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

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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^3, 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

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^3
- Vapor concentration above the vapor pressure
- Number of containers emptied corresponding to 250,000 kg in a Low Volume Exemption (LVE)

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

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?

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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