

## THE NEW REGIME AND EXISTING CHEMICAL COMPLIANCE

### DAY ONE: TSCA and the Changes Ahead

<b>Registration and Continental Breakfast</b>
<b>Common Elements</b>
<p><b>Overview - What Has and Has Not Changed Under TSCA</b> <i>Keller and Heckman LLP</i></p> <ul style="list-style-type: none"> <li>➤ New Definitions and Approaches</li> <li>➤ New Twists and Hurdles of Section 5 Review Process</li> <li>➤ Expanded Mandate to Review and Test Existing Chemicals</li> <li>➤ Inventory “Reset” and Confidential Business Information (CBI)</li> <li>➤ Fees, Penalties, Enforcement</li> </ul>
<p><b>The New Safety Standard</b> <b>Insufficient Information, Exposure, and Risk-Based Findings</b> <i>Keller and Heckman LLP</i></p> <ul style="list-style-type: none"> <li>➤ New Process and Standard for PMN Clearance</li> <li>➤ Written Approvals, Early Decisions</li> <li>➤ Failure to Render Decision</li> <li>➤ New Use Focus</li> <li>➤ New Authority for Data Development</li> <li>➤ Significant New Use Rules (SNURs), Consent Orders</li> <li>➤ Proposed Changes to SNUR Process</li> </ul>
<p><b>The Risk Assessment Paradigm and How it Applies to “New TSCA”</b> <i>Cardno ChemRisk</i></p> <ul style="list-style-type: none"> <li>➤ Risk Assessment Framework</li> <li>➤ Risk Assessment Under New TSCA - An Outline Of Proposed Framework</li> <li>➤ Late Breaking News</li> </ul>
<p><b>Hazard Assessment- Addressing Data Gaps</b> <i>Cardno ChemRisk</i></p> <ul style="list-style-type: none"> <li>➤ Identifying Acceptable Data—and Data Gaps</li> <li>➤ Role of GLP and Klimisch Scoring in the Hazard Assessment Process</li> <li>➤ Making the Most of “Less-Reliable” Data: Weight-of-Evidence Approach</li> <li>➤ Read-Across Approaches for Regulators</li> </ul> <p><b>Hazard Assessment: Managing Toxicity Testing</b> <i>Cardno ChemRisk</i></p> <ul style="list-style-type: none"> <li>➤ When In Silico Models Just Won’t Do</li> <li>➤ Standard Testing Paradigms</li> <li>➤ Finding a Lab to Trust</li> <li>➤ What to Do When the Unexpected Happens</li> </ul>

### **Hazard Assessment: New Alternative Testing Mandate**

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- Overview of Statutory Mandate
- Accepted Alternatives to Vertebrate Animal Models
- Managing EPA and Consumer Concerns

### **Exposure Assessment: Environmental Exposure**

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- Environmental Exposure Models Used By EPA
- Common Pitfalls In Assumptions
- Opportunities For Refinement In Models
- Alternate Exposure Models
- Collecting Exposure Data

### **Exposure Assessment: Occupational Exposure**

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- Occupational Exposure Models Used By EPA
- When To Do Exposure Modeling
- Exposure Reconstruction From Job Title And Historic Sampling Data
- Managing Sample Collection At Workplaces

### **Exposure Assessment: Consumer Exposure**

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- Consumer Exposure Models Used By EPA
- Understanding Consumer Activity Patterns
- Sampling Strategies For Refined Assessments

### **Making Use of Available Data**

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- Available Guidance from the Agency on Data Acceptability
- Identifying High Quality Data
- Refuting Poor-Quality Data
- Strategies for Accessing EU REACH Data to Support EPA Reviews

### **New Twists and Hurdles of Section 5 Review Process**

#### **PMN Preparation Under New TSCA**

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- Nomenclature and Chemical Identity
- EPA's New Affirmative Determination
- New Requirements for LVEs
- Is There A "Base Set" for Testing?
- Completing PMN Forms, Chemical Names, *Bona fide* Requests
- How Volume, Number of Sites, Cleaning Frequency, Transport and Wastewater Disposal Information Influences Review Outcomes
- EPA Models and How To Use Them in Predicting Review Outcomes

## Consent Agreements, SNURs, and NCEs

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- Overview of Tools At EPA's Disposal
- Implementing and Enforcing Selected Risk Management Controls
- Review of New Section 9 Consultation
- EPA's Ability to Regulate Workplace Exposures
- OSHA's Hazard Communication Hierarchy and Other Federal Laws In Play

## Regulation of Existing Chemicals

### Evaluating Existing Chemicals for Future Regulation – Legal Issues

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- The Case for Change: *Corrosion Proof Fittings*
- New Criteria and Their Implications
- How Alternatives Assessment Fits In
- Five PBT Chemicals Subject to Expedited Action
- Evaluating and Challenging EPA Existing Chemical Decisions
- Insights from OSHA's Response on Consultation

### Question and Answer Session

*Thomas C. Berger, Partner, Keller and Heckman LLP*

*David G. Sarvadi, Partner, Keller and Heckman LLP*

*Adrienne M. Timmel, Associate, Keller and Heckman LLP*

*Marisa L. Kreider, Ph.D., D.A.B.T., Senior Managing Health Scientist, Cardno ChemRisk*

*Denise S. Hill, Ph.D., Supervising Health Scientist, Cardno ChemRisk*

*Ken M. Unice, M.S., Science Advisor, Cardno ChemRisk*

*Rachel M. Novick, Ph.D. DABT, Supervising Health Scientist, Cardno ChemRisk*

## HAZARD AND EXPOSURE ASSESSMENT AND RISK MANAGEMENT

### DAY TWO: TSCA

<b>Registration and Continental Breakfast</b>
<b>Regulation of Existing Chemicals, Continued</b>
<p><b>What to Expect - Prioritization and Risk Evaluation: Which Chemicals May End Up In EPA's Sights</b></p> <p><i>Cardno ChemRisk</i></p> <ul style="list-style-type: none"> <li>➤ Fate of Work Plan Chemicals</li> <li>➤ Priority Decisions Beyond Work Plan Chemicals</li> <li>➤ Overview of Process, Comparison to Work Plan Reviews</li> <li>➤ What Will a Systematic Review Involve?</li> <li>➤ New Best Science and Weight of Evidence Provisions</li> <li>➤ Aggregate and Sentinel Exposure Considerations</li> </ul>
<p><b>Risk Assessment: Legal Issues</b></p> <p><i>Keller and Heckman LLP</i></p> <ul style="list-style-type: none"> <li>➤ Process and Deadlines</li> <li>➤ EPA's Obligations and Transparency</li> <li>➤ The Legal Standard of Review for Risk Assessment</li> </ul>
<p><b>Risk Assessment: PBT's: In the Spotlight</b></p> <p><i>Cardno ChemRisk</i></p> <ul style="list-style-type: none"> <li>➤ What Are PBTs?</li> <li>➤ How Can You Determine if a Chemical Will Be Classified as a PBT?</li> <li>➤ Modeling For PBT</li> <li>➤ Empirical Testing for PBTs</li> </ul>
<p><b>Risk Assessment: Consideration of the "Worst Case" Scenario</b></p> <p><i>Cardno ChemRisk</i></p> <ul style="list-style-type: none"> <li>➤ Worst Case In Hazard - Sensitive Subpopulations</li> <li>➤ Worst Case In Exposure - Highly Exposed Populations</li> <li>➤ Implications Of These Considerations</li> </ul>
<p><b>Risk Assessment: The MCCP Case Study- Real World Application</b></p> <p><i>Cardno ChemRisk</i></p> <ul style="list-style-type: none"> <li>➤ Agency Use of PMN Process to Evaluate an Existing Chemical</li> <li>➤ Decoding Agency Chemical Engineering Reports</li> <li>➤ Strategic Analysis of Agency Risk Assessment Assumptions and Conclusions</li> <li>➤ Role of Engagement in the Supply Chain</li> </ul>
<b>Changes in TSCA Administration</b>
<p><b>Inventory, Inventory "Reset," and Section 8</b></p> <p><i>Keller and Heckman LLP</i></p> <ul style="list-style-type: none"> <li>➤ Comparison to Initial Inventory Reporting</li> <li>➤ Fate of Existing Chemicals, Role of TSCA Nomenclature</li> <li>➤ Protection of Alternative Nomenclature</li> </ul>

- Non-Reporting Implications
- Section 8: Data Reports, Allegations and Substantial Risk Reporting
- Maintaining Preparedness for CDR

#### **CBI Claims and Substantiation**

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- Section 14 Changes
- Exemptions from Substantiation
- Timing
- Responding to Substantiation Requests
- Supporting Claims
- Impact Of Reverse Engineering, Commercial and Industrial Intelligence

#### **Supply Chain Challenges**

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- Facilitating Communication Throughout Supply Chain
- Incorporating Feedback From Supply Chain
- Evaluating Your Supply Chains For Potential Concerns
- Increasing Cost In Supply Chain And Market Deselection

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