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Foley's Quarterly Food Industry Web Conference Series

Presenters:
Sarah Key, Government & Public Affairs Practice
David Rosen, FDA Practice
Mopsi Villareal, Government & Public Affairs Practice
Eileen Ridley, Litigation Department

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Today's Presenters



Sarah Key **David Rosen** **Mopsi Villareal** **Eileen Ridley**

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Focus on Food Safety

What to Expect Under the New Administration

Lessons Learned From the Peanut Recall

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Just the Facts

- New administration is keenly aware and focused on food safety
- Safety of our food supply is of paramount importance
- FDA / USDA / States are likely to step up compliance and enforcement efforts on foods
- High Profile Recalls and Congressional Hearings have keep this issue in the news

Enforcement Efforts

- FDA / USDA are empowered with a renewed sense for enforcement
 - We expect more inspections
 - More violative conditions identified
 - More enforcement actions being taken

Why are the Problems Surfacing Within the Food Industry?

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

Inspections – Be Prepared

- Are you prepared for an inspection?
- What to do when FDA/USDA / State Inspector walks in the door
- What happens if / when the 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 federal and state officials and follow up inspections

A Food Safety Issue Surfaces - What Now

- Stay calm
- Alert the management team
- Stop shipping and quarantine of product
- Initiate an investigation
- Is it time to notify the government and public of the issue?
- Manage the recall
- Complete investigation
- Take corrective and preventative action

Be Ready for Inspection

- 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 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 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 organization

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

- Review procedures for **handling an 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 written procedures if they do not exist

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

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

Lessons Learned from the Peanut Recall How to Prevent Problems and Safeguard your Company

Know your suppliers

Federal health investigators have found that “most food manufacturers and distributors cannot identify the suppliers or recipients of their products despite federal rules that require them to do so . . .”

New York Times Mar. 26, 2009

Lessons Learned from the Peanut Recall How to Prevent Problems and Safeguard your Company (cont'd)

Audit your suppliers

- Consider having a third-party conduct periodic audits of the company's suppliers
- Sample and test from incoming shipments prior to accepting the shipment
- Reject any shipments that contain adulterated product, even if the problem does not appear to be widespread

Lessons Learned from the Peanut Recall How to Prevent Problems and Safeguard your Company (cont'd)

Audit your auditors

- Do not rely solely on the results of third-party audits conducted at your suppliers' facilities
- AIB conducted audits of Peanut Corporation of America for major food manufacturers but failed to flag serious problems. Instead, AIB issued a "certificate of achievement" and a "superior" rating for PCA last August

Washington Post March 20, 2009

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**Lessons Learned from the Peanut Recall
How to Prevent Problems and Safeguard your Company (cont'd)**

Revisit Your Recall Plan

Study the company's recall plan to ensure that it is adequate to facilitate a quick response in case of a serious food safety problem

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**Lessons Learned from the Peanut Recall
How to Prevent Problems and Safeguard your Company (cont'd)**

Consider Recall Insurance

Supply agreements that indemnify the company in the case of a recall will not be of much use if the supplier declares bankruptcy

Recall insurance should be comprehensive and cover not only the loss of product and costs associated with any consumer complaints, but also should cover lost productivity in case the facility is temporarily shut down, as well as attorneys fees

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Managing Your Company's Relationship with the Government

- 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 Government 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 the Government (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



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Legislative Update

Does the current food safety system have the resources, authority and structural organization to safeguard the health of consumers?

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Food Safety Modernization Act -- DeLauro

FDA Globalization Act -- Dingell



What does Congressman Waxman want?
"We must act now"

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Food Safety Modernization Act	FDA Globalization Act
National traceability system	
Inspection programs	
Food surveillance systems	
Up-to-date registry of all food facilities	

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Food Safety Modernization Act of 2009

- Establishes the Food Safety Administration in Dept. of Health & Human Services
- Imported food to meet the same standards as U.S. food
- Food establishments to adopt preventive process controls
- Performance standards for food safety

Voluntary/Mandatory Recalls

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Food and Drug Administration Globalization Act

- Requires for each food facility:
 - A hazard analysis of facilities that manufacture, process, pack, transport, or hold food for consumption in the US
 - Identification and implementation of preventive controls
 - A written food safety plan
 - Annual facility registration fees

Food and Drug Administration Globalization Act (cont'd)

- Accreditation system for food facilities
- Voluntary security guidelines for imported foods
- Safety plans for fresh produce
- Country-of-origin labeling
- Mandatory Recalls

Impact on Your Business

- "There has been too much influence by industry and not enough influence of science"
-- Congresswoman Rosa DeLauro
- More regulations
- More time spent complying instead of production
- Higher costs to your business

Recalls — Navigating Associated Litigation and Insurance Claims

Litigation – Strategies And Trends

- What Do You Do When A Claim Comes?
 - Initial Investigation
 - Review Letter or Complaint
 - Identify Product(s) Potentially Involved
 - Identify Facilities Potentially Involved
 - Identify Vendors Potentially Involved
 - Identify Potential Time Frame
 - Identify Insurance Potentially Involved (all levels including any additional insured coverage)
 - Determine if any similar claims have been received (either directly or through vendors)

Litigation – Strategies And Trends (cont'd)

- What Do You Do When A Claim Comes?
 - Initial Investigation (cont'd)
 - Determine if there is any governmental action involved or likely to be involved (FDA, etc.)
 - Ensure no associated materials, documents, etc. are destroyed (litigation hold)
 - If a recall is likely, work with regulatory counsel regarding activities keeping in mind that civil litigation will likely follow
 - Determine if any press has surfaced regarding the issue

Litigation – Strategies And Trends (cont'd)

- What Do You Do When A Claim Comes?
 - Early Action Items
 - Obtain all vendor contracts and insurance policies
 - Tender to all potential vendors and insurers (use broker for tender to insurers and keep apprised of progress)
 - Obtain Counsel
 - Research Plaintiffs' Counsel (Experience, strategies, depth of bench)
 - Work with Counsel to identify experts early
 - Respond to any tenders (keeping insurers apprised)

Litigation – Strategies And Trends (cont'd)

- What Do You Do When A Claim Comes?
 - Litigation Strategies
 - Consider challenge to complaint – especially if a class action is asserted
 - Typicality (difficult in medical claims)
 - Commonality (difficult in circumstances of exposure)
 - Causation (especially if more than one product or source of product)
 - Jurisdiction (state or federal)

Litigation – Strategies And Trends (cont'd)

- What Do You Do When A Claim Comes?
 - Litigation Strategies
 - Discovery
 - Obtain Plaintiff(s)' medical documents early
 - Use experts to assist discovery process
 - Obtain third party records (including Health Dept., FDA, etc.)
 - Outline timeline of exposure to illness
 - Obtain plaintiffs' investigatory documents (testing, analysis, witness statements etc.)
 - Depose plaintiff(s) early

Litigation – Strategies And Trends (cont'd)

- What Do You Do When A Claim Comes?
 - Litigation Strategies
 - Discovery (cont'd)
 - Concentrate discovery on differences between plaintiffs – symptoms, onset, product, handling, exposure, treatment etc.
 - Determine potential third party liability (how was product used, stored, handled, served, prepared)
 - What labels are involved (who produced)
 - What was plaintiffs' knowledge regarding food safety procedures (particularly regarding raw food handling)
 - Consider effect of customer/consumer list being produced

Litigation – Strategies And Trends (cont'd)

- What Do You Do When A Claim Comes?
 - Litigation Strategies
 - Dispositive Motions/Challenges To Class

 - Claims Against Third Parties
 - Cross-claims (indemnification, contribution, comparative fault, etc.)
 - Joint Defense Privilege
 - Safety background and compliance of vendors

Litigation – Strategies And Trends (cont'd)

- What Do You Do When A Claim Comes?
 - Litigation Strategies
 - Settlement
 - Assume some form of ADR will be employed
 - Determine whether early discussions are warranted
 - Ensure settlement is confidential (difficult with class – reason to consider early settlement)

 - Public Relations/Business Goals
 - Handling the press
 - Protecting the brand
 - Consider budget for case in light of likely outcome

Litigation – Strategies And Trends (cont'd)

■ Trends

- Pet Food (emotional distress claims)
- Genetically Engineered Food (testing issues)
- Nano Technology
- Health Claims
 - Sports Drinks
 - Organic Claims
 - Baby Food

Litigation – Strategies And Trends (cont'd)

■ Trends

- Commercial Claims
 - Consumer Statutes (e.g. CLRA – safe harbor provisions)
 - Unfair Competition Claims
 - Misrepresentation Claims
 - Warranty Claims

Litigation – Strategies And Trends (cont'd)

- *Williams v. Gerber Products Co.*, 552 F.3d 934 (9th Cir. Dec. 22, 2008)
 - Facts:
 - Plaintiffs – class action brought by parents of a two and third year old who sought healthy snacks for their children
 - Purchased Gerber's Fruit Juice Snacks as part of Gerber's "Graduates for Toddlers" product line
 - Plaintiffs contend that the packaging was deceptive as follows:
 - "Fruit juice" juxtaposed along side images of fruits (oranges, peaches, strawberries and cherries) while the product contained no fruit juice from these items but only white grape juice from concentrate

Litigation – Strategies And Trends (cont'd)

- *Williams v. Gerber Products Co.*, 552 F.3d 934 (9th Cir. Dec. 22, 2008)
 - Facts (cont'd):
 - Packaging Deceptive (cont.)
 - Side panel said product made from "real fruit juice and other all natural ingredients" even though the two most prominent ingredients were corn syrup and sugar
 - Side panel stated "Snacks" was "one of a variety of nutritious Gerber Graduates foods and juices"
 - The product was labeled as "snack" not a "treat", "candy" or "sweet"

Litigation – Strategies And Trends (cont'd)

- *Williams v. Gerber Products Co.*, 552 F.3d 934 (9th Cir. Dec. 22, 2008)
 - Ruling:
 - Standard: reasonable consumer standard used to determine if members of the public are likely to be deceived (prohibits false advertising but also advertising which is true but has a capacity, likelihood or tendency to deceive or confuse the public)
 - 9th Cir. reversed district court's ruling on motion to dismiss and determined packaging could be deceiving as alleged

Litigation – Strategies And Trends (cont'd)

- *Williams v. Gerber Products Co.*, 552 F.3d 934 (9th Cir. Dec. 22, 2008)
 - Rulings (cont'd):
 - Claim that product was “just one of a variety of nutritious Gerber Graduates foods and juices that have been specifically designed to help toddlers grow up strong and healthy” adds to the potential deception
 - Compliance with FDA requirement of ingredient list is not defense. “We do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on the ingredient list to correct those misrepresentations and provide a shield for liability for the deception. Instead, reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging”

Questions & Answers

Contact Us

Sarah A. Key
Senior Counsel
3000 K St. NW, Suite 500
Washington, D.C. 20007
Tel: 202.295.4720
skey@foley.com

David L. Rosen
Partner
3000 K St. NW, Suite 500
Washington, D.C. 20007
Tel: 202.672.5430
drosen@foley.com

Eileen R. Ridley
Partner
One Maritime Plaza, 6th Floor
San Francisco, CA 94111
Tel: 415.438.6469
eridley@foley.com

Cynthia (Mopsi) Villareal
Public Affairs Director
3000 K St. NW, Suite 500
Washington, D.C. 20007
Tel: 202.672.5419
cvillareal@foley.com