



American Conference Institute's 4th Summit on

FOOD SAFETY REGULATORY COMPLIANCE



How to Minimize Risk Exposure to Government Enforcement and Litigation by Building Robust Food Safety Compliance Protocols

Hear Directly from the USDA on How to Minimize Exposure from a Recall Event:

William Cranford
Supervisory Enforcement, Investigations and Analysis Officer
Food Safety and Inspection Service, Chicago District Office
U.S. Department of Agriculture

David DeJaynes
District Case Specialist
Food Safety and Inspection Service, Chicago District Office
U.S. Department of Agriculture

Special CDC Address:

Arthur P. Liang, MD, MPH
Senior Advisor for Food Safety
Center for Disease Control

Benchmark with your in-house peers on how to navigate the Food and Beverage compliance landscape:

John Luedke
General Counsel Global Food Law
Mars

Scott Boyer
Associate Director – Customs
Kraft Foods

Adam Ekonomon
Director, Marketing, Advertising and Regulatory
Law and Assistant General Counsel
The J.M. Smucker Company

Caren Fitzgerald
Vice President, Assistant General Counsel
SpartanNash Company

Heidi Wederquist
Director of Quality Assurance &
Food Safety – Supply Chain
Chipotle Mexican Grill

Cindy Kruger
Legal Senior Director
PepsiCo

Michael Divine
Director, Quality Assurance – Food Safety
HEB

Chrissy Eisenhard
Vice President, Division General Counsel
& Chief Compliance Officer
WhiteWave Foods

Gain in-depth guidance on how to update your program with a comprehensive overview of the most complex food safety requirements:

- ✓ Food Safety Risk Assessment
- ✓ Inspections
- ✓ Recalls
- ✓ Imported Food

Gain Critical Updates on How to Meet Food Safety Modernization Act (FSMA) Requirements:

- ✓ Preventive Controls
- ✓ Foreign Supplier Verification
- ✓ Record Keeping

Develop practical tools for addressing day-to-day compliance and food safety challenges including:

- *Focus on China*: Attorney from Beijing Provides an Update on Risk Management and Food Safety Initiatives in China
- How to Establish an Effective Recall Crisis Management Plan
- How Food Safety Professionals and In-House Counsel Can Collaborate to Achieve an Optimal Food Safety Compliance Program
- Post-Inspection Remediation and Corrective Action — *A Step by Step Action Plan*

FDA & USDA COMPLIANCE

September 28, 2015

Hilton Chicago Magnificent Mile Suites
Chicago, IL

BOOT CAMP

- Product Labeling — How to Make Sure Your Product Labels Comply with Government Requirements
- Marketing & Advertising Update — When Can You Use “Natural,” “Gluten-Free,” “Organic,” and “Non-GMO?”
- Hot Topics in Food Litigation — How to Avoid Pitfalls that Can Lead to Costly Litigation

www.AmericanConference.com/FoodBootCamp

THE HEADLINES SAY IT ALL:

“U.S. Bringing Charges on Food Safety Lapses”

The Wall Street Journal Asia, May 2015

“The food safety law puts the burden on food companies to make sure that their products are safe, instead of relying largely on inspectors from the understaffed F.D.A. It requires better record-keeping, contingency plans for handling outbreaks and measures to prevent the spread of contaminants. It also gives the agency the power to issue recalls, something it could not do previously.”

The New York Times, April 2015

With the implementation of Food Safety Modernization Act rules and continued food-related litigation, food safety compliance is a critical objective that food and beverage companies must take seriously. Food safety compliance professionals often struggle to understand what these rules mean for their daily workflow.

Back for a fourth successful installment, this Summit on Food Safety Regulatory Compliance has been developed to provide in-house food safety, regulatory and compliance officers and legal counsel with an opportunity to network and benchmark internal protocols and procedures in response to new food safety regulatory requirements. Featuring insights from a faculty of expert industry leaders and legal counsel, ACI's Food Safety Regulatory Compliance Summit will provide attendees with the most up-to-date information to help you address day-to-day food safety challenges.

ACI has conducted extensive research to design a unique program with an expert faculty to address provide practical solutions to addressing your most pressing concerns surrounding:

- *FSMA 2.0* — Practical Real Life Strategies for Integrating FSMA Protocols into Your Food Safety Compliance Program
- *Current Testing and Measurement Trends* — Identifying Pathogens, Allergens and Other Contaminants in Food Products
- *Policy Debate* — What a Single Food Safety Regulatory Agency Would Mean to Your Company and Is The President's Proposal a Good or a Bad Idea?

Take the Pulse of the Industry with Live Interactive Polling!

Get current on food safety regulations law while benchmarking with your compliance protocols with your peers.

ACI's 4th Summit on Food Safety and Regulatory Compliance will engage attendees in a nuts-and-bolts, two-day course on food safety regulatory requirements, including a deep dive exploration into:

- ✓ Preventive Controls
- ✓ Recalls
- ✓ Imported Food
- ✓ Inspections
- ✓ Foreign Supplier Verification
- ✓ Record Keeping

Reserve space now for your food safety and quality assurance team, in-house food lawyers, regulatory or government affairs executives, senior associates, junior partners or attorneys new to the food industry and use this event as your annual training! Register now by calling 888-224-2480, faxing your registration to 877-927-1563 or registering online at www.AmericanConference.com/FoodSafety.

Compliment Your Trip to Chicago with This Exclusive One Day Event!

FDA & USDA COMPLIANCE BOOT CAMP

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Don't miss this highly rated Boot Camp back by popular demand!

A Comprehensive Summit Designed for:

- ✓ **Food Manufacturers, Retailers, Distributors, Suppliers, Servers and Restaurant counsel, directors and officers specializing in:**
 - Food Safety
 - Quality Assurance/QA
 - Regulatory Affairs
 - Compliance
 - Government Affairs
 - Legal Counsel
 - Risk Management
- ✓ **Attorneys practicing in the following areas and industries:**
 - FDA Law
 - Food Law
 - Food & Beverage
 - Agribusiness & Food Regulation
 - Consumer Products

Continuing Legal Education Credits



Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as nontransitional for the purposes of CLE accreditation.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board.

ACI certifies that this activity has been approved for CLE credit by the State Bar of California.

You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4–8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and ACI will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE

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Wendy Tyler
Director of Sales, American Conference Institute
Tel: 212-352-3220 x5242
w.tyler@AmericanConference.com

SUMMIT DAY ONE

TUESDAY, SEPTEMBER 29, 2015

7:30	Registration Begins and Continental Breakfast	12:15	Networking Luncheon for Attendees and Speakers
8:30	Co-Chairs' Opening Remarks <hr/> <i>Michael Divine</i> Director, Quality Assurance – Food Safety HEB (San Antonio, TX) <i>Martin Hahn</i> Partner Hogan Lovells (Washington, DC)	1:30	Interactive Case Study — What Can and Should the Government Expect from Your Company During an On-Site Inspection <hr/> <i>Adam Ekonomon</i> Director, Marketing, Advertising and Regulatory Law and Assistant General Counsel The J.M. Smucker Company (Orrville, OH) <i>Nathan Beaver</i> Partner Foley & Lardner LLP (Washington, DC) <ul style="list-style-type: none"> • Knowing what the Government will be looking for during an inspection • How to prepare your records and employees for an inspection • How to handle a “surprise” inspection • How to respond to a government agent’s requests on-site • Distinguishing a valid investigation from a fishing expedition and how your staff should react to each
8:45	FSMA 2.0 — Practical Real Life Strategies for Integrating FSMA Protocols into Your Food Safety Compliance Program <hr/> <i>Michael Divine</i> Director, Quality Assurance – Food Safety HEB (San Antonio, TX) <i>Martin Hahn</i> Partner Hogan Lovells (Washington, DC) <ul style="list-style-type: none"> • Discussing Hazard Analysis and Risk Based Preventive Controls • Implementing the Foreign Supplier Verification Program • Interpreting and new animal feed rules • How to structure FSMA compliance protocols taking into account the type of company and business model (e.g. manufacturer, distributor, licensor) 	2:30	Live Interactive Polling: Post-Inspection Remediation and Corrective Action — A Step by Step Action Plan <hr/> <i>Jeannie Perron – Moderator</i> Partner Covington & Burling LLP (Washington, DC) <ul style="list-style-type: none"> • Outlining steps in remediation and corrective action plan • Ensuring compliance with new procedures outlined post-inspection • Handling food re-labeling and other issues for products identified during inspection
9:45	Special CDC Address: Inside the Science Behind the Different Types of Contaminants and Human Health Effects that Affect Your Food Safety Protocols <hr/> <i>Arthur P. Liang, MD, MPH</i> Senior Advisor for Food Safety Center for Disease Control (Atlanta, GA)	3:15	Coffee Break
10:15	Coffee Break	3:30	Food Safety Scenarios — How Should Your Company Handle These Challenges? <hr/> <i>Robert Hibbert</i> Partner Morgan Lewis & Bockius LLP (Washington, DC) <ul style="list-style-type: none"> • Conflicts within state and vs. federal food safety requirements • Understanding criminal liability and enforcement for food safety violations • Determining how whistleblower protection under FSMA Section 402 could affect your operations
10:30	GSFI Certification — How Third-Party Certification Benefits Your Compliance Program <hr/> <i>Ryan Fothergill</i> In-House Counsel Primus Labs (Santa Maria, CA) <i>David Ernst</i> Partner Davis Wright Tremaine LLP (Portland, OR) <ul style="list-style-type: none"> • Comparing Food Safety Standards — BRC, SQF, FSSC, and IFS • How to decide on the appropriate certification body • Determining when and how to use audits and pre-audits 	4:20	Policy Debate — What a Single Food Safety Regulatory Agency Would Mean to Your Company and is the President’s Proposal a Good or a Bad Idea? <hr/> <i>David Graham – Moderator</i> Senior Counsel Dykema (Minneapolis, MN) <ul style="list-style-type: none"> • President’s 2016 budget proposes a consolidation of FSIS and FDA’s food safety components into a new agency within the Department of Health and Human Services • Implications for the FDA, USDA, and CDC • Debating the pros and cons of one Federal Food Safety Regulatory Agency
11:15	Current Testing and Measurement Trends — Lessons Learned from Recent High Profile Food Recalls Involving Pathogens and Allergens <hr/> <i>William Marler</i> Managing Partner Marler Clark (Seattle, WA) <ul style="list-style-type: none"> • Understanding new trends for measuring and identifying contaminants — what to test for and how to test for it • What to do if a contaminant is found in your product • Current issues surrounding allergens and pathogens 	5:00	Summit Adjourns to Day Two

SUMMIT DAY TWO

WEDNESDAY, SEPTEMBER 30, 2015

8:30 **Co-Chairs' Opening Remarks**

8:35 **Anatomy of a Recall Case Study: Analysis of Key Steps to Minimize Exposure from a Recall Event**

William Cranford

Supervisory Enforcement, Investigations and Analysis Officer
Food Safety and Inspection Service, Chicago District Office
U.S. Department of Agriculture (Chicago, IL)

David DeJaynes

District Case Specialist
Food Safety and Inspection Service, Chicago District Office
U.S. Department of Agriculture (Chicago, IL)

- Making the decision to recall — when and how?
- Balancing time pressure and a less than complete set of data and information
- How to effectively remove products from the marketplace
- Working with state and federal government to streamline your recall process post-incident
- Identifying and correcting compliance violations that led to the recall
- Lessons learned and revisiting your food safety protocols in light of recent food recalls

10:00 Coffee Break

10:15 **Food Imports Compliance and Foreign Supplier Verification Program: How to Conduct Effective Screening of Suppliers for Imported Food**

Scott Boyer

Associate Director – Customs
Kraft Foods (Madison, WI)

Laura Siegel Rabinowitz

Special Counsel
Kelley Drye LLP (New York, NY)

- How to evaluate foreign suppliers to ensure their food safety protocols are in line with new requirements under FSMA
- What to do if your food products get stuck at Customs and detained without physical examination to detect a safety issue
- Ensuring prior notice of imported food is recorded in accordance with FDA's requirements

11:00 **How to Conduct an Effective Food Safety Risk Assessment — Developing a Strategic Approach**

Heidi Wederquist

Director of Quality Assurance & Food Safety – Supply Chain
Chipotle Mexican Grill (Denver, CO)

Jonathan Cohen

Partner
Gilbert LLP (Washington, DC)

- How to evaluate food safety risks across, facilities, functions, and departments
- Assessing how much risk your company can tolerate
- Understanding balance between the magnitude and frequency of risks
- How to protect against these food safety risks

11:45 **Record Keeping — How To Keep Up with More Rigorous Documentation Requirements Under FSMA and State Regulatory Agencies**

Cindy Kruger

Legal Senior Director
PepsiCo (New York, NY)

- Knowing what types of records are accessible to the Government and under what circumstances
- Understanding how far up and down the manufacturing, distribution and supply chain the record production obligation extends
- Tips for effectively documenting
 - testing and inspection results
 - instances of non-conformance
 - written plans and reanalysis
 - your internal food safety and regulatory compliance procedures vs. those of companies
- Using technology to get your documents in order and accessing these records when the regulators come knocking

12:30 Networking Luncheon for Attendees and Speakers

1:45 **Focus on China: Food Safety Update on China**

Fang He

Partner

Jun He Law Offices (Beijing)

- Update on recent enforcement initiatives and high risk areas in China
- Identifying risk exposure particular to your food operations in China
- Best practices for U.S. companies when importing food from China

2:30 Coffee Break

2:45 **How to Establish an Effective Recall Crisis Management Plan**

Jeannie Perron

Partner

Covington & Burling LLP (Washington, DC)

John Luedke

General Counsel Global Food Law

Mars Inc. (Washington, DC)

Joanne Henry

Executive Vice President

Neuger Communications Group (Minneapolis, MN)

- Preserving business and customer relationships during a high publicity food recall incident
- Developing a strategy to address publicity issues that arise as the direct result of a recall
- Preparing and executing customer communications during a recall
- Managing internal communications in a recall environment — from switchboard to board room
- Anticipating and preparing for potential litigation that may arise as the result of a recall — from customers and from within the supply chain

3:45 **Wrap Up Session: Working Together — How Food Safety Professionals and In-House Counsel Can Work Together to Achieve an Optimal Food Safety Compliance Program**

Summit co-chairs will lead you in this important dialogue. Come benchmark with your peers on how your company's cross functional food safety team can work together to build robust protocols that can respond quickly and effectively food safety risks.

4:45 Food Safety Summit Ends



FDA & USDA COMPLIANCE

BOOT CAMP

A Nuts and Bolts Course on How to Comply with FDA and USDA Requirements for the Food and Beverage Industry

September 28, 2015 | Hilton Chicago Magnificent Mile Suites | Chicago, IL

Hear Directly from Senior FDA and USDA Officials:

Latasha Robinson
Branch Chief of Labeling and Dietary Supplement Compliance
U.S. Food and Drug Administration (Washington, DC)

Paul Wolseley
District Manager, Chicago District
Food Safety and Inspection, Office of Field Operations
U.S. Department of Agriculture (Chicago, IL)

This highly rated Boot Camp is back by popular demand!

Can Your FDA & USDA Compliance Program Stand Up to Government Scrutiny?

With the myriad of **FDA and USDA** regulations and increased food-related litigation, regulatory compliance is at top of mind for food and beverage companies. This event provides a one-day executive forum for *in-house counsel, regulatory, compliance and government affairs executives, and private practice attorneys* to gain a comprehensive overview of food law regulations and a road map to navigating the complex nuances of food compliance.

Develop practical tools for addressing day-to-day compliance and regulatory challenges including:

- ➔ **Product Labeling** — How to Make Sure Your Product Labels Comply with Government Requirements
- ➔ **Marketing & Advertising Update** — When can you use “Natural,” “Gluten-Free,” “Organic,” and “Non-GMO?”
- ➔ **What's New in California?** — How Prop 65 Continues to Impact Your Food Products Marketed Nationwide
- ➔ **Hot Topics in Food Litigation** — How to Avoid Pitfalls that Can Lead to Costly Litigation

8:00 Registration Begins and Continental Breakfast

9:00 Co-Chairs' Opening Remarks

Caren Fitzgerald
Vice President, Assistant General Counsel
SpartanNash Company (Minneapolis, MN)

Richard Wegener
Partner
Faegre Baker Daniels (Minneapolis, MN)

Rebecca Cross
Partner
BraunHagey & Borden (San Francisco, CA)

9:15 FDA Update — Inside the Latest FDA Initiatives and How to Re-Adjust Compliance Protocols

Daniel Dwyer
Partner
Kleinfeld, Kaplan and Becker, LLP (Washington, DC)

In the context of a constantly evolving regulatory environment, this session will guide you through the significant regulatory changes to date including:

- Understanding FDA's Nutritional Labeling guidelines
- Outlining FDA's Social Media Guidance
- Update on “Gluten Free”

- Dissecting FDA's final guidance requiring Investigational
- New Drug Applications for clinical research involving foods and dietary supplements

10:00 Product Labeling — How to Make Sure Your Product Labels Stand Up to Government Requirements

Latasha Robinson
Branch Chief of Labeling and Dietary Supplement Compliance
Food and Drug Administration (Washington, DC)

- Understanding the regulatory landscape applicable to food labels
 - 21 CFR parts 100-199
 - FDCA Chapter IV
 - Fair Packaging and Labeling Act of 1966
- Distinguishing the role of the FDA and USDA in approving information listed on a product label
- Understanding the scope of authority of FSIS and AMS concerning product labels
- Distinguishing labels approvable under the prior label
- Approval system vs. under generic label approval
- Defining the product “label”
 - front-of-pack, information panel, package insert
 - label requirements — contents, ingredients, allergens
 - how to list information posted on website and advertisements
- How to avoid allegations of misrepresentation and misbranding

10:45 Coffee Break

11:00 **Marketing & Advertising Update — When Can You Use “Natural,” “Gluten-Free,” “Organic,” and “Non-GMO?”**

Richard Wegener
Partner

Faegre Baker Daniels (Minneapolis, MN)

“Natural,” “Organic,” “Sustainable,” “Fresh,” “Gluten-Free,” and “Grass-Fed” are claims that are causing companies to come under attack in various regulatory and judicial forums. Come prepared to ask questions on how to optimize your marketing efforts without exposing your company to litigation.

- “All Natural” Definition — Guidance on how to structure your claims
- Understanding the development of industry consensus standards and the role of self-regulation
- Update and learning from recent case law
- Understanding the latest from the Washington regulatory landscape
- Recent FDA warning letters
- Complying with the Organic Food Production Act

12:00 **Dissecting the Changing Landscape in GRAS Determinations**

Diane McColl
Director

Hyman Phelps & McNamara (Washington, DC)

- Who knows what GRAS really means?
- What are recent criticisms of GRAS determinations?
- When will FDA respond to these criticisms?
- Where does industry stand on GRAS?
- Why even worry about GRAS?

12:45 **Networking Lunch**

2:15 **What’s New in California? — How Prop 65 Continues to Impact Your Food Products Marketed Nationwide**

Rebecca Cross
Partner

BraunHagey & Borden (San Francisco, CA)

- Discussing recent enforcement trends
- How to respond to a Prop 65 Notice of Violation
- Defending a Prop 65 action — the latest on exposure and naturally occurring defenses
- Brainstorming creative settlement strategies
- Incorporating Prop 65 into your compliance programs

2:45 **Keynote Address: USDA Update — Understanding Dietary Guidelines and Other UDSA Initiatives**

Paul Wolseley

District Manager, Chicago District
Food Safety and Inspection, Office of Field Operations
U.S. Department of Agriculture (Chicago, IL)

3:20 **Hot Topics in Food Litigation — How to Avoid Pitfalls that Can Lead to Costly Litigation**

Chrissy Eisenhard

Vice President, Division General Counsel & Chief Compliance Officer
WhiteWave Foods (Broomfield, CO)

Angela Agrusa

Partner

Liner LLP (Los Angeles, CA)

Christopher Van Gundy

Partner

Keller and Heckman LLP (San Francisco, CA)

- Overview of highly targeted products for food litigation and enforcement
 - food-borne illness claims — poultry, produce
 - How recall, inspections, and agency warning letters can trigger private litigation
- Food and beverage consumer fraud claims
 - natural, HFCS, trans fat based on deceptive packaging and labeling based claims
 - marketing and advertising claims — claim substantiation
- How to minimize litigation exposure
- What’s next? Obesity law suits and other potential trends in litigation

4:20 **Record Keeping — How to Effectively Retain and Maintain FDA and USDA Compliance Documentation**

Chrissy Eisenhard

Vice President, Division General Counsel & Chief Compliance Officer

WhiteWave Foods (Broomfield, CO)

- Key record keeping requirements and common areas of non-compliance
- What happens if you don’t have the required records to present to FDA or USDA
- Who should keep your records, and when to delegate to a third party
- What types of records should be created to comply with FSMA
- Identifying where relevant records are kept
- Which records should be retained in hard copies vs. electronic copies

5:05 **Town Hall Wrap Up — What is the Biggest Compliance Challenge for 2016 and Beyond?**

Boot Camp co-chairs will lead you in this thought-provoking interactive discussion. What do you think will be the biggest or most important compliance challenges for the food and beverage industry in 2016 and beyond? Come share your thought with your peers on what you think the future “hot topics” will be and why.

5:30 **Boot Camp Ends**

A Comprehensive Boot Camp Designed for Food Manufacturers, Retailers, Distributors, Suppliers, Servers and Restaurant counsel, directors and officers specializing in:

- Regulatory Affairs
- Government and State Affairs
- Legal Affairs
- Compliance

Attorneys practicing in the following areas and industries:

- FDA Law
- Food Law
- Food & Beverage
- Consumer Products

Here's what past attendees of ACI's Food Compliance events have to say:

"Very insightful and relevant to current topics I deal with on a daily basis."

– Whole Foods Market

"The conference was very informative. The speakers are very knowledgeable and have excellent presentations."


– The Pampered Chef

"Very good content. I like the interaction."


– Sara Lee

REGISTRATION INFORMATION


5 Easy Ways to Register

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New York, NY 10010

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<input type="checkbox"/> FDA & USDA Compliance Boot Camp Only	\$995	\$1095
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<input type="checkbox"/> Please reserve ___ additional copies of the Conference Materials at \$199 per copy.		

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September 28, 2015

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