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

February 20, 2019

Redesigning the Rodent Bioassay for the 21st Century

Wiley Auditorium, US FDA, CFSAN, College Park, MD
Chair: Suzanne Compton Fitzpatrick, US FDA, College Park, MD
Co-Chair: Warren M. Casey, NTP/NIEHS, Research Triangle Park, NC

Food Safety Colloquia Series

The Society of Toxicology in conjunction with the US FDA Center for Food Safety and Applied Nutrition (CFSAN) have partnered to provide this colloquia series. The series presents scientific information that is high-quality, cutting-edge, future-oriented toxicological science to provide a well-grounded foundation to inform the work of US FDA employees. These sessions are open to the public to attend in person or via webcast. These events are not a public forum for discussion of toxicology regulatory issues.

Today, toxicological evaluation of chemicals is beginning to take advantage of the on-going revolution in biology and biotechnology. This revolution is making it increasingly possible to study the effects of chemicals using cells, cellular components, and tissues—preferably of human origin—rather than whole animals. In carrying out its mission to protect and promote public health, US FDA must use the best scientific and technological information available to make decisions on the products it regulates. Regulators must assure their toxicology toolbox keeps pace with advances in science and technology. This workshop will discuss how one important toxicology tool, the rodent chronic bioassay, should be redesigned to meet the needs of 21st century risk assessment.

US FDA envisions that this workshop will be the beginning of an ongoing dialogue between stakeholders on the utility of the chronic rodent bioassay for regulatory risk assessment.

Schedule *(All times are Eastern US, GMT-4)*

8:00 AM–8:30 AM	**Badge Pick Up**
8:30 AM–8:45 AM	**US FDA Welcome and Overview** **Admiral Denise Hinton,** Chief Scientist, US FDA, Silver Spring, MD **SOT Welcome and Introductions** **Suzanne Compton Fitzpatrick,** US FDA, College Park, MD
8:45 AM–9:25 AM	**The Chronic Cancer Bioassay Is Frequently Conducted for Pesticides When It Is Not Always Needed to Protect Human Health** **Doug Wolf,** Syngenta Crop Protection Inc., Research Triangle Park, NC
9:25 AM–10:05 AM	**Threshold-Based Risk Assessment Is the Same for Cancer and Non-cancer Endpoints for Non-DNA Reactive Carcinogens** **Samuel M. Cohen,** University of Nebraska Medical Center, Omaha, NE
10:05 AM–10:25 AM	**Break**
10:25 AM–11:05 AM	**Is the Two-Year Rodent Bioassay Needed to Address Carcinogenic Risk for Human Pharmaceuticals?** **Frank D. Sistare,** Merck & Co Inc., West Point, PA
11:05 AM–11:45 AM	**A Weight of Evidence Approach to Cancer Assessment** **Alan R. Boobis,** Imperial College, London, UK
11:45 AM–12:45 PM	**Roundtable Discussion: How Can the Rodent Bioassay Evolve to Meet the Need of Predictive Toxicology?** ***Moderator:*** **A. Wallace Hayes,** University of South Florida and Michigan State University, Temple Terrace, FL ***Panelists:*** **Todd Bourcier,** US FDA, Silver Spring, MD; and **Janet Zang,** US FDA, College Park, MD **All Speakers**

US FDA, College Park, Maryland • Live Webcast

Organizing Committee

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Betty Eidemiller, PhD, SOT Staff, Reston, VA

Future 2019 Colloquia

April	Bioprinting and Food Safety
May	*In Silico* and *In Vitro* Computational Modeling and Methods for Food and Cosmetic Safety

Most Recent Colloquia

- **Food from Genetically Engineered Plants: What Role for Metabolomics?**
- **Can Alternatives Inform the Risk Assessments of Mixtures in Food?**
- ***In Vitro* to *In Vivo* Concordance for Toxicity Prediction and Use in Safety Assessments**
- **Safety Assessment of Food Packaging and Other Food Contact Substances**
- **Considerations for the Determination of Adversity in Food Chemical Safety Evaluations**
- **Application of *In Vitro* to *In Vivo* Extrapolation in Safety Assessment**
- **State of the Science in Developmental Neurotoxicology**

……plus 8 additional diverse topics, and other learning opportunities, all available at www.toxicology.org

SOT | Society of Toxicology

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

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