TSCA Overview

Baltimore, Maryland
March 7, 2007

Beth Dryden Bosley
Director of Business Development
Pressure Chemical Co
Pittsburgh, PA
Program Outline

• TSCA Background
• Title I – Control of Toxic Substances
• The Inventory
• Compliance
  – New Chemicals
  – Exemptions and Exclusions
  – IUR
  – Risk reporting
  – Export / Import
  – Biotechnology
  – Nanoscale materials
• Testing
• Audits and Enforcement
# A Few Acronyms...

- **ATSDR** – Agency for Toxic Substances and Disease Registry
- **CAA** – Clean Air Act
- **CCD** – Chemical Control Division
- **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act
- **CRSS** – Chemical Review and Search Strategy
- **CSRAD** – Chemical Screening and Risk Assessment Division
- **EETD** – Economics, Exposure, and Technology Division
- **EPCRA** – Emergency Planning and Community Right to Know Act
- **FFDCA** – Federal Food, Drug, and Cosmetics Act
- **FIFRA** – Federal Insecticide, Fungicide, and Rodenticide Act
- **HERD** – Health and Environmental Review Division
- **HPV** – High Production Volume
- **IMD** – Information Management Division
- **IRIS** – Integrated Risk Information System
- **IUR** – Inventory Update Rule
- **LoREX** – Low Release/Low Exposure
- **LVE** – Low Volume Exemption
- **NOC** – Notice of Commencement
- **OECA** – Office of Enforcement and Compliance Assurance
- **OECD** – Organization for Economic Cooperation and Development
- **OPPT** – Office of Pollution Prevention and Toxics
- **PBT** – Persistent, Bioaccumulative, Toxic
- **PMN** – Pre-manufacture Notice
- **RCRA** – Resource Conservation and Recovery Act
- **RTECS** – Registry of Toxic Effects of Chemical Substances
- **SAT** – Structure-Activity Team
- **SNUN** – Significant New Use Notice
- **SNUR** – Significant New Use Rule
- **TMEA** – Test Marketing Exemption Application
- **TSCA** – Toxic Substances Control Act
- **TRI** – Toxic Release Inventory
Background

**TSCA (Toxic Substances Control Act)**

- Was enacted in 1976
- Is intended to protect public health and the environment from unreasonable risk without overburdening the chemical industry
- Gives EPA a broad authority to regulate the manufacture, use, distribution, and disposal of chemical substances
- Is federally mandated
- Full text: [www4.law.cornell.edu/uscode/15/ch53.html](http://www4.law.cornell.edu/uscode/15/ch53.html)
TSCA’s Four Titles

**Title I: the Control of Toxic Substances**
Regulates the manufacture, processing, use, distribution in commerce, and disposal of chemical substances and mixtures. In addition, it regulates the use and disposal of PCBs.

**Title II: the Asbestos Hazard Emergency Response Act (AHERA)**
EPA created a model program designed to minimize the hazards of asbestos-containing materials in schools.

**Title III: the Indoor Radon Abatement Act**
Seeks to reduce the threat of radon from all types of buildings, including schools.

**Title IV: the Lead-Based Paint Exposure Reduction Act**
Requires reduction of lead-based paint exposure in facilities owned or operated by local government.
Title I: Control of Toxic Substances

The sections most relevant to chemical manufacturers are found in Title I of the Act.

Title I is intended to:

- Prevent unreasonable risk of injury to human health or the environment
- Limit, prohibit, or ban chemical substances posing imminent hazards
Title I: Control of Toxic Substances

Authorizes EPA to:

• Regulate the manufacture, processing, use, distribution in commerce, and disposal of chemical substances.

• Require chemical manufacturers and processors to assess the risk to human health or environment posed by their chemical substances.

• Regulate Polychlorinated biphenyls (PCBs)
The TSCA Inventory

• The Inventory is comprised of two databases
  – The confidential inventory
  – The public inventory

• There are over 80,000 chemical substances included in the inventory (~ 70,000 of these are on the public inventory)

• A searchable extract of the inventory is available:
  – http://msds.pdc.cornell.edu/tscasrch.asp

• Copies of the full inventory are available for purchase:
  – www.ntis.gov
EPA classifies chemical substances as either "existing" or "new". Any substance that is not on the Inventory is classified as a new chemical.

TSCA regulates new chemicals under section 5.

TSCA authorizes EPA to promulgate SNURs limiting how manufacturers may produce, handle, and distribute substances on the Inventory.

Under TSCA section 4, EPA has established various testing rules as well as record keeping and reporting requirements.
Compliance: New Chemicals

- Confirm TSCA Inventory Status of raw materials, intermediates, and final products
  - A new chemical can be manufactured for a commercial purpose only if it is subject to an exemption.
  - Document the specific chemical name, CASRN, molecular formula, and TSCA Inventory status of each material you use, manufacture, and import.

- If the chemical substance of interest is not on the public inventory, it may be on the confidential inventory
  - Use a bona fide intent notice to verify whether a chemical substance is included on the confidential TSCA Inventory.
Compliance: New Chemicals

• PMN
  – If you intend to manufacture a new chemical substance in the US for commercial purposes, you must complete a PMN (Form 7710-25).
  – Detailed information is required and you must be as complete as possible.
  – Submit the PMN to EPA at least 90 days before manufacturing, importing, processing, or selling the new chemical substance.
  – Only manufacturers that are incorporated, licensed, or doing business in the US may submit a notice.
Once manufacture of a new substance for which you previously submitted a PMN begins, you must submit a NOC (Form 7710-56) of manufacture or import.

- The NOC must contain the specific chemical identity, PMN number, and the date when manufacture or import commences.
- If you claimed chemical identity as CBI in the PMN and want the substance to be listed on the confidential inventory, the claim must be reasserted and substantiated.
- The NOC must be submitted to EPA no later than 30 days after the first day of manufacture of the new chemical substance.
Facts and Figures: New Chemicals

Regulatory Action
- 5(e) consent orders: 1280
- 5(e) consent orders with 5(e) SNUR: 729
- Non-5(e) SNURs: 570
- PMNs withdrawn: 1662
- Voluntary testing actions: 300+

Total submitted: 43,729
Total regulated: 3812
Exclusions and Exemptions

Some new chemical substances are not subject to PMN reporting because EPA has determined that they do not require review under TSCA or require only a brief review.

• **Exclusions** – excluded substances usually *are not* subject to TSCA regulations or enforcement actions. Excluded substances include:
  – Tobacco, food, drugs, pesticides, impurities, certain mixtures, etc.

• **Exemptions** – exempted substances usually *are* subject to TSCA regulations, but certain circumstances may exempt them. Exemptions include:
  – Low volume, R&D, polymer, test marketing, etc.
Excluded substances...

Mixtures

– The definition of mixture under this exclusion is limited to materials that when mixed do not result in a chemical reaction creating a new chemical substance.

– Note that the individual components of the mixture are not excluded from TSCA.
Excluded substances...

Pesticides

– The definition of pesticide under this exclusion includes substances or mixtures intended for preventing, destroying, repelling, or mitigating any pest, or any substance or mixture intended for use as a plant regulator, defoliant, or desiccant.

– Note that a chemical substance that can be defined as a pesticide is only excluded from TSCA when it is used as a pesticide and is subject to regulation under FIFRA.
Excluded substances...

Food, food additive, drug, cosmetic, or device

- The definitions of the substances under this exclusion are based on the definitions in the Federal Food, Drug, and Cosmetic Act.  
  [www.fda.gov/opacom/laws/fdcact/fdcact1.htm](http://www.fda.gov/opacom/laws/fdcact/fdcact1.htm)

- Note that chemical substances that can be defined as food, drug, cosmetic, or device are only excluded from TSCA when used in these applications and are subject to regulation under FDA.
Excluded substances…

**Articles**

– Articles subject to tax under section 4181 of the Internal Revenue code are excluded from TSCA.

**Radioactive materials**

– Radioactive materials (source, nuclear, or byproduct material) that are regulated under the Atomic Energy Act are excluded from TSCA.

**Tobacco and tobacco products**

– Tobacco products that are regulated by the Bureau of Alcohol, Tobacco, and Firearms are excluded from TSCA.
Other Excluded Substances

- Substances in this class are excluded from TSCA since they have no commercial purpose of their own and include:
  - *Impurities*
    - chemical substance that is unintentionally present
  - *By-products*
    - including those burned as fuel
  - *Chemicals produced from incidental reactions*
    - such as products from corrosion inhibitors, antioxidants, stabilizers, etc
  - *Non-isolated intermediates*
    - intermediates that are not intentionally removed from production equipment
Exemptions

• EPA allows certain chemical substances and uses of those substances to be exempted from TSCA.

• Exemptions can be considered in two categories:
  – *Those that require prior EPA approval*
  – *Those that do not require prior EPA approval (self-executing exemptions)*
Exemptions: EPA approval

• Certain exemptions require EPA notification and/or approval prior to manufacture.

• These exemptions include:
  – Test Marketing Exemption (Section 720.38)
  – Low Volume Exemption (Section 723.50)
  – Low Release, Low Exposure Exemption (Section 723.50)
Exemption: Test Marketing

- Manufacturers are permitted to assess the commercial viability of a new chemical and to receive customer feedback before filing a PMN.

- Use of this exemption requires submission of an application for Test Marketing Exemption to EPA.

- The review period for this exemption is **45 days** and you will receive specific approval. You are not permitted to proceed until approval is granted.

- Notice of approval or denial of the application will be published in the Federal Register.
Exemption: Low Volume

- Manufacturers can produce low volumes (up to 10,000 kg) of certain new chemical substances without full PMN review under the Low Volume Exemption (LVE).

- Use of this exemption requires submission of Form 7710-25 (the standard PMN form) to EPA.

- The review period for this exemption is **30 days**. You are permitted to manufacture under the LVE once the 30-day review period has ended.

- LVE’s do not require submission of a NOC and these substances are not added to the Inventory.
Exemption: Low Release / Low Exposure

- EPA provides the LoREX exemption for chemical substances with low environmental releases and human exposure.

- All manufacturers are eligible to apply for the LoREX exemption as long as the stated release and exposure criteria are met.

- The LoREX exemption is independent of volume. Form 7710-25 is used to apply for this exemption.

- The review period for this exemption is 30 days.
Exemptions: Self-executing

- EPA has used its authority under TSCA 5(h) to exempt polymers without requiring prior Agency approval. Also, there are certain statutory exemptions under TSCA.

- These exemptions include:
  - Research and Development Exemption (Section 720.36)
  - Polymer Exemption (Section 723.250)
  - Export-only Exemption (Section 720.30 e)
**Exemption: Research and Development**

- The exemption for R&D purposes allows manufacturers of new chemical substances to produce limited quantities without PMN review.
- Guidance is available at: [www.epa.gov/oppt/newchems/tmeranddbulletin.pdf](http://www.epa.gov/oppt/newchems/tmeranddbulletin.pdf)
- R&D can include:
  - Analysis and testing of a new chemical compound
  - Synthesis of a new chemical compound
  - Process demonstrations
  - Performance testing
Exemption: Polymer

- Some polymers are recognized to present low risk of injury to human health and the environment.
- EPA has established criteria to predict which polymers are in this category and to exempt them from PMN review.
- Guidance is available at: www.epa.gov/oppt/newchems/polyguid.htm
**Exemption: Export-only**

- EPA generally exempts any substance that is manufactured or distributed solely for export.

- The substance must be clearly labeled stating that the shipment has been prepared for export only.

- Specific export reporting requirements may still apply.
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The TSCA Inventory Update Rule (IUR) was promulgated in 1986 and requires the submission of specific data on certain chemical substances every four (now five) years.

The next regularly scheduled collection of IUR data is in progress (reporting deadline was extended to March 23, 2007) and covers chemicals produced in 2005.

Substantive changes in the reporting requirements are in place for the current reporting cycle.

- The reporting threshold has been increased from 10,000 to 25,000 lb
- New threshold established at 300,000 lb
- Exposure data, physical form, concentration, and use information, in addition to the standard volume and site information, will be reported
Facts and Figures: IUR

The IUR Reporting database holds approximately 14,000 chemicals reported on by over 1,000 companies.
Facts and Figures: IUR

2002 IUR by Volume Range

Production Volume (lb)

Number of Chemicals

< 10,000
10,000 - 500,000
500,000 - 1MM
1MM - 10MM
10MM - 50MM
50MM - 100MM
100MM - 500MM
500MM - 1B
> 1B
Compliance: Significant Adverse Reactions

- Under section 8(c) of TSCA, manufacturers must keep records of allegations of significant adverse reactions to health or the environment alleged to have been caused by a substance or mixture under their control.
- Records must include:
  - Identification of plant site
  - Date
  - Chemical substance or mixture
  - Description of the effected person
  - Description of the effect including route of exposure
  - Original allegation, as received
  - Investigation and further reporting (if applicable)
- Retain records of significant adverse reactions to the health of employees for a period of 30 years from the date such reactions were first reported or known.
Under section 8(e) of TSCA, manufacturers must immediately (within 30 calendar days) report knowledge that a chemical substance presents a substantial risk of injury to human health or the environment.

Section 8(e) submissions are considered an ‘early warning’ mechanism and are required for chemical substances, including R&D materials, impurities, and by-products.

The risk may have been identified by a series of customer or employee complaints, health or environmental incidents, preliminary studies, etc.

Guidance is available:
http://www.epa.gov/oppt/tasca8e/pubs/june32003guidance.pdf
http://www.epa.gov/opptintr/tasca8e/index.htm
Facts and Figures: 8(e) submissions

Since 1977, EPA has received well over 15,000 initial 8(e) submissions.
Section 12(b) requires exporters to notify EPA of exportation to a particular country if any of the following actions have been taken under TSCA:

- Data are required under section 4 or 5(b)
- An order has been issued under section 5
- A rule proposed/promulgated under section 5 or 6
- Action is pending or relief granted under section 5 or 7

Notification must include:

- Name and address of exporter
- Identity of chemical substance or mixture
- Date of export
- Countries of import
- Applicable section of TSCA

EPA will notify the receiving country of the importation of the regulated chemical within 5 business days of receiving notification from the exporter.
Recent changes to the export notification requirements (effective Jan 16, 2007):

- **deminimus concentration**: reporting is not required if the concentration is less than 1% for most chemicals, 0.1% for known and potential carcinogens, and 50-ppm for PCBs.

- **one-time notification**: exporters are required to notify of intended export once per each destination country, rather than the previous requirement for annual notification (excluding substances subject to TSCA action under sections 5(f), 6, and 7, which still require annual reporting).
**Compliance: Import Notification**

- Under Section 13 of TSCA, chemical substances, mixtures, or articles not in compliance with TSCA, or whose importation is not in compliance with TSCA, must be denied entry into the customs territory of the US.

- The importer must certify by a statement on the entry document or invoice that any shipment of a chemical substance subject to TSCA, complies with TSCA, and that it is not offered for entry in violation of TSCA or any rule or order under TSCA, or that the chemicals imported are not subject to TSCA.
  - **Positive Certification Statement**: "I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order under TSCA."
  - **Negative Certification Statement**: "I certify that all chemicals in this shipment are not subject to TSCA."
Compliance: Biotechnology Rule

• EPA promulgated the ‘Microbial Products of Biotechnology’ final rule in 1997 under TSCA section 5.

• EPA reviews and has the right to regulate the use of intergeneric microorganisms since these microorganisms have the potential to express new traits or new combinations of traits.

• At least 90-days prior to commercial use of such microorganisms, you must submit a Microbial Commercial Activity Notice (MCAN)
**Compliance: Nanoscale Materials**

- EPA recognizes that the existence of structures at the nanoscale level may exhibit a distinct set of chemical, physical, and biological properties and has already reviewed a number of PMNs for nanoscale materials.

- Recently published White Paper encourages continued collaboration with industry and other agencies and increased research into the potentially unique health hazards posed.

- A Nanoscale materials Voluntary Pilot Program will collect information on: characterization, hazards, use and exposure, and current risk management practices.
Testing

• TSCA section 4 authorizes EPA to require health and environmental testing for chemicals regulated under TSCA.

• Testing triggers are risk and exposure based
  – **Risk** – if a chemical is found to present an unreasonable risk and existing data are not sufficient, EPA can require testing
  – **Exposure** – if a chemical is produced in substantial quantities, or if substantial release to the environment or significant human exposure is expected, EPA can require testing.

• Types of testing can include:
  – Physical and chemical properties
  – Health effects
  – Environmental effects
  – Environmental fate
Audits

• Performing internal TSCA audits is an important activity.
• EPA’s self-policing policy recognizes the benefits of internal audits.
• Audits are also an excellent way to familiarize yourself with your TSCA practices and procedures.
Enforcement

• Unlawful Acts
  – *TSCA Section 15 states that it is unlawful to fail or refuse to comply with TSCA regulations*

• EPA Enforcement Section 16
  – *TSCA Civil Penalty Policy – up to $32,500/violation/day*
    • Factors involved in penalty calculation are nature, extent, and circumstance of the violation. EPA also assesses the culpability, violation history, and ability to pay.
  – *TSCA Criminal Penalties – fines and imprisonment*
    • Knowing and willful violations – factors include extent of significant environmental harm, false statements or concealment of misconduct, failure to report, violation history.
Minimizing TSCA Liabilities

• TSCA Compliance Program
  – Written policy and procedures
  – Training
  – Self-audits

• Self-reporting
  – Significant penalty savings
    • Opportunity for up to 80% reduction in civil penalties and no recommendation for criminal prosecution when discovery results from audits or due diligence in accordance with EPA policy.
  – Notification in writing within 21 days of discovery
    • Factors in EPA discretion include cooperation and timely correction, no repeat violations, no serious harm.
The year 2000 increase was largely due to the Agency’s efforts encouraging Corporate-wide audits (agreements reached with telecommunications and iron & steel sectors).
Resources

• www.epa.gov
• www.epa.gov/oppt/newchems/index.htm
• TSCA hotline - tsca-hotline@epa.gov
• www.epa.gov/docs/CORR
• www.epa.gov/opptintr/iur
• www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200240
• www.SOCMA.org
• www.ehso.com/tscaPMN.htm
• www.khlaw.com/index.cfm?fuseaction=publications.showPubD
tail&pubID=1071
• http://assembler.law.cornell.edu/uscode/html/uscode15/usc_sup
  01_15_10_53.html
• http://msds.pdc.cornell.edu/tscasrch.asp
• Any of today’s speakers…
Questions.....

Thanks for your attention

Contact information:
Beth Dryden Bosley
Pressure Chemical Co
3419 Smallman Street
Pittsburgh, PA 15201
412-682-5882 ex 114
bbosley@presschem.com