



# *TSCA Fundamentals*

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- Overview
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  - Data Recording and Reporting
  - Existing Chemical Review
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# *TSCA OVERVIEW*

# *TSCA Overview*

U.S. chemical control law which covers most “industrial” chemicals

- *Intended use of the chemical is the driver for TSCA compliance*

## *TSCA Overview (2)*

Exclusions – not subject to TSCA regulations

- Substances controlled by other laws:

*Mixture – components are not excluded*

*Pesticides*

*Tobacco or tobacco product*

*Radioactives and Firearms*

*Articles*

*Food and Feed, Food and Feed Additives, Drugs, Cosmetics, Medical Devices*

## *TSCA Overview (3)*

Exclusions – not subject to TSCA regulations

- Substances with No Commercial Purpose

*Impurities*

*By-products with no commercial value*

*Chemicals produced from incidental reactions*

*Non-isolated intermediates*

## *TSCA Overview (4)*

Applies to products we manufacture or import,  
and to certain exports

- *TSCA is applied on the basis of individual chemical molecules – individual ingredients within mixtures*
- *Under TSCA, an importer = a manufacturer*

Important to R&D and Manufacturing, but some  
provisions apply to all employees

- *ACC TSCA Awareness Manual*

## *TSCA Overview (5)*

Language Conventions – refer to a section of the TSCA Statute

- *Section 4 – Testing for Existing Chemicals*
- *Section 5 – New Chemicals*
- *Section 8(a) – Reporting of manufacturing data*
- *Section 8(b) – The TSCA Inventory*
- *Section 8(c) – Recording of allegations*
- *Section 8(d) – Health and Safety Studies Data Call-in*
- *Section 8(e) – Reporting of Significant Adverse Effects*
- *Section 12 – Exports*
- *Section 13 – Imports*

## *TSCA Overview (6)*

### CAUTION:

- *Many other countries now have similar chemical control laws*
  - EU, Canada, Australia, China, Japan, Korea, New Zealand, Philippines
- *Compliance is not harmonized*
- *PMN requirements for each country are different. TSCA is the least prescriptive.*

## *TSCA Overview (7)*

### Resources:

- <http://www.epa.gov/opptintr/index.htm>
- <http://www.epa.gov/opptintr/pubs/opptprg.htm>
- *TSCA Handbooks*
- *SOCMA and ACC websites, staff and working groups*
- *40CFR700 +*

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# *NEW CHEMICALS*



## *Role of Inventory*

A chemical must be on the TSCA Inventory prior to commercial manufacture or import

Also applies to isolated intermediates

Public and confidential sections

Listing applicable only to discrete, unique chemicals, not mixtures or formulations

Do not assume CAS Registry Number = inventory listing!

Chemicals added to Inventory through PMN

## *Is Your Substance on the Inventory?*

### Public Inventory:

Copies available for purchase from NTIS

For-fee search services

### Confidential Inventory:

EPA will search after receipt of a *bona fide* intent notice

## *Exemptions to Inventory Listing Requirement*

### Self-executing Exemptions

- *Research and Development Exemption*
- *Polymer Exemption*
- *Export-only Exemption*

## *R&D Exemption*

Intent is R&D (not commercial development)

Small quantities (no fixed limit)

Conducted under supervision of technically qualified individual

Follow Prudent Laboratory Practices or have prior evaluation  
and notification of risk

Notify recipient of use for R&D only

Keep R&D records

## *Polymer Exemption*

Polymers manufactured under Polymer Exemption are exempt from inventory requirements and are NOT listed on the Inventory.

Intended for polymers that meet EPA criteria for low concern

Polymer Exemption Guidance Manual:

<http://www.epa.gov/opptintr/newchems/pubs/guideman.htm>

## *Exemptions to Inventory Listing Requirement*

### Exemptions Requiring EPA Notification and approval

- *Test Market Exemptions*
- *Low Volume Exemptions*
- *Low Release, Low Exposure Exemption*

## *Test Market Exemption*

Intended for commercial development

Must be reviewed by EPA just like PMN

PMN Form with 45 day wait

Must re-do as PMN once test period is over

## *Low Volume Exemption*

Limited to production/import < 10,000 kg/year

PMN form and 30 day review period

Controls on use, manufacturing site, release and exposure are binding

LVE substances are NOT added to the Inventory

Must re-do as PMN if manufacturing exceeds 10,000 kg/year

## *LoRex Exemption*

Meet low release and low exposure criteria

PMN form and 30 day review period

Pertinent provisions in PMN form are binding

No production volume limit

## *Isolated Intermediates*

Must be on TSCA Inventory

Manufacturing or processing in an open system, storage or removal from reaction vessel typically classify an intermediate as “isolated”

Important to consider when making process changes or developing processes for new products

## *PMN Process*

If new chemical is not on TSCA Inventory and not exempt, manufacturer (or importer) must file PMN to add chemical to inventory.

Agency has 90 days in which to object, or company is free to manufacture or import for commercial purposes

EPA Format – about 20 pages

- *Must complete the form and submit all available data*
- *Toxicity data is not mandatory, but must be included if available*

## *PMN Process (2)*

Possible EPA responses:

- *“Drop” – means approval*
- *Request additional data through a ‘hold’ or a consent order*
- *Approve, then issue a SNUR establishing some type of restrictions. A SNUR will apply to the submitter and all potential competitors – can also apply to customers.*



# *DATA RECORDING AND REPORTING*



## *Inventory Update (IUR)*

Required every 5 years for all manufacturers and importers of >25,000 lbs/year of a chemical

Information includes:

- *Specific chemical identity*
- *Basic manufacturing information: quantity manufactured or imported*
- *Data on processing and use of chemicals*

## *Recording and Reporting*

### Data Call-ins for certain listed chemicals:

- *Section 8(a) - EPA can require manufacturer or processor to submit information on quantity produced or processed, amount released to the environment and estimated uses*
- *Section 8(d) - EPA can require manufacturer or processor to submit all completed health and environmental safety studies and lists of ongoing studies*

## *Recording and Reporting (2)*

For all chemicals manufactured, imported or processed:

- *Section 8(c) - companies must keep records of “allegations” of adverse effects - no technical merit or substantiation needed*
  - No submission to EPA unless through data call-in
  - Is the alleged effect discussed on the MSDS?

## *Reporting and Recordkeeping (3)*

- *Section 8(e) - companies have 30 days to report findings of “substantial risk” to health or environment - technical merit required*
  - Large majority of 8(e) submissions are toxicity studies, but rules also apply to other types of studies

Some companies link the two requirements

- If “x” 8(c) allegations are received on the same subject, investigate as a possible 8(e) submission.



# *EXISTING CHEMICAL REVIEW*



## *Test Rule Process*

EPA maintains existing product review process. At their discretion, they can issue a Section 4 test rule mandating that manufacturers conduct health and safety studies

Manufacturers may negotiate scope of testing and may form consortia to share costs

## *Test Rule Process (2)*

Difficult process for EPA – legal process hurdles are high

- *Generally willing to negotiate testing through a consent order.*
- *Have placed more emphasis on voluntary programs such as HPV Chemical Challenge and Voluntary Children's Chemical Evaluation Program (VCCEP)*

EPA empowered to mandate additional risk management

## *HPV Chemical Challenge and ChAMP*

Voluntary submission of data for existing chemicals

Plan to fill base set data gaps, if any

Public comment on data and test plan

Test rule for “Orphan Chemicals”

Review of data and next steps under ChAMP

## *Imports*

Importers required to certify that all chemical imports  
comply with or are not subject to TSCA (excluded)

Chemicals not released from customs until certification  
signed

Use brokers or air freight companies for compliance

Brokers may contact you for clarification on your orders

## *Exports*

Companies required to notify EPA of first shipment each year to each country of certain TSCA-regulated substances, or the first-ever shipment to each country for other TSCA-regulated substances

- *Substances get on the list through Test Rules, Consent Orders and SNURs*

EPA then notifies receiving country's embassy

## *How Do I Keep Up?*

### Keep up TSCA Activities:

- *Participate in Trade Groups*
- *Federal Register*
- *Continuing Education Style Training Programs*
- *EPA e-mail alert lists*
- *Come to GlobalChem*

## *How Do I Keep Up (2)*

Keep up with the activities of your business:

- Develop TSCA Compliance, Auditing and Training Programs
- Be an integral part of your business team
- Close contact with Research and Development
- Develop a good New Product Stewardship Assessment Program



## *What's New*

Implementing ChAMP

Nanotechnology

Impact of REACH?

Will Congress Revise TSCA?

What will we learn at GlobalChem?