Toxic Substances Control Act (TSCA)

- **Purpose**
  - To control the manufacture, use, and distribution and disposal of chemical substances to protect human health and the environment
- **Scope**
  - Manufacturers have the burden of supplying the EPA with information on environmental and health effects of chemical substances and mixtures
  - The EPA then has broad power to regulate the manufacture, use, distribution, and disposal of chemical substances and mixtures
- **Who implements the EPA?**
  - The EPA
- **EPA Authority**
  - Review new chemicals and significant new uses of existing chemicals
  - Require testing of chemicals that may present a significant risk to human health or the environment
  - To study the effects of existing chemicals
  - To limit the manufacture, use, distribution and/or disposal of chemicals that present an unreasonable risk
Activities Subject to TSCA Regulation

- Manufacturing
  - *Manufacture* is defined as producing, preparing, importing, or compounding a toxic chemical, including the creation of substances produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, such as by-products, coproducts, or impurities
  - Premanufacture Notice (PMN)
    - When a company plans to manufacture, import, or process a substance deemed to be “new,” that company is required to provide the EPA with this notice, which includes detailed information concerning the substance and the proposed manufacturing operation

- Processing
  - *Process* is defined as the preparation of a chemical substance after its manufacture for distribution in commerce in the same form or physical state as, or in a different form or physical state from, that in which it was received by the persons so preparing such substance as part of an article containing the chemical substance or mixture

- Using

- Disposing
Requirements of Manufacturers

• Under the TSCA, manufacturers must
  – Conduct tests on chemicals they manufacture and submit data from these tests to the EPA
  – Submit a premanufacture notice (PMN) when they are manufacturing a chemical not already on the TSCA Inventory or prior to manufacturing a chemical for a significant new use
  – Avoid manufacturing PCBs
  – Create and maintain reports as required by the TSCA
  – Respond to subpoenas and allow the EPA to inspect their manufacturing facilities
  – Demonstrate compliance with the TSCA when importing chemicals or chemical mixtures
Requirements of Processors

• Processors must
  – Provide the EPA with certain data under test rules
  – Notify the EPA before processing a chemical for a significant new use
  – Comply with EPA orders and rules
  – Avoid processing PCBs unless permitted to do so by the EPA
  – Comply with the reporting requirements of the Comprehensive Assessment Information Rule (CAIR), and record keeping and reporting requirements
  – Respond to subpoenas and submit to inspections by the EPA
Requirements of Users

• Users, however defined, who are not also manufacturers, processors, or distributions must
  – Comply with applicable EPA regulations
  – Refrain from using PCBs except when permitted by the EPA
  – Refrain from using any chemical substance the user knows or has reason to know has been manufactured, produced, or distributed in violation of the TSCA
  – Respond to subpoenas and submit to inspections by the EPA
Requirements of Distributors

• Distribution
  – The process of selling, introducing, or delivering a chemical substance into commerce or holding the mixture or article after its introduction into commerce

• Distributors are required under the TSCA to
  – Comply with applicable rules and regulations
  – Refrain from distributing PCBs except as permitted by the EPA
  – Report “substantial risk information” to the EPA
  – Respond to subpoenas and submit to inspections by the EPA
Requirements of Disposers

• Disposers of chemicals or chemical mixtures are required to
  – Comply with applicable regulations
  – Dispose of PCBs properly
  – Respond to subpoenas and submit to inspections by the EPA
TSCA Inventory

• Since 1976, the list represents “each chemical substance which is manufactured or processed in the United States”
• Keeps tracks of existing and new chemicals
• The number of chemicals on the list presently exceeds 80,000
• The Inventory lists reportable chemical substances, defined as
  1. Chemical substances which are
     o “. . . any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical,”
  2. Manufactured, imported, or processed for a commercial purpose in the United States, and
  3. Not specifically excluded from the Inventory
• Delisting
• Update Rule
TSCA Inventory (cont.)

- Confidential chemical identity
  - A chemical formula permitted to be kept confidential under most circumstances pursuant to the Emergency Planning and Community Right-to-Know Act (EPCRA)
- Bona fide intent
  - A *bona fide* intent, submitted by the requester in writing, includes the following:
    - The specific chemical identity of the chemical the entity intends to manufacture or import
    - A signed statement demonstrating an intent to manufacture or import the chemical for commercial purposes
    - A description of the R&D activities conducted
    - The purpose for which the chemical will be manufactured or imported
    - An analysis of the elements in the chemical
    - An x-ray diffraction pattern (inorganic substances), a mass spectrum, or an infrared spectrum
Premanufacture Notice (PMN)

• Applies to (i) any new chemical substance, and (ii) significant new use of an existing chemical

• PMN Requirements
  – The PMN must include
    o The identity of the chemical
    o Its categories of use
    o The amounts to be manufactured or imported
    o By-products from the chemical
    o Exposure of employees to the chemical
    o Methods of disposal
    o Test data related to the chemical’s effect on human health or the environment
    o Any other data regarding the chemical that is “reasonably ascertainable” by the manufacturer or importer

• Exemptions
• Types of PMNs
• The PMN Process
• Significant New Use Rule (SNUR)
• Significant New Use Notice (SNUN)
TSCA Testing

• Interagency Testing Committee (ITC)
• ITC criteria for identifying new chemicals:
  – The quantities manufactured or introduced into the environment
  – The amount of human exposure
  – Whether the substance is similar to another chemical known to be harmful
  – Any data concerning effects of the chemical
  – Whether testing will assist in determining the possible risk of the chemical
• Preliminary Assessment Information Rule (PAIR)
Test Rules

• Test rules can be either
  – Risk-based rules
  – Exposure-based rules
• Published if the EPA determines that the risk trigger or the exposure trigger has been met for a particular chemical or chemical substance
• TSCA requires the EPA to follow its usual rulemaking procedures in enacting a test rule
• Test rules must specify how data is to be collected and explain any testing methodologies
• Exemptions
• Reimbursement Order
TSCA Recordkeeping

- Comprehensive Assessment Information Rule (CAIR)
- Record of Significant Adverse Reaction
  - A “significant adverse reaction” has been defined as one that “may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment” [40 C.F.R. sec. 710]
- Types of reactions that must be reported:
  - Gradual or sudden changes in the composition of animal or plant life
  - Abnormal numbers of deaths of organisms
  - Reduction in the reproductive rate of a species
  - Changes in the behavior or location of a species
Enforcement

• Civil penalties
  – Factors influencing civil penalties
    o Nature of the violation
    o Circumstances surrounding the violation
    o Extent of the violation
    o Seriousness of the violation
    o The violator’s role in the violation
    o The violator’s previous compliance history
    o The violator’s financial situation
    o Other factors “as justice requires”
  – Additional penalties may be imposed for willful violations
  – Credit for good attitude/good faith effort to comply with applicable regulations
  – Settlement agreements
Enforcement (cont.)

• Criminal liability
  – “Knowing” or “willful” violations may result in imprisonment and/or stiff monetary fines
  – Corporations may be found criminally liable for employees’ actions
    o No “corporate shield” in the TSCA protects corporations from criminal liability

• Citizen suits
  – May be brought by “any person” believing
    (1) that there has been a violation of the TSCA, or
    (2) that the EPA has failed to perform any of its nondiscretionary duties under the TSCA
Bhopal Disaster

- 12/3/1984 in Bhopal, India
  - 40 metric tons of methyl isocyanate (MIC) gas leaked from tank at a manufacturing plant operated by Union Carbide India Limited (UCIL)
- The plant manufactured carbyl, a pesticide used in India to help the productivity of the agricultural industry (MIC is part of the production of carbyl)
- Cause of Leak
- Why was the leak not contained?
- UCIL paid more than $470 million in damages to the disaster victims
- The gas immediately killed approximately 3,800 people and reports indicate 150,000 to 600,000 people were injured, of whom at least 15,000 later died
- One of the worst industrial and environmental disasters ever to occur primarily because of the great loss of human life and the damage caused to the survivors’ lives