State of the Art in the Cramer Classification Scheme and Threshold of Toxicological Concern

March 29, 2016
Welcome

Mary E. Torrence, DVM, PhD
Director, Office of Applied Research and Safety Assessment (OARSA) US FDA, College Park, MD
In vitro                              In vivo
• In silico
• Hepatotoxicity
• Cardiotoxicity
• Renal Toxicity
• Stem Cell Model
• 3 D Models
  – (skin, lung etc.)

• Acute Toxicity Testing
• Hepatotoxicity
• Cardiotoxicity Testing
• Renal Toxicity Testing
• Reproductive Toxicity
• Developmental Toxicity

In vitro                              In vivo

Significant Regulatory Research Outcome

Division of Applied Toxicology
Regulatory Need

Outcome
Colloquium Series

- Partnership SOT and US FDA Center for Food Safety and Applied Nutrition (CFSAN)
- High-quality, cutting-edge, future-oriented toxicological science
- Information for FDA employees and the public
- Not a public forum for discussion of toxicology regulatory issues
Welcome from SOT

Peter L. Goering, PhD, DABT, ATS
President, Society of Toxicology
Society of Toxicology Mission

To Create a Healthier and Safer World by Advancing the Science and Increasing the Impact of Toxicology

Strategic Priorities

• Strengthen the Relevance and Impact of Toxicology
• Develop and Support Toxicologists to Capitalize on Future Opportunities
• Expand Outreach and Impact Globally
Six Previous Colloquia

- Role of Mode of Action in Dose-Response Assessment for Carcinogens
- A Path Forward for Using Computational and *In Vitro* Methods for Food Ingredient Assessments
- Contemporary Issues in Risk Assessment
- Immunotoxicology in Food and Ingredient Safety Assessment: Approaches and Case Studies
- Application of ADME/PK Studies to Improve Safety Assessments for Foods and Cosmetics
- Complexities in Evaluating Human Clinical and Observational Data for Ingredient Safety Assessment: Partially Hydrogenated Oils As a Case Study
### Participation Summary 2014-2016

<table>
<thead>
<tr>
<th></th>
<th>Total for 6 Previous Colloquia</th>
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<tr>
<td>On-Site</td>
<td>365</td>
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<tr>
<td>Webcast</td>
<td>1498</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>1863</strong></td>
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Future Colloquia 2016

May 20, 2016
Safety Assessment Approaches in Young Children

Watch for additional colloquia in 2016-2017.
SOT FDA Organizing Committee

Ivan Rusyn, MD, PhD, Chair, Texas A&M University, College Station, TX
Jason L. Aungst, PhD, US FDA, CFSAN, College Park, MD
Ronald Chanderbhan, PhD, US FDA, CFSAN, College Park, MD
Bryan Delaney, PhD, DABT, ATS, DuPont Pioneer, Johnston, IA
Suzanne Compton Fitzpatrick, PhD, DABT, Colloquium Chair and Committee Member, US FDA, CFSAN, College Park, MD
Kristi Muldoon Jacobs, PhD, US FDA, CFSAN, College Park, MD
Norbert Kaminski, PhD, SOT Council Contact, Michigan State University, East Lansing, MI
Jieun Lee, PhD, DABT, Kellogg, Battle Creek, MI
James J. Pestka, PhD, Michigan State University, East Lansing, MI
Allen Rudman, PhD, FDA Lead, US FDA, Office of Food Additive Safety, CFSAN, College Park, MD
Catherine Whiteside, PhD, US FDA, CFSAN/OFVM/CFSAN, College Park, MD
Timothy Adams, PhD, US FDA, CFSAN, College Park, MD, for this colloquium
Moderators

Chair: Ivan Rusyn, Texas A&M, College Station, TX
Co-chair: Timothy Adams, US FDA, College Park, MD
8:50 AM–9:30 AM

9:30 AM–10:10 AM
Advancements in Food Ingredient Safety Prioritization: An Expanded Cramer Decision Tree Schema, Timothy Adams, US FDA, College Park, MD

10:30 AM-11:10
*In Silico* Methods for TTC Assessment, Andrew Worth, European Commission, Joint Research Centre, Ispra, Italy

11:10 AM-11:50 PM
Quantitative Prediction of Continuous Toxicity Values using Chemical Structure Information, Jessica Wignall, ICF International, Arlington, VA

11:50 AM-12:50 PM
Roundtable Discussion, Ivan Rusyn, Moderator, Kristi Jacobs, All Speakers
Threshold of Toxicological Concern Approach in Regulatory Decision-Making: The Past, Present, and Future

Grace Patlewicz
National Center for Computational Toxicology
US EPA

tier.grace@epa.gov

The views expressed in this presentation are those of the author and do not necessarily reflect the views or policies of the US EPA
State of the Art in the Cramer Classification Scheme and Threshold of Toxicological Concern
Greg Cramer
Roundtable Discussion: State of the Art in the Cramer Classification Scheme and Threshold of Toxicological Concern

11:50 AM-12:50 PM

Ivan Rusyn, Moderator
Tim Adams
Kristi Jacobs
Grace (Tier) Patlewicz
Andrew Worth
Jessica Wignall

Questions welcome.
Colloquia

- Recordings
- Slides
- Captioning Text

are available at

www.toxicology.org