

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



**State of the Art in the
Cramer Classification
Scheme and Threshold
of Toxicological
Concern**

March 29, 2016



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Welcome

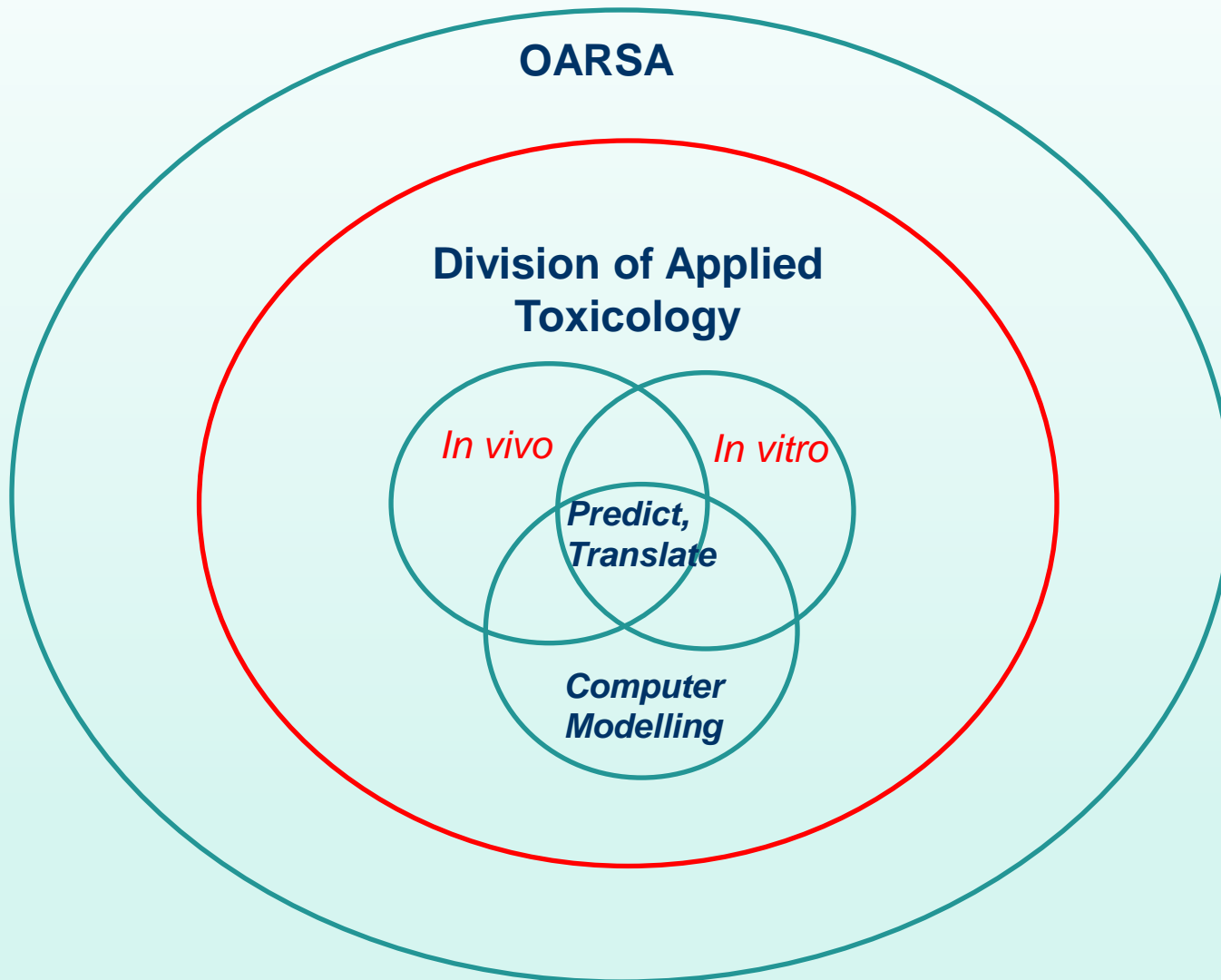
Mary E. Torrence, DVM, PhD

Director, Office of Applied Research and Safety
Assessment (OARSA) US FDA, College Park, MD





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Division of Applied Toxicology Regulatory Need

<ul style="list-style-type: none">• In silico• Hepatotoxicity• Cardiotoxicity• Renal Toxicity• Stem Cell Model• 3 D Models<ul style="list-style-type: none">– (skin, lung etc.)	↔	<ul style="list-style-type: none">• Acute Toxicity Testing• Hepatotoxicity• Cardiotoxicity Testing• Renal Toxicity Testing• Reproductive Toxicity• Developmental Toxicity
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In vitro

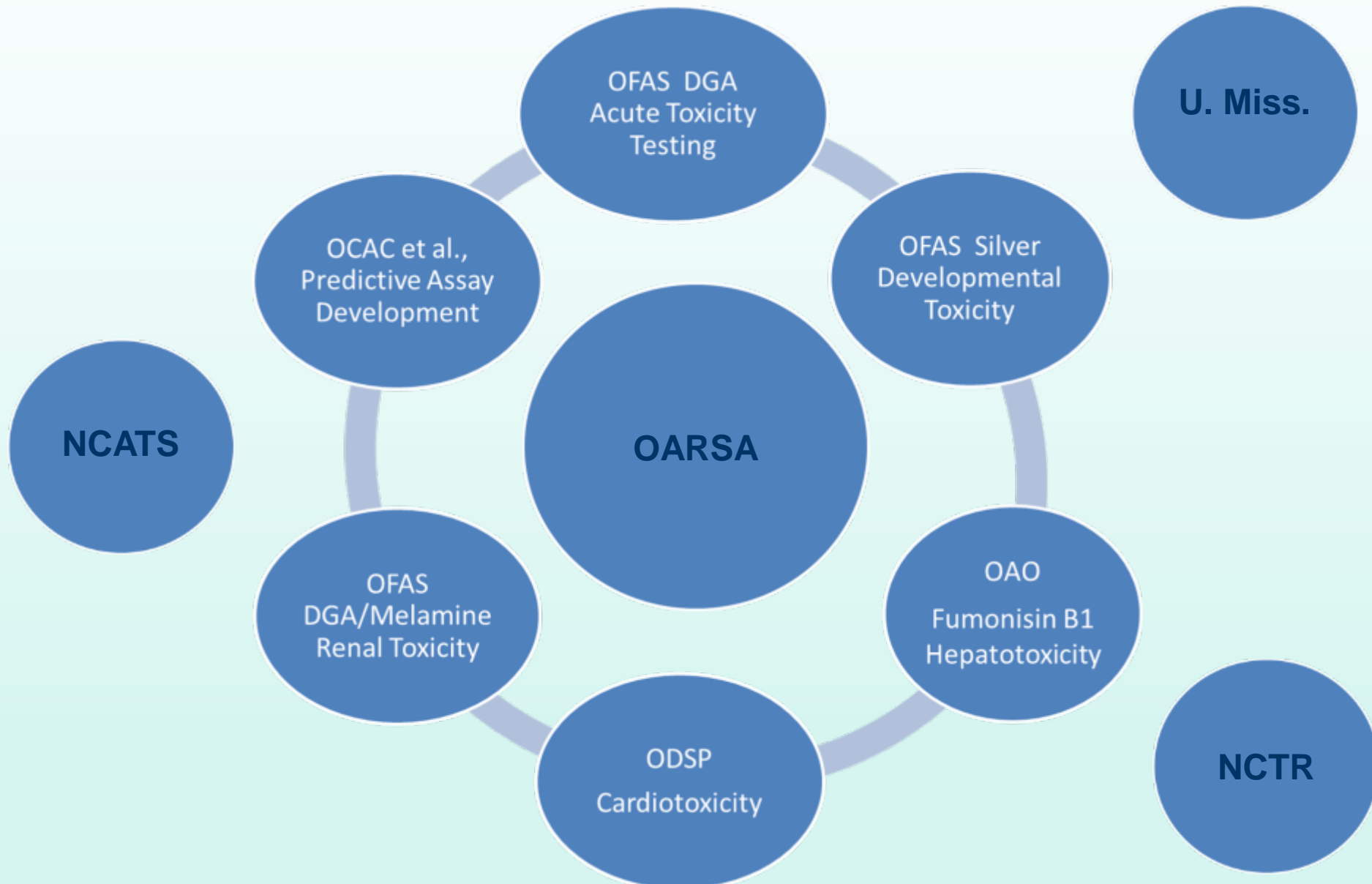
In vivo



**Significant Regulatory Research
Outcome**



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Colloquium Series

- Partnership SOT and US FDA Center for Food Safety and Applied Nutrition (CFSAN)
- High-quality, cutting-edge, future-oriented toxicological science
- Information for FDA employees and the public
- Not a public forum for discussion of toxicology regulatory issues



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Welcome from SOT

Peter L. Goering, PhD, DABT, ATS

President, Society of Toxicology

SOT | Society of
Toxicology



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Society of Toxicology Mission

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

Strategic Priorities

- Strengthen the Relevance and Impact of Toxicology
- Develop and Support Toxicologists to Capitalize on Future Opportunities
- Expand Outreach and Impact Globally



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Six Previous Colloquia

- Role of Mode of Action in Dose-Response Assessment for Carcinogens
- A Path Forward for Using Computational and *In Vitro* Methods for Food Ingredient Assessments
- Contemporary Issues in Risk Assessment
- Immunotoxicology in Food and Ingredient Safety Assessment: Approaches and Case Studies
- Application of ADME/PK Studies to Improve Safety Assessments for Foods and Cosmetics
- Complexities in Evaluating Human Clinical and Observational Data for Ingredient Safety Assessment: Partially Hydrogenated Oils As a Case Study



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Participation Summary 2014-2016

	Total for 6 Previous Colloquia
On-Site	365
Webcast	1498
Total	1863



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Future Colloquia 2016

May 20, 2016

**Safety Assessment Approaches in
Young Children**

**Watch for additional colloquia in 2016-
2017.**

SOT FDA Organizing Committee

Ivan Rusyn, MD, PhD, Chair, Texas A&M University, College Station, TX

Jason L. Aungst, PhD, US FDA, CFSAN, College Park, MD

Ronald Chanderbhan, PhD, US FDA, CFSAN, College Park, MD

Bryan Delaney, PhD, DABT, ATS, DuPont Pioneer, Johnston, IA

Suzanne Compton Fitzpatrick, PhD, DABT, Colloquium Chair and Committee Member, US FDA, CFSAN, College Park, MD

Kristi Muldoon Jacobs, PhD, US FDA, CFSAN, College Park, MD

Norbert Kaminski, PhD, SOT Council Contact, Michigan State University, East Lansing, MI

Jieun Lee, PhD, DABT, Kellogg, Battle Creek, MI

James J. Pestka, PhD, Michigan State University, East Lansing, MI

Allen Rudman, PhD, FDA Lead, US FDA, Office of Food Additive Safety, CFSAN, College Park, MD

Catherine Whiteside, PhD, US FDA, CFSAN/OFVM/CFSAN, College Park, MD

Timothy Adams, PhD, US FDA, CFSAN, College Park, MD, for this colloquium





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Moderators

**Chair: Ivan Rusyn, Texas A&M,
College Station, TX**

**Co-chair: Timothy Adams, US FDA,
College Park, MD**

Agenda

8:50 AM–9:30 AM

Threshold of Toxicological Concern Approach in Regulatory Decision-Making: The Past, Present, and Future, Grace (Tier) Patlewicz, US EPA, Research Triangle Park, NC

9:30 AM–10:10 AM

Advancements in Food Ingredient Safety Prioritization: An Expanded Cramer Decision Tree Schema, Timothy Adams, US FDA, College Park, MD

10:30 AM-11:10

In Silico Methods for TTC Assessment, Andrew Worth, European Commission, Joint Research Centre, Ispra, Italy

11:10 AM-11:50 PM

Quantitative Prediction of Continuous Toxicity Values using Chemical Structure Information, Jessica Wignall, ICF International, Arlington, VA

11:50 AM-12:50 PM

Roundtable Discussion, Ivan Rusyn, Moderator, Kristi Jacobs, All Speakers





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Threshold of Toxicological Concern Approach in Regulatory Decision- Making: The Past, Present, and Future

Grace Patlewicz

National Center for Computational Toxicology

US EPA

tier.grace@epa.gov

**The views expressed in this presentation are those of the author
and do not necessarily reflect the views or policies of the US EPA**



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Colloquium March 29, 2016

State of the Art in the Cramer Classification Scheme and Threshold of Toxicological Concern



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Greg Cramer





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Roundtable Discussion: State of the Art in the Cramer Classification Scheme and Threshold of Toxicological Concern

11:50 AM-12:50 PM

Ivan Rusyn, Moderator

Tim Adams

Kristi Jacobs

Grace (Tier) Patlewicz

Andrew Worth

Jessica Wignall

Questions welcome.



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

Colloquia

- Recordings

- Slides

- Captioning Text

are available at

www.toxicology.org

The screenshot shows the SOT (Society of Toxicology) website page for SOT FDA Colloquia. The header includes the SOT logo and navigation links such as 'About SOT', 'Members & Groups', 'Meetings & Events', 'Publications & News', 'Awards & Funding', 'Careers', 'Education', 'Endowment Fund', and 'My Links'. A search bar and social media icons are also present. The main content area features a blue banner with the SOT FDA logo and the title 'SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety'. Below the banner, there is a paragraph of text describing the partnership between SOT and the US FDA Center for Food Safety and Applied Nutrition (CFSAN). A blue button labeled 'Open All' is visible. On the right side, there are sections for 'Annual Meeting & ToxExpo', 'CCT Meetings', and 'Events Calendar', each with a brief description of the event.