Toxic Substances Control Act Reform Update

Potential Impacts to the Biotech Industry

October 25, 2016
Martin Bermudez, Principal Consultant
Mike Cheng, Senior Consultant

Toxic Substances Control Act Overview

TSCA History

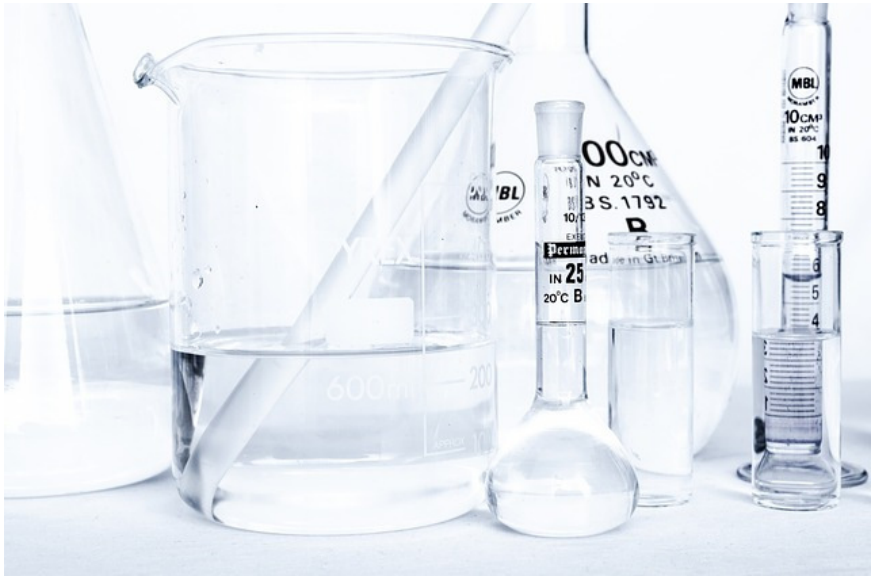
- Enacted by Congress in 1976
- Created a regulatory framework to manage risk posed by the manufacture, distribution, processing use and disposal of chemical substances
- Required evaluation of new chemicals entering into the consumer marketplace prior to manufacture
- Regulated existing substances deemed to pose unreasonable risk (e.g. asbestos and PCBs)

Impacts to Importers and Manufacturers

- Created list of approved chemicals (TSCA Inventory)
- Required notification and approval of the US EPA for the manufacture or importation of chemicals not listed on the TSCA Inventory (Pre-manufacturing Notices)
- US EPA able to restrict manufacturing processes in the event significant risks are identified (Significant New Use Rules)
- Created reporting requirements for certain categories of chemicals
  - Section 8(e) reports for substances with substantial risk
  - Priority Testing
  - Chemical data reporting for large scale manufacturing

Exemptions

- Mixtures
- Articles
- Pesticides
- Foods, Drugs and Cosmetics
- Nuclear Material
- Non-isolated Intermediates
- Research and Development Exemption
- Low Volume Exemption
- Polymer Exemption



Historic Issues

- Large number of grand-fathered chemicals that have not undergone evaluation
- Burdensome process to significantly restrict or ban chemicals
- Allowed substances into commerce without significant toxicity data evaluation
- Perceived over-use of confidential business information restrictions
- States restricting chemical use in the absence of effective Federal efforts

TSCA Reform

Frank R. Lautenberg Chemical Safety

for the 21st Century Act

TSCA Amendments

- Signed by President Obama on June 22, 2016
- Significant Changes Include:
  - Re-evaluation of chemicals on existing TSCA Inventory
  - New notification, risk analysis and control requirements
  - Changes to confidential business information protection requirements
  - Changes to Section 8 reporting to account for inventory reset
  - Federal – State Partnership, Pre-emption

TSCA Reform

Existing Chemicals on TSCA Inventory

- New process to conduct risk evaluations of chemicals currently on the TSCA inventory.
- TSCA Inventory chemicals will be reviewed and identified as active or inactive
- Prioritization process to be created to create "low" and "high" priority substances
- EPA will begin risk evaluations of high priority chemicals (10 in process by 12/16, 20 in process by 12/19)
- Priority will be on persistent/highly toxic Bioaccumulative chemicals and known human carcinogens with high acute and chronic toxicity.
- Evaluations limited to 3 years in duration.

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TSCA Reform

New Chemicals

- New authority to mandate testing (tiered testing approach required)
- Evaluation limited to 180 days as opposed to 90 day limit
- Must consider sensitive sub-populations
- Evaluations of PMNs will now have one of the following outcomes:
  - EPA determination that the chemical presents unreasonable risk of injury
  - EPA determination that information is insufficient to perform an evaluation
  - EPA determination that chemical does not present an unreasonable risk of injury
- New fee structure – TBD
- Procedural requirements for risk management have been reduced

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TSCA Reform

Confidential Business Information

- Allows disclosure of health and safety information on chemicals subject to reporting and significant new use rules.
- Identifies information not subject to CBI restrictions (production volumes, general process descriptions, information shared with general public or within industry)
- Includes requirements for additional requirements for CBI substantiation
- Allows EPA to request reassertion/re-substantiation of CBI if chemical is designated as a high priority or "active" chemical.

TSCA Reform

State-Federal Relationship

- States prohibited from requiring development of information that mirrors TSCA's information-gathering process
- Once EPA makes a "no-risk" determination, State are no longer allowed to restrict manufacturing, commerce or distribution. State may enforce laws and regulations enacted prior to a "no-risk" determination
- Prohibition on States requiring new use notification if a chemical is already subject to a SNUR
- States may require reporting, monitoring or information-gathering as long as they are not otherwise required by TSCA.
- Preserves state actions taken before April 22, 2016 and State laws enacted prior to August 21, 2003.

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TSCA Reform

Timelines

TSCA Reform Deadlines	
9/20/2016	List of mercury compounds banned from export published
12/20/2016	Risk evaluations of 10 high priority chemicals must be underway
6/22/2017	Prioritization screening process developed
	Risk evaluation process developed
	Inventory reset process established
6/22/2019	Risk evaluations of 20 high priority chemicals must be underway
1/1/2020	Export of mercury compounds prohibited

Impact of TSCA Reform on Industry

Who's impacted?

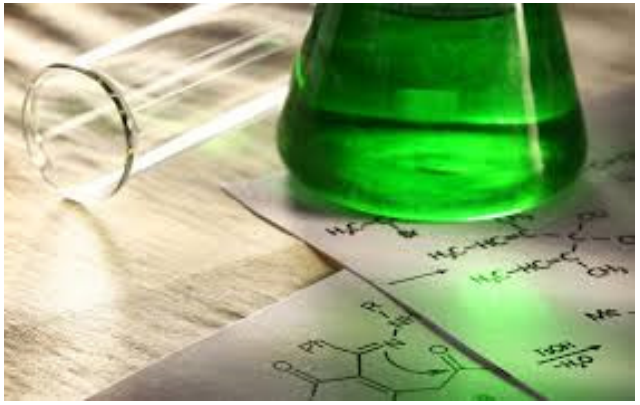
- Chemical manufacturers, processors, importers, and other users
- Innovators of chemicals and products
- Entities engaged in mergers and acquisitions
- Investors in chemical, manufacturing, and retail sector entities
- Corporate entities subject to US Securities and Exchange Commission (SEC) risk disclosures

Challenges for Industry

- Manufacturers should participate in rulemaking process for fees
- Inventory Reset Rule will require manufacturers and processors to report to the EPA all chemicals they have manufactured or processes within the preceding 10 years
- Manufacturers must provide confidentiality claims for chemicals manufactured during the proceeding 10 years
- Those who submit PMNs and SNUs should be aware of EPA's obligation to make an affirmative finding about risk and should consider developing additional information that will allow EPA to find that they are not likely to present an unreasonable risk
- Manufacturer can request that EPA designate a chemical as high-priority

Challenges for Industry

- Suppliers may submit request on behalf of processors (who are not authorized to make requests)
- Companies should review the TSCA Work Plan list for chemicals relevant to their business and plan accordingly
- As EPA prioritizes, conducts a risk evaluation for, and possibly regulates individual chemicals, affected companies or trade association should participate in the process



Language Changes with Potential Implications

- Conditions of Use
  - "Circumstances under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of"
  - Byproducts or Recycled products
- Potentially exposed or susceptible sub-populations
  - "Group of individuals within the general population who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture"
  - Previously evaluated against the young or elderly
  - Could be taken broadly to include other sub-populations

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Management of New Chemicals

Imports and Exports

- Certification of chemical imports
- Timing impacts to imports
  - Pre-Manufacture Notices (PMNs)
  - Significant New Use (SNUs)

Management of New Chemicals

New Chemicals

- Under Section 5, submittal of information required if:
  - Commercializing an intergeneric microorganism
    - Microbial Commercial Activity Notices (MCAN)
      - E.g. various E.coli strains, microalgae, etc.
  - Introducing such microorganisms into the environment for research purposes
    - TSCA Experimental Release Application (TERA)
- EPA anticipates the number and complexity will increase
- EPA's ability to compel testing may impact evaluations

Current Exemptions

- Low Volume Use
  - 10,000 kg/year or less
  - 30-day review and not added to the TSCA Chemical Substance Inventory
- Research & Development
  - No exemption application
  - Burden of proof
  - Certain circumstances (e.g. recycling of pharmaceutical waste streams) wouldn't be exempt
- Regulated under Federal Food, Drug, and Cosmetic Act (FFDCA)
  - Food and Drug Administration (FDA)

Preparing for Potential Impacts

- Inventory
  - Develop inventory of substances that are likely to be considered by EPA to be "high priority"
- Confidential Business Information
  - Develop justifications for existing and expected CBI claims, take inventory of proprietary data and data sharing agreements
- Supply Chain
  - Communicate with supply chain and downstream users regarding substances or products that might be subject to this act
- Business Impact
  - Determine which aspects of the rule have significant implications for business

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How Companies Can Prepare

- Review Product Lines Now
  - Determine which ones are likely to become 'high priority' targets for EPA risk evaluations
  - Flag chemicals that are persistent, bioaccumulate and carcinogenic. Collect and review all health, safety and environmental fate and effects data
  - Evaluate potential business impact if EPA decides to do a risk evaluation and customers may discontinue use
- Confirm the chemical nomenclature for all chemicals in the product lines to avoid a substance being treated as 'new'
- Monitor state chemical-regulator actions
- Review existing claims of confidentiality
- Submit new chemical and new use notifications soon before higher user fees kick in