition 65)
- ▣ The implementation of other **environmental** laws (e.g., air, water, waste treatment, disposal, reporting)
- ▣ **Co-enforcement** of identical requirements and penalties that do not exceed the federal maximum
- ▣ Actions on chemicals identified as **low-priority** by EPA

Some State Actions Undermined

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A state law, regulation, or administrative action is **preempted** when

- ▣ It requires development of **info** reasonably likely to be identical to info EPA has required industry to generate
- ▣ It restricts a chemical that is found not to present an **unreasonable risk**, following an EPA risk evaluation;
- ▣ It restricts a chemical that is found to present an unreasonable risk & a **risk management** regulation is in place.

Wiggle Room for State Action

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- Any preemption is limited to the “hazards, exposures, risks and uses or conditions of use . . . included in the scope of the [EPA] risk evaluation.”
- States can seek waivers from preemption, but must show “compelling conditions.”

Regulatory Void/ Pause

Preemption/ Early Preemption

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- State regulation of high priority chemicals is preempted starting when EPA publishes the scope of the risk evaluation until the date EPA must complete the risk evaluation (up to 3.5 years from initiation) or publishes the evaluation, whichever is earlier
- This pause preemption does not apply to the first 10 Workplan chemicals or the industry requested chemicals
- States may apply for a waiver from the “pause preemption.”

Now what can we do?

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- ▣ Chemicals/Uses not covered by TSCA
- ▣ Disclosure
- ▣ Procurement/
Purchasing
- ▣ Market campaigns
- ▣ Tort cases
- ▣ Actions to influence EPA choices/ fill the gap
- ▣ Petitions
- ▣ Work with states on waivers
- ▣ Other creative solutions?

Proposal: First 10 Chemicals

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Asbestos

Lead

Cadmium

I-
Bromopropane

Styrene

1,4-Dioxane

HBCD

PERC

NP/NPEs

D4

What are your priorities?

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89 chemicals to choose from:

https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf



For follow-up or questions, please contact me!

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