





Environmental Law Institute Summer School 2022

Law and Policy of Products Regulation

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Key Federal Chemical Use Laws

- Toxic Substances Control Act (TSCA)
 - Regulation of industrial chemicals

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - Regulation of pesticides (agricultural chemicals, biocides)



Other Consumer Product Regulations

- Federal Hazardous Substances Act (FHSA)
- Consumer Product Safety Improvement Act (CPSIA)
- Federal Trade Commission (FTC) Green Guides
- California Safer Consumer Product Regulations (SCPR)
- California Cleaning Product Right to Know Act
- State Consumer Protection Laws

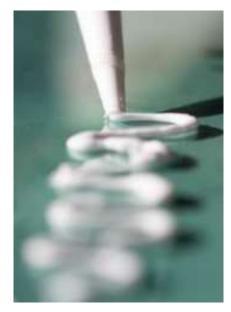




TSCA











Overview

Passed in 1976
Four decades passed without substantive amendment
Frank R. Lautenberg Chemical Safety for the 21st Century Act enacted on June 22, 2016 (Pub. L. No. 114-182)



Overview

- TSCA provides a chemical safety net
- TSCA is one of several statutes that regulate chemicals
- TSCA's unique focus is on industrial chemicals in commerce
- New TSCA dramatically changes how industrial chemicals are introduced and regulated in the United States



Purposes



- To encourage or require industry to develop adequate information on the human health and environmental effects of chemicals
- To regulate chemicals and mixtures that may present unreasonable risk of injury to health or the environment under intended conditions of use and to take action against imminent hazards
- No regulation should unduly impede or create unnecessary economic barriers to technological innovation



Definitions

Chemical substance" covers industrial chemicals and excludes pesticides, food additives, drugs, cosmetics, and preparations







Regulates manufacturers, including importers, and processors



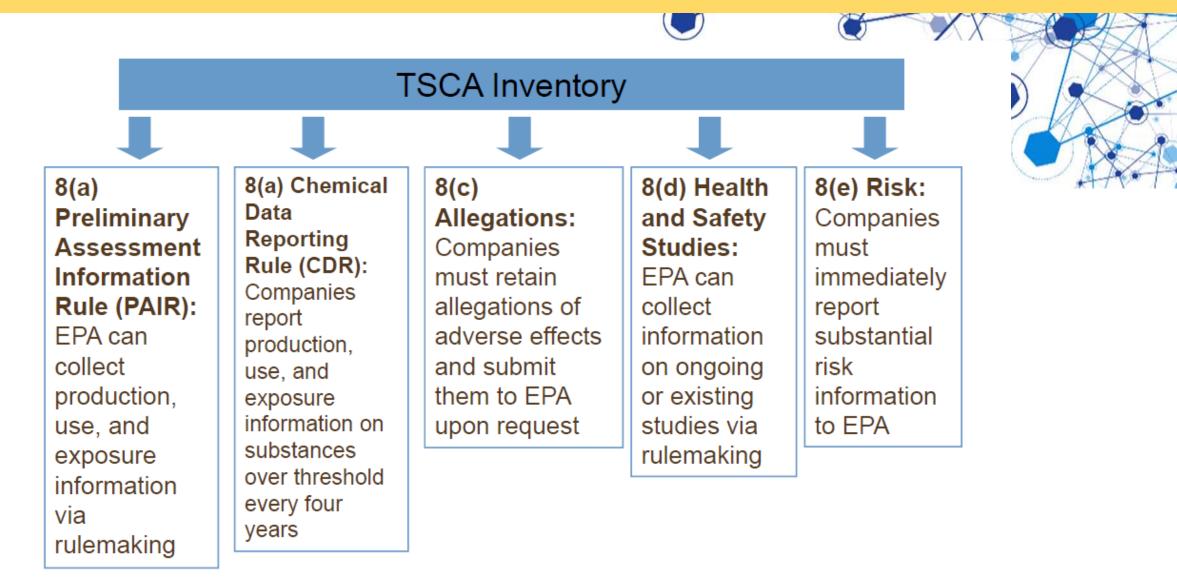
Major Changes over Current Law

- Mandatory duty on the U.S. Environmental Protection Agency (EPA) to evaluate existing chemicals with clear and enforceable deadlines
 - > Old TSCA -- No duty to review; no deadlines for action
- Chemicals assessed against a risk-based safety standard with no consideration of nonrisk factors
 - Old TSCA -- Risk-benefit balancing standard
- Unreasonable risks identified in the risk evaluation must be eliminated
 - Old TSCA -- Significant risks might not be addressed due to cost/benefit balancing and no mandate to act
- Expanded authority to compel development of chemical information when needed by order, rule, or consent agreement
 - > Old TSCA -- Required lengthy rulemaking

Major Changes over Current Law

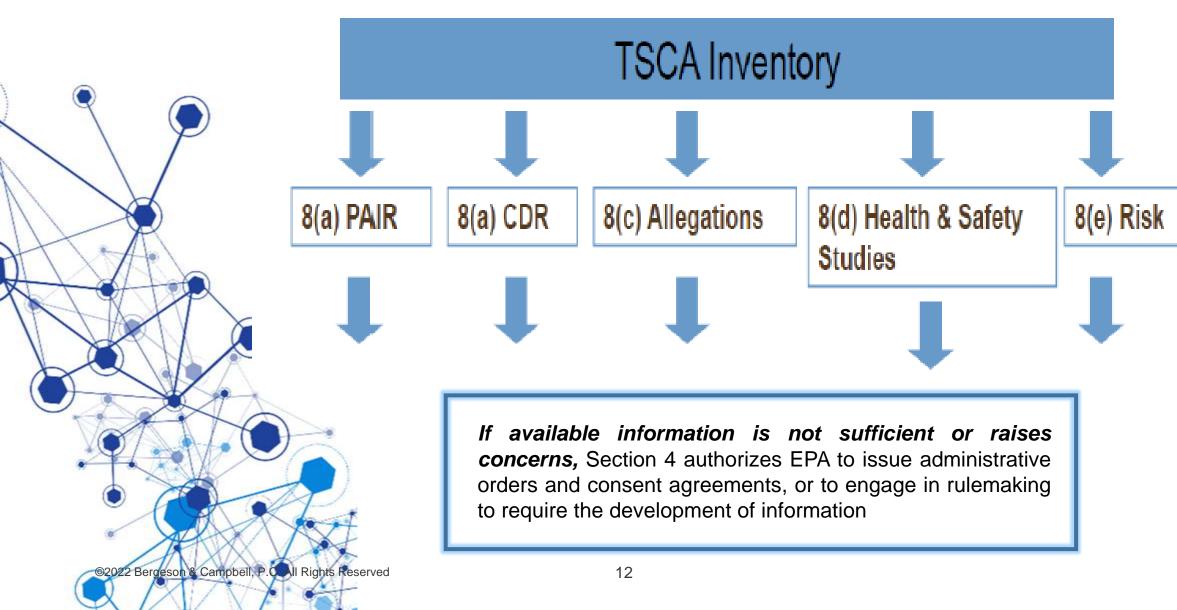
- Requires EPA to make an affirmative determination on new chemicals before entry into the marketplace
 - Old TSCA -- New chemicals enter the market in the absence of EPA action
- Requires substantiation of certain confidential business information (CBI) claims
 - > Old TSCA -- No statutory substantiation requirements for CBI claims
- New funding source (up to \$25 million total in annual user fees plus costs for manufacturer-requested risk evaluations), to be supplemented by Congressional appropriations
 - Old TSCA -- Cap on individual user fees at \$2,500 and limited fee collection authority

Information Collection on Existing Chemicals

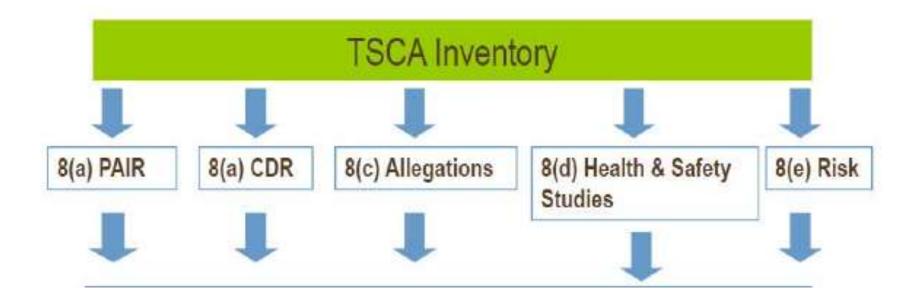


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Testing on Existing Chemicals



Risk Management on Existing Chemicals



Section 4 authorizes EPA to issue administrative orders and consent agreements, or to engage in rulemakings

If concerns continue after testing and information collection: Section 6 authorizes EPA to address unreasonable risk through restrictions, warning labels, recordkeeping, and product bans

Existing Chemicals

New TSCA -- Prioritizing Chemicals for Assessment

- > Establish a risk-based process to identify "high" and "low" priority substances
- High-priority -- The chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including to susceptible subpopulations
- Low-priority -- The chemical use does not meet the standard for high-priority



Existing Chemicals

Initial Set of Risk Evaluations

- EPA identified a list of ten TSCA Work Plan chemicals and formally initiated risk evaluations in December 2016
- In January 2021, EPA released the final risk evaluations for the last of the "first 10" chemicals



Existing Chemicals

- On June 30, 2021, EPA announced a path forward for the "first 10" chemicals
- For six of the "first 10" chemicals, EPA plans to assess whether the policy decision to exclude certain exposure pathways from the risk evaluations will lead to a failure to identify and protect fenceline communities
 - The six chemicals are methylene chloride, trichloroethylene, carbon tetrachloride, perchloroethylene, N-methyl-2-pyrrolidone (NMP), and 1-bromopropane



Existing Chemicals

Use of Personal Protective Equipment (PPE)

- EPA is also revisiting the assumption that PPE is always used in occupational settings
- EPA will consider information on use of PPE, or other ways industry protects its workers, as a potential way to address unreasonable risk during the risk management process
- This shift could impact conclusions about risk for some conditions of use for methylene chloride, 1-bromopropane, hexabromocyclododecane (HBCD), NMP, perchloroethylene, and 1,4-dioxane





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Existing Chemicals

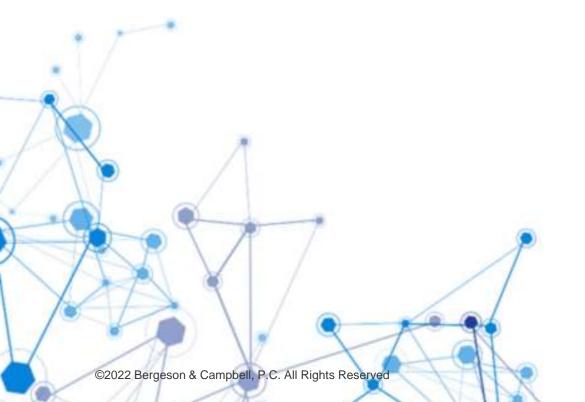
"Whole chemical" approach

- Under the previous Administration, EPA made separate unreasonable risk determinations for every identified condition of use
- For the "first 10" chemicals, EPA will continue to assess and analyze each condition of use
- Going forward, EPA plans to make the determination of unreasonable risk just once for the whole chemical when it is clear the majority of the conditions of use warrant one determination
- EPA intends to withdraw previously issued orders for those conditions of use for which no unreasonable risk was found for all the "first 10" risk evaluations
- EPA then intends to issue revised unreasonable risk determinations for these chemicals as a "whole substance" and seek public comment on this approach

Existing Chemicals

20 High-Priority and 20 Low-Priority Chemicals

- On December 20, 2019, EPA announced the final list of 20 high-priority chemical substances
- On February 20, 2020, EPA announced the final list of 20 chemical substances designated as low-priority substances





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Existing Chemicals

Persistent, Bioaccumulative, and Toxic Chemicals (PBT)

- New TSCA establishes a fast-track process to address certain PBT chemicals listed on TSCA Work Plan
- > No risk evaluation; only a use and exposure assessment
- > On January 6, 2021, EPA issued final rules to address five PBTs:
 - 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP)
 - Decabromodiphenyl ether (decaBDE)
 - Phenol, isopropylated phosphate (3:1) (PIP (3:1))
 - Pentachlorothiophenol (PCTP)
 - Hexachlorobutadiene (HCBD)

Existing Chemicals

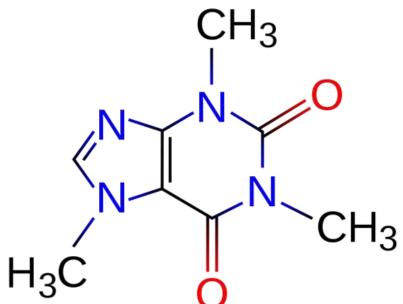
PBT Chemicals

- EPA requested and received comment on the January 2021 PBT rules in 2021
- In September 2021, EPA announced its intent to initiate a new rulemaking and anticipates proposing new rules in spring 2023 for the five PBTs
- In March 2022, EPA issued a final rule further extending the compliance dates for the prohibitions on processing and distribution and the associated recordkeeping requirement for PIP (3:1) when used in certain articles until October 31, 2024

Section 5 -- New Chemical Review

Company submits Premanufacture Notice (PMN)

- Chemical identity information
- > Production volume
- Intended categories of use
- Description of byproducts
- Molecular formula
- Available information
- EPA conducts initial review
- EPA develops hazard profile
 - Structure Activity Team (SAT) uses analogs



New Chemicals/Significant New Uses

Retains certain basic requirements for new chemicals (NC) and significant new uses (SNU)

- > 90-day review period, extensions permitted
- Now TSCA requires EPA determination on all notices





New Chemicals/Significant New Uses

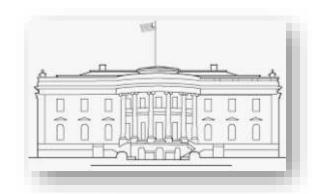
Five affirmative determinations:

- 1. NC/SNU presents an unreasonable risk
- 2. Available information is *insufficient* to permit a reasoned evaluation of the health and environmental effects associated with the NC/SNU
- 3. In the absence of sufficient information, the NC/SNU *may present* an unreasonable risk of injury to health or the environment
- 4. NC/SNU chemical has substantial production and exposure, or
- 5. NC/SNU is *not likely* to present an unreasonable risk



TSCA Implementation Issues

- Changes in Administration
- Ongoing litigation
- New chemicals review progress
- Alternative testing strategies
- Evolving risk evaluation process
- TSCA information gathering/testing authority
- Operational challenges:
 - > Resources
 - > Staffing
 - Institutional capacity
 - Congressional oversight









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FIFRA







FIFRA

Administered by EPA

Several states have developed state programs that are quite mature and well developed -- California, New York, Florida, among others



What Is a Pesticide?

- Any substance or mixture of substances <u>intended</u> for preventing, destroying, repelling, or mitigating any pest
- A substance is considered to be intended for a pesticidal purpose requiring registration if the person who distributes or sells the substance claims, states, or implies that the substance can or should be used as a pesticide





Regulatory Scope

Active Ingredients

- Ingredients that prevent, destroy, repel, or mitigate pests
- > Plant regulators, defoliants, desiccants, and nitrogen stabilizers
- Inert Ingredients
 - "Other ingredients" in pesticide formulations
- Pesticide Types
 - Conventional pesticides
 - Minimum-risk pesticides
 - > Biopesticides
 - Antimicrobials
 - Treated articles



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Regulatory Framework

- Premarket Approval
- Risk-Based Safety Standard
 - No unreasonable risk (non-food uses)
 - Reasonable certainty of no harm (food uses)
- Legal burden on registrant to meet safety standard
- Unlike TSCA, FIFRA is "use" specific, not "chemical" specific (but TSCA is evolving in this direction)



Regulatory Framework

EPA reviews registrant-submitted data against applicable standard

- Data requirements codified at 40 C.F.R. Part 158
 - Battery of testing requirements
 - > EPA has authority to require additional data
 - EPA discretion to waive data requirement

Data development can cost millions, and it can take years before an application can be submitted to EPA



Regulatory Framework

- Protections for trade secrets and CBI
- EPA has adopted a narrow interpretation of protected information; enhanced transparency
- Compensation provisions for third-party use of proprietary data





Regulatory Framework

- Mandatory Label Requirements
 - Ingredients
 - Approved claims
 - Use directions
 - Warning statements
 - Registrant information
- Use inconsistent with label prohibited
- Labeling covers all written materials (and then some)

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Regulatory Framework

- New Actives/Products/Uses
 - Review timeframes established by statute (Pesticide Registration Improvement Act (PRIA))
 - > Four months to 24 months review standard, but can be longer
- Existing Actives/Products/Uses
 - > Review older pesticides against current health standards
 - Mandate to complete review by September 30, 2022
 - This review typically yields label amendments, use restrictions, or other legal redress (cancellation)

Regulatory Framework

- Promote "Safer" or "Reduced-Risk" Pesticide Alternatives
 - Reduced fees
 - Expedited reviews
 - Dedicated resources
- Various Programs to Register Reduced-Risk Pesticides
 - Minimum-risk pesticides
 - Reduced-risk conventional pesticides
 - > Biopesticides



Enforcement Framework

- Restrict Future Sale of Products
- Response to COVID-19
- Stop Sale, Use, or Removal Orders (SSURO)
- Civil Penalties
- Criminal Penalties





Current FIFRA Issues

- Endangered Species Act (ESA)
- Registration Review (September 30, 2022)
- Pollinator Policy
- Proposition 65 Warning Requirements and FIFRA
- Evolving Technologies and Institutional Literacy







Thank You

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