



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

**May 28, 2020—Integrated Approaches to Testing and
Assessment: The Future of Regulatory Toxicology Assessment**

Live Webcast

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

May 28, 2020

**Integrated Approaches to Testing and Assessment:
The Future of Regulatory Toxicology Assessment**

Chair: Lidia Ceriani, Humane Society International

Co-chair: Suzanne C. Fitzpatrick, US FDA CFSAN

This colloquium will feature an emerging flexible approach to evaluating and generating information to meet different regulatory purposes by means of Integrated Approaches to Testing and Assessment (IATA). IATAs are pragmatic, science-based frameworks for chemical hazard or risk characterization, which follow an iterative, integrative approach to answer a defined question with the required certainty in a specific regulatory context. Development of an IATA begins with problem formulation: the context of the decision and taking into account the overall risk management goals. Different types of information from existing sources, new testing (e.g., *in chemico*, *in vitro*, and *in vivo*), and non-testing (e.g., *in silico*), can be considered as needed, potentially using Integrated or Sequential Testing Strategies (ITS/STS) and evaluated using Weight of Evidence in an iterative process. IATA can be supported by Adverse Outcome Pathways (AOPs) that can inform hypothesis generation, weight of evidence analysis, and choice of assays for integrated assessment.

This session will introduce the concept, process, and components that comprise an IATA and present several case studies demonstrating different applications of this decision tool. Issues, challenges, and prospects of adopting IATAs in regulatory risk assessment will be discussed.

Schedule (All times are Eastern US, UTC -4)

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| 8:30 AM–8:40 AM | Welcome and Speaker Introductions
Suzanne Fitzpatrick, Colloquium Co-chair, US FDA CFSAN,
College Park, MD |
| 8:40 AM – 8:55 AM | Integrated Approaches to Testing and Assessment (IATA)–
An Introduction |

	Lidia Ceriani, Humane Society International, Brussels, Belgium
8:55 AM-9:15 AM	Learnings and Recommendations from Four EU-ToxRisk Case Studies on Applying New Approach Methodologies Data to Support Read-Across Susanne Hougaard Bennekou, Technical University of Denmark, Copenhagen, Denmark
9:15 AM–9:50 AM	Uncertainty Characterization in IATA for Chemical Safety Assessment: Overview of Available Guidance Andrea-Nicole Richarz, ECHA, Helsinki, Finland
9:50 AM–10:00 AM	Break
10:00 AM–10:35 AM	IATA as an Opportunity for Next-Generation Risk Assessment: The Propylparaben Case Study Gladys Ouédraogo, L'Oréal, Paris, France
10:35 AM–11:10 AM	Global Harmonization Efforts for Skin Sensitization IATA Nicole Kleinstreuer, NICEATM, Durham, NC
11:10 AM–11:45 AM	Applications of New Multi-Organ-Chip Tools for Toxicity Assessment Reyk Horland, TissUse GmbH, Berlin, Germany
11:45 AM–12:45 PM	Roundtable Discussion Moderator: Lidia Ceriani All speakers