

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



Dermal Absorption and Toxicity: Concepts for Application to Safety Assessment

December 12, 2019



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

Welcome, Overview, and Speaker Introductions

Jeffrey Yourick, PhD

Division of Toxicology

Office of Applied Research and Safety Assessment

Center for Food Safety and Applied Nutrition

US Food and Drug Administration





Welcome, Overview, and Speaker Introductions

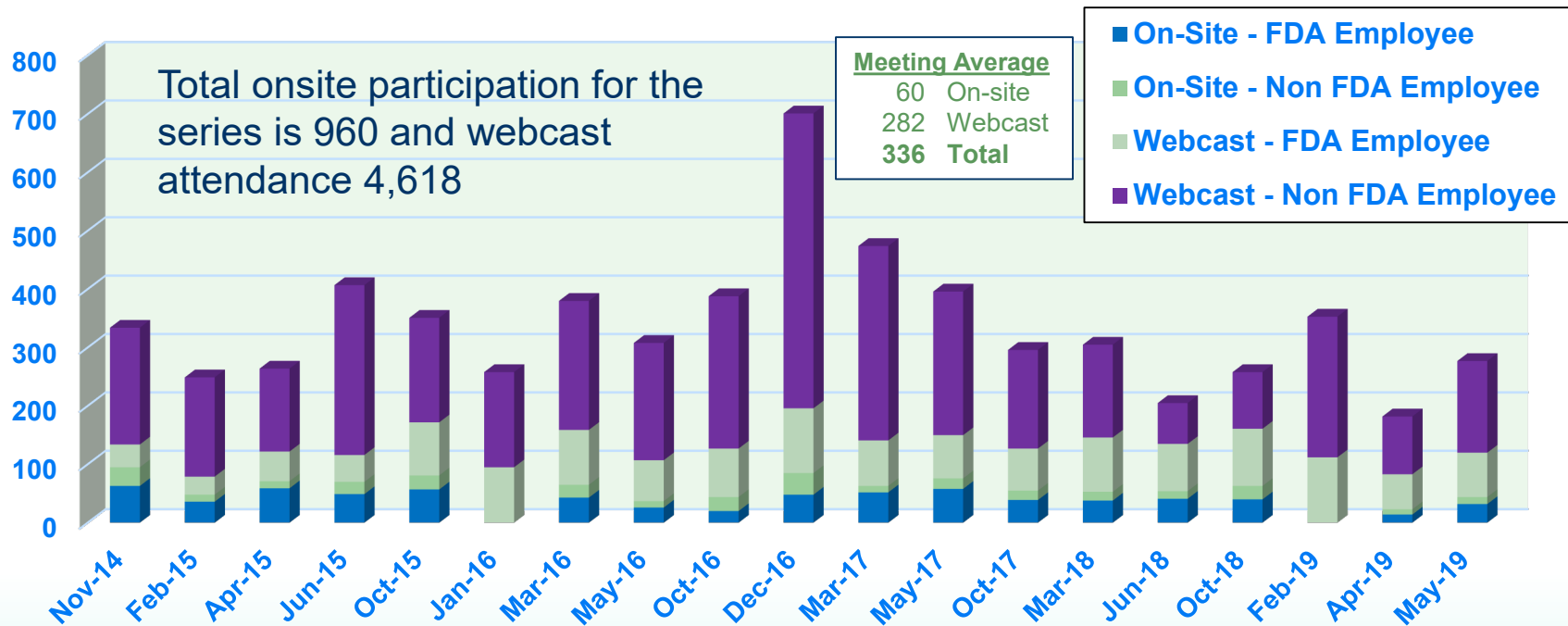
- Society of Toxicology and US FDA Center for Food Safety and Applied Nutrition (CFSAN) have partnered to provide this colloquia series.
- Provide high-quality, cutting-edge, future-oriented toxicological science
- Provide well-grounded foundation to inform the work of US FDA employees.



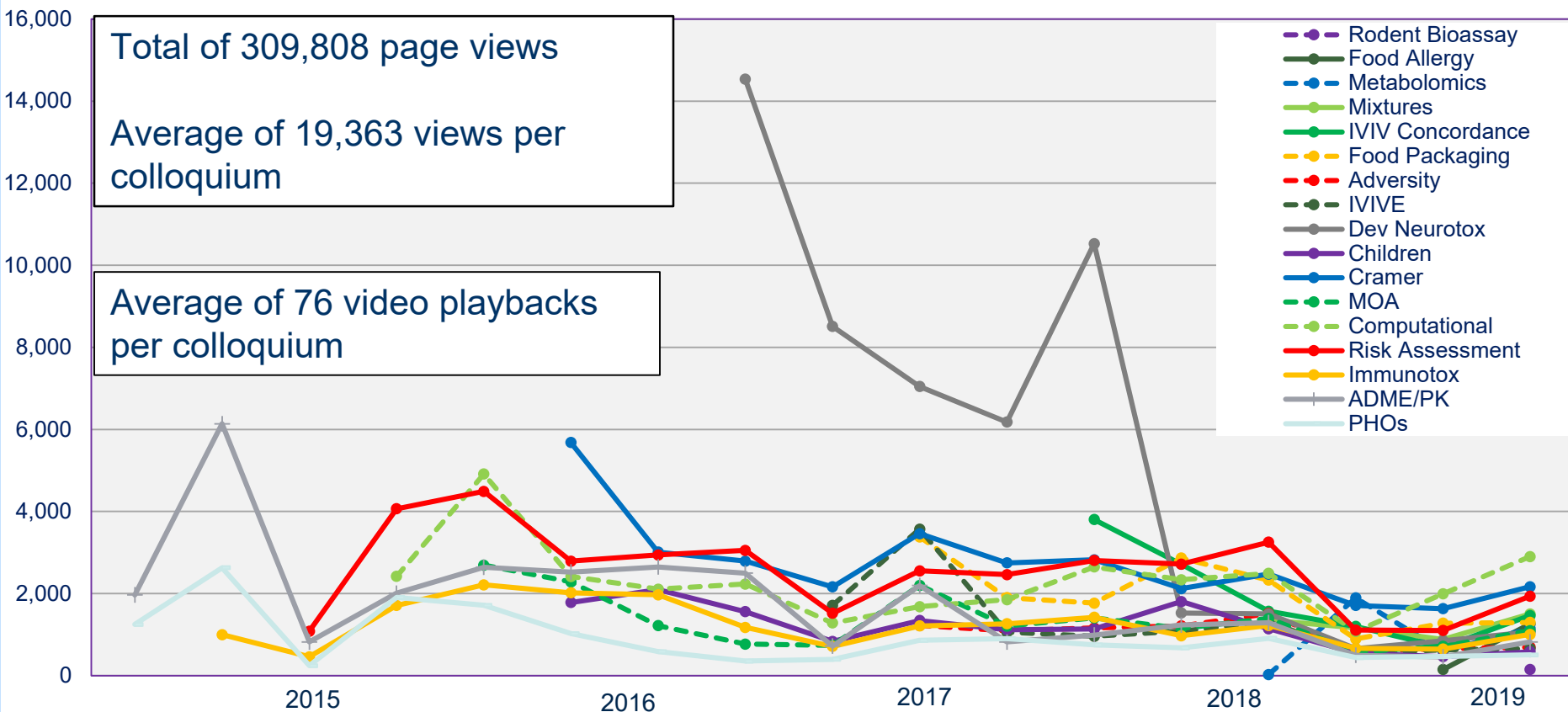
Welcome, Overview, and Speaker Introductions

- These colloquia are open to the public to attend in person or via webcast.
- These colloquia are not a public forum for discussion of toxicology regulatory issues.

SOT FDA Colloquium Attendance (all 5 years)



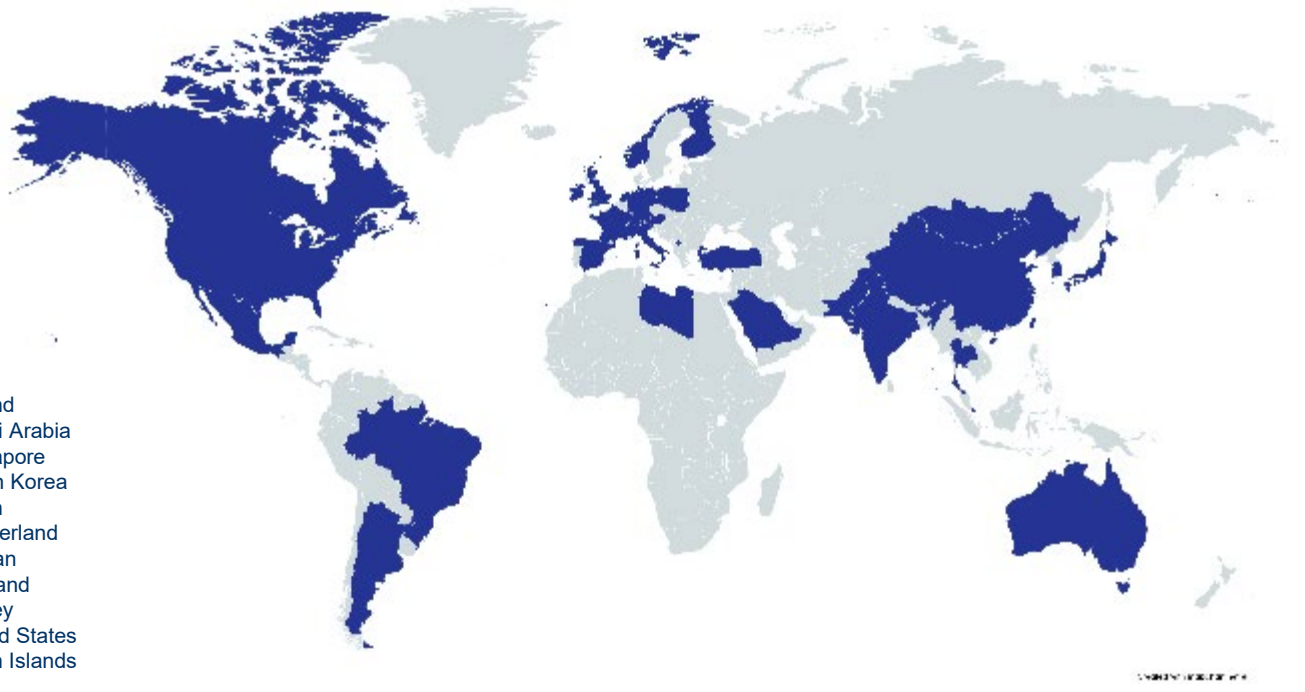
Colloquium Material Page Views



2018-2019 Webcast Registration by Country

34 Countries

Argentina
Australia
Austria
Belgium
Brazil
Canada
China
Denmark
Finland
France
Germany
Great Britain/UK
Hong Kong
India
Italy
Japan
Libya
Macedonia
Mexico
Mongolia
Netherlands
Norway
Pakistan
Poland
Saudi Arabia
Singapore
South Korea
Spain
Switzerland
Taiwan
Thailand
Turkey
United States
Virgin Islands

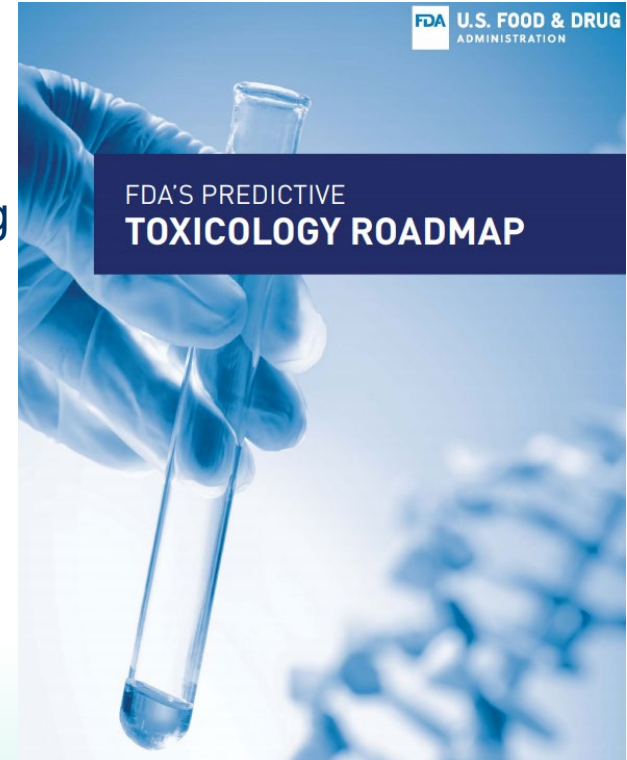


FDA's Predictive Toxicology Roadmap

Roadmap Goals:

- Foster the development and evaluation of emerging toxicological methods and new technologies
- Incorporate these methods and technologies into regulatory review, as applicable.

<https://www.fda.gov/science-research/about-science-research-fda/fdas-predictive-toxicology-roadmap>



Division of Toxicology – CFSAN/Office of Applied Research and Safety Assessment (OARSA)



Key Research Initiatives:

- Stem cell models for tox testing
- Dermal and buccal absorption
- *In vitro* renal and gastrointestinal models
- Liver organ chip -hepatotoxicity
- Bioprinting
- *In silico* models for tox testing
- Alternative animal models



Future
Direction



Integrate/apply modern toxicological approaches to support regulatory/public health decision-making on chemical hazards in foods, dietary supplements and cosmetics





Today's Colloquium-Dermal Absorption and Toxicity: Concepts for Application to Safety Assessment

- Dermal absorption information is needed to conduct a realistic exposure assessment for a chemical that contacts skin.
- Safety evaluation begins with an estimate of dermal human exposure.
- Dermal exposure is a function of:
 - the amount of chemical applied to the skin
 - the duration of skin contact
 - area of body contact
 - chemical physio-chemical properties
 - extent of dermal absorption.



Today's Colloquium-Dermal Absorption and Toxicity: Concepts for Application to Safety Assessment, cont.

- This colloquium will explore how different factors can affect the extent of dermal absorption.
- A reasonable dermal estimate of human exposure can be calculated if the extent of skin absorption is realistically determined.

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

8:00 AM–8:30 AM

Badge Pick Up

8:30 AM–8:40 AM

Welcome, Overview, and Speaker Introductions

Jeffrey Yourick, US FDA, Laurel, MD

8:40 AM–9:15 AM

Introduction to the Comparative Anatomical Factors Affecting Topical Skin Delivery

Nancy Monteiro-Riviere, North Carolina State University, Raleigh, NC; and Kansas State University, Manhattan, KS

9:15 AM–9:50 AM

Simulation and Modeling of Dermal Absorption Kinetics: What Level of Detail is Needed?

Gerald Kasting, University of Cincinnati, Cincinnati, OH

9:50 AM–10:25 AM

Assessing Mixture and Formulation Influence on Skin Absorption

Ronald Baynes, North Carolina State University, Raleigh, NC

10:25 AM–10:40 AM

Break

10:40 AM–11:15 AM

Cutaneous Metabolism and Its Importance for Skin Permeation and Toxicity

Simon Charles Wilkinson, Newcastle University, Newcastle upon Tyne, United Kingdom

11:15 AM–11:50 AM

Practical Considerations for Incorporating Skin Penetration Data into a Risk Assessment for a Consumer Product Launch

Timothy McCarthy, Johnson and Johnson, Skillman, NJ

11:50 AM–12:50 PM

Roundtable Discussion

Moderator: Nancy Monteiro-Riviere, North Carolina State University, Raleigh, NC; and Kansas State University, Manhattan, KS

All Speakers

Nakissa Sadrieh, US FDA, College Park, MD

SOT- Dermal Toxicology Specialty Section

- Dermal Toxicology Specialty Section (DTSS)
- Mission – DTSS provides a forum for the interaction of individuals involved in risk assessment, pharmacokinetics, dermal penetration/absorption, hypersensitivity and dermal toxicity, regulatory issues, basic skin biology, and other professionals working in the field of dermal research.
- More information on DTSS:
<https://www.toxicology.org/groups/ss/DTSS/mission.asp>





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

Welcome

**Nancy Monteiro-Riviere, PhD
Colloquium Chair**

Enjoy the Colloquium!

SOT FDA Organizing Committee

Allen Rudman, PhD, Colloquium Series Chair, US FDA, College Park, MD

Jia-Sheng Wang, MD, PhD, Colloquium Series Co-Chair, University of Georgia, Athens, GA

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

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

A. Wallace Hayes, University of South Florida and Michigan State University, Temple Terrace, FL

Jieun Lee, PhD, DABT, CJ Foods, Inc., LaPalma, CA

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

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

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

Betty Eidemiller, PhD, SOT Staff, Reston, VA

