



NewsFeed™
Foley's Quarterly Food Industry Web Conference Series

Presenters:
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Today's Presenters



Vicki Hicks **Sarah Key** **David Rosen**

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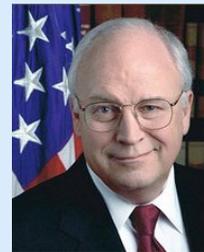
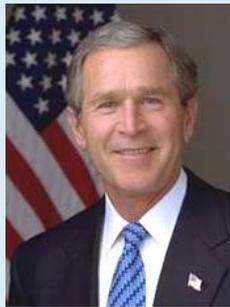
- We will take questions throughout the program via the Q & A tab at the top of your screen and live questions at the end of the program
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Regulatory Inspections: Practical Advice for When the FDA Visits and for Responding to FDA 483 Observations and Warning Letters

Welcome From the Food Nation's Capitol



The President and Cabinet Send Their Regards



The Presidential Hopefuls



President and Mrs. Bush Wave Bye-Bye



Just the Facts

- Safety of our food supply is of paramount importance
- FDA has developed a comprehensive Food Protection Plan to protect the food supply from unintentional contamination and deliberate attack
- Bioterrorism Protection Act – a very burdensome process
- Product Safety / High Profile Recalls

Counter-Terrorism Measures

- Bioterrorism Preparedness and Response Act of 2002
- Safeguard Food Supply - Requirements for Businesses That Manufacture, Process, Distribute, or Otherwise Process Food and Food Ingredients
 - Registration Of Food Facilities
 - Prior Notice Of Food Shipments
 - Record-keeping Requirements
 - Administrative Detention

Counter-Terrorism Measures (cont'd)

- Food Protection Plan
- Addresses the changes in food sources, production, and consumption
 - Prevention
 - Education of consumers and the industry
 - Intervention
 - Risk based inspections and sampling
 - Response
 - Traceability
 - Rapid response

Recalls in the News

- Food recalls cause a big public stir and get significant press coverage
 - Contamination with microorganisms
 - Salmonella (Serrano Peppers)
 - Listeria Monocytogenes (fish products)
 - Allergens present in foods that are not declared
 - Milk
 - Nuts
 - Soy
 - Adulterated food products
 - Shellfish with Toxins that cause paralytic shellfish Poisoning
 - HACCP deficiencies

Food Safety Issues Have the Attention of

- Consumers
- FDA
- Congress

Agenda for Today's Discussion

- Are you prepared for an inspection?
- What to do when FDA walks in the door
- What happens if/when the FDA inspector issues observations
- How to respond to observations
- Disclosable information under FOI
- What happens if FDA issues a Warning Letter
- Responding to a Warning Letter
- Preparation for meeting with FDA and follow up inspections

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Why are the Problems Surfacing Within the Food Industry?

- High profile recalls impacting consumer health
- Closer review of the operations and data by FDA
- Congressional pressure to increase oversight
- Cutback in resources at food processing, packaging and labeling firms
- Efforts to package and label products quickly

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Why are the Problems Surfacing Within the Food Industry? (cont'd)

- Failure to have routine auditing / monitoring systems
- Lack of Corrective and Preventative Action Plan
- Lack of continued training and understanding by the operators of what is expected
- Lack of commitment to quality from the top management down throughout the organization

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Be Ready for FDA Inspection

- FDA inspectors will visit when there is a safety issue, recall, consumer complaint
- To prep – they will evaluate the company's compliance history
- What are the first items they want to see:
 - Product Complaints
 - Rejected Lots
 - Trending of issues
 - Thorough and complete investigations
 - Communication with CFSAN headquarters staff about the issues and how they are going to be further investigated and addressed
 - Corrective and preventative action plans
 - Revised SOPs and staff training
- Be prepared

Practical Measures to Prepare For an FDA Inspection Before Such an Inspection Commences

- Conduct periodic unannounced **audits** of all operations studies to evaluate whether procedures are being followed
- **Review** the **results of the audit** with all personnel involved; document all **changes** that are initiated to bring the study in compliance
- Quality starts from the top management and must be integral throughout the entire operation

Practical Measures to Prepare For an FDA Inspection Before Such an Inspection Commences (cont'd)

- Review procedures for **handling an FDA inspection**
 - (e.g., who should interact with the inspector, how do you respond to questions, how do you respond to requests for documents, which records is an inspector entitled to review; can they take pictures; will you sign an affidavit)
- Establish such procedures if they do not exist

Practical Measures to Prepare For an FDA Inspection Before Such an Inspection Commences (cont'd)

- Review procedures for **follow up to FDA observations** made during the inspection, the post-inspection interview, FDA 483 observations
- Establish a plan for remedial action, if necessary, and to prepare and review documentation and response to issues raised by FDA

Consequences of Failing to Comply With FDA Requirements

- FDA 483 – Notice of Observations
- Warning Letter
- Administrative sanctions including an injunctive relief; consent decrees
- Civil fines
- Criminal prosecution
- Negative publicity

Warning Letter

- Defined by FDA
 - "Written communication... notifying an individual that the agency considers one or more practices to be in **violation** of the Federal Food, Drug, and Cosmetic Act, or other acts, to the extent that failure of the responsible party to take appropriate and prompt action to correct the violation may be expected to result in **enforcement (administrative and/or regulatory) action** without further notice"

Managing Your Company's Relationship with FDA

- Commitment to Quality – at all levels of the organization
- If enforcement issues arise - senior management involvement is **key**
 - Demonstrate understanding of issues
 - Attend meeting with FDA Officials
 - Commit to address issues in a timely manner
 - Meet time commitments
 - Dedicate sufficient resources
 - Communicate progress on an ongoing basis

Managing Your Company's Relationship with FDA (cont'd)

- Thorough response
 - To inspectional observations and issues identified in the Warning Letter
 - Review of overall operations and quality systems
 - Provide documentation of investigations and change
- Respond timely and completely to further questions
- Be prepared for re-inspection

Chief Enforcer

- FDA will soon have new top cop – will new enforcement priorities
 - Margaret O. Glavin recently left



Legislative Update: Proposed Food Safety Legislation

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Prospects for Food Safety Legislation in the 110th Congress

- Background on current regulatory responsibilities
- Durbin Proposal:
 - Registration of food facilities
 - Hazard Analysis and Risk-Based Preventative Control Plans
 - Fresh Produce Standards
 - Increased Frequency of Inspections
 - Mandatory Recall Authority
 - Enhanced Traceback and Recordkeeping
 - Surveillance
 - Foreign Supplier Verification Program
 - Certification of Certain Imports
 - Inspection of Foreign Food Facilities
 - Accredited Third Party Auditors

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Prospects for Food Safety Legislation in the 110th Congress (cont'd)

- Dingell Discussion Document
 - Registry of all Food Facilities
 - Facility Fee
 - Safety Plans
 - Voluntary Certification
 - Non-Certified Facilities Face Restrictions
 - Country of Origin Labeling of Processed Foods
 - GRAS Publication Required
- Prospects for Passage

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**COOL: *The Expanded Country of
Original Labeling Requirements*
USDA's August 1, 2008 Interim Final
Rule (73 Fed. Reg. 45206)**

Background

- 2002 Farm Bill established COOL requirements for the following commodities:
 - Beef
 - Lamb
 - Pork
 - Fish
 - Shellfish
 - Perishable Agricultural Commodities (fresh and frozen fruits and vegetables)
 - Peanuts

- However, implementation of the requirements was delayed for all commodities except for fish and shellfish until September 30, 2008. The labeling requirements for fish and shellfish went into effect on April 4, 2005 pursuant to an Interim Rule issued by USDA on October 5, 2004

2008 Farm Bill

- The 2008 Farm Bill expanded COOL requirements enacted by the 2002 Farm Bill to include the following commodities:
 - Chicken
 - Goat
 - Macadamia Nuts
 - Pecans
 - Ginseng
- The COOL requirements for all covered commodities (including those addressed by the 2002 Farm Bill) go into effect on September 30, 2008

Who Must Comply with the COOL Requirements?

- Retailers must inform consumers of the country of origin of all covered commodities
- Suppliers must provide retailers with the information needed for retailers to make the required country of origin declaration at the point of sale

Processed Food Exemption

- Covered commodities that are an ingredient in a processed food item are exempt from the COOL requirements. A *processed food item* means:
 1. a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered commodity, or
 2. that has been combined with at least one other covered commodity or other substantive food component (e.g., breading, tomato sauce)
- *Except that:* the addition of a component (such as water, salt, or sugar) that enhances or represents a further step in the preparation of the product for consumption, would not in itself result in a processed food item

7 C.F.R. § 65.220

Examples of Processing that Results in a Change to the Character of the Covered Commodity

- Cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting)
- Curing (e.g., salt curing, sugar curing, drying)
- Smoking (hot or cold)
- Restructuring (e.g., emulsifying and extruding)

Commingled Covered Commodities

- A *commingled covered commodity* is a single type of covered commodity (e.g., lettuce), presented for retail sale in a consumer package, that has been prepared from raw material sources that have different origins. 7 C.F.R. § 65.125
- *Note that if the retail product contains two or more different types of covered commodities (e.g., peas and carrots) it is considered a processed food and is exempt from the requirements*

Labeling for Commingled Covered Commodities

- Labeling for Commingled Nuts, Ginseng, and Perishable Agricultural Commodities: Label declaration must indicate countries of origin for all covered commodities in accordance with Customs and Border Protection (“CBP”) marking regulations. See 19 C.F.R. Part 134
- Labeling for Commingled Ground Meat Products: The labels of commingled ground meat products must include a list of all the countries of origin contained therein or reasonably contained therein

Recordkeeping Requirements – Suppliers

- Persons engaged in supplying covered commodities to retainers, whether directly or indirectly, have the following responsibilities:
 1. Make available information to the buyer as to the country(ies) of origin of the covered commodity. This information can be provided on the product itself, on the master shipping container, or in a document that accompanies the product through retail sale.
 2. If the supplier is responsible for initiating a country(ies) of origin claim must possess or have legal access to records that are necessary to substantiate that claim
 3. Maintain records to establish the immediate previous source (where applicable) and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction

Recordkeeping Requirements – Importer of Record

- For imported covered commodities, the importer of record must ensure that records:
 1. provide clear product tracking from the port of entry into the United States to the immediate subsequent recipient; and
 2. accurately reflect the country of origin as identified in the relevant CBP entry documents and information systems
- These records must be maintain for a period of 1 year from the date of the transaction

Recordkeeping Requirements – Retailers

- Records and other documentary evidence relied upon at the point of sale to establish country(ies) of origin must be maintained for a period of 1 year from the date the origin declaration is made at retail
- For pre-labeled products, the label itself is sufficient evidence on which the retailer may rely to establish the product's origin

Implementation Date

- The implementation date of the IFR is September 30, 2008. However, the requirements of the rule do not apply to covered commodities produced or packaged before September 30, 2008. In addition, USDA plans to exercise a period of enforcement discretion following the implementation date.

Enforcement Discretion Period

- While the COOL requirements for all covered commodities go into effect on September 30, 2008, USDA will conduct an industry education and outreach program concerning the requirements of the IFR for the first 6 months after the effective date, until March 30, 2009

Penalties

- The law contains enforcement provisions for both retailers and suppliers that include civil penalties of up to \$1,000 per violation
- If USDA determines that a retailer or supplier is in violation of the requirements, the retailer/supplier will be notified and given a 30-day period to come into compliance with the requirements
- If, at the end of the 30-day corrective period, the Secretary determines that the retailer/supplier has (1) not made a good faith effort to comply; and (2) continues to willfully violate the provisions of the law, the retailer/supplier may be fined up to \$1,000 per violation

Questions & Answers

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