

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



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

January 25, 2016



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

Welcome and Overview

Suzanne Compton Fitzpatrick, PhD, DABT

Center for Food Safety and Nutrition

College Park, MD



SOT | Society of
Toxicology



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Dr. Susan Mayne

@DrMayneFDAFood

Director, FDA's Center for Food Safety and Applied Nutrition, Scientist, public health professional, mom, wife, and yes, pragmatic optimist!

fda.gov/Food

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Tweets Tweets & replies Photos & videos



Dr. Susan Mayne @DrMayneFDAFood · Mar 12

Great article by @NCState about why we all need to be concerned and informed about foodborne illnesses! bit.ly/1wyi87p #foodsafety



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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



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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



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Participation Summary 2014-2015

	PHOs	ADME	Immuno- tox	Risk Assmnt	Computa- tional	Total
	Nov. 7	Feb. 23	April 14	June 17	October 13	
On-Site	95	48	71	70	81	269
Webcast	239	201	193	337	270	970
Total	334	249	264	392	351	1239



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Future Colloquia 2016

- | | |
|------------------|--|
| March 29 | State of the Art in the Cramer Classification Scheme and Threshold of Toxicological Concern |
| April/May | Safety Assessment Approaches to Sensitive Subpopulations |

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

Ji-Eun 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

Dan Levy, PhD, US FDA, CFSAN, College Park, MD, for this colloquium



Agenda

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, Berkeley, CA

9:20 AM–10:10 AM

Mode of Action, Distinguishing between Mode and Mechanism of Action, and Some Key Events for MOA, Michael Dourson, TERA, Cincinnati, OH

10:25 AM–11:05

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 PM

Risk21 Quantitative Key Events Dose-Response Framework, J. Craig Rowlands, Dow Chemical Company, Midlands, MI

11:40 AM–12:50 PM

Roundtable Discussion, Elaine Faustman, Moderator, All Speakers





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Moderator

**Elaine Faustman, PhD
University of Washington,
Seattle, WA**



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Colloquium January 29, 2016

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