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

The Toxicology of Nanoparticles

April 8, 2021

Welcoming Remarks

George Daston, PhD

President, Society of Toxicology

Procter & Gamble Company

Colloquium Series

- Partnership of US FDA Center for Food Safety and Applied Nutrition (CFSAN) and the Society of Toxicology (SOT)
- Sixth year of colloquia series, two this year, and this is the 25th event
- Stimulate dialogue among leading toxicology experts on future-oriented toxicological science relevant to food and food ingredient safety assessment
- Provide well-grounded foundation to inform the work of US FDA employees and others
- Not a forum for soliciting regulatory advice or discussing food or food ingredient regulatory issues

Colloquium Series

- These colloquia are open to the public via webcast at no cost
- Global audience from all employment sectors
- Recording and slides for all the colloquia are available at www.toxicology.org

Society of Toxicology Vision/Mission

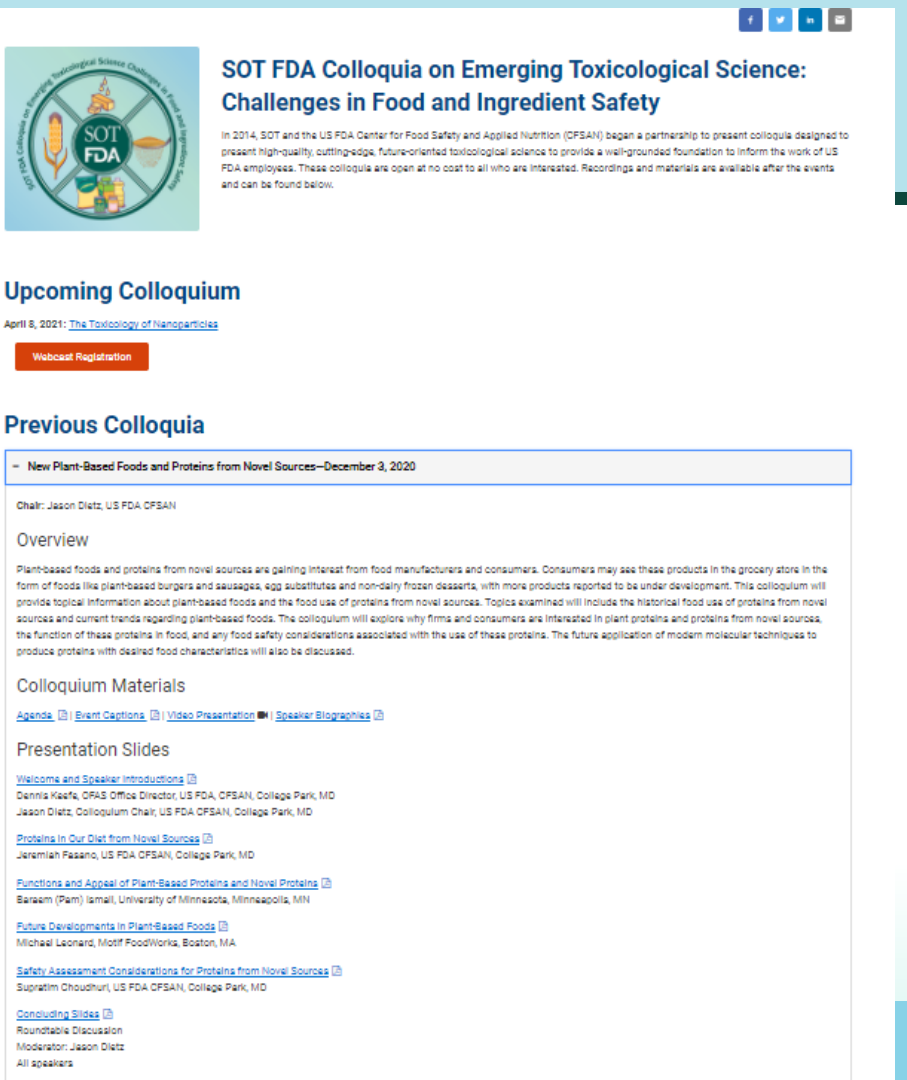
To Create a Healthier and Safer World by Advancing the Science and Increasing the Impact of Toxicology

Among Strategic Objectives

- Promote Transdisciplinary Science and Cooperation with Other Disciplines
- Expand Global Outreach, Engagement, and Collaboration
- Provide Opportunities to Capitalize on Scientific Advancements
- Develop Communication Partnerships with Key Influencers
- Promote Use of Science in Decision Making

SOT FDA Colloquium Website

- Resource for 24/7 learning
- www.toxicology.org



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

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.

Upcoming Colloquium

April 8, 2021: The Toxicology of Nanoparticles

Webcast Registration

Previous Colloquia

– New Plant-Based Foods and Proteins from Novel Sources—December 3, 2020

Chair: Jason Dietz, US FDA CFSAN

Overview

Plant-based foods and proteins from novel sources are gaining interest from food manufacturers and consumers. Consumers may see these products in the grocery store in the form of foods like plant-based burgers and sausages, egg substitutes and non-dairy frozen desserts, with more products reported to be under development. This colloquium will provide topical information about plant-based foods and the food use of proteins from novel sources. Topics examined will include the historical food use of proteins from novel sources and current trends regarding plant-based foods. The colloquium will explore why firms and consumers are interested in plant proteins and proteins from novel sources, the function of these proteins in food, and any food safety considerations associated with the use of these proteins. The future application of modern molecular techniques to produce proteins with desired food characteristics will also be discussed.

Colloquium Materials

Agenda | Event Captions | Video Presentation | Speaker Biographies

Presentation Slides

Welcome and Speaker Introductions
Dennis Keefe, OFAS Office Director, US FDA, CFSAN, College Park, MD
Jason Dietz, Colloquium Chair, US FDA CFSAN, College Park, MD

Proteins in Our Diet from Novel Sources
Jeremiah Fasano, US FDA CFSAN, College Park, MD

Functions and Appeal of Plant-Based Proteins and Novel Proteins
Bareem (Pam) Ismail, University of Minnesota, Minneapolis, MN

Future Developments in Plant-Based Foods
Michael Leonard, Motif FoodWorks, Boston, MA

Safety Assessment Considerations for Proteins from Novel Sources
Supratim Choudhuri, US FDA CFSAN, College Park, MD

Concluding Slides
Roundtable Discussion
Moderator: Jason Dietz
All speakers

SOT FDA Organizing Committee

- **Jia-Sheng Wang**, MD, PhD, Colloquium Committee Chair, University of Georgia, Athens, GA
- **Udayan Apte**, PhD, DABT, Colloquium Committee Co-chair, University of Kansas Medical Center, Kansas City, KS
- **Jason L. Aungst**, PhD, FDA Liaison, US FDA, College Park, MD
- **Omari Bandele**, PhD, US FDA, College Park, MD
- **Stephen W. Edwards**, PhD, RTI International, Chapel Hill, NC
- **Suzanne C. Fitzpatrick**, PhD, DABT, US FDA, College Park, MD
- **A. Wallace Hayes**, PhD, DABT, ERT, ATS, FRSB, FACFE, University of South Florida and Michigan State University, Temple Terrace, FL
- **Stephen M. Roberts**, PhD, University of Florida, Gainesville, FL
- **Mary Beth Genter**, PhD, SOT Council Contact, University of Cincinnati, Cincinnati, OH

Overview and Speaker Introductions

Richard Canady, PhD
NeutralScience LC3

Schedule (times Eastern US UTC-4)

9:10 AM	**Lessons Learned from Nanomaterial Characterization: Critical Quality Attributes that Influence Biological Properties** Anil Patri, NCTR, Jefferson, AK
9:45 AM	**Standard Dose Measurement for Nanomaterials: What to Include in Exposure and Toxicity so That We Can Bound Dose Estimates for Safety?** Christie Sayes, Baylor University, Waco, TX
10:20 AM	**Break**
10:30 AM	**Dosing-Related Challenges in Toxicity Studies and Risk Assessment of Titanium Dioxide in Food** Walter Brand, RIVM, Bilthoven, The Netherlands
11:05 AM	**Practical Application to Regulatory Toxicology: Issues Faced in Consideration of Developing Health Guideline Values** Lynne Haber, University of Cincinnati Risk Science Center, Cincinnati, OH
11:40 AM	**Roundtable Discussion**, Moderator: Rick Canady, all speakers and panelists Agnes Oomen, RIVM; and Timothy Duncan, US FDA.
12:40 PM	**Conclusion**

Panelist Questions

To stimulate discussion, Drs. Agnes Oomen of NL RIVM and Timothy Duncan of US FDA reviewed the slide sets and offer the following questions.

We ask that you consider these questions during the speaker presentations. Drs. Oomen and Duncan will initiate the panel discussion based on one or more of their questions.

Agnes G. Oomen, PhD
National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands

1. Should well-dispersed nanomaterials be used for toxicity testing to cover worst case exposure situations?

2. How should we interpret toxicity studies in which there was some degree of agglomeration?

3. To which extent is information on toxicokinetics, e.g., internal exposure, needed to aid understanding the relationship between external exposure and hazard?

Timothy V. Duncan, PhD
US FDA, Bedford Park, IL

4. What are the key challenges that nano introduces to comparison of acceptable intake estimates to measured intake estimates?

5. What recommendations would you give for standardizing operational procedures to determine and report critical nano-toxicological and nano-exposure data?

6. Should the approach to safety assessment differ when a nanomaterial is intentionally added to a food vs. indirectly or unintentionally present?

7. Because key metrics like dose, identity, etc., are much more complicated for nanomaterials across concentrations and local conditions, should procedures be changed to ensure that allowable limits have enough of a safety margin?