

# **TSCA: New Chemicals and Industry**

TSCA Fundamentals  
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Beth D. Bosley  
Pressure Chemical Co  
Pittsburgh, PA

# Outline

- The Inventory
- Compliance
  - Plan, train, search
  - PMN process
  - CBI
  - NOC
  - Exemptions and Exclusions
  - Biotechnology
  - Nanoscale materials
- Audits

# The Inventory – it all starts here

- The Inventory is comprised of two databases (Public and Confidential)
- There are over 80,000 chemical substances included in the inventory (~ 70,000 of these are on the public inventory)
- EPA classifies chemical substances as either "existing" or "new". Any substance that is not on the Inventory is classified as a new chemical.
- 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.

# Searching the Inventory

- Public Inventory:
  - Federal Depository Libraries
    - <http://catalog.gpo.gov/fdlpdir/FDLPdir.jsp>
  - For-fee search service
    - CAS, others
  - Copies of the full inventory are available for purchase (updated every 6-months):
    - [www.ntis.gov](http://www.ntis.gov)
- Confidential Inventory:
  - EPA will search the confidential inventory after receipt of a *bona fide* intent notice

# Compliance: New Chemicals

- First and foremost: plan, plan, plan
  - Regular meetings between R&D and regulatory staff
    - *Helps eliminate surprises*
    - *Can observe and advise all along the new product path*
    - *If stage-gate process, make sure the TSCA checkpoint is early enough*
  - Train sales, marketing, and executive staff
    - *Need to understand the difference between R&D uses and commercial uses*
    - *Sales targets and planning should include milestones for new chemical review*

# 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.
  - Need to include specific information proving manufacturing interest.

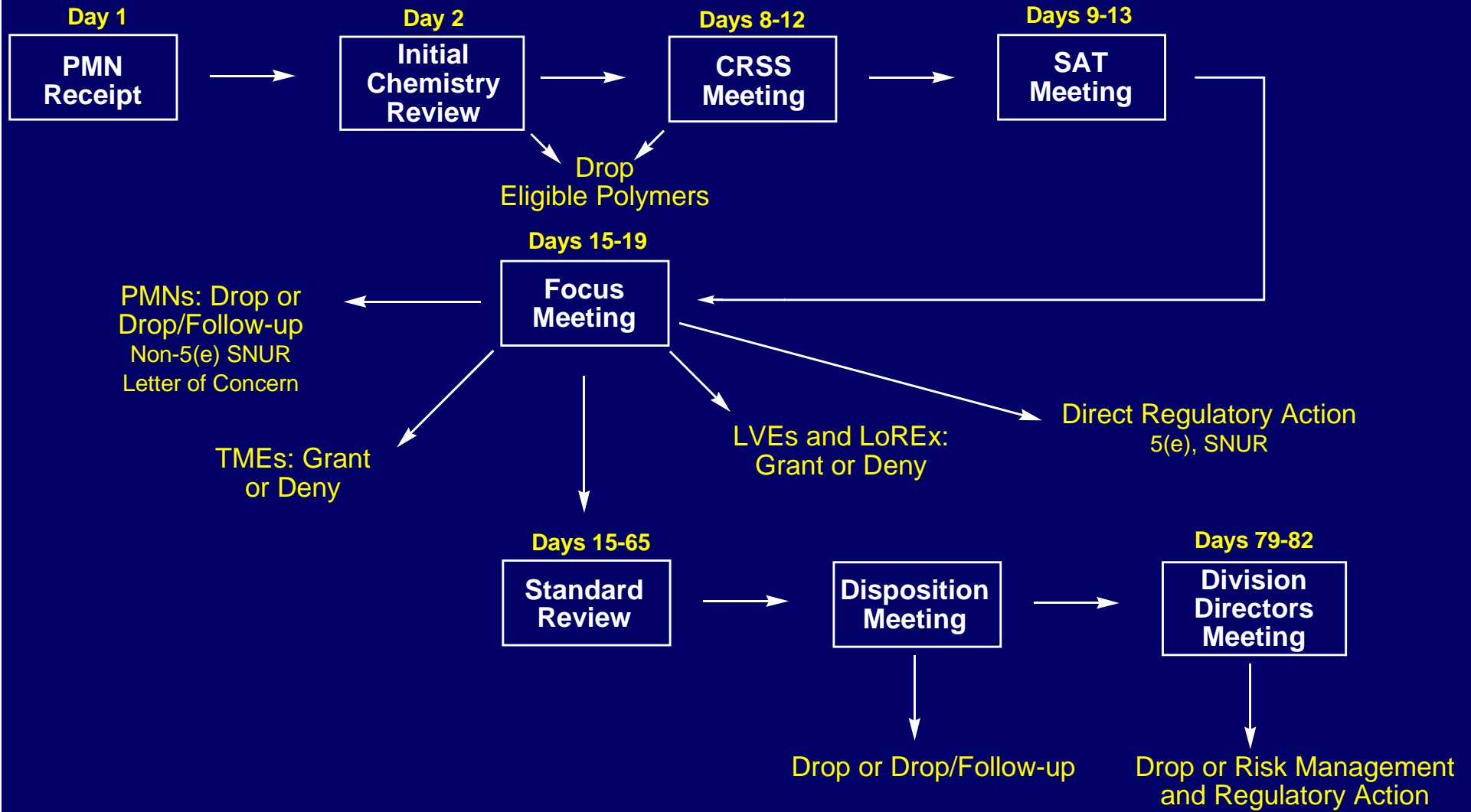
# Compliance: New Chemicals

- PMN

- If you intend to manufacture a new chemical substance in the US for commercial purposes, you must complete a PMN (Form 7710-25). The form and guidance materials are available at:
  - <http://www.epa.gov/opptintr/newchemicals/pubs/pmnforms.htm>
- Detailed information is required and you must be as complete as possible.
- Submit the PMN to EPA at least 90 days before manufacturing or importing the new chemical substance.
- Only manufacturers that are incorporated, licensed, or doing business in the US may submit a notice.
- PMN status updates are available at:
  - <http://www.epa.gov/opptintr/newchemicals/tools/dropstat.htm>

U.S. ENVIRONMENTAL PROTECTION AGENCY		<b>AGENCY USE ONLY</b>																	
 <b>PREMANUFACTURE NOTICE</b> FOR NEW CHEMICAL SUBSTANCES	DOCUMENT CONTROL OFFICER OFFICE OF POLLUTION PREVENTION AND TOXIC SUBSTANCES, 7407 U.S. E.P.A. 1200 Pennsylvania, NW WASHINGTON, D.C. 20460		Date of receipt																
	When completed send this form to		<input type="button" value="Save Draft"/> <input type="button" value="Validate PMN"/> <input type="button" value="Create Sanitized PMN"/>																
Enter the total number of pages in the Premanufacture Notice	18	Document control number	EPA case number																
<b>GENERAL INSTRUCTIONS</b> <span style="float: right;">TS -                    </span>																			
<ul style="list-style-type: none"> <li>You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.</li> <li>Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).</li> <li>If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance, which is sent to EPA, Washington Financial Management Center (3303), P.O. 360399M, Pittsburgh, PA 15251-6399, Attn. TSCA User fee.</li> </ul>																			
<p><b>Part I — GENERAL INFORMATION</b></p> <p>You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS user fee identification number. You must submit an original and two copies of this notice including all test data. If you claimed any information as confidential, a single sanitized copy must also be submitted.</p>	<p><b>TEST DATA AND OTHER DATA</b></p> <p>You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. <u>Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature.</u> You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).</p>																		
<p><b>Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE</b></p> <p>If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.</p>	<p><b>Test Data (Check Below any included in this notice)</b></p> <table style="width:100%;"> <tr> <td>• Environmental fate data</td> <td><input type="checkbox"/> Yes</td> <td>• Other data</td> <td><input type="checkbox"/> Yes</td> </tr> <tr> <td>• Health effects data</td> <td><input type="checkbox"/> Yes</td> <td>• Risk assessments</td> <td><input type="checkbox"/></td> </tr> <tr> <td>• Environmental effects data</td> <td><input type="checkbox"/> Yes</td> <td>• Structure/activity relationships</td> <td><input type="checkbox"/></td> </tr> <tr> <td>• Physical/Chemical Properties*</td> <td><input type="checkbox"/> Yes</td> <td>• Test data not in the possession or control of the submitter</td> <td><input type="checkbox"/></td> </tr> </table> <p>* A physical and chemical properties worksheet is located on the last page of this form.</p>			• Environmental fate data	<input type="checkbox"/> Yes	• Other data	<input type="checkbox"/> Yes	• Health effects data	<input type="checkbox"/> Yes	• Risk assessments	<input type="checkbox"/>	• Environmental effects data	<input type="checkbox"/> Yes	• Structure/activity relationships	<input type="checkbox"/>	• Physical/Chemical Properties*	<input type="checkbox"/> Yes	• Test data not in the possession or control of the submitter	<input type="checkbox"/>
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<p><b>Part III — LIST OF ATTACHMENTS</b></p> <p>Attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.</p>	<p><b>TYPE OF NOTICE (Check Only One)</b></p> <table style="width:100%;"> <tr><td><input type="checkbox"/></td><td>PMN (Premanufacture Notice)</td></tr> <tr><td><input type="checkbox"/></td><td>INTERMEDIATE PMN (submitted in sequence with final product PMN)</td></tr> <tr><td><input type="checkbox"/></td><td>SNUN (Significant New Use Notice)</td></tr> <tr><td><input type="checkbox"/></td><td>TMEA (Test Marketing Exemption Application)</td></tr> <tr><td><input type="checkbox"/></td><td>LVE (Low Volume Exemption) @ 40 CFR 723.50(c)(1)</td></tr> <tr><td><input type="checkbox"/></td><td>LOREX (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)</td></tr> <tr><td><input type="checkbox"/></td><td>LVE Modification <input type="checkbox"/>    LOREX Modification <input type="checkbox"/></td></tr> </table> <p>IS THIS A CONSOLIDATED PMN? <input type="checkbox"/> Yes</p> <p># of chemicals or polymers <u>1</u> (Prenotice Communication # required, enter # on page 3)</p>			<input type="checkbox"/>	PMN (Premanufacture Notice)	<input type="checkbox"/>	INTERMEDIATE PMN (submitted in sequence with final product PMN)	<input type="checkbox"/>	SNUN (Significant New Use Notice)	<input type="checkbox"/>	TMEA (Test Marketing Exemption Application)	<input type="checkbox"/>	LVE (Low Volume Exemption) @ 40 CFR 723.50(c)(1)	<input type="checkbox"/>	LOREX (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)	<input type="checkbox"/>	LVE Modification <input type="checkbox"/> LOREX Modification <input type="checkbox"/>		
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<p><b>OPTIONAL INFORMATION</b></p> <p>You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance.</p> <p>So-called "binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . This option is intended to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Except in the case of exemption applications (such as TMEA, LVE, LOREX) where certain information provided in such notification is binding on the submitter when the Agency approves the exemption application, checking a binding box in this notice does <u>not</u> by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form.</p>	<p><b>CONFIDENTIALITY CLAIMS</b></p> <p>You may claim any information in this notice as confidential. To assert a claim on the form, mark (C) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. <u>If you claim information in the notice as confidential, you must also provide a sanitized version of the notice, (including attachments).</u> For additional instructions on claiming information as confidential, read the Instructions Manual.</p> <p><input type="checkbox"/>  Mark (x) if any information in this notice is claimed as confidential.</p>																		

# PMN Review Process at EPA



# Compliance: New Chemicals

- Confidential Business Information Claims
  - Companies can assert that much of the information contained in the PMN is CBI
    - Balance public Right-to-Know with valuable industry property rights
  - EPA maintains elaborate procedures to protect CBI.
  - Consider carefully your real and defensible business needs when deciding what should be claimed
    - Process – easiest to defend
    - Impurities – also easy
    - Chemical or company ID – sometimes a real need
  - Some information *cannot* be claimed as CBI
    - Information disclosed to other governments, in patents, or other publicly available documents
    - Tumor or disease type


# Compliance: New Chemicals

- Confidential Business Information Claims
  - Remember to separate CBI from non-CBI and clearly label your envelopes
  - If you use CAS expert service and you are claiming the chemical ID as CBI, remember to put a CDA in place.
  - Remember that confidentially claims on the PMN cover the period before manufacture.
  - If chemical ID is confidential, remember to redact all references (tox reports, MSDSs, spectra, etc).
  - If a confidential search has been requested, the *bone fide* Intent to Manufacture request must indicate CBI claim.

# Compliance: New Chemicals

*You're not done yet...* Submitting your NOC

- Train manufacturing management – they are part of the process, as well
- Once manufacture of a new substance for which you previously submitted a PMN begins, you must submit a Notice of Commencement (Form 7710-56).
  - *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.*

 <b>U.S. Environmental Protection Agency</b> <b>NOTICE OF COMMENCEMENT OF</b> <b>MANUFACTURE OR IMPORT</b> (40 CFR§720.102)		Agency Use Only	Date of Receipt
<b>Part I - SUBMITTER IDENTIFICATION</b>			Document Control #:
Manu- facturer/ Importer (in U.S.)	Name of Authorized Official	Mailing Address (number and street)	CBI*
	Company Name	City, State, ZIP code	
Technical Contact (in U.S.)	Name	Telephone Number	CBI*
<b>Part II - Premanufacture Notice (PMN) "P" Case Number:</b>			
<b>Part III - Check the appropriate box and provide the exact date of manufacture or importation:</b>			
<input type="checkbox"/> First Commercial Manufacture** <input type="checkbox"/> First Commercial Importation*** date: _____ date: _____			
<small>** Date of commencement is the date of completion of non-exempt manufacture of the first amount (batch, drum, etc.)          ***For importers, the date of commencement is the date that the new chemical substance clears U.S. customs.</small>			
<b>Part IV - Manufacturing Plant Site(s) or Importing Site(s):</b> (Importers, provide street address of destination)			
			CBI*
<b>Part V - Specific Chemical Identity:</b> (For Consolidated submissions, each substance must have a separate NOC form with the specific identity of each chemical substance.)			
			CBI*
<b>Part VI - Generic Chemical Name</b> (if chemical identity is claimed CBI*):			
<b>Part VII - Substance Identity Confidentiality Status:</b>			
<input type="checkbox"/> I wish to continue to claim the substance identity confidential and the substantiation to support this claim is attached. Failure to submit the required substantiation in accordance with 40 CFR 720.85(b) will result in a waiver of your claim.			
<input type="checkbox"/> I previously claimed the substance identity as confidential and hereby relinquish that claim.			
<input type="checkbox"/> I did not claim the substance identity as confidential in my original PMN submission.			
You must submit your completed notice no later than 30 calendar days after the first date of commercial manufacture/importation to the address shown below:			
U.S. Environmental Protection Agency OPPT Document Control Office (7407M) 1200 Pennsylvania Ave., NW Washington, D.C. 20460 ATTN: Notice of Commencement			
Signature of authorized official			Date
<small>Note: CBI* - refers to the term "Confidential Business Information". Mark (X) in the box if the information is to be held Confidential.</small>			

# Compliance: Exclusions and Exemptions

## Know your 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:
- **Exemptions** – exempted substances usually *are* subject to TSCA regulations, but certain circumstances may exempt them. Exemptions include:

# Excluded Substances

**Mixtures** – Note that the individual components of the mixture *are not* excluded from TSCA.

**Pesticides** – Materials regulated under FIFRA

**Food, food additive, drug, cosmetic, device** –  
Materials regulated under FDA

**Articles** – Materials subject to tax under section 4181  
of the Internal Revenue Code

**Radioactives** – Materials regulated under the AEA

**Tobacco and tobacco products** – Materials  
regulated under BATFE

# 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 requiring 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)

# Self-executing Exemptions

- 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)

## Summary: Exemptions

Exemption	Application	Form or report	Review period	Specific approval
TME	Yes	7710-25	45-days	Yes
LVE	Yes	7710-25	30-days	No
LoREX	Yes	7710-25	30-days	No
R&D	No	None	None	No
Polymer	No	Report	None	No
Export	No	Report	None	No

# ***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.

# 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.
  - [www.epa.gov/Compliance/resources/policies/incentives/auditing/audpolguid.pdf](http://www.epa.gov/Compliance/resources/policies/incentives/auditing/audpolguid.pdf)
  - [www.epa.gov/compliance/resources/newsletters/incentives/auditupdate/spr2001.pdf](http://www.epa.gov/compliance/resources/newsletters/incentives/auditupdate/spr2001.pdf)



United States  
Environmental Protection Agency

Office of Enforcement and  
Compliance Assurance (2248A)

EPA 300-N-01-004

## *AUDIT POLICY UPDATE*

# 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.

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](mailto:bbosley@presschem.com)