BERGESON & CAMPBELL PC

2018 Bloomberg BNA/ Bergeson & Campbell, P.C. Chemical Policy Summit Series

TSCA at 2: An Update on Implementation and Hot Topics

June 25, 2018

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Program

Opening -- **Lynn L. Bergeson**
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Agency Update -- **Nancy B. Beck, Ph.D., DABT®**
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Key Section 5 Concerns -- **Misty L. Bogle**
Global Product Stewardship Manager
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Key Section 5 Concerns -- **Michael Gould**
EH&S Committee Chairman
RadTech North America

Questions

Close

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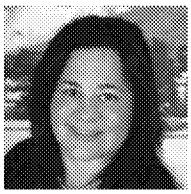

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EPA Office of Chemical Safety & Pollution Prevention (OCSPP) Accomplishments and Priorities under TSCA

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June 25, 2018
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Toxic Substances Control Act (TSCA) Year 2 Accomplishments

- Addressing Persistent, Bioaccumulative, and Toxic (PBT) Chemicals
- Dust-Lead Hazard Standards
- Final Mercury Reporting Rule
- Transparency and Confidential Business Information (CBI)
  - Unique Identifier
  - Generic Name Guidance
  - Expanded Access to CBI Guidance
- Alternative Strategy to Reduce Animal Testing

TSCA Year 2 Accomplishments

- New Chemicals Points to Consider
- Ten Problem Formulations
- Asbestos Significant New Use Rule (SNUR)
- Systematic Review Approach
- Proposed Fees Rule

Near-Term Priorities

- Methylene Chloride Final Rule
- Establishing a Fee Program
- Updating TSCA Chemical Substance Inventory
  - CBI Review Plan Rule
- Completing First Ten Chemicals Risk Evaluations
- Selecting the Next 40 Chemicals for Prioritization
- Addressing PBTs
- Refining New Chemicals Review

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Conditions of Use (COU)

- **Section 3 Definition:** "… the circumstances, as determined by [EPA], under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed…"
- The Office of Pollution Prevention and Toxics (OPPT) considered COU in the past, including foreseeable COU, and would impose restrictions (*e.g.*, use limitations, water release limitations) to protect against those foreseen COU

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Key Concerns

- If the U.S. Environmental Protection Agency (EPA) identifies a COU in which hazard is not low for health and for ecotoxicity ("low/low" cases), EPA is proposing regulation in nearly all cases
  - Basis: "somebody might" exceed the level of concern
  - Any conceivable *vs.* reasonably foreseeable

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Key Concerns

- If EPA determines it is required to regulate under Section 5(f) or Section 5(e), it must do so "to the extent necessary" to protect against unreasonable risk
  - What is "the extent necessary"?
- Example for consideration:
  - An employer requires workers to wear gloves and gloves are provided to all workers
  - If EPA believes that a worker may choose not to wear the required gloves, is that a foreseeable COU and reasonable basis for a SNUR? Does adding a TSCA regulation in addition to the existing Occupational Safety and Health Administration (OSHA) regulation meet the "extent necessary" provision?

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Key Concerns

- Notable outcomes
  - EPA requiring workplace protection duplicative to OSHA requirements
  - Very difficult to “test out” of restrictions -- absent testing to demonstrate low hazard, EPA imposes regulation

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Case Study

BACKGROUND

- Stereoisomer -- non-specific analog already on TSCA Inventory
- Ester -- no releases to water, worker protections included
- Low Volume Exemption (LVE) granted -- no unreasonable risk
- Premanufacture Notification (PMN) application in June 2017
- Added aquatic test data
- Same controls in place
- PMN conditions – "not likely to present unreasonable risk"
- Concern about changes to COU -> non-5(e) SNUR

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Questions for EPA

- Will we see additional guidance on the Agency's interpretation of "reasonably foreseen" circumstances in new chemical review?
- Can industry expect to be regulated in every case, unless our substance is completely non-hazardous?
- When will the backlog of non-5(e) SNURs be resolved?
- Feedback on issues of concern related to COU
- Could/should EPA revisit the option to consider relative risk?
  - Because EPA no longer considers relative risk in new chemical review, less hazardous new chemicals are more highly regulated than more hazardous existing chemicals

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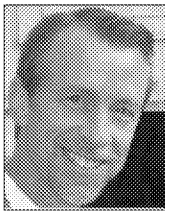

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Business Concerns with SNURs

- Consent order or non-order SNUR trigger
  - Section 12(b) export notification if substance present at >1 percent
  - Supply chain communication to all recipients
  - Recordkeeping requirements apply to all levels of supply chain
  - Lower reporting thresholds for Chemical Data Reporting (CDR)
- Some companies prohibit purchasing a substance with a SNUR due to a perception of enhanced risk

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Current Forecast on SNURS

- Many more SNURs in our future
  - Recent analysis shows:
    - About 5 percent of initial determinations are not likely
    - 11.5 percent of final determinations are not likely
    - Is this trend reversible?
- Necessity of SNURs
  - Role of workplace standards
  - Is EPA coordinating with OSHA?

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Case Study

BACKGROUND

- Pre-amended TSCA, PMN filed for substance regulated under LVE
  - Substance is low molecular weight polymer of a discreet chemical substance with known toxicity concerns
- PMN initially dropped, but pulled back into re-evaluation after amended TSCA passed

CURRENT STATUS

- Conclusion of re-evaluation under amended TSCA included certain restrictions
  - Including concentration limitation for imported products
  - Concentration limitation makes it impossible for manufacturer to import raw material
- Re-evaluation also focuses on toxicity of parent compounds versus final product

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Question for EPA

- Does EPA evaluation take into account the fact that by making the discreet substance into a polymer, the substance has less exposure potential?
  - Less accessible at the cellular level
  - More secure in final cured articles

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Related SNUR Issues

- Significant delays, especially in SNUR publication
  - Order SNURs -- no reason to delay; required by statute, restrictions established in consent order
  - Non-order SNURs -- authority has been questioned
- Section 5(e) SNURs must be prompt
- Fish or cut bait on non-order SNURs
- Creative solutions when hazards can be addressed by limiting how substance is manufactured
  - Proposal to create new Inventory flag for chemicals with workplace exposure concerns
- Example for consideration: The EPA conservative model predicts exposure a level order of magnitude below a chemical's concentration of concern (COC)
  - Is it foreseeable that COC could be exceeded?
  - Is this a reasonable basis for a SNUR?

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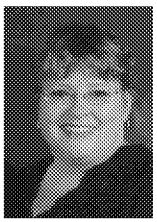

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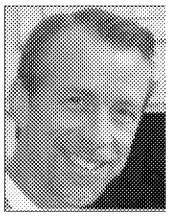

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Thank You

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