June 28 & 29, 2010 • Millennium Knickbocker Hotel • Chicago, IL

Advanced Summit on
FOOD SAFETY REGULATORY COMPLIANCE

Responding to Increased Government Enforcement, Product Scrutiny and Litigation Exposure

Enforcement and Regulatory Update from Senior Government Officials:

Inspections

Kris Mazurczak, D.V.M
Illinois Department of Agriculture

Elizabeth M. Watkins, B.S., L.E.H.P.
Illinois Department of Public Health

Paul Wolseley*
U.S. Department of Agriculture
Food Safety and Inspection Service

Product Labeling

Scott McIntire
Food and Drug Administration

C. Steven Baker
Federal Trade Commission

Mark Levine*
National Advertising Division

Make sense of complex food safety regulations and learn how to:

- Design a compliant marketing strategy to minimize the risk of product labeling and representation claims
- Prepare for and survive government inspections
- Properly execute a recall and crisis management plan
- Implement effective food contamination response mechanisms to mitigate downstream litigation risks
- Meet new food reporting requirements and ensure "one up, one down" accountability
- Handle and respond to government requests, alerts, warning letters and inquiries
- Minimize criminal liability exposure as the result of a food incident
- Probe weak spots in your compliance protocols

Benchmark your current regulatory compliance practices with

Cargill
Del Monte
Dr Pepper Snapple
Frito-Lay
H.J. Heinz
McDonald's
Nestle
Nestle Purina Petcare
Smithfield Foods
Tyson Foods
Whole Foods Market
Unilever
Yum! Brands

Exclusive Workshops June 30, 2010

A – How to Prove Substantiation of Claims in Product Marketing, Advertising and Labeling

B – Conducting Effective Due Diligence and Internal Audits into Suspected or Alleged Safety Violations

Gain firsthand insights from the following industry associations:

Tomato Division of the **Fresh Produce Association of the Americas** on *Detecting Food Contamination*

National Meat Association on *Surviving a Facility Inspection*

Earn CLE Credits

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"The FY 2011 resources [+ $318.3 million] will strengthen our ability to act as a STRONG AND SMART REGULATOR…"

– FDA Commissioner Margaret A. Hamburg, M.D.

The Food Industry Is Under Attack On All Sides.

Contamination issues continue to plague the food industry, sparking wide-reaching recalls on what seems an almost daily basis. Increased focus by the Obama Administration on the "safety" of the U.S. food supply has pushed the Food and Drug Administration to create a new Office of Foods that will be dedicated entirely to "enhanc[ing] the Agency's ability to meet today's great challenges and opportunities in food and feed safety."

Drawing into question many of the advertising tactics that are being utilized by food companies alleging health and other types of product claims, the Federal Trade Commission has also stepped up its enforcement within the food industry, increasing its monitoring of marketing claims and questioning the science behind the claims being made. Inter-agency cooperation and coordination between agencies at the state, local, and federal level, have made unannounced facility inspections commonplace in today's enforcement environment, putting those within the industry on edge, fearful that the government could come knocking at any moment.

Learn how your colleagues are managing the litigation RISK and EXPOSURE created by current enforcement initiatives.

In response to the enforcement, regulatory and compliance challenges that are currently facing the food indsutry, American Conference Institute is proud to introduce its **Advanced Summit on Food Safety Regulatory Compliance.** Providing a forum for in-house regulatory and government affairs, food safety and compliance officers to share and discuss best practices while also hearing directly from the **FDA, FTC, NAD,** and *relevant state and local agencies* regarding what their current enforcement priorities are, this advanced conference will put all of the relevant stakeholders in the food industry – *both in-house and government* – in one place for two days of knowledge-sharing, policy shaping and strategy development.

What NEW REQUIREMENTS will the anticipated food safety legislation impose on your legal and business operations?

The key to surviving in this type of regulatory environment lies in the ability of your legal department to *consistently* and *properly* identify behavior that exposes your company to potential government enforcement or civil litigation and then translating that undesirable behavior into compliantbusiness and legal practices that will keep your company out of the regulatory crosshairs.

Is your company measuring its current compliance protocol against the new focus of food regulators and the continuing aggressiveness of the plaintiff's bar?

Don't allow your company to become the next headline! Armed with the proper tools – that will be provided by the in-house and government speakers at this conference – you can create [or update] your internal policies, procedures and practices in a manner that will minimize your client's risk of non-compliance, litigation exposure and reputational damage that often accompany today's food crises.

Take this opportunity to get the information you need from those on the leading edge of the food industry as you gather practical information you can take back to your company. Also, add value to your experience by joining us at the interactive workshop sessions – **How to Prove Substantiation of Claims in Product Marketing, Advertising and Labeling** and **Conducting Effective Due Diligence and Internal Audits into Suspected or Alleged Safety Violations.**

Register now by calling **888-224-2480,** faxing your registration form to **877-927-1563** or registering online at **www.AmericanConference.com/Food.**

"New FDA General Counsel Is Just What the Doctor Ordered"
– Corporate Counsel, January 11, 2010

"Obama Budget Devotes $1.4B to Food Safety Efforts to implement recommendations from the President's Food Safety Working Group."
– Product Liability Law 360, February 1, 2010

"FDA aims to identify risky food, drug imports"
– Reuters, February 5, 2010

"FDA unveils program to stop contaminated drug, food imports"
– The Wall Street Journal, February 4, 2010

"United States seizes more than 1500 cases of food…"
– FDA Press Release, February 3, 2010

"FDA Concerned About Substance in Food Packaging"
– The New York Times, January 16, 2010

"The number of inspections of foreign manufacturers carried out by the FDA this year could rise by 50%."
– Clinica, February 3, 2010

"FDA Toughens Stance on Front-of-Package Food Labeling"
– FDA Law Blog, October 22, 2009

"FDA Requests $4.03 Billion to Transform Food Safety System"
– FDA News Release, February 1, 2010

Monday, June 28, 2010

7:45 **Registration Opens and Coffee Served**

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

Scott T. Rickman
Associate General Counsel
Del Monte Foods (San Francisco, CA)

Christine Daugherty
Senior Counsel
Tyson Foods, Inc. (Springdale, AR)

8:45 **FDA Keynote Address: New Enforcement Priorities for the Food Industry**

*Michael Taylor**
Deputy Commissioner for Foods
Food and Drug Administration (Silver Spring, MD)

PRODUCT LABELING – REPRESENTATION CLAIMS

9:15 **Government Panel: Labeling Enforcement Priorities and How the FDA, FTC and NAD Coordinate Cases**

Scott McIntire
Director, Chicago District Office
Food and Drug Administration (Chicago, IL)

C. Steven Baker
Director, Midwest Region
Federal Trade Commission (Chicago, IL)

*Mark Levine**
Senior Attorney
National Advertising Division (New York, NY)

- What product marketing and claims are likely to be targeted for enforcement
- NAD activity in targeting deceptive, false and misleading advertising – track record to date
- Understanding the agencies' current thinking on
  - the industry's response to regulatory guidance for evaluating scientific evidence for health claims and qualified health claims
  - food marketing to children
- Update on proposed rulemaking concerning front of pack (FOP) labeling
- What agencies view as compliant product marketing and labeling concerning "natural" food claims

10:15 **Morning Coffee Break**

10:30 **Designing a Compliant Marketing Strategy to Minimize Product Representation Exposure**

Marc Kesselman
Vice President & General Counsel
Frito-Lay North America (Dallas, TX)

Leslie T. Krasny
Partner
Keller and Heckman LLP (San Francisco, CA)
General Counsel, Produce Marketing Association

Kim Carson
Regulatory & Scientific Affairs Manager
Dr Pepper Snapple Group (Dallas, TX)

- Balancing industry guidance with the "letter of the law" when implementing a marketing compliance program
- Fostering communication between marketing, scientific, regulatory and legal affairs departments when launching a product and deciding on marketing claims
- Establishing marketing and legal SOPs to select marketing claims that will – or not- be used – who decides and when?
- Tackling claim substantiation – ensuring proper scientific support for your product's health, performance, structure and function claims
- Organic vs. natural, menu labeling: complying with current nutritional labeling guidelines
  - understanding what needs to be revealed in the label in terms of chemicals or risk
  - meeting testing requirements
- Addressing emerging issues in labeling for allergans
- How successful is the preemption defense in food labeling cases?
- How to compete with companies whose practices are not FDA or FTC compliant

INSPECTIONS

11:30 **What Triggers an Inspection: How Agencies Select Companies and Facilities**

Kris Mazurczak, D.V.M.
Bureau Chief
Bureau of Meat and Poultry Inspection
Illinois Department of Agriculture (Springfield, IL)

Elizabeth Watkins
Food Processing Program Coordinator
Illinois Department of Public Health (Springfield, IL)

*Paul Wolseley**
District Manager
U.S. Department of Agriculture
Food Safety and Inspection Service (Lombard, IL)

- Understanding how the various agencies work together in the context of inspections
  - how is information received and filtered?
  - defining the jurisdiction and authority of each agency – FDA, FSIS, Department of Public Health, USDA
- Knowing what types of incidents, reports, and behavior prompt the government to launch an investigation
- What government is looking for once an investigation is launched – red flags for pursuing action beyond the investigation
- Best practices for working with inspectors once an investigation begins, during and post-investigation

12:30 **Networking Luncheon**

** denotes invited speaker at time of print*

1:45 **Surviving a Facility Inspection: How to Prepare and What to Do When Inspectors Come Knocking**

Norm Robertson
Director of Regulatory Issues
National Meat Association (Oakland, CA)

Stewart T. Leeth
AVP Environmental and Corporate Affairs
and Senior Regulatory Counsel
Smithfield Foods, Inc. (Smithfield, VA)

- Preparing effective internal controls and procedures for a "surprise" inspection
  - ensuring your staff is clear about what types of behavior are viewed as cooperative vs. uncooperative
  - how to respond to agent's requests
  - defining senior management's role during inspections
  - distinguishing between valid investigations and fishing expeditions - and how your staff should react to each
- Ensuring proper shipment records are retained and preparing your books for inspection
- Knowing what's going on in your food facilities – assigning responsibility for food tracking and country of origin labeling
- Post-inspection —
  - outlining corrective steps for problems identified during inspection
  - handling food re-labeling issues for products identified as adulterated during inspection
- Evaluating new OSHA and EPA emphasis on process safety and risk management programs in the context of facility inspections
  - evaluating current guidelines and requirements for maintaining ammonia refrigerated facilities

2:45 **Recall Execution: Effective Crisis Planning to Prevent the Onslaught of Litigation**

Susan M. Denigan
Vice President & General Counsel
Nestle Purina Petcare Company (St. Louis, MO)

Jonathan Cohen
Partner
Gilbert LLP (Washington, DC)

- Making the decision to recall – when and how
- Identifying and correcting compliance mishaps that led to the recall
- Anticipating and preparing for downstream litigation that will arise as the result of a recall – *from customers and from within the supply chain*
- How to effectively remove products from the market place
- Revisiting your GMP compliance in light of recent food recalls
- Product recall notification – analysis of GMA's rapid recall exchange
- Working with state and federal government to streamline your recall process post-incident

3:45 **Afternoon Refreshment Break**

4:00 **Detecting Food Contamination: Implementing Response Mechanisms to Mitigate Downstream Liability Risks**

Alejandro N. Canelos
Chairman, Tomato Division
Fresh Produce Association of the Americas (Nogales, AZ)

- Controlling the crisis – having an effective internal process in place to immediately respond when food contamination is suspected
- Implementing an effective traceback protocol to determine the cause of food contamination, if identified during inspection
  - what methods are most effective to treat and test various types of food products
  - detectionability and genetic fingerprinting – weighing the risks and benefits of utilizing irradiation, ammonia treatments and other emerging forms of technology
- Determining who should be contacted first
- Unique issues in tracking the food supply when a commingling product is at issue
- Knowing in advance what your consumer exposure is and how to immediately reduce it

4:30 **Meeting New Food Reporting Requirements under the Reportable Food Registry**

Alicia K. White
Global Procurement and Distribution Transactional Counsel
Whole Foods Market (Austin, TX)

Hih Song Kim
Assistant General Counsel, Marketing/Regulatory & Litigation
Unilever United States, Inc. (Englewood Cliffs, NJ)

Christine M. Pfeiffer
Senior Counsel
Nestle USA, Inc. (Glendale, CA)

Moderator:

Frederick H. Degnan
Partner
King & Spalding LLP (Washington, DC)

- Understanding the reporting obligations of a "responsible party" – manufacturers, distributers, suppliers, restaurants and sellers
- Deciphering what notification duties apply when –
  - more than one "responsible party" is involved
  - there are multiple immediate previous sources or subsequent recipients
- Delineating acceptable means of notification
- Ensuring each department understands what qualifies as reportable behavior
- Maintaining an appropriate balance between disclosure and reporting
- Exploring what constitutes a "transfer" of food from a responsible party to "another person"

5:30 **Conference Adjourns to Day Two**

Tuesday, June 29, 2010

9:00 **Co-Chairs' Remarks**

9:15 **Update on Food Safety Reform Legislation: A Practical Analysis of Proposed Statutory Reforms under the Obama Administration**

Miriam J. Guggenheim
Partner
Covington & Burling LLP (Washington, DC)

At press time, the status of several key bills proposing substantial regulatory reforms impacting on the food industry is still unknown. The outcome of these pending legislative matters could impose substantial additional regulatory requirements on both the domestic and the imported food supply. During this session, learn how these proposed changes, if passed, could impact your company's day-to-day business and legal practices.

- The FDA Food Safety Modernization Act (S. 510) & the Food Safety Enhancement Act (H.R. 2749) which would expand the authority of the FDA to regulate food, including new authority to –
  - require food firms to conduct hazard analyses and implement preventive controls
  - access food company records
  - increase the frequency of inspections
  - mandate a recall of food
  - oversee foreign supplier verification activities
  - impose per-facility registration fees

9:45 **Effectively Responding to Negative Media Coverage: How to Avoid the Backlash**

Scott T. Rickman
Associate General Counsel
Del Monte Foods (San Francisco, CA)

Kenneth Odza
Partner
Stoel Rives LLP (Seattle, WA)

- Developing and implementing corporate wide policies for responding to negative PR and media coverage
- Establishing a crisis management team
- How response strategy should differ for a government investigation vs. private litigation vs. the media
- Effectively handling corporate communications, both inside and outside the company
- Countering media coverage of the food industry by utilizing corporate and success stories to your advantage
- Strategies for (re)connecting with the consumer post-crisis

10:45 **Morning Coffee Break**

11:00 **Handling Government Requests: How to Respond to Alerts, Inquiries, Investigations and Warning Letters**

Christine Daugherty
Senior Counsel
Tyson Foods, Inc. (Springdale, AR)

Greg Thompson
Senior Food Attorney
Cargill (Wayzata, MN)

Sarah Roller
Chair, Food and Drug Law Practice
Kelley Drye & Warren LLP (Washington, DC)

- Managing the liability risk associated with increased government access to company records and filings
- Understanding what types of behavior can trigger negative attention from the government
- Responding to increased cooperation between federal, state and local agencies
- Managing the liability risk associated with increased government access to company records and filings
- Understanding what types of behavior can trigger negative attention from the government
- Responding to increased cooperation between federal, state and local agencies

12:00 **Creating "One Up, One Down" Accountability for Your Food Supply Chain**

Cate McGinn
Managing Counsel, Global Nutrition
McDonald's Corporation (Oak Brook, IL)

- Evaluating your company's internal tracking procedures to ensure proper documentation is maintained both within your company and the larger distribution network
- Auditing compliance with internal food accountability and reporting programs
- Understanding what the government is looking for in terms of "one up, one down" recordkeeping
- Creating an accountability chain for your product – from origin to destination

12:30 **Networking Luncheon**

1:45 **Preparing for Increased Criminal Liability and Exposure to State, Federal and Congressional Investigations**

Alan Maxwell
Partner
Weinberg Wheeler Hudgins Gunn & Dial LLC (Atlanta, GA)

The legal consequences of a large-scale food-borne illness outbreak or recall can be significant. Triggering a series of events that may open the door to criminal liability or even congressional investigation, a food contamination turned bad could become your general counsel's worst nightmare. Renowned food-borne illness defense attorney Alan Maxwell will engage you in a thought-provoking discussion on how to avoid opening the door to personal or criminal liability of your company's directors and officers.

Topics of discussion will include:

- Revisiting your company's D&O insurance coverage – knowing what's covered (and not covered) and what the liability limits of your company's policy
- Attorney-client privilege – ensuring your management is clear about when attorney-client privilege is triggered as well as what the limitations of the privilege are
- The role of the in-house counsel – understanding who the client is and delineating to your management, regulatory affairs and compliance officers what the limits of confidentiality and attorney-client privilege are, particularly once a government investigation has been launched

- Discussing what information should be shared with outside counsel vs. in-house counsel
- Preparing for a Congressional investigation

2:30 **Conducting Effective Self Assessments: How to Probe Weak Spots in Your Compliance Protocols**

Daniel Forrest Shaw
Vice President, Deputy General Counsel
H.J. Heinz Company (Pittsburgh, PA)

Don Becker
Corporate Counsel and Managing Attorney, Insured Litigation
Yum! Brands, Inc. (Louisville, KY)

- Identifying what your self-assessment process needs to accomplish
- When, how often and by whom should risk assessments be conducted
- Addressing consumer claims and product complaints – what's your process and how is it working?
- Evaluating whether or not your company is utilizing sustainable business practices to prevent downstream litigation
  - detecting behavior that can open the door to class/mass action litigation
  - understanding the difference between regulatory action and company behavior that can trigger consumer fraud litigation vs. personal injury litigation
- Resolving compliance challenges and potential regulatory target areas to anticipate later enforcement issues
- Implementing an effective HACCP plan post-PCA – identifying weak points in your supply chain that may open the door to contamination or adulteration
- Ensuring key members in each department – legal, marketing and regulatory – are clear regarding what the reporting structure is for compliance infractions

3:30 **Afternoon Refreshment Break**

3:45 **Minimizing Liability Risks from the Globalization of the Food Supply**

Benjamin L. England
Founder & Attorney
Benjamin L. England & Associates, LLC
FDAImports.com, LLC (Columbia, MD)

- How the FDA (and other US regulatory agencies) monitor food import/export activity outside the US
- Current pending reform initiatives to address imported food safety
- Understanding what other countries are doing and how changes in foreign regulations will impact your domestic food operations
- Update on new European regulations addressing imported and exported food and health claims
  - an overview of new border control initiatives in Europe specific to food products
  - assessing your marketing plans based on heightened scrutiny and new regulation of health claims in the EU
  - taking the appropriate steps to insulate your company from liability when importing food products
    - analyzing unique issues related to contamination and food supply chain safety when products (or ingredients) are manufactured abroad
    - incorporating procedures into your import protocol for evaluating the purity of raw materials exported from countries without good quality control
    - ensuring foreign product manufacturers, marketers and ingredient suppliers are complying with current FDA guidance on security measures for food importers that produce, process or transport food

4:30 **Conference Concludes**

** denotes invited speaker at time of print*

Who You Will Meet at This Important Conference

Food Manufacturers, Retailers, Distributors, Suppliers, Servers and Restaurants:

- Regulatory Affairs
- Compliance Officers
- Government Affairs
- In-House Counsel
- Risk Management
- Food Safety

Attorneys practicing in:

- FDA Law
- Food Law
- Regulation of Food Advertising and Labeling

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A How to Prove Substantiation of Claims in Product Marketing, Advertising and Labeling

9:00 am – 12:30 pm *(Registration Begins at 8:30 am)*

Jessie F. Beeber
Partner
Frankfurt Kurnit Klein & Selz, PC (New York, NY)

Being able to successfully prove and show scientific and other substantiation for claims made in your product marketing and advertising is key to keeping your product out of the regulatory, consumer, and competitive crosshairs. As the FDA and FTC tighten their approval and monitoring of health claims and qualified health claims, particularly within the food industries, companies should be now re-visiting what protocols are in place for reviewing product claims prior to market entry.

During this practical working session, outside counsel to the food industry's leading companies will walk you through the development process of a product, exploring how product claims originate, what information should be provided in order to adequately show substantiation and what one can expect in the event a complaint or information demand is filed against your company. This interactive session will provide practical and compliant best practices, tips, and advice on how to establish solid claim substantiation of your product.

Topics of discussion will include:

- Drafting, evaluating, and substantiating proposed claims, including:
  - health claims and qualified health claims
  - nutrient content claims
  - structure and function claims
  - dietary guidance claims
  - testimonials
  - before-after claims
  - comparative claims
- Emerging issues in food marketing to children and front-of-pack labeling
- Assuring that all claims are qualified with clear and prominent disclosures to reflect the science and avoid deceptive implications through omitted material facts
- Developing an internal review process for substantiating product labeling and advertising claims of supplements and functional foods prior to market entry
- Ensuring regulatory compliance when using endorsed claims and product demonstration techniques
- Withstanding competitive and self-regulatory scrutiny of marketing practices by having the substantiation required by regulatory agencies, the courts, and NAD
- Knowing how and when to challenge a competitor's claim

B Conducting Effective Due Diligence and Internal Audits into Suspected or Alleged Safety Violations

1:30 pm – 5:00 pm *(Registration begins at 1:00 pm)*

Sarah Brew
Partner
Nilan Johnson Lewis PA (Minneapolis, MN)

Scott Rickman
Associate General Counsel
Del Monte Foods (San Francisco, CA)

Bradley Sullivan
Managing Attorney
Lombardo & Giles LLP (Salinas, CA)

Nancy Husnik
Senior Corporate Counsel Target Corporation (Minneapolis, MN)

In light of recent increased scrutiny by regulators on all sides – FDA, FTC, USDA, FSIS – as well as private plaintiffs, it is clear that the time to investigate one's own internal behavior is not at the onset of a government investigation. Rather, because of the increased pressure on companies *within and throughout* the food supply chain, it is critical to remaining out of the regulatory crosshairs that your company continuously audits compliance with internal practices and procedures.

To address the unique issues that arise in the context of internal audits, special attention will be paid during this session to proper document tracking and preservation protocols, as well as best practices for utilizing an internal audit to update your company's overall approach to ensuring due diligence is carried out by everyone within the food supply chain.

This intensive workshop session will provide you with a rare opportunity to brainstorm and benchmark your internal compliance, audit and record keeping protocols with those of your peers.

Topics of discussion will include:

- Best practices for creating uniformity in your internal audit process
- Putting together the "dream team" audit team and conducting the audit – what to look for *and when to stop looking*
- Handling knowledge or suspicion of potential regulatory violations and assessing the potential risk and liability exposure of a suspected violation
- Identifying whether or the "problems" uncovered are systemic or isolated in nature
- Addressing privilege issues – when is privilege waived or triggered during the context of an internal investigation
- Understanding when there is a duty to "investigate" suspected client violations
- Dealing with whistle blowers
- Record maintenance and preservation – deciding whether to retain or not
  - establishing (or improving) on an effective document retention policy
  - creating specific guidelines that will address special concerns related to electronic vs. paper document management throughout your food supply chain
  - reducing the risk of creating "bad" documents during an internal investigation (or otherwise) and controlling the dissemination of information within the company
- Effective techniques for ensuring compliance with an established policy
- Communicating the policy and its consequences to your work force
- Common internal audit pitfalls that should be avoided

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June 30, 2010 Interactive Working Groups

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B Conducting Effective Due Diligence and Internal Audits into Suspected or Alleged Safety Violations

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