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**The Effect of TSCA Reform on  
New and Existing Chemicals:  
EPA Review, Regulation, and  
Testing Requirements**

**TSCA: Best Practices in Toxicology,  
Risk, and Chemical Management  
Strategies Fall 2017 Symposium  
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## Key Provisions

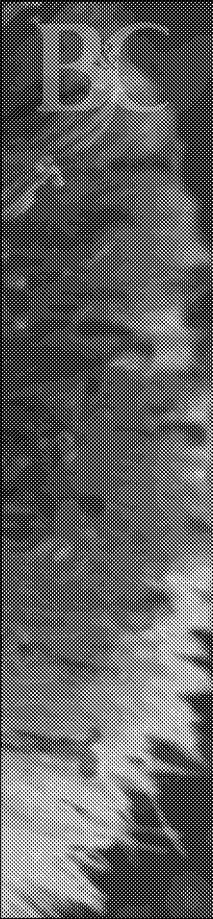
- Section 4 -- Testing
  - New order authority
  - Use tiered testing
  - Minimize vertebrate testing
- Section 5 -- New Chemicals
  - Must make determinations
  - Must take regulatory action if potential for risk
- Section 6 -- Existing Chemicals
  - Must undertake prioritization, risk evaluation, risk management
  - Tight deadlines

## Key Terms

- Unreasonable risk
- Conditions of use
- Reasonably foreseeable
- Potentially exposed and susceptible subpopulations (PESS)
- Not likely to present
- Sound science

## Challenges

- No phase-in -- Effective immediately; policies, processes, and interpretation are still in flux
- Many short deadlines for rulemaking
- Brain drain – The U.S. Environmental Protection Agency (EPA) had been losing and continues to lose senior staff to retirements
- Staff shortages -- Between hiring freeze and retirements, staff is stretched thin; EPA using “details” (temporary internal transfers) to fill the gaps
- Funding for contract support -- Expanding capacity of contracts takes time



## Existing Chemicals Issues

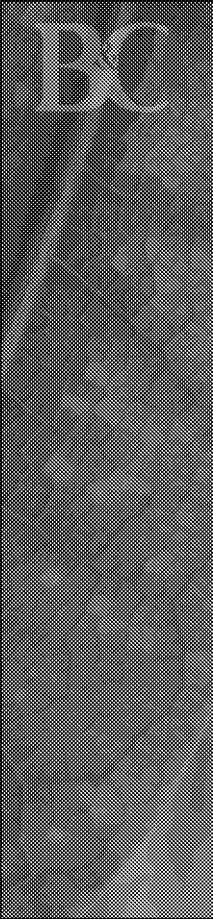
- Stakeholders must take care not to pre-judge outcomes
- EPA will have to require testing to fill gaps on existing chemicals
- Prioritization and risk evaluation are resource intensive
  - If EPA cannot demonstrate low priority with sufficient information, must designate as high priority
- Blurred lines between commercial and consumer use -- many "professional-grade" products available to consumers
- Recognize that while in-place substances may contribute to exposure, the Toxic Substances Control Act (TSCA) may not be the best mechanism to protect against exposures
- TSCA does not have authority to regulate non-TSCA uses

## Expected Changes

- More consent orders (CO) and more Significant New Use Rules (SNUR)
- More testing, especially on existing chemicals

## Unexpected Changes

- >90% new chemicals regulated
- Polymer eligible for the Polymer Exemption being regulated
- New chemicals bias worsened
- 90-day clock “reset”



## Inhalation Categories

- Surfactant default exposure limit of about  $10^{-5}$  mg/m<sup>3</sup>, or about two sprays from a spray bottle
- Water-proofing of lungs
- Lung overload (due to high molecular weight polymers)
- Cationic binding to lung tissue

### Notes:

All known categories prior to Lautenberg; EPA routinely identified the potential hazard

EPA says it has "insufficient information", but does not exercise testing authority over existing chemicals

EPA spent 6 months doing a literature search, but did not search data in OPP

EPA's initial finding is insufficient information; upfront inhalation testing;

now require APF 1000 or APF of 50 after break-through testing

If the surfactants on the SCIL were submitted without test data, EPA would require APF 1000 respiratory protection (full-face supplied air)

## Common EPA Responses

- If low/low -- Not likely to present unreasonable risk; otherwise, 5e/SNUR
- Most common PESS: Workers
- Most common regulatory outcome: Required personal protective equipment (PPE); limits to water releases

## Examples of Flawed Risk Evaluations

- Mist concentrations equivalent of 16 L/m<sup>3</sup>
- Vapor concentration above the vapor pressure
- Number of containers emptied corresponding to 250,000 kg in a Low Volume Exemption (LVE)

Notes:

Submitters need to scrutinize risk evaluations

## COs and SNURs

- SNURs are a “black mark” in the market
- Until more existing chemicals have SNUR-like burden (testing, restrictions, recordkeeping), many customers (especially unsophisticated far down the supply chain) will avoid CO/SNUR substances

## Creative Solutions

- Exempt polymer flag
- Non-order SNURs

### Notes:

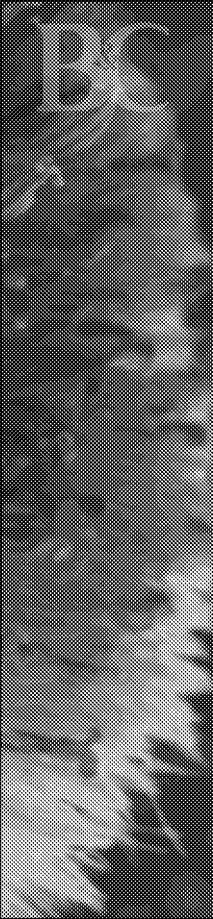
Non-order SNURs as now envisioned require that EPA promulgate the SNUR, then EPA makes non-likely finding, after which submitter may commence

## Suggestions for Submitters

- Detailed release and exposure data
- Duplicate key information, make it less likely an assessor will miss it
  - Key information in the premanufacture notification (PMN) form, not just attachments
- Equipment cleaning and maintenance
- Specify medium of release
- Specify treatment method -- “appropriate WWT” is not enough
- Pollution Prevention (P2) statements
- Learn Sustainable Futures (SF) tools; use them before submitting
- Request prenotice review meeting to identify weaknesses

## Suggestions for EPA

- Can SNURs focus on critical portions of supply chain?
- Issue test orders related to inhalation categories -- spread the burden among new and existing chemical manufacturers
- Must improve the quality and consistency of assessments
- Prepare new chemical review reports to be ready to send upon request
- Points to Consider must be more than just what to put in a PMN
  - Provide insight into EPA's thinking and EPA's approaches to hazard, exposure, and risk assessments
  - Explain role of P2 statements/risk reduction



## Questions for Stakeholders

- Is EPA required to regulate for PPE?
  - Can PPE be reasonably assumed to be a “condition of use” in an industrial setting?
  - Can PPE be reasonably assumed if there are other reasons to use PPE?
- If EPA is not required to regulate for PPE, are COs/SNURs for PPE the best use of EPA’s resources?
- Is skin or eye irritation an “unreasonable risk” that requires EPA to regulate?
- Is corrosion an endpoint that requires a SNUR? Is a clear warning sufficient?
- What is “reasonably foreseeable”? Is it the same as “someone could”?
- How likely is “not likely”?
- Does it make sense to require confirmatory testing for substances with high aquatic toxicity?
- Should there be a stakeholder group in which these and other issues can be discussed to provide EPA input?

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## Closing Thoughts

- Cooperation among stakeholders is vital to get TSCA implementation right
- EPA needs to exercise its test authority for existing chemicals
  - Even the playing field between new and existing chemicals
- Submitters must provide more complete data set
  - Identify potential analogs
- Have some patience



## Thank You

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