REGULATORY SUMMIT
USA

Focusing on the latest developments in international, national and regional legislation, including TSCA reform

WASHINGTON DC, USA

2016

27 OCTOBER
28
DAY ONE: 27 OCTOBER 2016

09:00  Registration

SESSION 1: TSCA reform in the US

Chair: Kelly Franklin, Editor North America, Chemical Watch

09:30  The basics – what the new law does
• Key changes
• New rules of engagement
• Implementation & key timing considerations
Lynn L. Bergeson, Managing Partner, Bergeson & Campbell, P.C.
Charles M. Auer, Senior Regulatory and Policy Advisor, Bergeson & Campbell, P.C.

10:30  Refreshments

10:45  Key impact on chemical manufacturers & importers
Karyn Schmidt, Senior Director, Regulatory and Technical Affairs Committee, American Chemistry Council

11:05  Key impact on processors/formulators
René Viñas, MS, PhD, Toxicologist, Consumer Product Safety, Grocery Manufacturers Association, Scientific & Regulatory Affairs

11:25  Key impact on producers of personal care products
• A downstream formulator’s perspective on the most impactful provisions of the Lautenberg Chemical Safety Act for the 21st century (LCSA)
• Planning steps a downstream company can take now to prepare for U.S. EPA’s implementation activities under LCSA
Julie Froelicher, NA Regulatory & Technical Relations Manager Global Product Stewardship, The Procter & Gamble Company

11:45  One view of how TSCA reform happened & how it’s going so far
• How did TSCA reform finally happen even in a highly partisan climate?
• How does the new law changes business as usual for companies and other stakeholders?
• How’s it going so far?
Richard A. Denison, Lead Senior Scientist, Environmental Defense Fund

12:15  Q&A panel discussion session

12:30  Lunch

13:30  EPA TSCA Implementation Update
• Overview of EPA implementation activities to date
• Key upcoming milestones
Wendy Cleland-Hamnett, Director, Office of Pollution Prevention & Toxics, U.S. EPA

14:00  Life after TSCA Reform: Actions & Implementation Perspectives from the States
• What actions are underway in the states related to TSCA implementation?
• How will preemption impact the states in the future?
• What are the future trends in states’ chemicals policy?
Ken A. Zarker, Pollution Prevention & Regulatory Assistance Manager, Washington State Department of Ecology

14:30  Q&A panel discussion session

15:10  Refreshments

SESSION 2: Other North American developments

Chair: Lynn L. Bergeson, Managing Partner, Bergeson & Campbell P.C.

GHS implementation in North America

15:25  The United States
• Overview of the GHS and how it is different than OSHA’s older system
• Review the benefits of GHS
• Discuss implementation status and issues
• Future plans
Maureen Ruskin, Deputy Director, Directorate of Guidance & Standards, Occupational Safety & Health Administration, United States Department of Labour

15:55  Canada
Health Canada released Phase 1 of its Technical Guidance relating to WHMIS 2015 on July 29, 2016. An overview of the structure of the document, to help orient users, as well as a review of the guidance in areas of particular interest will be provided:
• Background and Transition Timelines
• Purpose of the Technical Guidance
• Structure of the document
• Content
• Accessing a Copy of Phase 1

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16:25 The Next Phase of Canada’s Chemicals Management Plan (CMP): Continuity and Evolution

The next phase of Canada’s Chemicals Management Plan was launched in May 2016 continuing the evolution of chemicals management in Canada. The presentation will cover background on Canada’s CMP, and what lies ahead in Canada towards meeting the 2020 goal for the sound management of chemicals.

Jake Sanderson, Manager, Horizontal Policy & Planning Environment Canada

16:55 Green Chemistry & Regulations – Opportunities & Challenges

- The connection between chemicals legislation and green chemistry
- The challenge of chemicals regulations
- The need for reframing the global chemistry enterprise
- The opportunities in sustainable and green chemistry

David Constable, Director, ACS - Green Chemistry Institute

17:25 Q&A Panel discussion session

17:40 Close of Day One

17:45 – 18:45 Cocktail Reception

Kindly sponsored by

Lynn L Bergeson
Managing Partner, Bergeson & Campbell P.C., USA
Owner of Bergeson & Campbell, P.C. (B&C®), Ms. Bergeson has earned an international reputation for her deep and expansive understanding of the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), European Union Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), and especially how these regulatory programs pertain to nanotechnology, biotechnology, and other emerging transformative technologies. Her knowledge of and involvement in the policy process allows her to develop client-focused strategies whether advocating before Congress, the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), or other governance and standard-setting bodies.

Charles M. Auer
Senior Regulatory and Policy Advisor, Bergeson & Campbell P.C., USA
For more than three decades, Charles M. Auer, Senior Regulatory and Policy Advisor with Bergeson & Campbell, P.C. (B&C®), has provided sagacious, informed, and deeply insightful guidance on legal, policy, and scientific matters related to the regulation of chemicals under the Toxic Substances Control Act (TSCA) and related domestic and international chemical control laws. Mr. Auer’s experience includes over 32 years at the U.S. Environmental Protection Agency (EPA), most recently as the Director of the Office of Pollution Prevention and Toxics (OPPT), responsible for implementation of TSCA.

Karyn Schmidt
Senior Director, Regulatory and Technical Affairs Committee, American Chemistry Council, USA
Karyn M. Schmidt is Senior Director in the American Chemistry Council’s Regulatory and Technical Affairs Division where she focuses on Health, Products, and Science Policy. In ACC’s legal department from 2000-2015, Ms. Schmidt provided wide-ranging legal and strategic counsel to product-specific chemical and plastics groups facing legislative, regulatory, litigation, and private sector challenges and opportunities. Ms. Schmidt has joined ACC’s Lautenberg Chemical Safety Act implementation team at ACC in its Regulatory & Technical Affairs Department, where she is working on a broad range of LCSA implementation issues.

René Viñas, MS, PhD
Toxicologist, Consumer Product Safety, Grocery Manufacturers Association, Scientific & Regulatory Affairs, USA
Dr. René Viñas is currently Toxicologist, Consumer Product Safety at the Grocery Manufacturers Association where he performs safety assessments of food ingredients, packaging materials, contaminants and manufacturing processes. In particular, he works with advocacy teams to translate scientific data into language meaningful to state and federal legislators. Dr. Viñas also serves as a chair for the International Council of Grocery Manufacturers Associations on various Codex Alimentarius committees where he advocates for the consumer product goods industry on the global scientific arena.

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**EXPERT SPEAKERS – DAY ONE**

**Julie Froelicher**

*NA Regulatory & Technical Relations Manager, Global Product Stewardship, The Procter & Gamble Company, USA*

Julie Froelicher is a Regulatory and Technical Relations Manager for The Procter & Gamble Company and regularly engages with Congressional, Regulatory, and public interest stakeholders on US federal and state chemical policy. During her 18 years with Procter & Gamble, Julie has managed a broad range of regulatory compliance and legislative advocacy activities primarily for P&G’s Fabric & Home Care business.

Julie earned a B.S. in Biology from Xavier University and a Master’s Degree in Environmental Management from California’s Green Chemistry Initiative. She is a member of the NAS Board on Environmental Studies and Toxicology and the NAS Board on Environmental Health Decisions. Until recently, she served in this position since 2009 and as the Deputy Administrator’s Office. Wendy received her law degree from George Washington University.

**Richard Denison**

*Lead Senior Scientist, Environmental Defense Fund, USA*

Richard has 30 years of experience in the environmental arena, specializing in policy, hazard and risk assessment and management for industrial and consumer chemicals and nanomaterials. Richard is a member of the National Academy of Sciences’ Standing Committee on Emerging Science for Environmental Health Decisions. Until recently, he was on the NAS Board on Environmental Studies and Toxicology and served on the Green Ribbon Science Panel for California’s Green Chemistry Initiative.

**Wendy Cleland-Hamnett**

*Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention (OCSPP), U.S. EPA*

Wendy Cleland-Hamnett is the Director of the Office of Pollution Prevention and Toxics, or OPPT, in EPA’s Office of Chemical Safety and Pollution Prevention. She has served in this position since 2009 and as the Deputy of the Office several years before that. As the Director of OPPT, Wendy oversees EPA’s new and existing chemicals programs, numerous safer chemical and pollution prevention activities, enhanced efforts to make chemical information more accessible to the public, and a range of efforts to manage lead, formaldehyde, and other legacy chemicals. Ms. Cleland-Hamnett has worked across the agency in a number of offices and capacities, including the Office of Environmental Information, the Office of Policy and the Administrator’s Office. Wendy received her law degree from George Washington University.

**Ken A. Zarker**

*Pollution Prevention and Regulatory Assistance Manager, Washington State Department of Ecology, USA*

Ken has over 30 years of experience with environmental and public health regulatory program with the Washington State Department of Ecology. Ken team is responsible for compliance with the Washington Children’s Safe Products Act (CSPA) program, including conducting consumer product testing for 66 toxic chemicals of concern. Ken is also working to implement the states’ Better Brakes copper-free brake pad law to eliminate a source of copper to Puget Sound, a model for the 2015 national memorandum of understanding between manufacturers, states and the U.S. EPA. Ken also lead efforts among the states on the reform of the Toxic Substances Control Act.

**Maureen Ruskin**

*Deputy Director, Directorate of Guidance & Standards, Occupational Safety & Health Administration, United States Department of Labour*

Maureen Ruskin is currently the Deputy Director of the Directorate of Standards and Guidance for US Occupational Safety and Health Administration (OSHA). Ms. Ruskin has been the lead person in the rulemaking process to align the US Hazard Communication Standard with the GHS for work place chemicals. Now in the implementation phase, Ms. Ruskin leads the team in the producing guidance materials to facilitate the implementation of GHS. In addition to her regulatory work, Ms Ruskin is head of the US Delegation for UN Sub-Committee of Experts on the GHS since July 2010 and Chair of the UN Sub-committee since December 2012.

**Amira M. Sultan**

*Manager, Policy and External Relations Division, Workplace Hazardous Materials Bureau, Consumer Product Safety Directorate, Health Canada*

Amira is the Acting Manager of the Policy and External Relations Division in the Workplace Hazardous Materials Bureau at Health Canada. She leads the team responsible for providing technical and regulatory expertise for the WHMIS program and recently led the development of the WHMIS program. Ms. Sultan leads the team responsible for the implementation phase, Ms. Sultan leads the team responsible for the implementation of GHS. In addition to her regulatory work, Ms Ruskin is head of the US Delegation for UN Sub-Committee of Experts on the GHS since July 2010 and Chair of the UN Sub-committee since December 2012.

**Jake Sanderson**

*Manager, Horizontal Policy and Planning, Environment Canada*

Jake Sanderson is the Manager of Horizontal Policy and Planning, within the Science and Risk Assessment Directorate at Environment Canada. He currently holds the responsibilities of being the focal point for international initiatives on chemicals within the risk assessment program. Jake joined the Existing Substances Program in 1998 and has worked on a range of initiatives including: the priority substances assessment program, Canada’s Prioritization of its’ Domestic Substances List, planning and launch of the Chemicals Management Plan (CMP), stakeholder engagement and outreach under the CMP as well as a Senior Advisor to the Assistant Deputy Minister of Science and Technology.

**David Constable**

*Director, ACS: Green Chemistry Institute, USA*

David Constable is the Director of the American Chemical Society’s Green Chemistry Institute. His previous positions included VP of Environment, Safety & Health at Lockheed Martin and Director of Operational Sustainability at GlaxoSmithKline. He earned his bachelor’s from Slippery Rock University and Ph.D. from the University of Connecticut. He has served as a staff liaison to the ACS GCI Governing Board since 2013.
08:00 Registration

SESSION 3: Global developments

Chair: Jake Sanderson, Manager, Horizontal Policy & Planning, Environment Canada

08:15 Brazil: industrial chemicals policy
Leticia Reis de Carvalho, Director of Environmental Quality in Industry, Brazil Ministry of the Environment

08:45 Updates of MEP Order 7th & Decree 591 in China
- Overview of Chinese chemicals legislation;
- Updates of MEP Order 7th and its guidance document
- Practical experience under MEP Order 7th
- Case analysis
- Updates of Decree 591
Eric Xiong, Head of Industrial Chemicals Sector, Chemical Inspection & Regulation Service Ltd (CIRS), China

09:15 China RoHS 2: The New, the Old & the TBD
- Overview of requirements for the Newly In-Scope
- Similarities between the new requirements and the old requirements
- Key differences and their implications
- What is still to come: the steps to substance restriction
- Recommendations for manufacturers
- Recommendations for industry associations
Michael Kirschner, President, Design Chain Associates, LLC

09:45 Q&A Session

10:00 Refreshments

10:15 K-REACH: Compliance and Challenges
- Regulatory landscape with regards to the Act of Registration and Evaluation of Chemicals of Korea (K-REACH)
- K-REACH requirements including exclusion and exemptions; reporting, registration and notification processes; data hazard evaluation and risk assessments
- K-REACH regulatory timelines and current challenges that industry experiences
Sookie Hong, Senior Manager, Regulatory Research, 3E Company.

10:45 Current Status on Regulation of New & Existing Chemical Substances Registration in Taiwan
- Framework and Regulation
- Multiple Ways of Counseling and Statistics
- Strategies for the future
Ya-hui Ni, Deputy General Manager, Environment Resource & Information Co Ltd, ROC

11:15 Australian Chemical Framework Update
- Overview of the reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
- Regulatory developments with Classification, Safety Data Sheets and labelling
Nick Zovko, Regulatory Policy Manager, Plastics and Chemicals Industries Association (PACIA), Australia

11:45 Q&A Session

12:00 Lunch

SESSION 3: ...continued

Chair: Emma Chynoweth, Managing Editor, Chemical Watch

13:00 Middle East regulatory update
Daniella Taveau, Partner, King & Spalding, USA

13:30 REACH – ECHA Regulatory strategy, the 2018 registration deadline & other updates
- ECHA Regulatory strategy on substances that matter – Principles and objectives
- What does it mean for the registrants – How to ensure regulatory compliance
- The 2018 registration deadline for substances in volumes from 1 to 100 tonnes per annum – How to get prepared
- Other regulatory updates including substance evaluation and authorization
Christel Musset, Director, Registration, The European Chemicals Agency (ECHA), Finland

14:00 EU RoHS2 requirements, enforcement actions & new substance restrictions
- Comparison of RoHS1 and RoHS2 requirements
- RoHS2 enforcement actions and EU product withdrawals
- Materials at risk of containing the new RoHS restricted phthalates
- Using EN 50581 to manage supply chain compliance
Aidan Turnbull, Director, BOMcheck Net, UK
### 15:00 Taking Action on Toxics & Chemical Safety: Enforcing TSCA & Implementing Next Generation Compliance & Enforcement

- Enforcement Outcomes and Priorities for FY 16 and 17
- Continued Focus on Addressing Risk in Enforcement Actions
- Next Generation Compliance and Enforcement
- TSCA Reform

*Gregory Sullivan, Acting Director, Waste & Chemical Enforcement Division, US EPA*

### 15:30 REACH enforcement & the role of the ECHA forum

- Enforcement of REACH is done by the Member State authorities
- ECHA’s Forum provides strong coordination of national enforcement activities and continuous stream of enforcement projects that focus on key areas of REACH and CLP, such as registration, information in the supply chain, authorisation or restrictions
- Enforcement findings relevant for American companies

*Christel Musset, Director, Registration, The European Chemicals Agency (ECHA), Finland*

### 16:00 Q&A Session

### 16:15 Close of Summit

### EXPERT SPEAKERS – DAY TWO

#### Leticia Reis de Carvalho
**Director of Environmental Quality in Industry, Ministry of the Environment, Brazil**

Leticia Carvalho has been a member of the Ministry of the Environment of Brazil since 2001. On February 2013 she was appointed Director of Environmental Quality at the Secretariat for Climate Change and Environmental Quality. In her role as Director of Department, Mrs. Carvalho is responsible for policy making and coordinating the implementation of the chemicals and waste policies and promoting chemicals safety. She acts as the President of the National Commission for Chemicals Safety and SAICM Focal Point in Brazil. She also oversees the implementation of actions to reduce air emissions of pollutants from transportation and industry, promoting air quality strategies and urban development.

Mrs. Carvalho has published nationally and internationally on issues relating to chemicals and waste management, air emissions, fisheries, marine and coastal management and international law. She is Bachelor in Oceanography by the University of Rio Grande and has a Master in Sustainable Development by the University of Brasilia.

#### Michael Kirschner
**President, Design Chain Associates LLC, USA**

Mike Kirschner is an environmental and social compliance and performance expert providing advice and expertise to manufacturers in a variety of industries. Mike helps manufacturers define, implement and troubleshoot internal product lifecycle management systems and supply chains to reduce business risk while improving the environmental performance of their products. He also helps manufacturers understand, monitor and assess environmental and social regulations, risk and opportunities around the world. He has focused on China RoHS and related Chinese initiatives since 2005.

#### Sookie Hong
**Senior Manager, Regulatory Research, 3E Company.**

Ms. Hong has 18 years of Asia Pacific regulatory expertise. In her new role as the head of 3E’s Regulatory Research, she oversees the global team of regulatory analysts (North America, Latin America, Asia-Pacific, Europe, and Middle East/Africa) who are responsible for regulatory management, research, and analysis. Ms. Hong is also tasked with delivering the most accurate and timely regulatory content to support 3E WebInsight, Ariel Logic, and other products such as SDS authoring and solutions, as well as with providing sales/business development support for 3E Company’s products.

#### Eric Xiong
**Head of Industrial Chemicals Sector, Chemical Inspection & Regulation Service Ltd (CIRS), China**

Mr Eric Xiong has about 10 years working experience in product stewardship and regulatory compliance service for chemical industry in China and other east Asian countries. He has provided solutions for hundreds of enterprises to remove chemical regulatory barriers in Asian Pacific countries and his team has got approximately 100 new substances approved under typical notification in China.
Ya-hui Ni  
*Deputy General Manager, Environment Resource & Information Co Ltd, ROC*

Ya-Hui (Cherish) Ni holds a B.S. in Agriculture Chemistry from the National Taiwan University in 1996, and she received her M.S. in Environmental Engineering from NTU in 1998. She has served in China Technical Consultants, Inc, which is one of the biggest consulting companies in Taiwan, and become a founder of Environment Resource & Information Co., Lt. since 2001. Her career highlight includes chemical substance management; toxic chemical substance management; industrial waste management; resource recycles management; soil and groundwater pollution remediation technique. She engaged in the e-manifest system for industrial waste control center, and assisted policy practice, control system establishment for over 17 years.

Nick Zovko  
*Regulatory Policy Manager, Plastics and Chemicals Industries Association (PACIA), Australia*

Mr Nick Zovko currently holds a degree in Bachelor of Applied Science in Chemistry from RMIT University. He is currently employed with pre-eminent national body representing Australia’s chemistry industry, which represents the second largest manufacturing sector in Australia - PACIA. The position provides key services support to member companies, undertakes high level government and stakeholder engagement and delivers strong advocacy to achieve favourable industry outcomes with chemical and safety laws.

Daniella Taveau  
*Partner, King & Spalding, USA*

Daniella Taveau is a Regulatory and Global Trade Strategist for King & Spalding’s International Trade Practice. She also works closely with other areas of the firm including the Energy & Environment, FDA & Life Sciences, and Government and Public Policy practice groups. Ms. Taveau is a recognized expert in developing global regulatory strategies encompassing areas such as chemicals and pesticides, agriculture and food safety, new technologies and cosmetics. She has extensive experience working with senior political officials in the U.S. government and Embassies, foreign governments in Europe, Asia, Latin America and Australia, the Middle East and within international bodies such as the WTO, WHO, and OECD.

Christel Musset  
*Director, Registration, The European Chemicals Agency (ECHA), Finland*

Christel Musset joined the European Chemicals Agency (ECHA) in 2007. She is in charge of the directorate for Registration. She is responsible for all activities related to the registration process under the REACH legislation - this also comprises data sharing, dissemination of information to the public and coordination of IT systems in support of these activities.

Aiden Turnbull  
*Director, BOMCheck Net, UK*

Aidan is Director of the www.BOMcheck.net industry-led substances declarations web database and the www. EC4P.com web database system for WEEE, Batteries and Packaging compliance. Aidan holds a Doctorate in Physics and Electronics, sponsored by British Telecom through a CASE award. In 2010 Aidan was appointed co-chair of the IPC 1752A Materials Declaration Standard. In 2012 he was appointed UK National Expert on the IEC 62474 Materials Declaration Standard and the EN 50581 Standard for RoHS2 Technical Documentation. In 2013 he was appointed as European Regional Coordinator for the IEC 62474 Materials Declaration Standard.

Gregory Sullivan  
*Acting Director, Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency*

As acting Director, Greg leads a group of attorneys, environmental specialists, scientists, engineers and inspectors in the Waste and Chemical Enforcement Division. The Division is responsible for developing and implementing national policy for RCRA, FIFRA, TSCA, CAA section 112(r) and EPCRA/CERCLA civil administrative and judicial enforcement cases. The Division also directly assures compliance with, and initiates and resolves cases under, each of the above statutory areas.

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Monticchio, Kate  
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Nike, United States

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Rios, Daniel  
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