Toxics Substance Control Act (TSCA) Reform - The Frank R. Lautenberg Chemical Safety for the 21st Century Act

Deb MacKenzie-Taylor
Michigan Department of Environmental Quality
517-614-7333 or mackenzie-taylord@michigan.gov
What is TSCA?

Prevent unreasonable risk of injury to health or the environment from chemical substances or mixtures

• Control risks of Chemicals on the market
  – Testing of chemicals and mixtures
  – New chemical or significant new use
  – Regulation of hazardous chemicals and mixtures
  – Reporting and recordkeeping
What is TSCA?

• Control of Toxic Substances - 1976
  – Frank R Lautenberg Chemical Safety for the 21\textsuperscript{st} Century Act, Amendment June 22, 2016
• Asbestos Hazard Emergency Response - 1986
• Indoor Radon Abatement - 1988
• Lead Exposure Reduction - 1992
• Healthy High-Performance Schools - 2007/8
• Formaldehyde Standards for Composite Wood Products - 2010
Some Previous Challenges for old TSCA

- Focused on new chemicals/uses
- Needed more clear duties and authorities
- Difficult to require information to determine safety of existing chemicals
  - EPA tried voluntary program for high production volume chemicals
- Confidential business information claims did not require substantiation
- No timely review requirements
- Limited funding
Frank R. Lautenberg
Chemical Safety for the 21st Century Act

- Signed into law June 22, 2016
- Large bipartisan support in U.S. House and Senate
- Broad stakeholder support
- Many years to get TSCA reform enacted
Major Improvements

- EPA duty to evaluate existing chemicals – clear/enforceable deadlines
  – *Previous no duty to review or deadlines*
- Chemicals assessed with risk-based standards
  – *Previous risk-benefit balancing standard*
- Unreasonable risks must be eliminated
  – *Previous cost/benefit balancing and no mandate to act*
Major Improvements

• Quickly require information/testing
  – *Previously required rulemaking*

• New chemicals need approval before marketing
  – *Previously marketed in absence of EPA action – submit premanufacturing notice*

• Some CBI claims must be substantiated
  – *Previously no substantiation required*

• New Fees - Additional Funding Source
New Chemicals/ Significant New Uses

• Premanufacturing Notice submitted >90 days before manufacturing

• EPA public notices in Federal Register
  – 5 business days from receipt

• EPA affirmative risk evaluation finding
  – 90 day review time for EPA
Risk Evaluation

• “conditions of use”
  – Intended, known, reasonably foreseen
  – Manufacturing, processing, distribution, use, disposal

• Susceptible and highly exposed populations must be considered
  – Infants, children, pregnant women, workers, or the elderly

• Determine without consideration of costs or other non-risk factors
Risk Evaluation Finding

• “presents an unreasonable risk”
  – EPA issues restrictions/limitations to address risk

• Insufficient information
  – EPA requires testing

• “not likely to present an unreasonable risk”
  – may proceed as proposed
New/Significant New Use Risk Evaluation Findings

Since enacted in June 22, 2016

• EPA completed 55 reviews
  – 37 chemical substances
  – 18 microbes
  – Determination “not likely to present an unreasonable risk” for all
Unreasonable Risk

• Risk management actions – 2-4 years
  – Prohibitions, restrictions/limits on manufacturing, processing, distribution, particular use;
  – Notifications, warnings;
  – Regulation of disposal; and/or
  – Requirements for monitoring, reporting, recordkeeping

• Costs and alternatives considered in selecting among options

• Exemption process for critical uses
  – e.g., national defense
Insufficient Information

• To determine prioritization or risk
• “May present an unreasonable risk”
  – based on available information,
  – requires additional information for determination, and/or
• Substantial quantities
  – Likely substantial human exposure or
  – Likely substantial release to environment
Insufficient Information - Testing Authority

• EPA may require to make prioritization or risk evaluation decisions
  – Orders, consent agreements, rules

• 6/2018 - strategic plan to promote alternative (non-animal) testing methods and protocols
Existing Chemicals

• Prioritized for assessment
  – **High priority** – potential unreasonable risk from hazard, route of exposure, includes consideration of susceptible subpopulations
  – **Low priority** – does not meet high priority

• EPA must establish prioritization process
  – Proposed 1/17/2017 (71 comments received);
  – Final 6/2017
Existing Chemicals

• Risk Evaluation – High priority designated chemicals
  – Must designate new high priority chemicals with each risk evaluation completed
  – 10 first year
  – 20 evaluations to be ongoing in 3.5 years

• EPA must establish risk evaluation process
  – Proposed 1/19/2017 (87 Comments)
  – Final 6/2017
Existing Chemicals

- Initial Set – 10 Work Plan Chemicals
  - Federal Register Notice 12/19/2016
  - Release scope of review for each by 6/2017

- 1,4-Dioxane
- 1-Bromopropane
- Asbestos
- Carbon Tetrachloride
- Cyclic Aliphatic Bromide Cluster
- Methylene Chloride
- N-Methylpyrrolidone
- Pigment Violet 29
- Trichloroethylene
- Tetrachloroethylene
Existing Chemicals

- Must have 20 risk evaluations ongoing and 20 low priority ID by 12/2020

- Manufacturer Requested Assessments
  - Administrator’s discretion
  - 25-50% of ongoing reviews (5-10)
    - Not part of 20 required from prioritization
  - Requestor pays 50-100% costs of risk evaluation
Persistent, Bioaccumulative, and Toxic Chemicals

- Fast-track process for PBTs already on TSCA workplan – 5 PBTs
- No risk evaluation necessary, only use and exposure assessment
  - Manufacturer requested risk evaluation for 2 PBTs
- Rules to reduce exposure proposed by 6/2019, final by 12/2020
- PBT required prioritization for risk evaluations
Updating TSCA Inventory

• Reporting requirements for chemicals manufactured or processed in last 10 years – **active** chemicals

• Chemicals will not be removed
  – Identified as active or inactive
  – Only active chemicals prioritized
  – No premanufacturing notifications for inactive ➔ active
Ongoing Risk Management Chemicals

• Risk Assessment completed before 6/22/2016

• EPA proposed rules 1/19/2017 to prohibit:
  – Trichloroethylene
    • Use for spot cleaning and aerosol degreasing
    • Use in vapor degreasing
  – Methylene chloride use in paint removers
  – N-methylpyrrolidone use in paint removers

• Comments due by 5/19/2017
Confidential Business Information

• Manufacturers must substantiate CBI claims
  – EPA must:
    • Affirmatively review all new & past chem ID
    • Screen a subset (25%) of new non-chem ID
  – Sunset after 10 years unless reasserted
  – EPA may share CBI information with other states, medical professionals, first responders
    • May require a confidentiality agreement
Preservation of State Laws

• State authority if chemical not acted on by EPA.

• If EPA acts, State actions preserved:
  – Actions taken before April 2016
  – Other environmental laws (air, water, waste treatment, disposal, reporting, monitoring, etc.)
  – Co-enforcement of identical requirements
  – Actions on chemicals identified as low-priority by EPA
Preemption of State Laws

• If EPA determines chemical is safe,

• If EPA final action to address a chemical’s risks,

• If EPA imposes a comparable Significant New Use requirement,

• Unless waivers or exceptions are identified.
30 chemicals every 6 years > 85,000 chemicals – may not get through existing chemicals in my grand 485x children’s lifetime (assume 30 chems each 6 years and children born every 35 years)
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Pause Preemption

- New State action is “paused” during EPA’s high priority risk evaluation.
  - If deadline exceeded, pause is lifted
- If risks identified, pause is lifted temporarily until effective date of EPA’s final risk management rule (expect 2-4 years)
- If EPA determines chemical is safe, preemption continues
State Waivers for Preemption

• Pause preemption - EPA must grant if:
  – State enacted statute, proposed/finalized admin action, prohibits or restricts a chemical, or
  – State provision meets certain criteria

• General preemption - EPA may grant (rules) if:
  – “Compelling conditions” that necessitate the waiver;
  – No undue burden on interstate commerce; and
  – EPA support for the State’s scientific judgment of the risk, based on best available science and weight of evidence

• 110 day review period or automatically granted

• Waivers can be challenged in court.
Chemical Substance

• **Includes**
  – Any organic or inorganic substance of particular molecular identity,
  – Combination of substances from a chemical reaction or found in nature
  – Element or uncombined radical

• **Excludes**
  – Mixtures
  – Pesticides
  – Tobacco
  – Nuclear material
  – Food, food additive, drug, cosmetic or device
Regulation of Chemicals

• Prohibitions, restrictions, limitations, notifications
  – Required least burdensome
  – Challenges through court – asbestos

• PCBs - specifically identified for rulemaking - 40 CFR 761

• Imminent hazard – serious or widespread injury likely to result before final rule would protect against such risk
Evaluation of Uses

• Intended uses are those identified in the section 5(a) notification

• “known” and “reasonably foreseen” current use of new chemical or structural analog
  – CBI EPA PMN databases
  – National Library of Medicine’s Hazardous Substances Data Bank (HSDB), the
  – Chemical Abstract Service STN Platform,
  – REACH Dossiers,
  – technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and
  – Internet searches.
Persistence

• Limited
  – half-life in water, soil or sediment of less than 2 months

• Persistent
  – half-life in water, soil or sediments of greater than 2 months but less than or equal to 6 months

• Very persistent
  – half-life in water, soil or sediments of greater than 6 months

Can use equivalent or analogous data
Bioaccumulation

• Low potential
  – BCF or BAF of <1,000

• Bioaccumulative
  – BCFs or BAFs of >1,000 and ≤ 5,000

• Very bioaccumulative
  – BCFs or BAFs of >5,000

Can use equivalent or analogous data
Human Health Hazard

• Low
  – Animal NOAEL ≥ 1,000 mg/kg/day

• Moderate
  – Animal NOAEL < 1,000 mg/kg/day

• High
  – Evidence of human adverse effects
  – Severe effect animal NOAEL ≤ 10 mg/kg/day

Can use analogous chemical data, in vitro, chemical categories, SAR, structural alerts to support characterization
Ecotoxicity Hazard

• Low
  – Fish, Daphnid and Algae LC50s ≥100 mg/L
  – Fish and Daphnid ChVs >10.0 mg/L
  – No effects at saturation or log Kow > QSAR

• Moderate
  – Fish, Daphnid and Algae LC50s >1 & <100 mg/L
  – Fish or Daphnid ChVs >0.1 mg/L & <10.0 mg/L

• High
  – Fish, Daphnid or Algae LC50s <1 mg/L
  – Fish or Daphnid ChVs <0.1 mg/L
Major Improvements

• New additional funding source
  – User fees of up to 25% of costs but no more than $25M for general provisions
    • New chemical or new use
    • Required to submit test data
  – Cover costs for risk evaluations (50-100%)
  – Lower fees for small businesses
  – Previous cap of $2500 per individual with limited collection ability
  – Final Rule Due 6/2017
Toxic Substances Control Act (TSCA) vs. Lautenberg Act (FRL)

New chemicals (≈10,000 notices received per year)

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

The EPA may issue order to require additional data

TSCA: No action by the 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

Company may begin manufacturing, and the EPA must publish finding

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

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

Source: Adapted from materials prepared by the Environmental Defense Fund
How the Lautenberg Act Works: Existing Chemicals

1 Identify Chemicals in Commerce

- 85,000 chemicals on the TSCA inventory
- Inventory “reset”: the EPA identifies active, inactive chemicals

2 Prioritization

- Chemicals identified as high priority

3 Evaluation

- Risk evaluation
- Chemicals identified as low priority

4 Determination

- Does present unreasonable risk

5 Risk Management

- Does not present unreasonable risk
- The EPA must issue a regulation banning or restricting the chemical

Safety standard: “No unreasonable risk to human health or the environment.”
- Based solely on risks to health/environment
- The EPA cannot consider costs
- Eliminates “least burdensome” requirement

Not enough information: If information is insufficient or more is needed, EPA can require testing and issue an order to get additional data

Source: Adapted from materials prepared by the Environmental Defense Fund