

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



## **State of the Science in Developmental Neurotoxicology**

**October 12, 2016**



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

## Welcome

**Mickey Parish, PhD**

Acting Director, Senior Science Advisor Staff  
CFSAN, US FDA, College Park, MD





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

## 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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## Eight Previous Colloquia: Topics

- 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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## Survey Feedback—All 8 Colloquia

	Excellent + Good
Overall session quality	95%
Amount of time devoted to the topic	97%
Relevancy of content for my work	84%
Appropriate depth of content	91%
Match of colloquium to my expectations	89%
Overall session quality	95%

N=478





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

## **Feedback: Safety Assessment Approaches in Young Children May 20, 2016**

- This was one of the most useful webcasts I have attended in terms of the speaker's presentation skills and the presentation of useful information.
- Speakers were great choices and presentations were very well done.
- These colloquia address my training needs and are on a diverse set of topics related to toxicology. Please keep this series going for as long as possible.



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## Feedback: Safety Assessment Approaches in Young Children May 20, 2016 (continued)

- I have attended all of the colloquia to date via the web. I have generally been impressed with the quality of the presentations.
- These colloquium are an excellent opportunity to extend continuing education and professional development opportunities to the people who do not have funding to attend meetings or special topics in person. It is a marvelous chance to hear thought leaders in the subject matter give updates and opinions.
- An excellent initiative.

# 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

**Timothy J. Shafer, PhD**, Colloquium Chair, US EPA, Research Triangle Park, NC

**Yen-Ching Wu, BA, PhD**, for this colloquium, US FDA, CSFAN, College Park, MD





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## **Colloquium Leads**

**Chair: Timothy J. Shafer, PhD**

US EPA, Research Triangle Park, NC

**Co-chair: Jeffrey J. Yourick, PhD,  
DABT, ATS**

US FDA, CFSAN, Laurel, MD

# Agenda

• 8:50 AM–9:30 AM

**Developmental Neurotoxicity Testing: An Introduction to the State of the Science and Opportunities for Improvement**, Charles V. Vorhees, Cincinnati Children's Hospital Research Foundation, Cincinnati, OH

• 9:30 AM–10:10 AM

**Zebrafish as an Alternative Species for Developmental Neurotoxicity Testing that can Provide Hazard Identification and Mechanistic Information**, Randall T. Peterson, Harvard University, Boston, MA

10:30 AM-11:10 AM

• **In Vitro Approaches to Screening Compounds for Developmental Neurotoxicity Hazard**, Ellen Fritsche, University of Düsseldorf, Düsseldorf, Germany

11:10 AM-11:50 AM

• **Adverse Outcome Pathways for Developmental Neurotoxicity**, Anna K. Price, ECVAM, Ispra, Italy

11:50 AM-12:50 PM

• **Roundtable Discussion**, Timothy Shafer, Moderator, Jason, Aungst, All Speakers





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## **Developmental Neurotoxicity Testing: An Introduction to the State of the Science and Opportunities for Improvement**

**Charles V. Vorhees**

Cincinnati Children's Hospital Research Foundation  
Cincinnati, OH