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# **Environmental Law Institute Summer School 2021**

## **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
- New York Household Cleansing Product Information Disclosure Program
- 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 **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

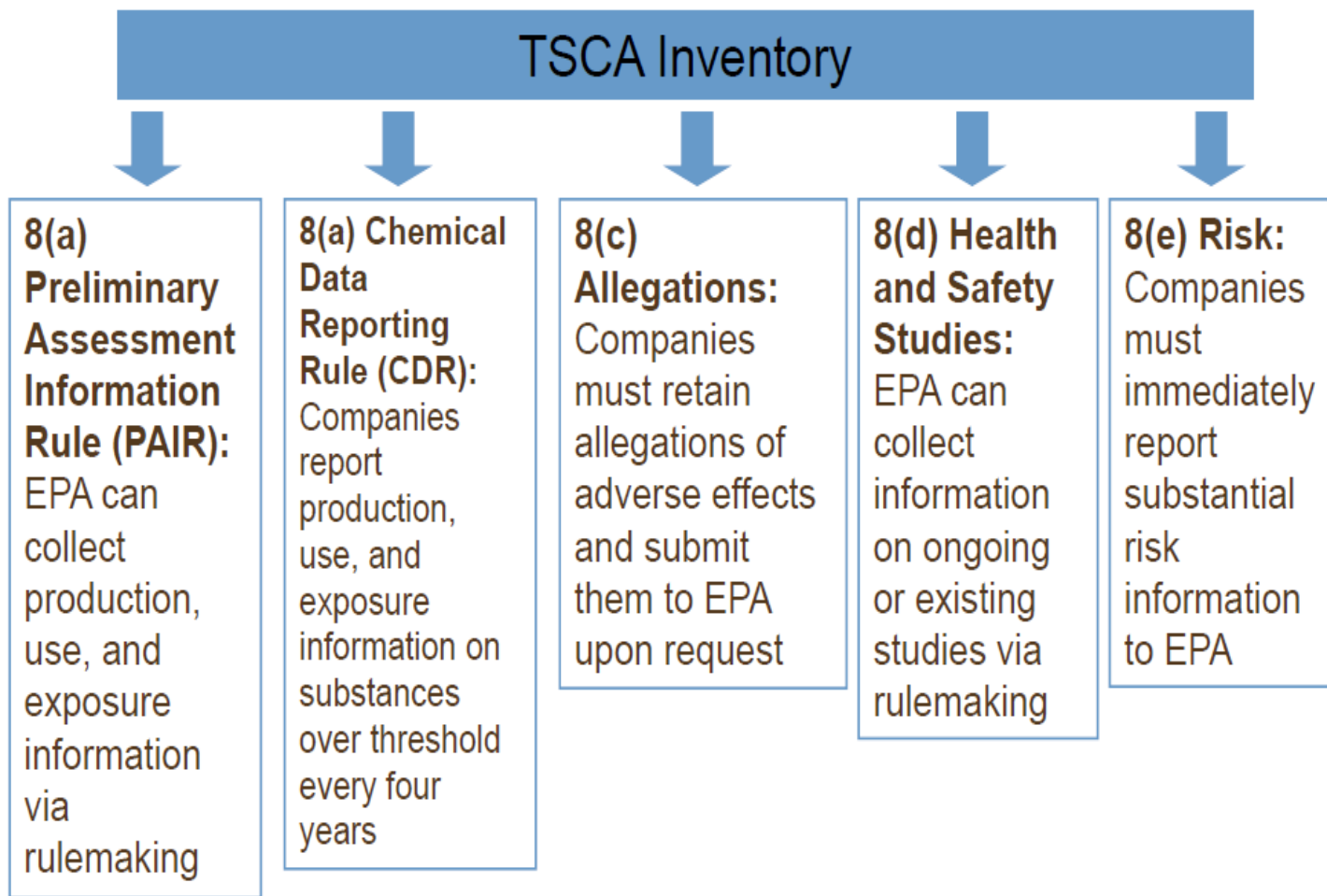
- Mandatory duty on the U.S. Environmental Protection Agency (EPA) to evaluate existing chemicals with clear and enforceable deadlines
  - *Old TSCA -- No duty to review; no deadlines for action*
- Chemicals assessed against a risk-based safety standard with no consideration of nonrisk factors
  - *Old 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*



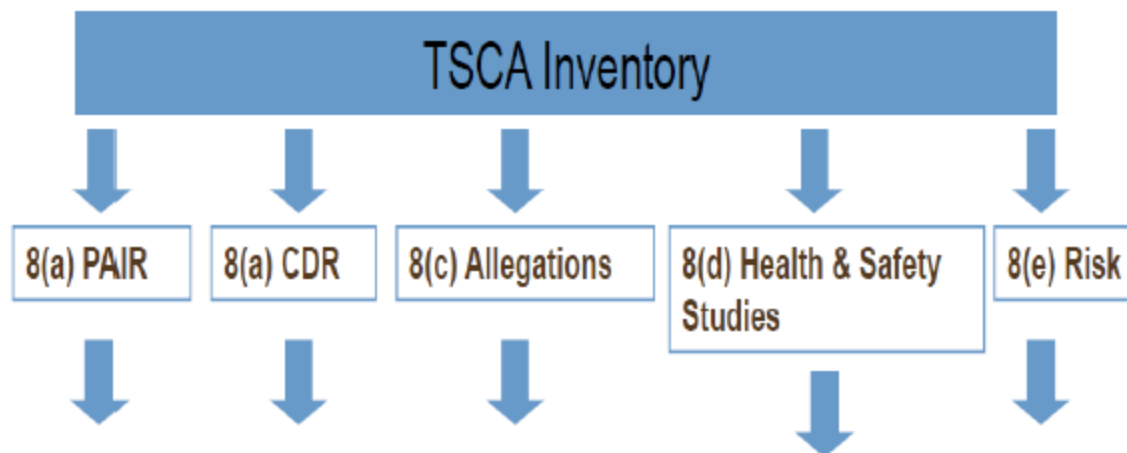
## Major Changes over Current Law

- 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



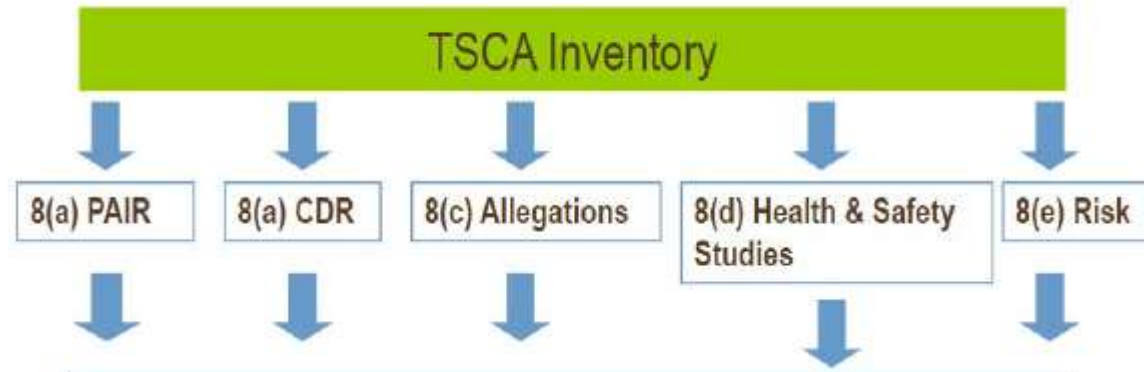
# Testing on Existing Chemicals



***If available information is not sufficient or raises concerns,*** Section 4 authorizes EPA to issue administrative orders and consent agreements, or to engage in rulemaking to require the development of information



# 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 from Work Plan Chemical Assessments
  - 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 “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 fence-line 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

# 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

# Existing Chemicals

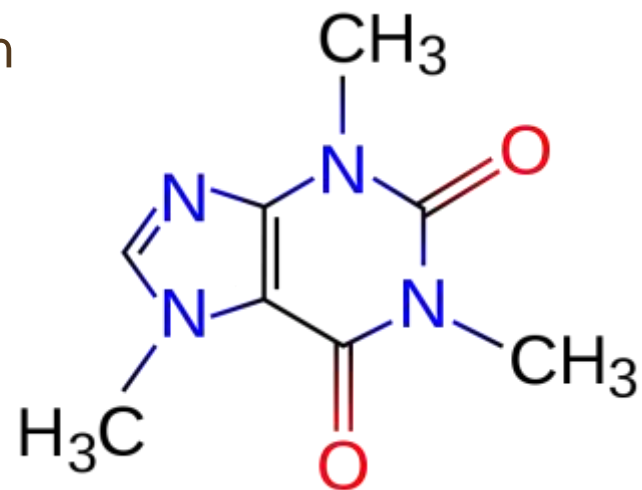
- Persistent, Bioaccumulative, and Toxic Chemicals (PBT)
  - New TSCA establishes a fast-track process to address certain PBT chemicals listed on TSCA Work Plan
  - No risk evaluation; only a use and exposure assessment
  - EPA Issued a final PBT rule on March 8, 2021



## 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
- Three alternative determinations:
  1. NC/SNU *presents* an unreasonable risk
  2. Available information is *insufficient* **or** NC/SNU *may present* unreasonable risk **or** NC/SNU chemical has *substantial production and exposure*, or
  3. NC/SNU *not likely* to present 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



# 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 intended 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



## 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

## ■ 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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