



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

Welcome and Overview

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FRSB, ERT**

Senior Advisor for Toxicology

Office of the Center Director

CFSAN US FDA, College Park, MD





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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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Welcome from SOT

Peter L. Goering, PhD, DABT, ATS

Past President, Society of Toxicology

SOT | Society of
Toxicology



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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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Ten Previous Colloquia: Topics

- Overview and Principles Underpinning *In Vitro* to *In Vivo* Extrapolation
- State of the Science in Developmental Neurotoxicology
- Safety Assessment Approaches in Young Children
- Cramer Classification and Threshold of Toxicological Concern
- Mode of Action in Dose-Response Assessment for Carcinogens
- Computational and *In Vitro* Methods for Assessments
- Contemporary Issues in Risk Assessment
- Immunotoxicology in Safety Assessment
- ADME/PK Studies to Improve Safety Assessments
- Clinical and Observational Data for Safety Assessment: Partially Hydrogenated Oils



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SOT- FDA MOU Signed will Extend Colloquium Series

December 5, 2016 – Signing Ceremony with representatives from SOT and US FDA to renew the SOT-FDA Memorandum of Understanding that facilitates collaborative efforts in training, education, professional development, and innovative toxicology methods and regulatory science.





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Upcoming Colloquia

- **Safety Assessment of Food Packaging and Food Contact Substances**

May 23, 2017

US FDA, College Park, Maryland and Live Webcast

- Chair: Charles Barton, PhD, DABT, Valspar, Manager of Toxicology & Risk Assessment (Global)
- Co-chair: Jason Aungst, PhD, FDA/CFSAN/OFAS Division of Food Contact Notifications Toxicology Supervisor

SOT FDA Organizing Committee

Ivan Rusyn, MD, PhD, Committee 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 Kaminski, PhD, Michigan State University, East Lansing, MI

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

Allen Rudman, PhD, FDA Lead, US FDA, CFSAN, College Park, MD

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

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

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

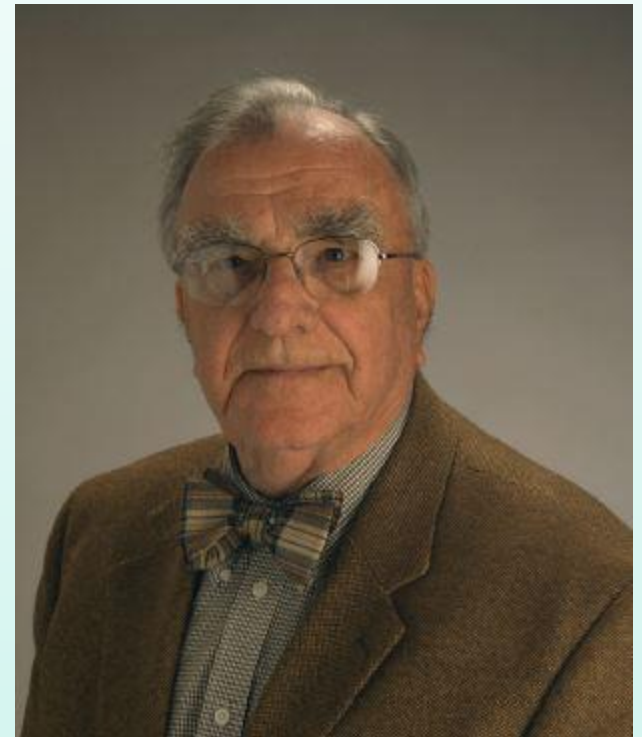
Sabine Francke, DVM, PhD, IATP, Colloquium Co-chair CFSAN, US FDA, College Park, MD



In Memoriam

John Doull, MD, PhD

- Emeritus Professor, Kansas University Medical Center
- Founding co--editor of Casarett and Doull's *Toxicology: The Basic Science of Poisons*
- 26th president, Society of Toxicology (1986-87)
- A founder of the discipline of toxicology in the modern era
- *"Toxicology is what we do; risk assessment is why we do it."*





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Colloquium Leads

Chair: Bernadene Magnuson, PhD, ATS
Health Science Consultants, Mississauga,
ON, Canada

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

Agenda

8:50 AM–9:30 AM

- **Adversity in Regulatory Science: Historical Perspective and Future Challenges**

Nigel J. Walker, National Institute of Environmental Health Sciences, Research Triangle Park, NC

9:30 AM–10:10 AM

- **When is Adversity Legally Cognizable?**

Ricardo Carvajal, Hyman, Phelps & McNamara, P.C., Washington, DC

10:30 AM-11:10 AM

- **No Observed Adverse Effect Level: Sucralose as a Case**
Bernadene Magnuson, Health Science Consultants, Mississauga, ON Canada,

11:10 AM-11:50 AM

- **New Approaches to Adversity Assessment in Food Safety Evaluation**
Daniel Krewski, University of Ottawa, Ottawa, Canada

11:50 AM-12:50 PM

- **Roundtable Discussion**, Bernadene Magnuson, Moderator

