The “New” Old TSCA

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Exponent®, Inc.
The “New” Old TSCA

- TSCA Overview
- TSCA New Chemicals
- TSCA Chemical Data Report
- TSCA Existing Chemicals
- TSCA Reform
TSCA Overview and What’s New
Scope

• TSCA regulates all chemicals in the US other than:
  – Substances regulated as pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
  – Substances regulated under the Federal Food Drug and Cosmetic Act (FFDCA)
  – Articles
  – Tobacco, firearms and certain nuclear materials

• If it’s a chemical and not a pesticide or FDA-regulated chemical, it’s subject to TSCA in the US
TSCA Regulations

• Specific requirements are commonly referenced by the name of the law (TSCA) followed by the relevant section of the law. Examples are:
  – TSCA Section 8(c)
  – TSCA Section 5(e)

What TSCA Can Do

- Prohibit/control chemical manufacture, import, processing or use of certain chemicals
- Require chemical testing
- Require reporting and recordkeeping of chemical production, use, health and safety information
- Require import certification and export notification
TSCA Sections

• TSCA § 4: Testing
• TSCA § 5: Premanufacture Notification
• TSCA § 6: Regulation of Existing Chemicals
• TSCA § 8: Recordkeeping and Reporting
  – 8(a) Chemical Data Reporting and Preliminary Assessment Information Rule (PAIR) submissions
  – 8(c) Allegations of Significant Adverse Reactions
  – 8(d) Health and Safety Studies
  – 8(e) Substantial Risk Reporting
• TSCA § 12: Export
• TSCA § 13: Import
General TSCA “Rules”

- Import = manufacture
- Mixture not regulated only individual components
- Polymer name must include all monomers at > 2% by weight
- Isolated intermediates must also be considered
TSCA - Chemical Groups

• Existing Chemicals
  • Manufactured 1975-1979 and reported to EPA
  • Chemicals added through Premanufacture Notifications (PMNs)

• New Chemicals
  • Everything else!
TSCA Data Gathering

• Chemical Data Report (CDR)
  – Information on manufacturing, processing and use of manufactured and imported chemicals
  – Report every 4 years; next report 2016

• TSCA § 8(e) – immediate reporting of significant adverse effects to EPA
  – Recent EPA emphasis on keeping as much of this information public as possible
  – Voluntary program to encourage companies to release old confidential business information (CBI)
Expanded Access to Data

- ChemView (www.epa.gov/chemview)
  - Data submitted under TSCA
  - EPA actions (e.g., SNURs)
  - Manufacturing, processing, use (CDR, TRI)
  - EPA assessments (IRIS, Hazard Characterization, DfE)

Public availability of data
TSCA Recordkeeping

• Each section of TSCA generally requires specific records be kept
  • Commenced PMNs – first three years volume
  • Significant New Use Rules (SNURs) – compliance with requirements

SNUR Recordkeeping: Manufacturers, processors and users
Electronic TSCA

- PMNs required to be submitted electronically via Central Data Exchange (CDX) since 2010
- Electronic submission of CDR required 2012
- Recent rule requiring other reporting to be done electronically via CDX
  - TSCA section 4 test rules
  - TSCA section 8(a) Preliminary Assessment Information Rule (PAIR) submissions
  - TSCA section 8(d) health and safety studies
New Chemicals
High Level Overview of PMN Process

• Check Inventory
• If not on Inventory, prepare and submit PMN
• EPA review of PMN - 90 days
• Outcomes of review
  - Ban manufacture
  - Restrict manufacture/distribution
  - No action, free to manufacture
• Submit Notice of Commencement of Manufacture (add to Inventory)
• Keep records
Information for PMN

• Chemical Identity and Use
• Manufacturing Information
  – Annual volume
  – Manufacturing site, process description, worker exposure and environmental releases
• Processing and Use Information
  – Number of locations (specific if possible)
• All known health and safety data
Key PMN Information

- State what you know at the time
- Be realistic with annual volumes proposed
- Remember to discuss cleaning and disposal of tank and container residues
- Be specific regarding how material is disposed
Sustainable Futures Initiative

• Goal to make new chemicals safer
• Access to risk screening models used by EPA
• Allows assessment of chemicals early in development process without testing
• Periodic training held by EPA
Outcomes of EPA Review

- No action (“Drop”); after 90 days free to manufacture
- 5(e) Consent Order
- Significant New Use Rule (SNUR) (with or without Consent Order)
- Ban
# Status of 2014 PMNs

<table>
<thead>
<tr>
<th>Status</th>
<th>2014 Data</th>
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<tbody>
<tr>
<td>Drop</td>
<td>355</td>
<td>48.8</td>
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<tr>
<td>Drop with Letter</td>
<td>84</td>
<td>11.6</td>
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<tr>
<td>Drop with Non 5e SNUR</td>
<td>60</td>
<td>8.3</td>
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<tr>
<td>Pending Standard Review</td>
<td>65</td>
<td>8.9</td>
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<tr>
<td>Pending 5e Consent Order</td>
<td>83</td>
<td>11.4</td>
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<tr>
<td>Withdrawn</td>
<td>2</td>
<td>0.3</td>
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<tr>
<td>Invalid</td>
<td>78</td>
<td>10.7</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>727</strong></td>
<td><strong>100.0</strong></td>
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What is a SNUR? and What Does it Mean?

- **SNUR** – Significant New Use Rule
  - EPA’s tool to put restrictions on chemicals
  - Restrictions based on EPA’s concerns

- Restrictions can include:
  - Personal protective equipment (PPE) requirements
  - Release to water limits
  - Specific testing requirements
  - Import only

- **SNURs trigger**
  - TSCA 12b export notification
  - Chemical Data Reporting 2,500 lb/year reporting limit
  - Recordkeeping
## 2014 EPA SNUR Activity

<table>
<thead>
<tr>
<th>Total 2014 SNURs Issued</th>
<th>182</th>
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<table>
<thead>
<tr>
<th>Basis of SNUR</th>
<th>#</th>
<th>%</th>
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<tbody>
<tr>
<td>Subject to 5e Consent Order</td>
<td>52</td>
<td>28.6</td>
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<tr>
<td>Non 5e SNUR</td>
<td>130</td>
<td>71.4</td>
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</table>

<table>
<thead>
<tr>
<th>Type of Restriction</th>
<th>#</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Concern</td>
<td>91</td>
<td>50.0</td>
</tr>
<tr>
<td>Release to Water Restriction</td>
<td>91</td>
<td>50.0</td>
</tr>
<tr>
<td>Nano Material</td>
<td>9</td>
<td>4.9</td>
</tr>
<tr>
<td>Respiratory and Aquatic Restrictions</td>
<td>9</td>
<td>4.9</td>
</tr>
<tr>
<td>Respiratory Restrictions</td>
<td>39</td>
<td>21.4</td>
</tr>
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</table>
Chemical Data Report (CDR)
What is the CDR Report?

• A submission to EPA every 4 years
  – By company, by site, on production or import of certain chemicals
  – Cumulatively produced or imported to the site in quantities > 25,000 lb (or 2,500 lb for certain regulated chemicals)
  – During the prior 4 calendar years
Next CDR Report

• Reporting period
  June 1 - September 30, 2016
• Will include data from
  2012 – 2015
• Must be submitted
electronically via CDX
• Fines for not reporting
Next CDR Report

• 2012 – 2014
  – Only data on production or import volume
  – Trigger volume – 25,000 lb/year except for certain chemicals
  – Chemicals subject to certain TSCA regulations have a trigger volume of 2,500 lb/year

• 2015
  – Full data set of information; same as 2012 CDR reporting
  – Includes: physical form, concentration, number of workers exposed, processing and use information
Changes to 2016 CDR

- Lower reporting threshold (2,500 lb) for chemicals subject to certain TSCA actions
  - Proposed or final rule under § 5(a)(2) (SNURs), 5(b)(4) or 6
  - Order under § 5(e) (Consent Order) or 5(f)
Who is a Manufacturer or Importer?

- The company performing the manufacturing activity is typically the reporter (even contract manufacturers).
  - For contract manufacturing either company can report

- Companies must ensure manufacturing activity occurring at another site is being reported
Imports

- Treated as manufacture
- Reported by the Importer of Record
- Polymers not reported but need to consider additives in imported polymers
Existing Chemicals
TSCA Sections Applicable to Existing Chemicals

- **Section 4** Generate hazard and exposure information
- **Section 5(a)** SNURs
- **Section 5(b)(4)** List of chemical substances that present an unreasonable risk of injury
- **Section 6** Regulation of hazardous existing chemical substances and mixtures
TSCA Sections Applicable to Existing Chemicals

- Section 8a, 8d: Maintain records and report data “PAIR” and “HaSDR”
- Section 9: Governs the relationship of TSCA to other Federal laws
- Section 21: Allows citizens to petition EPA to take specific regulatory actions on chemicals and mixtures under TSCA
TSCA Work Plan Process

• Prioritization
• Scoping and problem formulation
  – Exposures of concern, identify hazards and if sufficient data exist
• Risk assessment
• Risk reduction
Work Plan Chemicals

• 2 Step Process for Prioritization
  – Step 1: Screening Process based on:
    • Potential concern for children’s health (for example, because of reproductive or developmental effects)
    • Neurotoxic effects
    • Persistent, bioaccumulative and toxic
    • Probable or known carcinogens
    • Used in children’s products or in products to which children may be highly exposed
    • Detected in biomonitoring programs
Work Plan Chemicals - Step 2

Step 2 Process to Identify the TSCA Work Plan Chemicals Candidate Chemicals from Step 1

Hazard Score 3 – 1 Based on highest scoring human health OR environmental toxicity endpoint

Exposure Score 3 – 1 Normalized from rankings based on use type, general population and environmental exposure, and TRI or surrogate release information

Persistence/Bioaccumulation Score 3 – 1 Normalized from separate scores for persistence and bioaccumulation

Chemical Score Calculation = Hazard Score + Exposure Score + Persistence/Bioaccumulation Score

If Scores for All Three Components: Normalized and Priority-Binned, 7-9 = High 5-6 = Moderate, 3-4 = Low

If No Score for Hazard OR No Score for Exposure but a 2 or 3 for Hazard OR for Persistence/Bioaccumulation: Potential Candidate for Information Gathering

Further Analysis Through TSCA Work Plan for High Rankings

Source: http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf
Work Plan Chemicals - 2012

• 1,235 chemicals identified in Step 1
  – Refined based on exclusions
    • Not subject to TSCA, already significant regulation under TSCA, radioactivity, complex process streams, natural occurrence, or other properties

• 345 chemicals into Step 2

• 83 chemicals after Step 2
  – Combined score based on hazard, exposure, and potential for persistence and bioaccumulation

http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf
Work Plan Chemicals - 2014+

- 2014 Step 2 rerun
  - Rescreened 2012 chemicals
    - Updated TRI and CDR exposure data
  - Added Action Plan chemicals
  - Added flame retardant chemicals
- 90 Chemicals identified after Step 2
  - Removed 15 from 2012 list
  - Consolidated one
  - Added 23 new
- 2014+
  - Ongoing refinements based on TRI and CDR data
Work Plan Chemical Risk Assessment Process

- Scoping and problem formulation – 1,4-Dioxane
- Data needs gap / assessment
- Draft risk assessment
- Public review and comment
- Independent peer review
- Response to comments
- Final risk assessment

Source: http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html#completed
<table>
<thead>
<tr>
<th>Chemical</th>
<th>Use</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trichloroethylene</td>
<td>degreaser, a spot-cleaner in dry cleaning and a spray-on protective coating</td>
<td>health risks to consumers and workers</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>6a initiated!!!</strong></td>
</tr>
<tr>
<td>Methylene chloride</td>
<td>paint and coating removal products</td>
<td>health risks workers and consumers and to bystanders in workplaces and residences</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>6a initiated!!!</strong></td>
</tr>
<tr>
<td>N-Methylpyrrolidone</td>
<td>paint and coating removal products</td>
<td>health risks to people, particularly pregnant women and women of childbearing age, who have high exposure</td>
</tr>
<tr>
<td>(NMP)</td>
<td></td>
<td><strong>6a initiated!!!</strong></td>
</tr>
<tr>
<td>HHCB</td>
<td>fragrance ingredient in commercial and consumer products</td>
<td>no concern for this use on ecological receptors</td>
</tr>
<tr>
<td>Antimony trioxide</td>
<td>synergist in halogenated flame retardants</td>
<td>no concern for this use on ecological receptors</td>
</tr>
</tbody>
</table>
## Action Plan Chemicals

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzidine Dyes</td>
<td>SNUR Removed article exemption</td>
</tr>
<tr>
<td>Bisphenol A (BPA)</td>
<td>Testing /Alternative Evaluations</td>
</tr>
<tr>
<td>Hexabromocyclododecane (HBCD)</td>
<td>SNUR</td>
</tr>
<tr>
<td>Nonylphenol and Nonylphenol Ethoxylates</td>
<td>SNUR</td>
</tr>
<tr>
<td>Perfluorinated chemicals (PFCs, including PFOA)</td>
<td>SNUR / Stewardship Program / Alternative Evaluations</td>
</tr>
<tr>
<td>Penta, octa, and decabromodiphenyl ethers (PBDEs) in products</td>
<td>Phase-out / SNUR</td>
</tr>
<tr>
<td>Phthalates</td>
<td>SNUR / Alternative Evaluations</td>
</tr>
<tr>
<td>Short-chain chlorinated paraffins</td>
<td>SNUR / Enforcement Actions</td>
</tr>
<tr>
<td>Methylene diisocyanate (MDI) / Toluene diisocyanate (TDI)</td>
<td>Data call in / 6a – MDI SNUR – TDI Removed article exemption</td>
</tr>
</tbody>
</table>
Ongoing Chemical Management

- Asbestos
- Formaldehyde
- Ethylene Glycol Ethers (Glymes)
- HPV Un-sponsored Chemicals (SNUR, test rules, Section 8(a)/8(d) Rules)
- Lead
- Mercury
- Polychlorinated Biphenyls (PCBs)

Existing Chemical - SNURs

• Intent to manufacture or process the specified chemicals for the described significant new uses before that activity begins
• Notice alerting the Agency to a reversal of an industry trend toward deselecting for a chemical
• Removal of article exemption
  – “Leveling the playing field” for imports
  – Consumer uses
  – Contentious!!!!!
Existing Chemicals – Take Homes

- EPA utilizing all sections of TSCA
- Risk assessments are use specific
- SNURs
- Phasing out
- Design for the Environment (DfE) alternative assessments
- Testing, recordkeeping and data call-in
- Using CDR/TRI data
Status of TSCA Reform
EPA’s 6 Principles of TSCA Reform

• **Principle No. 1**: Chemicals Should be Reviewed Against Safety Standards that are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.

• **Principle No. 2**: Manufacturers Should Provide EPA with the Necessary Information to Conclude That New and Existing Chemicals are Safe and Do Not Endanger Public Health or the Environment.

• **Principle No. 3**: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations.
EPA’s 6 Principles of TSCA Reform

- **Principle No. 4:** Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner.

- **Principle No. 5:** Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened.

- **Principle No. 6:** EPA Should Be Given a Sustained Source of Funding for Implementation.
Process
Major Issues

- State preemption
  - When does preemption take place
    - Listing of TSCA review
    - Finding of no unreasonable risk
- Confidential Business Information
- Prioritization
- Timelines for EPA
- Cost – where do funds go?
- Industry initiated risk assessments
Senate

- 2 Senate Bills
  - The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Udall-Vitter Bill)
  - Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act (Boxer-Markey Bill)
    https://www.congress.gov/bill/114th-congress/senate-bill/725?q=%7B%22search%22%3A%5B%22toxic+chemical+protection+act%22%5D%7D
House

- TSCA Modernization Act – J. Shimkus
- House Subcommittee on Environment and the Economy on May 14, 2015
- House Energy and Commerce Committee – Early June 2015
- House Floor – by end of June 2015

Summary
It’s Not the Same Old TSCA!

• More targeted use of models and surrogates to assess risk for specific uses
• Moving toward more transparency; public availability of data
• Along with recent movement for TSCA reform
Thanks for your attention!!!