Welcome from FDA

Kristi Muldoon Jacobs, PhD
Current Director, Office of Food Additive Safety
US FDA
Center for Food Safety and Applied Nutrition
Rockville, MD
FDA’s Scientific Origins:
Dr. Wiley’s Poison Squad

In the early 1900s, a group of U.S. government scientists started a private dinner club, in which they only ate poisonous food. They documented their illnesses in order to convince Congress to pass food safety laws. They were called "The Poison Squad."
Colloquium Series

- Partnership of US FDA Center for Food Safety and Applied Nutrition (CFSAN) and the Society of Toxicology (SOT)
- Eighth year of colloquia series, the 27th event!
- Stimulate a dialogue among leading toxicology experts on future-oriented toxicological science relevant to food and food ingredient safety assessment
- Not a forum for soliciting regulatory advice or discussing food or food ingredient regulatory issues
- Global audience from all employment sectors, open to the public via webcast at no cost
- Recording and slides for all colloquia are available at www.toxicology.org
Welcome from SOT

Dori Germolec, PhD
Vice-President, Society of Toxicology
Division of Translational Toxicology
National Institute of Environmental Health Sciences
Durham, NC
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 Organizing Committee

- **Stephen W. Edwards**, PhD, Colloquium Series Chair 2022-2023, RTI International, Chapel Hill, NC
- **David C. Dorman**, DVM, PhD, DABT, DABVT, ATS, Colloquium Series Co-chair 2022-2023, North Carolina State University, Raleigh, NC
- **Udayan Apte**, PhD, DABT, University of Kansas Medical Center, Kansas City, KS
- **Jason L. Aungst**, PhD, FDA Liaison, US FDA, College Park, MD
- **Omari Bandele**, PhD, US FDA, FDA Liaison, College Park, MD
- **Suzanne C. Fitzpatrick**, PhD, DABT, US FDA, College Park, MD
- **Willie McKinney**, PhD, DABT, McKinney Regulatory Science Advisors, LLC, Henrico, VA
- **Jason R. Richardson**, PhD, DABT, ATS, Florida International University, Miami Beach, FL
- **Jeffry J. Yourick**, PhD, DABT, ATS, US FDA, Laurel, MD
- **Christine Perdan Curran**, PhD, SOT Council Contact, Northern Kentucky University, Highland Heights, KY

SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety
Previous Sessions Have Covered a Wide Range of Topics

- Models and methods
  - Genomics, NAMs, bioassay, MPS and tissue models, IVIVE
- Organ/systems toxicity
  - Neurotoxicity, ADME, Immunotoxicity, Food Allergy
- Safety assessment
  - Packaging, food contaminants and constituents

https://www.toxicology.org/events/shm/fda/fda.asp
Upcoming Sessions of Interest

- **SOT Annual Meeting**
  - New Approach Methodologies to Evaluate Botanical Safety
    Monday, March 20 1:45-4:30 pm

- **SOT FDA Colloquium on Developmental Immunotoxicity in Food and Ingredient Safety–Spring 2023**
  - Leigh Ann Burns Naas and Patrick Crittenden, co-chairs
Schedule and Speaker Introductions

Steven J. Hermansky, Pharm D, PhD, DABT
Colloquium Co-Chair
US FDA CFSAN, College Park, MD
Conflict of Interest Statement

The author reports no conflict of interest.

Views expressed in this presentation are those of the author and do not necessarily reflect the views or policies of the Food and Drug Administration.
<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:10 AM</td>
<td>Introduction of Topic and Speakers</td>
<td>Steven Hermansky, PharmD, PhD, US FDA CFSAN, College Park, MD</td>
</tr>
<tr>
<td>9:25 AM</td>
<td>Analytical Challenges Related to the Analysis of Processing Contaminants in Foods and Impacts on Risk Assessment</td>
<td>Jessica Beekman, PhD, US FDA CFSAN, College Park, MD</td>
</tr>
<tr>
<td>9:55 AM</td>
<td>Next Generation Systemic Toolbox</td>
<td>Matthew Dent, PhD, IDT, Unilever, Sharnbrook, UK</td>
</tr>
<tr>
<td>10:30 AM</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>10:40 AM</td>
<td>Codex Alimentarius: Guidelines for Rapid Risk Analysis Following Instances of Detection of Contaminants in Food Where there is No Regulatory Level</td>
<td>Lauren Robin, PhD, US FDA CFSAN, College Park, MD</td>
</tr>
<tr>
<td>11:05 PM</td>
<td>The Challenge of Assessing Minor Constituents: An Example from the Flavor Industry</td>
<td>Sean Taylor, PhD, Verto Solutions, Washington, DC</td>
</tr>
<tr>
<td>11:35 AM</td>
<td>Summary and Current Challenges of New Approach Methods for Industry</td>
<td>Paul Hanlon, PhD, Abbott Nutrition, Columbus, OH</td>
</tr>
<tr>
<td>12:00 PM</td>
<td>Roundtable Discussion, Moderator: Paul Hanlon; all speakers and Suzanne Fitzpatrick, PhD, USFDA, College Park, MD</td>
<td></td>
</tr>
</tbody>
</table>
History of Topic

- Acrylamide discovered in food in (2002)
- Multiple regulatory agencies involved
- Extensive resources committed
  - Millions of dollars
  - Countless hours
Definition (Squishy)

Includes
- Heat generated
- Reactions
- Storage related

Out of scope
- Environmental
- Added to food
- Intended reactions
Discussion

- Hundreds of compounds
- Public health impact/benefit
- Role of NAMS
  - Prioritization?
  - Test case?
- An opportunity?
THANK YOU