

All sessions will take place in the Eastern Time Zone.

DAY ONE: October 27, 2020

10:25 a.m. – 10:30 a.m. **Welcome Address**

10:30 a.m. – 11:35 a.m. **The Basics of FDA Food-Contact Regulation – An Overview**

George G. Misko, Partner

- Defining a Food Additive
- Clearance Options and Exemptions
- FDA's Food Contact Notification Program

11:40 a.m. – 11:45 a.m. **Break**

11:45 a.m. – 12:25 p.m. **Understanding Food Additive Regulatory Clearances**

Pamela L. Langhorn, Partner

- Interpreting Scope and Limitations
- End Tests
- Cross-References

12:30 p.m. – 12:45 p.m. **Break**

12:45 p.m. – 1:30 p.m. **Filing a Food Contact Notification – A Technical Focus**

Kristin Price Wiglesworth, Ph.D., Scientist

- Elements of an FCN
- Describing the FCS
- Estimating Exposure to the FCS
- Assessing Toxicology of the FCS
- Traps and Pitfalls

1:35 p.m. – 1:40 p.m. **Break**

1:40 p.m. – 2:10 p.m. **Updates from FDA's Division of Food Contact Substances**

Guest Speaker: Kenneth McAdams, Consumer Safety Officer, Food and Drug Administration

2:15 p.m. **Q&A**

Join us for a Q&A session in the Networking Lounge.

2:30 p.m. **Seminar Adjourns for the Day**

DAY TWO: October 28, 2020

- 10:00 a.m. – 10:50 a.m. **The Basics of European Food-Contact Regulation – An Overview**
Rachida Semail, Partner
- Framework Regulation
 - GMP Regulation
 - Plastics Regulation
 - Introduction to the Mutual Recognition Principle
- 10:55 a.m. – 11:25 a.m. **EU Member State Laws on Non-Harmonized Materials**
Hazel O’Keeffe, Partner
- Paper
 - Coatings
 - Rubber
 - Printing Inks
- 11:30 a.m. – 11:35 a.m. **Break**
- 11:35 a.m. – 12:20 p.m. **Assessing Compliance in the EU – Technical Considerations**
Tjoena Siere, Scientist
- Compliance Testing Requirements
 - Toxicity Data Requirements
 - NIAS Evaluations
- 12:25 p.m. – 12:55 p.m. **Join the Conference Speakers for a Q&A Lunch in the Networking Lounge**
- 12:55 p.m. – 1:30 p.m. **Regulation of Food Packaging in China**
David J. Ettinger, Partner, Eric Gu, Associate, and Chen Hu, Scientist
- Overview
 - Preparation of New Standards
 - Petitioning Procedure
- 1:35 p.m. – 2:15 p.m. **Regulation of Food Packaging in Japan**
Mitzi Ng Clark, Partner and Mark Thompson, Partner
- Overview
 - New Positive List System
 - Petition Procedures and Data Requirements
- 2:15 p.m. – 2:45 p.m. **Regulation of Food Packaging in MERCOSUR Member Countries**
Kathryn C. Skaggs, Associate
- Regulatory Framework
 - Sector-Specific Legislation
 - Update to Revision of Positive List of Additives
- 2:45 p.m. **Seminar Adjourns for the Day**

DAY THREE: October 29, 2020

10:00 a.m. – 10:50 a.m. **Good Manufacturing Practices and What to Do When Something Goes Wrong**

Catherine R. Nielsen, Partner

- GMP Requirements
- GMP Failure - Assessing the Situation/Scope
- Customer Communications
- Recalls

10:55 a.m. – 11:40 a.m. **Customer Assurance Considerations in the U.S., EU, and China**

Jeffrey A. Keithline, Partner

- FDA Guaranties and Other Forms of Assurance in the U.S.
- EU Declaration of Compliance
- Chinese Declaration of Compliance
- Pitfalls and Best Practices in Providing Customer Assurance

11:45 a.m. – 12:00 p.m. **Break**

12:00 p.m. – 12:50 p.m. **Industry Sustainability Initiatives – Establishing Regulatory Status**

Cynthia B. Lieberman, Partner

- Recycled Plastics in Food Packaging
- Recycled Paper in Food Packaging
- Regulatory Considerations for Biopolymers

12:55 p.m. – 1:40 p.m. **The Role of Packaging in a Sustainable Future**

Guest Speaker: Ron Sasine, Principal, Hudson Windsor LLC

- What is the Size of the Problem?
- Who Holds the Levers of Power?
- Who is in Charge: The Regulators, The Retailers or the Brands?
- What Will It Take to Define the Finish Line (and then Cross It)?

1:45 p.m. – 1:50 p.m. **Break**

1:50 p.m. – 2:20 p.m. **California's Proposition 65: Recent Developments**

Robert S. Niemann, Partner

- Overview of Requirements
- Safe Harbor Warnings

2:20 p.m. – 2:55 p.m. **Hot Topics***

Rachel A. Bond, Partner and Hazel O'Keeffe, Partner

- U.S. State Law Activities
- Developments Related to Per- and Polyfluoroalkyl Substances (PFAS)
- Single-Use Plastics Directive

3:00 p.m. **Q&A and Closing Remarks**

3:15 p.m. **Seminar Adjourns**