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

Contemporary Issues in Risk Assessment

June 17, 2015
Welcome from FDA

Suzanne Compton Fitzpatrick, PhD, DABT
Center for Food Safety and Nutrition
College Park, MD
Welcome from SOT

Peter L. Goering, PhD, DABT, ATS
President, Society of Toxicology
SOT 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
Colloquium 1

November 7, 2014

Complexities in Evaluating Human Clinical and Observational Data for Ingredient Safety Assessment: Partially Hydrogenated Oils (PHOs) As a Case Study

Onsite Participants 95
Webcast 239
Video Recording Views 140
Presentation Slide Downloads 1,278

Video, slides, captioning text available at http://www.toxicology.org/fda
Colloquium 2

February 23, 2015

Application of ADME/PK Studies to Improve Safety Assessments for Foods and Cosmetics

Onsite Participants          46
Webcast             195

Video, slides, available at http://www.toxicology.org/fda
(captioning text is pending)
Colloquium 3

April 23, 2015

Immunotoxicology in Food and Ingredient Safety Assessment: Approaches and Case Studies

Onsite Participants       64
Webcast                   192

Video, slides, available at http://www.toxicology.org/fda
(captioning text is pending)
Colloquium 4

June 17, 2015

Contemporary Issues in Risk Assessment
Perspectives on “Risk Assessment”

Arnold P. Lehman, MD, PhD
Chief, Division of Pharmacology, USFDA
Honorary President, Society of Toxicology (1961-62)
Co-founder, Society of Toxicology (1961)
Perspectives on “Risk Assessment”

“You, too, can become a toxicologist in two easy lessons... each one taking about 10 years.”

Arnold P. Lehman, MD, PhD
Chief, Division of Pharmacology, USFDA
Honorary President, Society of Toxicology (1961-62)
Co-founder, Society of Toxicology (1961)
Perspectives on “Risk Assessment”

John Doull, MD, PhD
Professor Emeritus, Kansas University Medical School
President, Society of Toxicology, 1986-87
Perspectives on “Risk Assessment”

“Toxicology is what we do. Risk assessment is why we do it.”

John Doull, MD, PhD
Professor Emeritus, Kansas University Medical School
President, Society of Toxicology, 1986-87
Today’s Agenda

8:15 AM-8:25 AM  US FDA Welcome and Overview,  Suzanne Fitzpatrick, US FDA, CFSAN, College Park, MD

8:25 AM-8:30 AM  Welcome from SOT, Peter Goering, SOT President, US FDA, Silver Spring, MD

8:30 AM-8:35 AM  Speaker Introduction, Ivan Rusyn, SOT FDA Colloquium Organizing Committee Chair, Texas A&M, College Station, TX

8:35 AM-9:15 AM Problem Formulation and Scoping for Human Health Assessments, Juleen Lam, University of California San Francisco, San Francisco, CA

9:15 AM-10:00 AM Identification and Selection of the Evidence Base for Human Health Assessments, Kathryn Guyton, International Agency for Research on Cancer Monographs Programme, Lyon, France

10:00 AM-10:15 AM Break
Today’s Agenda, continued

10:15 AM-11:00 AM Harmonizing Dose-Response Assessment for Cancer and Non-cancer Endpoints in Human Health Assessments, Weihsueh Chiu, Texas A&M University, College Station, TX

11:00 AM-11:45 PM The Use of the Mechanistic Evidence in Human Health Assessments, J. Vincent Cogliano, US EPA, Crystal City, VA

11:45 PM-12:30 PM Roundtable Discussion
   Ivan Rusyn, Moderator
   All Speakers

12:45 PM-1:30 PM Optional time for FDA employees with speakers
FDA-SOT Organizing Committee

Ivan Rusyn, MD, PhD, Chair, Texas A&M University, College Station, TX
Suzanne Compton Fitzpatrick, PhD, DABT, Colloquium 4 Chair and member, US FDA, CFSAN, College Park, MD
Bryan Delaney, PhD, DABT, ATS, DuPont Pioneer, Johnston, IA
Ji-Eun Lee, PhD, DABT, Kellogg, Battle Creek, MI
Ivan Rusyn, MD, PhD, Texas A&M University, College Station, TX
James J. Pestka, PhD, Michigan State University, East Lansing, MI
Norbert Kaminski, PhD, Michigan State University, East Lansing, MI
Allen Rudman, PhD, FDA Lead, US FDA, Office of Food Additive Safety, CFSAN, College Park, MD
Ronald Chanderbhan, PhD, US FDA, CFSAN, College Park, MD
Kristi Muldoon Jacobs, PhD, US FDA, CFSAN, College Park, MD
Sabine Francke-Carroll, DVM, PhD, US FDA, CFSAN, College Park, MD
Catherine Whiteside, PhD, US FDA, CFSAN/OFVM/CFSAN, College Park, MD
Moderator

Ivan Rusyn, MD, PhD
Chair, SOT FDA Colloquium Organizing Committee
Texas A&M University
College Station, Texas
Problem Formulation and Scoping for Human Health Assessments

Juleen Lam
University of California San Francisco
San Francisco, California
Identification and Selection of the Evidence Base for Human Health Assessments

Kathryn Guyton, PhD
International Agency for Research on Cancer Monographs Programme
Lyon, France
Harmonizing Dose-Response Assessment for Cancer and Non-cancer Endpoints in Human Health Assessments

Weihsueh Chiu, PhD
Texas A&M University
College Station, Texas
The Use of the Mechanistic Evidence in Human Health Assessments

J. Vincent Cogliano, PhD
US EPA
Crystal City, Virginia
Roundtable Discussion: Contemporary Issues in Risk Assessment

Moderator: Ivan Rusyn, MD, PhD

All speakers

Questions welcome.
Colloquia

- Recordings
- Slides
- Captioning Text

are available at www.toxicology.org
Thank you for your participation.