Program

Thursday, November 19, 2015

8:30 AM–9:00 AM

Greeting and Conference Charge

Daland R. Juberg, PhD, Chair, Dow AgroSciences, Indianapolis, Indiana, USA

Peter L. Goering, SOT 2015–2016 President, US Food and Drug Administration, Silver Spring, Maryland, USA

George P. Daston, PhD, SOT Council Contact, Procter & Gamble Company, Cincinnati, Ohio, USA

Thomas B. Knudsen, PhD, Co-Chair, US Environmental Protection Agency, Research Triangle Park, North Carolina, USA

9:00 AM–10:00 AM

Keynote Lecture 1

Agency Perspective on 21st Century Approaches in Regulatory Decisions

Jim Jones, Assistant Administrator, US Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Washington, DC, USA

Keynote Lecture 2

High Throughput Risk Assessment—What's It Good For?

Maurice Whelan, PhD, Head of System Toxicology Unit, European Commission Joint Research Centre—Ispra, Italy

10:00 AM–10:15 AM Break

10:15 AM–12:15 PM

Plenary Session I— Hazard Characterization Using Tox21 Tools/Approaches

Session will cover new hazard identification/characterization approaches that are underpinned and informed by more traditional approaches (e.g., animal testing) and pathway-based mechanisms: (1) approaches for mechanistic understanding of the ways in which chemicals and pharmaceutical agents perturb biological systems, leading to adverse outcomes; (2) integrative analytical tools and computational strategies for gaining mechanistic knowledge of biological networks; (3) identification and application of biomarkers for improved safety assessments; and (4) systems-based approaches for more quantitative evaluation of adverse outcome pathways (AOPs).

Chairs: John "Jack" R. Fowle III, PhD, DABT, Science to Inform, LLC, Pittsboro, North Carolina, USA; and Raymond R. Tice, PhD, National Institute of Environmental Health Sciences/National Toxicology Program, Durham, North Carolina, USA (Retired); and Discussant Leader: Suzanne Compton Fitzpatrick, PhD, DABT, US Food and Drug Administration, College Park, Maryland, USA.

How Tox21 Risk Assessments Can Help Bridge Risk Management Uncertainties Facing 21st Century Regulatory Decisions

Steven P. Bradbury, PhD, Steven P. Bradbury and Associates, Washington, DC, USA

AOP Framework and OECD Knowledge-Base Development

Dan Villenueve, PhD, National Health and Environmental Effects Research Laboratory, US Environmental Protection Agency, Duluth Minnesota, USA

Identification, Application, and Regulatory Qualification of New Translational Kidney Biomarkers for Improved Safety Assessment in Drug Development

Frank D. Sistare, PhD, Merck & Co. Inc, West Point, Pennsylvania, USA

Systems-Based Approaches for More Quantitative Evaluation of AOPs

Richard J. Brennan, PhD, DABT, Sanofi, Waltham, Massachusetts, USA

12:15 PM–1:30 PM Lunch

1:30 PM–4:30 PM

Plenary Session II—Exposure Characterization Using Tox21 Tools/Approaches

Session covers: (1) a systems approach to exposure modeling (ExpoCast); (2) high-throughput Physiologically Based Pharmacokinetics (PBPK) models; (3) new approaches/concepts such as *In Vitro* to *In Viro* Extrapolation (IVIVE), biomonitoring equivalents, toxicokinetic use in dose-setting, and informing on non-linearity in dose-response; and (4) lifestage-specific considerations in susceptibility.

Chairs: David Watson, MBA, Lhasa Limited, Leeds, United Kingdom; and Ronald N. Hines, PhD, US Environmental Protection Agency, Research Triangle Park, North Carolina, USA; and Discussant Leader: Barbara Anne Wetmore, PhD, The Hamner Institutes for Health Sciences, Research Triangle Park, North Carolina, USA

A Systems Approach to Exposure Modeling (ExpoCast)

John Wambaugh, PhD, National Center for Computational Toxicology—US Environmental Protection Agency, Research Triangle Park, North Carolina, USA

High-Throughput PBPK Models,

Jos G. M. Bessems, PhD, European Commission, DG Joint Research Center, Ispra, Italy

2:45 PM–3:00 PM Break

3:00 PM–4:00 PM

New Approaches/Concepts such as IVIVE , Biomonitoring Equivalents, Toxicokinetic Use in Dose-Setting, and Informing on Non-Linearity in Dose-Response

Miyoung Yoon, PhD, Center for Human Health Assessment, The Hamner Institutes for Health Sciences, Research Triangle Park, North Carolina, USA

Life-Stage-Specific Considerations in Susceptibility

Melissa Runge-Morris, MD, Wayne State University, Institute of Environmental Health Sciences, Detroit, Michigan, USA

4:00 PM–4:30 PM

First Day Rapporteur

Tina Bahadori, DSc, US Environmental Protection Agency, Office of Research and Development, Washington, DC, USA

4:30 PM–6:00 PM

Poster Reception: Introduction and Awards Presentation

Display and discussion of posters and recognition of award recipients.

Nicole C. Kleinstreuer, PhD, Integrated Laboratory Systems, Inc. Contractor supporting the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods, Research Triangle Park, North Carolina, USA

Chairs: Elaine M. Faustman, PhD, DABT, University of Washington, Seattle, Washington, USA; Thomas B. Knudsen, PhD, National Center for Computational Toxicology, US Environmental Protection Agency, Research Triangle Park, North Carolina, USA; and Emmanuel Lemazurier, PhD, INERIS NERIS-Chronic Risk Division, Paris, France

Friday, November 20, 2015

8:15 AM–8:30 AM

Welcome

Thomas B. Knudsen, US Environmental Protection Agency, Research Triangle Park, North Carolina, USA

8:30 AM–10:15 AM

Plenary Session III—21st Century Risk Assessment—Program-Specific Considerations on How New Approaches Can Impact Regulatory-Decision Making

The regulatory laws and expectations are different for drugs, medical devices, and chemicals. The talks in this session will provide insight into these differences and begin the discussion of how Tox21-type approaches may help in regulatory-decision making. Speakers will cover regulatory programs at the US FDA and US EPA, provide the viewpoint from US FDA- and US EPA-regulated industries, and discuss perspectives from academia.

Chair: Thomas Hartung, MD, PhD, Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing, Baltimore, Maryland, USA; and Douglas A. Keller, PhD, DABT, Sanofi, Bridgewater, New Jersey, USA; and Discussant Leader: Patience Browne, PhD, US Environmental Protection Agency, Endocrine Disruptor Screening Program, Washington, DC, USA

US FDA

Robert M. Califf, MD, US Food and Drug Administration, Silver Spring, Maryland, USA

US EPA

David J. Dix, PhD, US Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Washington, DC, USA

Pharmaceutical Industry

Russell T. Naven, Takeda Pharmaceuticals International Co., Cambridge, Massachusetts, USA

10:15 AM–10:30 AM Break

Chemical/Consumer Products Industry

George P. Daston, PhD, Procter & Gamble, Cincinnati, Ohio, USA

Academia

Elaine M. Faustman, PhD, University of Washington, Seattle, Washington, USA

EU/REACH

Emmanuel Lemazurier, PhD, INERIS -Chronic Risk Division, Paris, France

Breakout Group Introduction and Discussant Leader:

Nancy B. Beck, PhD, DABT, American Chemistry Council, Washington, DC, USA

12:15 PM–1:00 PM Lunch

1:00 PM–2:45 PM

Breakout Groups

Groups will address four key areas in regulatory toxicology and safety assessment within the context of scientific drivers where new methodologies can improve safety assessment in:

A. Drug Development

David Watson, MBA, Lhasa Limited, Leeds, United Kingdom (Moderator)

B. Identifying Endocrine Active Chemicals for Environmental Health Protection Using Pathways-Based Approaches for Screening and Testing

Nicole C. Kleinstreuer, PhD, Integrated Laboratory Systems, Inc. Contractor supporting the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods, Research Triangle Park, North Carolina, USA (Moderator)

C. TSCA Reform

Catherine Willett, PhD, The Humane Society of the United States, Washington, DC, USA (Moderator)

D. Impact on Global Harmonization

Donna L. Mendrick, PhD, US Food and Drug Administration, Silver Spring, Maryland, USA (Moderator)

2:45 PM–3:00 PM Break

3:00 PM–3:45 PM Breakout Group Reports

3:45 PM–4:00 PM

Wrap Up and Program Closing

Kevin Michael Crofton, PhD, US Environmental Protection Agency, National Center for Computational Toxicology, Research Triangle Park, North Carolina, USA

FutureTox III: Transforming 21st Century Science into Risk Assessment and Regulatory Decision-Making