



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

**January 19, 2023—Alternative Toxicological Approaches  
for Process-Formed Constituents in Food**

*Live Webcast*

**January 19, 2023**

**Alternative Toxicological Approaches for Process-Formed  
Constituents in Food**

**Co-Chairs:** Steven J. Hermansky, PharmD, PhD, DABT, FDA CFSAN, and Paul Hanlon, PhD, DABT, Abbott Nutrition

**Overview**

Compounds such as acrylamide, 4-MEI, furan, PAH, and 3-MCPD created during food processing including cooking at home have been identified as constituents of food. Hundreds of such process-formed compounds have been identified in food, and improvements in analytical methodology are likely to lead to identification of more in the future. While the discovery of these compounds in food has been relatively recent, it is recognized that most have been a component of food for centuries. Never-the-less, there is increasing interest to understand the potential human health risk associated with these compounds and using risk-based prioritization, developing techniques to reduce or eliminate compounds from the diet that could be expected to pose risk to consumers. Experience with acrylamide and other process-formed compounds demonstrate that the resources expended for traditional toxicology studies are not practical for the high number of these compounds known to exist in food. Furthermore, when compounds such as these are found unexpectedly in the diet, there can be a need for a rapid risk assessment that would benefit from methods that can be executed faster than traditional *in vivo* methods. Thus, these compounds represent an interesting test case to leverage New Approach Methods (NAMS) to help risk assessors and regulators better understand the biological effects of these compounds and prioritize them for additional investigation. This colloquium brings together researchers, risk assessors, and regulators to discuss opportunities to leverage a mixture of traditional testing and NAMS to help solve real-world, complex toxicology problems.

**Schedule (All times Eastern US, UTC -5)**

9:00 am–9:10 am

Welcome from US FDA: Kristi Muldoon Jacobs, PhD, Acting Director OFAS, FDA, Rockville, MD

Welcome from SOT: Dori Germolec, PhD, SOT Vice President, NIEHS-NTP, Durham, NC

9:10 am–9:25 am

Introduction of Topic and Speakers

Steven Hermansky, PharmD, PhD, US FDA CFSAN, College Park, MD

9:25 am–9:55 am

Analytical Challenges Related to the Analysis of Processing Contaminants in Foods and Impacts on Risk Assessment

Jessica Beekman, PhD, US FDA CFSAN, College Park, MD

9:55 am–10:30 am

Next Generation Systemic Toolbox

Matthew Dent, PhD, IDT, Unilever, Sharnbrook, UK

10:30 am–10:40 am Break

10:40 am–11:05 am

Codex Alimentarius: Guidelines for Rapid Risk Analysis Following Instances of Detection of Contaminants in Food Where there is No Regulatory Level

Lauren Robin, PhD, US FDA CFSAN, College Park, MD

11:05 am–11:35 am

The Challenge of Assessing Minor Constituents: An Example from the Flavor Industry

Sean Taylor, PhD, Verto Solutions, Washington, DC

11:35 am–12:00 pm

Summary and Current Challenges of New Approach Methods for Industry

Paul Hanlon, PhD, Abbott Nutrition, Columbus, OH

12:00 pm–1:00 pm

Roundtable Discussion

Moderator: Paul Hanlon

Panelists: Speakers and Suzanne Fitzpatrick, PhD, US FDA CFSAN, College Park, MD