

DAY ONE: Basic TSCA and the Changes Ahead

- 7:30 a.m. – 8:00 a.m. **Registration and Continental Breakfast**
- 8:00 a.m. – 8:30 a.m. **Introduction and Overview**
Thomas C. Berger, Partner
- Impact of LCSEA
 - Continually Evolving Section 5 Review/Approval Process
 - Expanded Mandate to Prioritize and Regulate Existing Chemicals
 - Inventory Reset, Confidential Business Information (CBI)
 - Fees, Penalties, Enforcement
- 8:30 a.m. – 9:45 a.m. **New Chemical Notification**
James G. Votaw, Partner
- Overview of TSCA Inventory and New Chemical Notification
 - Scope and Definition of “Chemical Substance”
 - Exclusions and Exemptions from PMN Reporting
 - Post-LSCA PMN Process
 - Written Approvals, Early Decisions
 - Failure to Complete Review, Extensions
- 9:45 a.m. – 11:00 a.m. **PMN Preparation Under New TSCA**
Matthew B. Harney, Ph.D., Scientist
- Completing TSCA PMN Form, Chemical Names
 - Impact of Production Volume, Number of Sites, Cleaning Frequency, Transport, and Wastewater Disposal on PMN Review Outcomes
 - Use of EPA Models to Predict Review Outcomes
- 11:00 a.m. – 11:15 a.m. **Break**
- 11:15 a.m. – 12:15 p.m. **Regulation of New and Existing Chemicals**
James G. Votaw, Partner
- PMN Review -- Insufficient Information, Exposure-Based, and Risk-Based Findings
 - Evaluating and Challenging Agency Decisions to Regulate New Chemicals
 - Significant New Use Rules (SNURs), Section 5(e) Consent Orders
 - Proposed Changes to SNUR Process
 - New Section 4 – Compelled Testing and Data Development
 - New Section 6 – Prioritization, and Risk Evaluation and Management for Existing Chemicals
- 12:15 p.m. – 1:15 p.m. **Lunch**, provided by Keller and Heckman LLP

- 1:15 p.m. – 2:00 p.m. **Recordkeeping and Reporting**
Thomas C. Berger, Partner
- §8(a) PAIR, Chemical Data Reporting (CDR), Inventory “Reset”
 - §8(b) TSCA Inventory
 - §8(c) Allegations of Significant Adverse Reactions
 - §8(d) Submission/Listing of Unpublished H&S Studies §8(e) Substantial Risk Reporting
- 2:00 p.m. – 3:00 p.m. **Confidential Business Information (CBI) Protection Considerations**
Adrienne M. Timmel, Associate
- Asserting and Certifying CBI Claims
 - Substantiating CBI Claims
 - Review and Appeals Process
 - Responding to FOIA Requests
 - Rulemakings and Guidance
- 3:00 p.m. – 3:15 p.m. **Break**
- 3:15 p.m. – 3:45 p.m. **Imports and Exports**
Gregory A. Clark, Associate
- §13 Import Certification
 - §12(b) Export Notification
 - Tracking Inventory Status and Emerging Regulations
 - New Requirements for Mercury Compounds
- 3:45 p.m. – 4:45 p.m. **Inspections, Enforcement, Audits, and Self-Disclosures**
Thomas C. Berger, Partner
- EPA Inspection and Enforcement Authority
 - Preparing for Compliance Inspections, Conducting Self-Audits
 - New Penalties and New Areas for Potential Violations
 - Liability/Risk Management - EPA “Audit Policy” and “New Owners Policy”
 - “Economic Benefit” Considerations
- 4:45 p.m. – 5:00 p.m. **Question and Answer Session**
- 5:00 p.m. – 6:30 p.m. **Cocktail Reception**, hosted by Keller and Heckman LLP

DAY TWO: TSCA Reform Implementation, Advanced TSCA Issues

- 7:30 a.m. – 8:00 a.m. **Networking Breakfast**
- 8:00 a.m. – 8:30 a.m. **TSCA Reform Implementation and Key Legal Issues**
James G. Votaw, Partner
- Post-LCSA Enactment Events
 - Emerging Implementation Issues
 - TSCA Three Years from Now
 - Shifts in Fees, Focus, Enforcement
- 8:30 a.m. – 9:15 a.m. **TSCA Litigation Update**
Herb Estreicher, Partner
- Rules of Engagement in the Trump EPA
 - EPA on the Ropes
 - Can Industry Come to the Rescue?
- 9:15 a.m. – 10:00 a.m. **Prioritization for Risk Evaluation**
Gregory A. Clark, Associate
- Prioritization Process Overview
 - How Chemicals are Selected for Prioritization
 - What to Do If One of Your Substances is Selected for Prioritization
 - Alternatives to Prioritization: Manufacturer Requests and Section 21 Petitions
- 10:00 a.m. – 10:15 a.m. **Break**
- 10:15 a.m. – 11:15 a.m. **Risk Evaluation Proceedings and Risk Management Rules**
James G. Votaw, Partner
- Overview of Risk Evaluation Process for Existing Chemicals
 - What are the Issues with Conditions of Use?
 - Preemption of State Chemical Control Laws
 - CBI Considerations
 - Risk Evaluation Consortia and Fees
 - So EPA Found a Risk – Then What?
 - Current Status of Risk Evaluations Underway and Insights on the Process
 - What to Do If One of Your Substances is Selected for Risk Evaluation
 - Risk Management Rules for PBTs and Risk Evaluation Substances
- 11:15 a.m. – 12:15 p.m. **California's Proposition 65 and State Ingredient Disclosure Rules**
Javaneh Nekoomaram, Associate
- How Chemicals Become Listed
 - Determining if a Warning is Required (NSRLs, MADLs)
 - Consumer Product Warning Requirements
 - Occupational and Environmental Exposure Warnings
 - SUDs: Alternatives to Warnings
 - Legal and Product Stewardship Obligations for Out-of-State Manufacturers
 - Defending Against Bounty Hunter "Enforcement" Claims and Recent Trends
 - California's Cleaning Product Right to Know Act
 - New York's Household Cleansing Product Information Disclosure Program

- 12:15 p.m. – 1:15 p.m. **Lunch**, provided by Keller and Heckman LLP
- 1:15 p.m. – 2:00 p.m. **TSCA Inventory “Reset”**
Thomas C. Berger, Partner
- Scope and Basic Requirement
 - Retrospective Reporting
 - Prospective Reporting
 - CBI Handling and Considerations
 - Status and Ramifications of Non-Compliance
- 2:00 p.m. – 2:45 p.m. **Polymer Exemption**
Matthew B. Harney, Ph.D., Scientist
- Interpreting the Eligibility Criteria and Exclusions
 - Recordkeeping and Notification Requirements
 - Avoiding Common Mistakes
- 2:45 p.m. – 3:00 p.m. **Break**
- 3:00 p.m. – 3:30 p.m. **Biotechnology Regulation**
Gregory A. Clark, Associate
- Coordinated Federal Framework for Regulation of Biotechnology
 - New Chemical Notification for Microorganisms: MCANs and Tiered Exemptions
 - TSCA Regulation of Biotech Research Activities
 - Special TSCA Nomenclature Issues for Microorganisms, Chemical Substances, and Enzymes
- 3:30 p.m. – 4:15 p.m. **Electronic Reporting**
Amanda C. Price, Scientist
- PMN Submissions and Fee Payments
 - Consolidation Requests
 - *Bona fide* Inquiries
 - Notices of Commencement (NOC)
 - Confidentiality Substantiation Requirements
 - Other Electronic Reporting Requirements - Section 8(e) and Audit Policy Submissions
- 4:15 p.m. – 4:30 p.m. **Question and Answer Session**
- 4:30 p.m. **Seminar Adjourns**