



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

January 25, 2016

Role of Mode of Action in Dose-Response Assessment for Carcinogens

Suzanne Fitzpatrick, Chair, US FDA, College Park, MD • Ji-Eun Lee, Co-Chair, Kellogg, Battle Creek, MI

Food Safety Colloquia Series

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

Schedule

8:00 AM–8:30 AM	Badge Pick Up Meeting Desk
8:30 AM–8:40 AM	Welcome and Overview Suzanne Fitzpatrick, US FDA/CFSAN, College Park, MD
8:40 AM–9:20 AM	The Role of Mode of Action in Dose-Response Assessments: Recommendations from the 2009 NRC Report “Science and Decisions” Lauren Zeise, NRC Committee Member, Oakland, CA
9:20 AM–10:10 AM	Mode of Action, Distinguishing between Mode of Mechanism of Action, and Some Key Events for MOA Michael Dourson, TERA, Cincinnati, OH
10:10 AM–10:25 AM	Break
10:25 AM–11:05 AM	The Mutagenic Mode of Action and the Choices for the Dose-Response Analysis Rita Schoeny, US EPA (retired), Washington, DC
11:05 AM–11:45 AM	Risk21 Quantitative Key Events Dose-Response Framework J. Craig Rowlands, Dow Chemical Company, Midlands, MI
11:45 AM–12:50 PM	Roundtable Discussion Elaine Faustman, University of Washington, Seattle, WA, Moderator All Speakers
1:00 PM–2:00 PM	Informal Lunch for Speakers and FDA Employees Room 2A-023 (Bring your own lunch) FDA employees are welcome up to the capacity of the room.

FDA, College Park, Maryland • Live Webcast

Organizing Committee

Ivan Rusyn, MD, PhD, Colloquia Series Chair, Texas A&M University, College Station, TX
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Catherine Whiteside, PhD, US FDA, CFSAN, College Park, MD
Norbert E. Kaminski, PhD, SOT Council Contact, Michigan State University, East Lansing, MI
Dan Levy, PhD, US FDA, CFSAN, College Park, MD, for this colloquium

Other SOT FDA Colloquia

Upcoming Colloquia

**State of the Art in the Cramer Classification Scheme and
Threshold of Toxicological Concern, March 29, 2016**

Safety Assessment Approaches to Sensitive Subpopulations, April/May 2016

Previous Colloquia

Recordings and Materials available at: <http://www.toxicology.org/fda>

**A Path Forward for Using Computational and *In Vitro* Methods for
Food Ingredient Assessments, October 13, 2015**

Contemporary Issues in Risk Assessment, June 17, 2015

**Immunotoxicology in Food and Ingredient Safety Assessment:
Approaches and Case Studies, April 14, 2015**

**Application of ADME/PK Studies to Improve Safety Assessments for
Foods and Cosmetics, February 23, 2015**

**Complexities in Evaluating Human Clinical and Observational Data for Ingredient Safety
Assessment: Partially Hydrogenated Oils (PHOs) As a Case Study, November 7, 2014**

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