



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

**March 27, 2017—Considerations for the Determination
of Adversity in Food Chemical Safety Evaluations**

US FDA, Wiley Auditorium, College Park, Maryland • Live Webcast

**Bernadene Magnuson, Chair, PhD, ATS, Health Science Consultants, Inc.,
Mississauga, ON, Canada**
**Sabine Francke, Co-chair, DVM, PhD, Fellow IATP, CFSAN, US FDA, College Park,
MD**

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 US 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 (All times are Eastern US, GMT-5)

8:00 AM–8:30 AM Badge Pick Up, Meeting Desk

8:30 AM–8:35 AM **US FDA Welcome and Overview**
**Suzanne Fitzpatrick, PhD, DABT, CFSAN, US FDA, College
Park, MD**

8:35 AM–8:50 AM **Welcome from SOT and Introductions**
**Peter L. Goering, PhD, SOT Past President, US FDA, Silver
Spring, MD**

**Speaker Introductions: Bernadene Magnuson, Chair, PhD,
ATS, Health Science Consultants, Inc., Mississauga, ON, Canada;**
**Sabine Francke, Co-chair, DVM, PhD, Fellow IATP, CFSAN, US
FDA, College Park, MD**

8:50 AM–9:30 AM **Adversity in Regulatory Science: Historical Perspective and
Future Challenges**
**Nigel J. Walker, PhD, DABT, Deputy Division Director for
Research, Division, National Toxicology Program, National
Institute of Environmental Health Sciences, National Institutes of
Health, Research Triangle Park, NC**

9:30 AM–10:10 AM **When is Adversity Legally Cognizable?**
**Ricardo Carvajal, JD., MS, Hyman, Phelps & McNamara, P.C.
Washington, DC**

10:10 AM–10:30 AM Break

10:30 AM–11:10 AM **No Observed Adverse Effect Level: Sucralose as a Case Study**
Bernadene Magnuson, PhD, ATS, Health Science Consultants, Inc., Mississauga, ON, Canada

11:10 AM–11:50 AM **New Approaches to Adversity Assessment in Food Safety Evaluation**
Daniel Krewski, PhD, MHA, NSERC Chair in Risk Science, Professor and Director, McLaughlin Centre for Population Health Risk Assessment, University of Ottawa, Ottawa, ON, Canada

11:50 AM–12:50 PM **Roundtable Discussion**
Moderator, **Bernadene Magnuson**, PhD, ATS

1:00 PM–2:00 PM **Informal Lunch for Speakers and US FDA Employees**
Room 1A001 (Bring your own lunch) US FDA employees are welcome up to the capacity of the room.

US FDA, College Park, Maryland • Live Webcast

Organizing Committee

Ivan Rusyn, MD, PhD, Colloquia Series Chair, Texas A&M University, College Station, TX

Jason L. Aungst, PhD, US FDA, CFSAN, College Park, MD

Bryan Delaney, PhD, DABT, ATS, DuPont Pioneer, Johnston, IA

Suzanne Compton Fitzpatrick, PhD, DABT, US FDA, CFSAN, College Park, MD

Norbert E. Kaminski, PhD, Michigan State University, East Lansing, MI

Jieun Lee, PhD, DABT, Kellogg, Battle Creek, MI

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Jeffrey J. Yourick, PhD, DABT, ATS, US FDA, CFSAN, Toxicology Branch, Laurel, MD

Peter L. Goering, PhD, DABT, ATS, SOT Council Contact, US FDA, CDRH, Silver Spring, MD

Bernadene Magnuson, Colloquium Chair, ATS, Health Science Consultants, Inc., Mississauga, ON, Canada

Sabine Francke, Colloquium Co-chair, DVM, PhD, Fellow IATP, CFSAN, US FDA, College Park, MD

Other SOT FDA Colloquia

May 23, 2017

Safety Assessment of Food Packaging and Food Contact Substances

Previous Colloquia

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

Application of *In Vitro* to *In Vivo* Extrapolation in Safety Assessment

State of the Science in Developmental Neurotoxicology

Safety Assessment Approaches in Young Children

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

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

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 (PHOs) As a Case Study

Visit **www.toxicology.org** to explore other learning opportunities.

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