

# 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 distributors 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
    - “. . . 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
    - The identity of the chemical
    - Its categories of use
    - The amounts to be manufactured or imported
    - By-products from the chemical
    - Exposure of employees to the chemical
    - Methods of disposal
    - Test data related to the chemical's effect on human health or the environment
    - 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
    - Nature of the violation
    - Circumstances surrounding the violation
    - Extent of the violation
    - Seriousness of the violation
    - The violator's role in the violation
    - The violator's previous compliance history
    - The violator's financial situation
    - 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
    - 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 carbaryl, a pesticide used in India to help the productivity of the agricultural industry (MIC is part of the production of carbaryl)
- 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