Main U.S. chemical safety legislation

• Toxic Substances Control Act of 1976 (TSCA)
  – Covers most chemicals used in industry and in commercial/consumer products
  – Excludes:
    • uses in drugs, cosmetics, food and food packaging regulated by FDA
    • uses in pesticides covered by EPA under FIFRA
  – Basic provisions have never been amended
Drivers for chemical policy reform
Chemicals are ubiquitous

- 10 trillion pounds produced per year in the U.S.
  - 90 pounds per person per day
- Used to make 96% of all materials and products
- 85,000 chemicals on Toxic Substances Control Act (TSCA) Inventory – not all in use today
- Chemical production:
  - 25x ↑ globally since ’76
  - Projected to grow by more than 4x by 2050
- ↑ diversity of use in products, building materials
Science drivers: Connecting the dots

• Certain chronic diseases are on the rise
• Certain chemicals are linked to those same chronic diseases
• Many of those same chemicals are in us
Diseases linked to chemical exposures

- Cancer
- Learning and Developmental Disabilities
- Parkinson’s and Alzheimer’s Disease
- Reproductive Health and Fertility Problems
- Asthma
- Diabetes
- Obesity
- Immune disorders
- Cardiovascular disease
Why legislative reform?
TSCA: Problems with current paradigm

- Presumption of innocence: TSCA grandfathered 62,000 chemicals
- High hurdle to require testing
- Even higher hurdle to regulate
- Government must prove harm
  - Contrast to pesticides, drugs
- Excessive trade secret allowances
TSCA, the dog that didn’t even bark

By the numbers:

• 62,000 chemicals grandfathered in when TSCA was passed in 1976

• Required testing on <300 in 39 years

• 5 chemicals have been regulated in limited ways

• 24 years since EPA last tried (and failed) to regulate a chemical: asbestos
Why now?
Drivers for TSCA reform

• State legislation
• Top priority of last 2 EPA Administrators
• Market demand, esp. from downstream users
• Retail regulation: Walmart, Target, CVS
• Major reform of others’ policies:
  – Canadian Environmental Protection Act (1999)
Industry position shifts

“The public’s confidence in the federal chemical management system has been challenged.”

Cal Dooley, President, American Chemistry Council
Congressional testimony, February 26, 2009

“In the absence of reforms to TSCA we are seeing a plethora of State actions that are serving to create tremendous uncertainty in our markets.”

Linda Fisher, Chief Sustainability Officer, DuPont
Congressional testimony, March 9, 2010
TSCA reform bills

• Frank Lautenberg was key champion
• First bill: Kid-Safe Chemicals Act of 2005
• Bills in 6 successive Congresses
• No bipartisan support until May ’13
• Lautenberg negotiated a bill with Sen. David Vitter
  – First bipartisan TSCA reform legislation
  – Introduced 11 days before his death
  – Gained 26 cosponsors (13 D, 13 R)
The Lautenberg Act (S. 697)

The Frank R. Lautenberg Chemical Safety for the 21st Century Act

- Introduced on March 10, 2015
- Sens. Tom Udall, David Vitter main sponsors
- Heavily renegotiated version of 2013 Lautenberg-Vitter bill
- Passed Senate EPW Cmte on April 28 on a bipartisan 15-5 vote
- Now has 25 D+35 R very diverse cosponsors
Basic framework of Lautenberg Act

• Identify all chemicals in active commerce

• Prioritize them as high- or low-priority

• Low-priority chemicals are set aside until and unless new information emerges

• High-priority chemicals must undergo:
  – safety assessments
  – safety determinations as to whether they meet safety standard

• If a chemical fails the standard, EPA must issue a regulation banning or restricting the chemical
The TSCA Modernization Act (H.R. 2576)

• First draft issued on April 7, 2015
• Bill formally introduced May 26
• Reps. Shimkus, Pallone main sponsors
• Passed House E&C Cmte on June 3
• Passed full House on June 24 on a 398-1 vote on suspension
• Far more skeletal reform of TSCA
# How S 697 & HR 2576 Address Problems in TSCA

<table>
<thead>
<tr>
<th>Problem in TSCA</th>
<th>Senate Bill</th>
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<tbody>
<tr>
<td><strong>Paralyzing Regulatory Hurdle, Failure to Protect Most Vulnerable</strong></td>
<td>Health-Only Safety Standard that Protects Vulnerable Populations</td>
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</tr>
<tr>
<td>Requires onerous cost-benefit analysis that has left dangerous chemicals unregulated.</td>
<td>Prohibits EPA from considering costs in safety determinations.</td>
<td>Prohibits EPA from considering costs in risk evaluations.</td>
</tr>
<tr>
<td>No requirement to consider elevated risks to children, pregnant women, the elderly.</td>
<td>Expressly requires the protection of those most susceptible to harm from chemicals.</td>
<td>Precludes finding a chemical does not present unreasonable risk if any potentially exposed populations face such risk.</td>
</tr>
</tbody>
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<tr>
<th><strong>Chemicals are Presumed Innocent</strong></th>
<th>Mandate to Review All Chemicals</th>
<th>Limited Mandate to Review Chemicals</th>
</tr>
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<tr>
<td>No requirement to review the safety of existing chemicals.</td>
<td>Requires prioritization of all chemicals, safety determinations on all those not deemed low-priority.</td>
<td>Limited process, evidentiary burden, to identify chemicals for reviews.</td>
</tr>
<tr>
<td></td>
<td>Limited pathway for industry-requested reviews.</td>
<td>Virtually unlimited pathway for industry-requested reviews.</td>
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<td><strong>New Chemicals Lack Adequate Safety Check</strong></td>
<td>Safety Finding for New Chemicals Before Use</td>
<td>No Change Is Made to Status Quo</td>
</tr>
<tr>
<td>New chemicals are allowed onto market without affirmative EPA safety decision.</td>
<td>New chemicals can enter the market only after an affirmative safety finding standard by EPA.</td>
<td>Draft makes no changes to TSCA Section 5.</td>
</tr>
<tr>
<td><strong>Weak Testing Powers</strong></td>
<td>New Testing Authority</td>
<td><strong>Some New Testing Authority</strong></td>
</tr>
<tr>
<td>Test rules take years.</td>
<td>EPA can order testing, with justification.</td>
<td>EPA can order testing.</td>
</tr>
<tr>
<td>EPA must first show potential risk/high exposure, a Catch-22.</td>
<td>Catch-22 is eliminated.</td>
<td>Catch-22 NOT eliminated except for tests needed to do risk evaluations.</td>
</tr>
<tr>
<td><strong>Insufficient Funding</strong></td>
<td>Broad Dedicated Fees</td>
<td><strong>Limited Fees</strong></td>
</tr>
<tr>
<td>Fees only for new chems, $2,500/co cap. Don’t go to EPA.</td>
<td>Fees cover all parts of program. Go directly to EPA.</td>
<td>Fees only for industry-requested chemicals. Go directly to EPA.</td>
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<td><strong>Excessive CBI Claims</strong></td>
<td><strong>Greater Transparency</strong></td>
<td><strong>Partial Transparency</strong></td>
</tr>
<tr>
<td>Companies can claim virtually any info CBI.</td>
<td>Upfront justification for most claims. EPA review of most claims, past and future.</td>
<td>Upfront justification for all new claims. No EPA review of past or future claims mandated.</td>
</tr>
<tr>
<td>Rare EPA reviews.</td>
<td>State must be given access, no prior notification.</td>
<td>State may be given access, prior notification required.</td>
</tr>
<tr>
<td>Can’t share with public, states, health providers.</td>
<td>Health providers are given access, prior notification except in emergencies.</td>
<td>Health providers are given access, no prior notification required.</td>
</tr>
<tr>
<td><strong>CBI Kept Indefinitely</strong></td>
<td><strong>Time Limits, Reviews for Past and New Claims</strong></td>
<td><strong>Time Limits Only for New Claims, No EPA Reviews</strong></td>
</tr>
<tr>
<td>Claims have no time limits, and remain in place unless the EPA challenges them.</td>
<td>Claims expire after 10 years if not re-justified.</td>
<td>Past claims don’t expire, no EPA review.</td>
</tr>
<tr>
<td></td>
<td>EPA to review most past and new claims.</td>
<td>New claims subject to 10 years, but no EPA review.</td>
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<td>Limited preemption</td>
<td>More preemption</td>
<td>More preemption</td>
</tr>
<tr>
<td>EPA requirements on new or existing chemicals generally preempt states’ existing or new requirements. EPA may grant waivers.</td>
<td>Preemption after EPA final action limited to state restrictions (e.g., not disclosure). Preemption applies only to existing chemicals. No new state restrictions on a chemical under EPA review except via a waiver. Higher bar for final waiver; state can challenge denial.</td>
<td>Preemption after EPA final action extends to any requirements “designed to protect against exposure.” Preemption applies to new and existing chemicals. No early preemption of new requirements. Lower bar for final waiver; but state can’t challenge denial.</td>
</tr>
</tbody>
</table>
Start of a paradigm shift

• **Current**: Unless there is evidence of harm, assume safety and don’t look any further

• **Needed**: Require affirmative evidence of safety to enter or remain on the market
For more information

EDF’s Chemicals Policy Webpage
www.edf.org/health/policy/chemicals-policy-reform

EDFHealth Blog
http://blogs.edf.org/health/