

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



Route-to-Route Extrapolation in the 21st Century

February 19, 2020

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

Welcome and Overview

Jason Aungst, PhD

Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
US Food and Drug Administration

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Colloquium Series

- **Partnership of US FDA Center for Food Safety and Applied Nutrition (CFSAN) and the Society of Toxicology (SOT)**
- **Stimulate a dialogue among leading toxicology experts on future-oriented toxicological science relevant to food and food ingredient safety assessment**
- **Information for FDA employees and the public**
- **Not a forum for soliciting regulatory advice or discussing food or food ingredient regulatory issues**
- **Are a forum to discuss the latest toxicological science in the context of food chemical safety**

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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**

Among 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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SOT FDA Colloquium Website

- Resource for 24/7 learning
- <http://www.toxicology.org/events/shm/fda/fda.asp>

SOT FDA Colloquia



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

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

In 2014, SOT and the US FDA Center for Food Safety and Applied Nutrition (CFSAN) began a partnership to present colloquia designed to present high-quality, cutting-edge, future-oriented toxicological science to provide a well-grounded foundation to inform the work of US FDA employees. These colloquia are open at no cost to all who are interested. Recordings and materials are available after the events and can be found below.

Topics for 2020

February 19: Route-to-Route Extrapolation in the 21st Century

• Registration for on-site participation closed February 11. Federal employees may register at the event.

• Webcast Registration

April 29: Artificial Intelligence in Food and Cosmetic Safety

May: Integrated Approaches to Testing and Assessment (IATA)—The Future of Predictive Toxicology (Webcast only)

Open All

Dermal Absorption and Toxicity: Concepts for Application to Safety Assessment—December 12, 2019



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SOT FDA Colloquium Organizing Committee

Allen Rudman, PhD, Committee Chair, College Park, MD

Jia-Sheng Wang, MD, PhD, Committee Co-chair, University of Georgia, Athens, GA

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

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

A. Wallace Hayes, PhD, DABT, ERT, ATS, FRSB, FACFE, University of South Florida and Michigan State University, Temple Terrace, FL

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

Stephen M. Roberts, PhD, University of Florida, Gainesville, FL

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

Anne H. Chappelle, PhD, DABT, SOT Council Contact, Chadds Ford, PA

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Route-to-Route Extrapolation in the 21st Century

Times ET, GMT-5

8:30 AM–8:40 AM	<p>Welcome, Overview Jason L. Aungst, US FDA, College Park, MD</p> <p>Speaker Introductions Harvey J. Clewell, III, Ramboll, Research Triangle Park, NC</p>
8:40 AM–9:15 AM	<p>Introduction to Route-to-Route Exposure Harvey J. Clewell, III, Ramboll, Research Triangle Park, NC</p>
9:15 AM–9:50 AM	<p>OECD Guidance on the Characterization, Validation, and Reporting of Physiologically Based Kinetic (PBK) Models Alicia Painsi, European Commission's Joint Research Centre, Ispra, Italy (via webcast)</p>
9:50 AM–10:25 AM	<p><i>In Vitro</i> to <i>In Vivo</i> Extrapolation of Metabolism Data to Support Physiologically Based Modeling for Route-to-Route Extrapolation John C. Lipscomb, CTEH, North Little Rock, AR</p>
10:25 AM–10:40 AM	Break



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10:40 AM–11:15 AM	<p>Determination of an Internal Margin of Exposure Between Rodent Oral and Human Dermal Exposures to Phenoxyethanol using Physiologically Based Modeling John Troutman, Procter and Gamble, Cincinnati, OH</p>
11:15 AM–11:50 AM	<p>Examples of Route-to-Route Extrapolation Conducted at the FDA Center for Food Safety and Nutrition Shruti V. Kabadi, US FDA, College Park, MD</p>
11:50 AM–12:50 PM	<p>Roundtable Discussion Moderator: Harvey J. Clewell, III, Ramboll, Research Triangle Park, NC All Speakers Jeffrey Fisher (via webcast)</p>



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Speaker Introductions

Harvey J. Clewell, III, PhD

Colloquium Chair
Ramboll
Research Triangle Park, NC



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