



**BERGESON & CAMPBELL PC**

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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 following several years of debate and revisions
- Almost 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

## Key Sections of TSCA

- Section 4 -- Testing of Chemical Substances and Mixtures
- Section 5 -- Manufacturing and Processing Notices (New Chemicals)
- Section 6 -- Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures (Existing Chemicals)
- Section 8 -- Reporting and Retention of Information
- Section 9 -- Relationship to Other Federal Laws
- Section 14 -- Confidential Information
- Section 26 -- Administration of the Act



## Definitions

- “Chemical substance” covers industrial chemicals and excludes pesticides, food additives, drugs, cosmetics, and preparations



- Regulates both manufacturers and processors (including importers)
- Distinguishes “new” from “existing” substances
  - A new chemical substance is “any chemical substance which is not included in the chemical substance list compiled and published under [TSCA Section 8(b)]”
  - TSCA Inventory is a list of all chemical substances in commerce prior to 1979 and those that have been commercialized since (about 86,000 chemicals)

## 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*

## Section 8 -- Information Gathering

- Authorizes EPA to require chemical manufacturers and processors to maintain records and report data to EPA -- established through rulemaking (small manufacturers exempt)
  - Chemical identity, use categories, health and environmental information, people exposed
  - Chemical Data Reporting (CDR) rule -- Requires manufacturers of non-polymeric chemicals over 25,000 pounds listed on Inventory every four years to report current data on production use, exposure, and related information (2,500 pounds if subject to certain restrictions)
  - Reporting period for 2020 cycle is **June 1 to November 30, 2020**



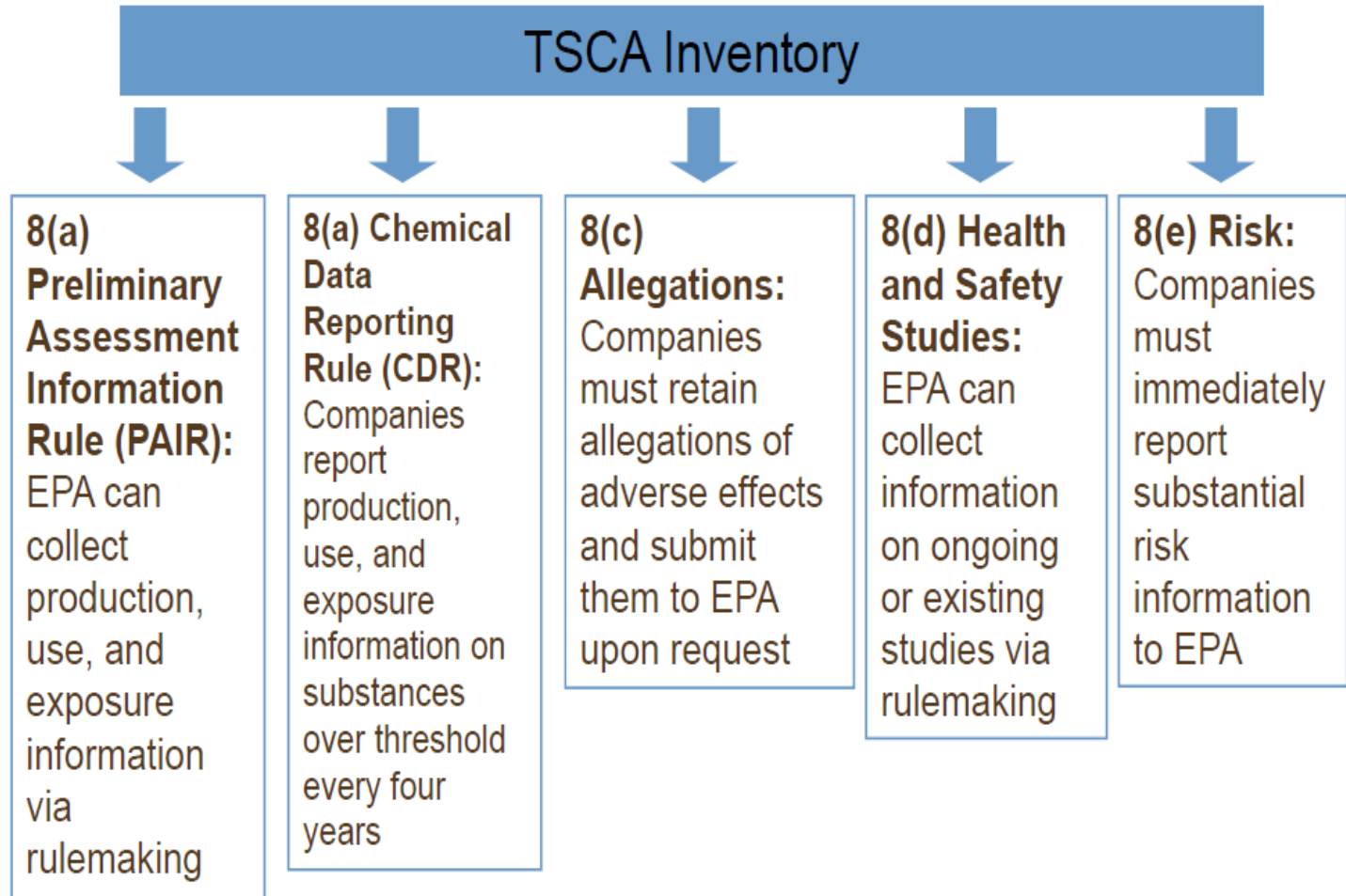


## Section 8 -- Information Gathering

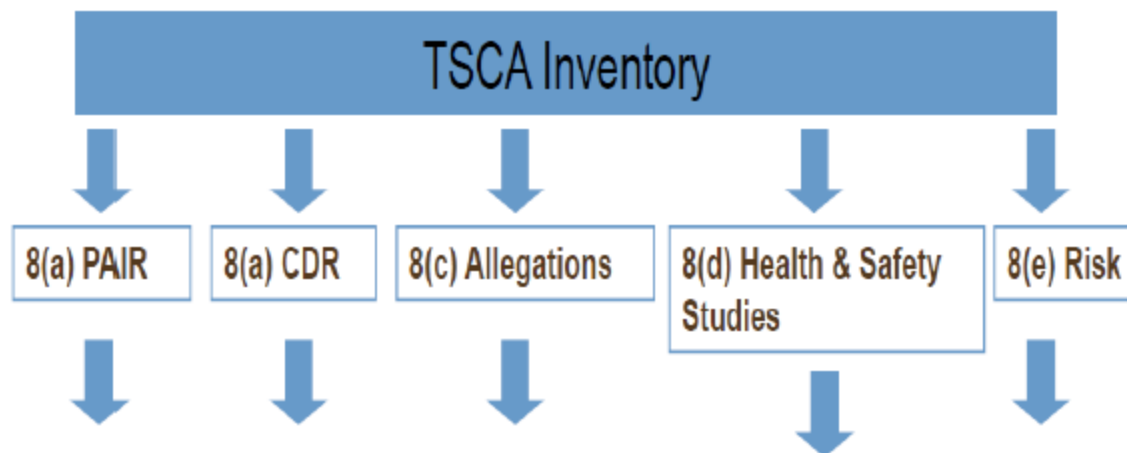
- Requirement that companies immediately notify EPA of substantial risk information
- Requirement that companies record and retain “allegations” of adverse effects and submit them to EPA upon request
- EPA can require companies to submit information on ongoing or existing health and safety studies



# Information Collection on Existing Chemicals



# Testing on Existing Chemicals



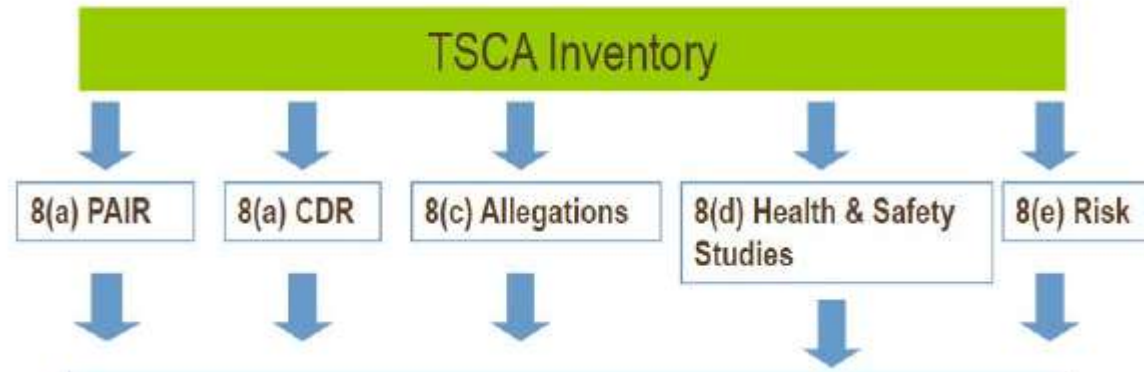
***If available information is not sufficient or raises concerns,*** Section 4 authorizes EPA to issue administrative orders and consent agreements, or to engage in rulemaking to require the development of information

## Testing on Existing Chemicals

- New TSCA expands EPA's authority to require development of information
  - Authorizes administrative orders and consent agreements in addition to rulemakings
  - Permits EPA to require testing needed for prioritization
  - New authority does not require EPA findings
  - May not be used to establish "a minimum information requirement of broader applicability"
- New Section 4(h) concerns vertebrate animal testing and requires EPA to:
  - Reduce and replace such testing to the extent practicable, scientifically justified, and consistent with policies of diminished animal testing
  - Develop, within two years of enactment, and implement a strategic plan to promote alternative test methods (June 22, 2018)



# 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

## Specific Requirements -- 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
- Procedural rule issued on June 22, 2017, established a process for prioritizing chemicals

## Specific Requirements -- 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
  - EPA released the scope of each assessment in June 2017
  - EPA published the problem formulation documents in June 2018
  - EPA began releasing draft risk evaluations, beginning with pigment violet 29, in November 2018
  - To date, EPA has issued only one final risk evaluation, for methylene chloride

## Specific Requirements -- 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
    - EPA published a *Federal Register* notice on January 27, 2020, identifying the preliminary lists of manufacturers (including importers) of the 20 high-priority chemical substances for risk evaluation for which fees will be charged
    - EPA released the draft scope documents in April 2020
    - EPA intends to issue final scope documents for the next 20 risk evaluations in summer 2020 and will publish the final list of fee payers no later than concurrently with the final scope documents
  - On February 20, 2020, EPA announced the final list of 20 chemical substances designated as low-priority substances

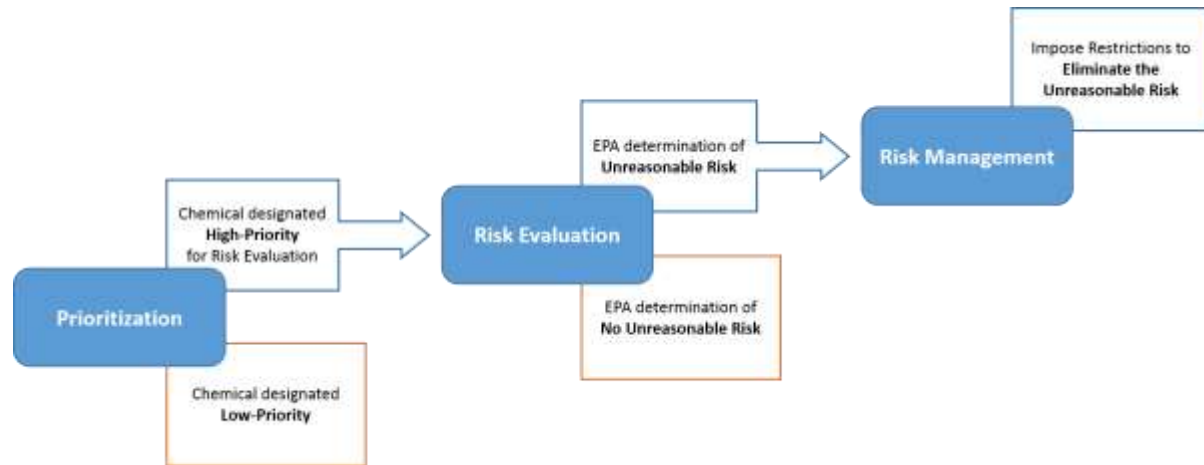


## Specific Requirements -- Existing Chemicals

- Risk-Based Safety Standard
  - Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an “unreasonable risk”
  - The risk determination is to be made without consideration of costs or other nonrisk factors
  - Risks to susceptible and highly exposed populations must be considered
- EPA must take risk management action to address unreasonable risks
  - Costs and availability of alternatives to be considered when selecting among risk management options
  - Exemption process for critical uses
  - Risk management actions must be promulgated within two years of completing risk evaluation, with extension of up to two additional years

# Specific Requirements -- Existing Chemicals

- EPA issued Final Risk Evaluation Process Rule on June 22, 2017



## Specific Requirements -- Existing Chemicals

- Persistent, Bioaccumulative, and Toxic Chemicals (PBT)
  - The new law establishes fast-track process to address certain PBT chemicals already on TSCA Work Plan
  - No risk evaluation; only a use and exposure assessment
  - Rules to reduce exposure to the extent practicable must be proposed within three years of enactment and issued in final 18 months later, unless a manufacturer requested a risk evaluation by September 22, 2016 (EPA proposed a rule on July 29, 2019)
  - Additional requirements encourage prioritization of PBTs in overall risk evaluation process

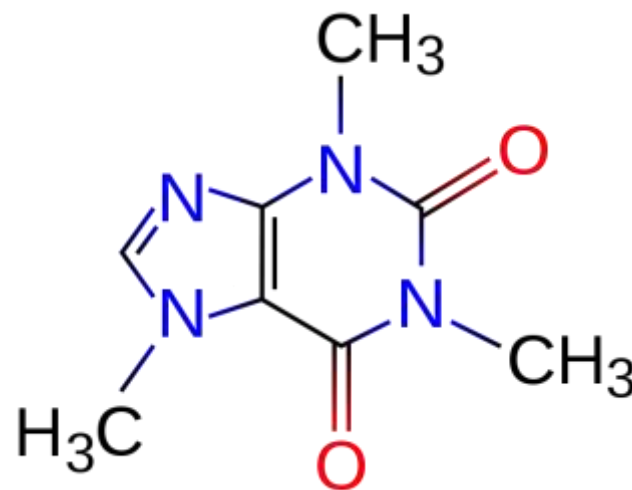
## Specific Requirements -- Existing Chemicals

- TSCA Inventory
  - Requires industry to report on the chemicals they manufactured or processed in the previous ten years to determine if chemicals are currently “active” in the marketplace
  - The chemicals on the TSCA Inventory will not change
  - Chemicals will be designated as “active” or “inactive”
  - Only “active” chemicals may be prioritized
  - No premanufacture notification (PMN) required to move from “inactive” to “active”
- Final Inventory Notification rule issued on August 11, 2017



## Section 5 -- New Chemical Review

- Company submits 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



## Section 5 -- New Chemical Review



- Evaluates health effects, environmental effects, environmental fate
- Establishes health and environmental hazard potential
- EPA develops Exposure/Release Profile
- EPA holds Focus Meeting -- drop or full review
- *Prior bullets = “old” EPA new chemical review process. Mandate for affirmative finding has adjusted process and outcomes*

## New Chemicals/Significant New Uses

- Retains certain basic requirements for new chemicals (NC) and significant new uses (SNU)
  - 90-day review period, extensions permitted
- 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

## New Chemicals/Significant New Uses

- EPA required to regulate under determinations 1 and 2
- EPA has limited ability to regulate articles/category of articles compared to prior TSCA, but requires EPA also to apply a SNU rule (SNUR) under determinations 1 and 2 or “make public” a statement explaining its findings
- Under determination 3, the submitter can begin to commercialize immediately, and EPA will later publish in the *Federal Register* a notice that the chemical is most likely to pose an unreasonable risk

# TSCA Implementation Issues

- Ongoing litigation
- New chemicals review progress
- Alternative testing strategies
- Risk evaluation process
- Host of operational challenges
- TSCA information gathering/testing authority
  - Resources
  - Staffing
  - COVID-19
  - Institutional capacity
  - Congressional oversight





# FIFRA



# FIFRA

## ■ Who Implements the Program?

### ➤ EPA

- Office of Pesticide Programs (OPP)
  - Antimicrobials Division (AD)
  - Biological and Economic Analysis Division (BEAD)
  - Biopesticides and Pollution Prevention Division (BPPD)
  - Environmental Fate and Effects Division (EFED)
  - Field and External Affairs Division (FEAD)
  - Health Effects Division (HED)
  - Information Technology and Resources Management Division
  - Pesticide Re-Evaluation Division
  - Registration Division



# FIFRA

- Where a state has a federally-approved pesticide program, the state is the primary enforcement authority
- Several states have developed separate state programs that are quite mature and pose formidable market entry challenges -- California, New York, Florida





## 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)
- Burden on registrant to meet safety standard
- Unlike TSCA, FIFRA is “use” specific, not “chemical” specific



## 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 Extension Act of 2018 (PRIA 4))
- Four months to 24 months review standard, but can be longer

## ■ Existing Actives/Products/Uses

- Review older pesticides against current health standards
- 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)
- COVID-19 Issues
- Pollinator Policy
- Chlorpyrifos Update
- Proposition 65 Warning Requirements and FIFRA
- Evolving Technologies and Institutional Literacy



## Thank You

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