



The Toxic Substances Control Act (TSCA) in Ten Slides

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Different Meanings of TSCA

For us today, TSCA means Title I

- ➔ Title I – “Core TSCA” or “New and Existing Chemicals Program” (1976)
 - Includes a standalone program for polychlorinated biphenyls (PCBs).
 - Amended by Mercury Export Ban Act (2008).
 - Significantly amended by Lautenberg Chemical Safety Act (LCSA) in 2016.
- Title II – In-place management of asbestos in schools (1986)
- Title III – Indoor radon abatement (1988)
- Title IV – Preventing poisoning from residential lead-based paint (1992)
- Title V – Healthy school environments (2007)
- Title VI – Emissions of formaldehyde from pressed wood products (2010)
 - Preceded by CARB’s Composite Wood Products Airborne Toxic Control Measure (2007).

Execution of TSCA

TSCA is a federal-only program

- Administered by the U.S. Environmental Protection Agency's (EPA's) Office of Pollution Prevention and Toxics (OPPT).
- But enforced by EPA's Office of Enforcement and Compliance Assurance (OECA).
- Also enforced by EPA's Regional Offices under a new resource-sharing arrangement.
- The states, tribes, and territories do not jointly administer or enforce TSCA.
 - But section 18 of TSCA allows state and local governments to enforce “identical requirements.”

Scope of TSCA

TSCA regulates chemicals in commerce

- TSCA primarily regulates the manufacture and processing of chemical substances for commercial purposes.
 - “Manufacture” includes importation.
 - “Processing” includes any preparing of substances or mixtures after their manufacture or import for distribution in commerce, including as part of articles.
- TSCA also can regulate the distribution in commerce (including export), use, and disposal of chemical substances following their manufacture or processing for commercial purposes.
- TSCA can apply to chemical substances alone, in mixtures, or as part of articles and in any quantity.

“Chemical Substance”

Broadly defined and includes microorganisms

- “Any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.” TSCA § 3(2)(A)
 - Includes microorganisms, but TSCA currently regulates only “intergeneric” microorganisms (formed by combining genetic material originally isolated from organisms of different genera) that are “new” and manufactured for non-excluded uses.
 - Also includes a chemical substance produced by any microorganism for a use that is not excluded, e.g., industrial oils for biofuel and industrial enzymes.

“Chemical Substance”

Important exclusions apply

- Pesticides (excluding intermediates, inert ingredients, adjuvants)
 - Regulated by EPA under Federal Insecticide, Fungicide, and Rodenticide Act.
- Food, food additives, drugs, cosmetics, and medical devices, including components
 - Regulated by FDA under Federal Food, Drug, and Cosmetic Act (FFDCA).
 - Pesticide chemical residues in or on raw agricultural commodities are jointly regulated by EPA and FDA under the FFDCA.
- Source material, special nuclear material, and byproduct material
 - Regulated by NRC and DOE.
- Tobacco and tobacco products
 - Regulated by FDA and DOJ/ATF.
- Firearms, shells, cartridges, and components of shells and cartridges
 - Regulated by ATF.

New Chemicals Program

Section 5 of TSCA

- “Existing” chemical substances are listed on the TSCA Chemical Substance Inventory, and unlisted (including exempt) substances are “new.”
- The primary TSCA requirement for a new chemical substance is the submission of a section 5 premanufacture notice (PMN) to EPA at least 90 days before importing or manufacturing any quantity of the substance in the U.S. for a non-exempt commercial purpose.
- There are many PMN exemptions (R&D, low-volume, test marketing, polymers, etc.) of differing nature and complexity.
- EPA can approve a PMN subject to restrictions.
 - Section 5(e) order or 5(f) rule or order

Existing Chemicals Program

Sections 5 and 6 of TSCA

- Section 5(a)(2): EPA may promulgate a rule designating an activity as a “significant new use” of an existing chemical.
 - Manufacture or processing “for” a designated significant new use is unlawful without 90 days’ prior notice to EPA in a significant new use notice (SNUN), which is like a PMN.
- Section 6(a): EPA can ban or restrict an existing chemical by rule if it
 - Presents an unreasonable risk of injury to human health or the environment, ignoring costs and other nonrisk factors and including any unreasonable risk to any potentially exposed or susceptible subpopulation that EPA identifies as relevant under the conditions of use.
- LCSA (2016) requires EPA to prioritize “active” substances on the Inventory, systematically review them for risks, and regulate them by rule, as necessary.
 - Three EPA “framework” rules have been challenged in federal court.

Other TSCA Duties

Sections 4, 8, 12, 13

- Under section 4, EPA can promulgate test rules, negotiate enforceable consent agreements (become testing consent orders), and issue test orders (since 2016).
- Section 8 mandates numerous reporting and recordkeeping requirements.
 - Section 8(a) Chemical Data Reporting Rule
 - Section 8(b) Notice of Activity Form B reporting (since Aug. 5, 2019)
 - Section 8(c) recordkeeping for allegations of “significant adverse reactions”
 - Section 8(e) “substantial risk information” reporting
- Section 12(b) export notices apply only to chemicals substances that are subject to certain proposed or final rules, orders, or actions under TSCA.
 - And a 1.0% or 0.1% (for carcinogens) concentration threshold applies.
- Importers must certify under section 13 that imported TSCA substances comply with TSCA and are not offered for entry in violation of TSCA.

Managing Expectations

TSCA does not do things some people might expect

- Classification, packaging, and labeling
 - Although chemical-specific TSCA rules, orders, and actions can and do mandate hazard communication, including labeling, TSCA is not primarily a classification, packaging, and labeling law.
- Chemical facility safety and security
 - TSCA does not directly address chemical process safety, chemical facility security, or site emergency planning and response.
- TSCA does not ordinarily duplicate but can overlap other environmental laws administered by EPA.
 - For example, CERCLA designates Superfund sites and mandates cleanup.
 - But contaminating property with PCBs can violate TSCA (as disposal), and both using and cleaning up property contaminated with PCBs have TSCA requirements.

Preemption

Are California laws preempted?

- TSCA precludes few state laws.
 - Duplicate section 4, 5, or 6 testing or significant new use notification.
 - Restrict a use for which EPA has made a final section 6 determination and
 - Determined that the use presents no unreasonable risk or
 - Determined that the use presents an unreasonable risk and promulgated a final section 6 rule to prohibit or restrict the use.
 - But EPA has discretion to grant waivers.
 - And states can continue to regulate any uses not evaluated by EPA.
- Even “high priority pause” involves mandatory waivers.
- And numerous state laws are expressly allowed.



Panel Discussion