



SOT FDA Colloquia on Emerging Toxicological Science: Challenges in Food and Ingredient Safety

May 15, 2019

In Silico Methods for Food Ingredient, Dietary Supplement, and Cosmetic Safety

Wiley Auditorium, US FDA, CFSAN, College Park, MD • Live Webcast

Chair: Kirk Arvidson, US FDA, College Park, MD

Co-Chair: Chihae Yang, MN AM, Nurnberg, Germany

Food Safety Colloquia Series

The Society of Toxicology in conjunction with the US FDA Center for Food Safety and Applied Nutrition (CFSAN) have partnered to provide this colloquia series. The series presents scientific information that is high-quality, cutting-edge, future-oriented toxicological science to provide a well-grounded foundation to inform the work of US FDA employees. These sessions are open to the public to attend in person or via webcast. These events are not a public forum for discussion of toxicology regulatory issues.

This colloquium will feature the science behind new international trends in the *in silico* safety assessment of chemical exposure. Two common themes shared by international regulatory bodies are the critical issues involved in alternative methods to animal testing and the rigorous treatment of uncertainties to obtain reproducible and transparent weight-of-evidence approaches to decision making. For alternative methods to repeated-dose toxicity, toxicokinetics and metabolism are emphasized to understand chemical exposure and bioavailability. Biokinetics is further being applied to data-waiving methods such as the Threshold of Toxicological Concerns (TTC). Internal TTC is a TTC concept for situations of low internal exposure, where this value is more relevant than the external exposure. Development of internal TTCs requires a significant amount of data and computational tools (e.g., PBPK modeling) to convert the chemical specific external doses (i.e., NOAELs) in the TTC databases into an estimate of the internal exposure. The common concerns related to the relevance of *in silico* chemical safety assessment that may hinder its adoption if not properly addressed will be discussed.

Schedule (All times are Eastern US, GMT-4)

8:00 AM–8:30 AM	Badge Pick Up
8:30 AM–8:40 AM	Welcome Suzanne Fitzpatrick , US FDA, CFSAN, College Park, MD
	Speaker Introductions Kirk Arvidson , US FDA, College Park, MD
8:40 AM–9:20 AM	Drivers for the Application and Acceptance of <i>In Silico</i> Safety Assessment Based on Chemical Exposure Mark Cronin , Liverpool John Moores University, Liverpool, UK
9:20 AM–10:00 AM	Identifying, Estimating, and Communicating Uncertainty within <i>In Silico</i> Approaches to Chemical Safety Assessment James F. Rathman , The Ohio State University, Columbus, OH
10:00 AM–10:20 AM	Break
10:20 AM–11:00 AM	A Case Study on PBPK and Biologically Based Dose-Response Modeling for Safety Assessment Considerations: Utility and Challenges Annie Lumen , NCTR, Jefferson, AR
11:00 AM–11:40 AM	Transformation of Threshold of Toxicological Concerns (TTC) to Internal TTC: Why Internal Exposure Matters and How We Will Get There Corie Ellison , Procter and Gamble, West Chester, OH
11:45 AM–12:45 PM	Roundtable Discussion Moderator: Kirk Arvidson , US FDA, College Park, MD Chihae Yang , MN AM, Nurnberg, Germany All speakers

Organizing Committee

Allen Rudman, PhD, Colloquium Series Chair, US FDA, College Park, MD

Jia-Sheng Wang, MD, PhD, Colloquium Series Co-Chair, University of Georgia, Athens, GA

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Anne H. Chappelle, PhD, DABT, Council Contact, International Isocyanate Institute, Chadds Ford, PA

Betty Eidemiller, PhD, SOT Staff, Reston, VA

Future Colloquia Topics

October 2019 Integrated Approaches to Testing and Assessment

December 2019 Dermal Absorption Concepts

February 2020 Route-Route Extrapolation

April 2020 Use of Artificial Intelligence/Big Data in Food Additive, Ingredient, and Cosmetics Evaluation

Most Recent Colloquia

- **Alternative Methods for Predictive Safety Testing: 3D Bioprinted Tissue Models**
- **Redesigning the Rodent Bioassay for the 21st Century**
- **Food from Genetically Engineered Plants: What Role for Metabolomics?**
- **Can Alternatives Inform the Risk Assessments of Mixtures in Food?**
- ***In Vitro* to *In Vivo* Concordance for Toxicity Prediction and Use in Safety Assessments**
- **Safety Assessment of Food Packaging and Other Food Contact Substances**
- **Considerations for the Determination of Adversity in Food Chemical Safety Evaluations**
- **Application of *In Vitro* to *In Vivo* Extrapolation in Safety Assessment**
- **State of the Science in Developmental Neurotoxicology**

.....plus 8 additional diverse topics, and other learning opportunities,
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