



TriVista McGUIREWOODS

**MAKING HEALTHY
FOOD INVESTMENTS:**

*Managing Food
Safety & Legal Risks*

JENNIFER FRANKENBERG

Vice President, TriVista

JAMES F. NEALE

Partner, McGuireWoods LLP



QUALITY of OPERATIONS

DUE DILIGENCE



Jennifer Frankenberg
Vice President



- Leads Regulatory Compliance Practice
 - Food, Beverage, Consumables
 - Consumer Products
- Leader in TriVista's Transaction Advisory Practice
- Advised on 75+ mid-market food transactions

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AREAS OF EXPERTISE:

- Food Safety – Regulatory Compliance
- FSMA – Food Safety Modernization Act
- Food Safety Due Diligence
- Consumer Products Safety
- Quality of Operations® Due Diligence
- Food Production & Manufacturing
- Supply Chain & Sustainability
- Foodservice
- Distribution



James F. Neale
Partner

McGUIREWOODS

- Trial Attorney with focus on food and beverage industry
 - Food Borne Illness
 - Regulatory Compliance
 - Labeling
- Co-Chair of McGuireWoods' Food & Beverage Industry Group
- Co-Author, Food Safety Law

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AREAS OF EXPERTISE:

- Defense of Food Borne Illness at Trial
- Food Safety – Regulatory Compliance
- FSMA – Food Safety Modernization Act
- Due Diligence in Industry Transactions
- Root Cause Investigations



FOOD SAFETY DILIGENCE



- Is the company fully compliant with all regulations? If not, what is the action plan and timeline to fill those gaps?
- Who has reviewed and scientifically validated the food safety programs – are they adequate considering the operation’s supply chain? Have label claims been verified and validated?
- Is the management team aware of the complexity and risks of their supply chain? How have product identity risks been assessed?
- What are the facility conditions and how are associated risks factored into food safety programs?
- Does the operation have a comprehensive Crisis Management plan for all critical potential events?
- Is there a robust top-down food safety culture?

What do Consumers Want?

- Better health
- Social conscience
- Transparency
- Safe food
- Organic, GMO-free, “clean label”



A Perfect “Storm” for Increased Risk...

- Smaller, nimble and innovative “disruptor” companies stealing market share
- Inexperienced management team unaware of potential risks
 - Don’t know what “good” looks like
- Consumer trends driving new inherent dangers
 - Novel ingredients, new processes, etc.

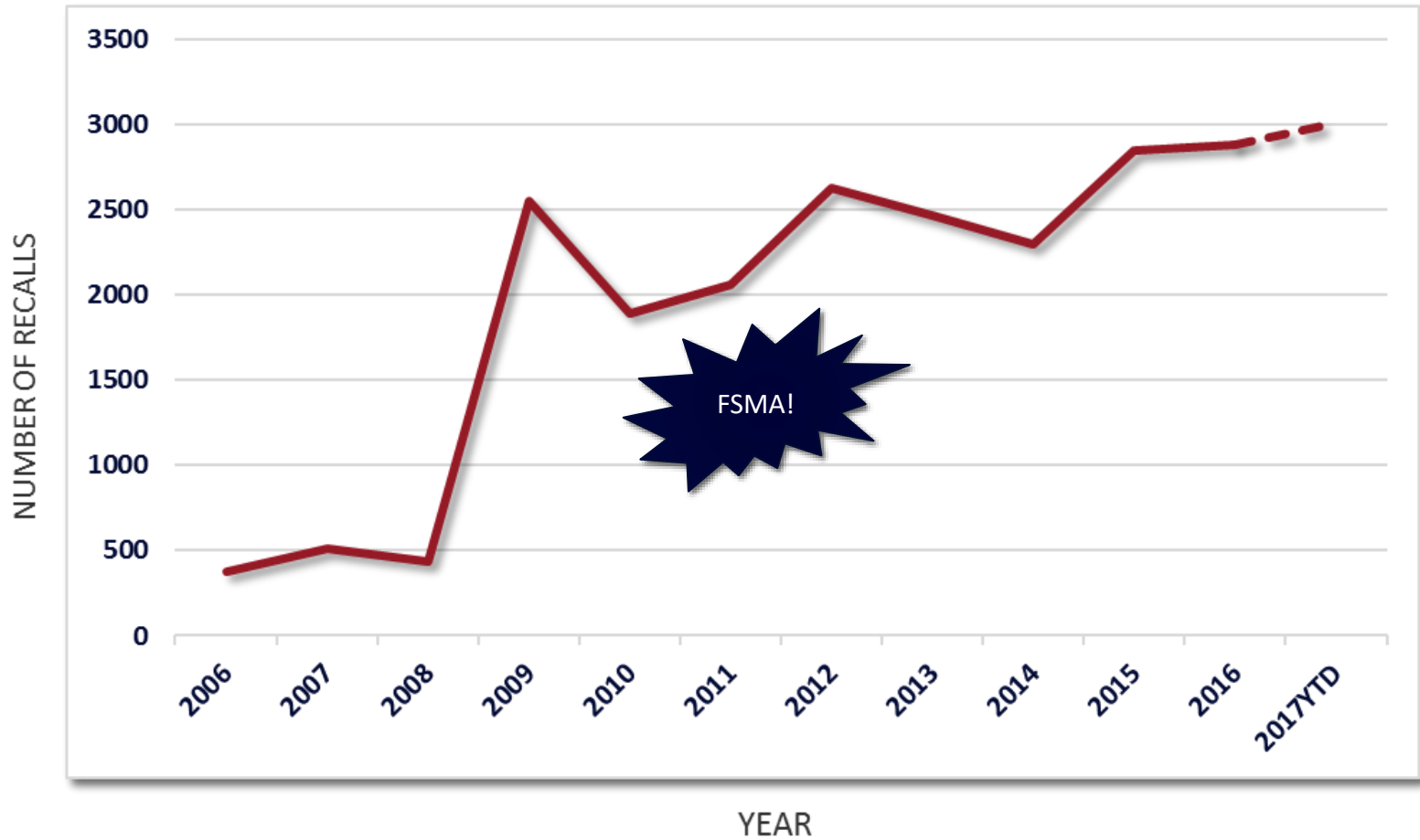
- **Topps** Liquidates Company after Massive Beef Recall
 - PE-backed
- *Detour Bar Maker, **Forward Foods**, Files Bankruptcy on Peanut Recall*
 - PE-backed
- *Massive Chicken Recall Puts \$2B Transaction on Hold*
 - **AdvancePierre** deal postponed following a USDA recall of 1.7 million pounds of chicken
 - PE owner taking final bids
 - Bidders taken by surprise by the recall
 - Transaction delayed
- **Jeni's Ice Cream** Recalls Products Following Listeria Discovery
 - Multiple recalls in 2015 and 2016
 - 265 tons of ice cream worth \$2.7 million destroyed (1/10th of estimated annual sales)



Risk to Private Equity Can Be Huge!

SINCE FSMA, RECALLS ARE ON THE RISE

FDA FOOD PRODUCT RECALLS





- Regulatory Non-compliance and/or Recalls can Result in Significant Financial Losses:
 - Halt in production
 - Product removal and destruction costs
 - Lost sales
 - Lawsuits
 - Government sanctions
 - Brand degradation
 - **Individual criminal liability – jail, debarment, fines, restitution**

FOOD SAFETY MODERNIZATION ACT (FSMA)



- First Major Reform to FDA in over 70 Years
- Shift in Focus from Reaction to Prevention of Food Safety Risks throughout the Entire Supply Chain
- Private Equity Investors Need to Pay Attention to FSMA
 - Complex regulation - most companies NOT PREPARED
 - Can impact PortCo financial performance
 - Private Equity is an easy target for the press!
- Food Safety Certifications do not Equate to FSMA Compliance

- FDA's Approach to Inspections has Changed
 - Can be collaborative with companies, rather than punitive
- Audits Include Actively Searching for Pathogens
 - “Swab-a-thons” - FDA will typically take hundreds of swabs throughout the facility looking for pathogens
 - May also take ingredient and/or finished product samples
 - Trying to match specific pathogens with current or past foodborne illness outbreaks
- FDA Requiring More Documentation
 - Often will review documented Preventive Control programs or specific records (production, sanitation, etc.) during audit
 - Can take copies of these documents with them



SUPPLY CHAIN TRANSPARENCY & TRACEABILITY



- Consumers Want Transparency
 - What is in the product?
 - Where did the ingredients come from?
 - Are there sustainability or social compliance aspects?
- Global Supply Chain Increasing Complexity
 - More choices for consumers
 - Reduced costs for industry
 - Yet, difficulty preventing foodborne contamination!
- Traceability is Critical
 - Country of origin / transshipping
 - Brokers
 - Handling of product – cross-contaminated equipment
 - More stringent risk management prevention of foreign-supplied ingredients and products is required

Perform Food Safety Due Diligence on Pending & Future Investments

- ✓ Verify your investment is compliant with all regulations
- ✓ Conduct 3rd party review of food safety programs (with dual focus on science and regulations), label claims, and product identity
- ✓ Know your supply chain
- ✓ Inspect facility conditions
- ✓ Assist your investment with their crisis management preparations
- ✓ Ensure management is building a top-down food safety culture

FOOD SAFETY DILIGENCE IS CRITICAL

- ✓ Quickly identify and quantify risks in the value chain
- ✓ Ensure facility, processes, and programs support a safe, compliant product
- ✓ Understand where Food Safety Risk exists



- Good Manufacturing Practices / Employee Hygiene
- HACCP/HARPC
- Microbiological Programs
- Allergen Program
- Supply Chain Management
- Sanitation
- Equipment Condition & Maintenance Program
- Grounds & Facility Condition
- Storage Practices
- Pest Control
- Traceability
- Recall & Crisis Management Programs
- Food Defense Program
- Employee Training
- Product Specifications
- Customer Complaints
- Internal Assessment Programs
- Third Party Audits
- Management Commitment
- Label Claims

Have a robust risk mitigation plan with roadmap and timeline for completion



LEGAL DILIGENCE IN FOOD & BEVERAGE TRANSACTIONS

PRIMARY AREAS OF LEGAL CONCERN

- Regulatory Compliance
- Labeling Exposure
- Slack-fill and Prop 65 Exposure
- Allergen Disclosure
- Foodborne Illness Outbreak
- Criminal Prosecutions



- ✓ Registered with the FDA?
- ✓ FSMA Compliant?
 - ✓ cGMPs and preventive controls
 - ✓ Supply Chain audited
 - ✓ Transport button down
- ✓ History of Warning Letters or FDA Form 483s?
- ✓ Reportable Food Registry Reports?
- ✓ Environmental Sampling Results?



- USDA v FDA Exposure
- Consumer Preferences Increase Exposure
- 25x Increase in Last Six Years
- Claims are Usually NOT Insurable



Non-functional Unused Packaging is Misleading, Especially if:

- Vulnerable demographic
- Opaque packaging
- Reduced net weights, but same size package



- Ballot Initiative from '86
- 800+ Chemicals Thought to Cause Cancer/Reproductive Toxicity
- Requires Conspicuous Disclosure
- Enforced by AG/Prosecutor/City Atty/Private Individual
- Penalties up to \$2,500/day + Injunctions



- Most Frequent Cause of Misbranding Recalls
- FALCPA, 21 U.S.C. § 301
 - Must disclose any of the “Big Eight”
 - Need not disclose any other allergen
 - Must call out in ingredient list or “CONTAINS” statement
- Cross Contamination Warnings



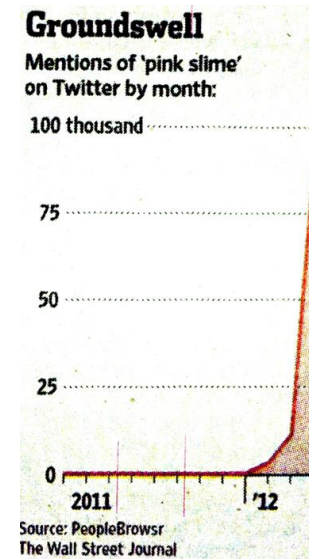
Figure 1: The “Big Eight” Allergens: Tree Nuts, Peanuts, Soy, Egg, Milk, Fish, Wheat and Shellfish.

INGREDIENTS: Whole-grain sprouted brown rice protein concentrate, natural flavor, stevia.

ALLERGEN INFORMATION: This product is manufactured in a facility that processes other products which may contain soy, dairy, wheat, tree nuts, shellfish, fish, peanuts, and eggs and may contain traces of all of the above.

FOODBORNE ILLNESS OUTBREAK

- More Recalls but Fewer Outbreaks
 - Preventive controls working?
- Most Expenses are Insurable
- Most Illnesses are Relatively Minor
- Real Risk is to Brand (Chipotle Stock)
- Publicly available information:
 - iwaspoisoned.com (real-time crowd sourcing)
 - MMWR



- Selling Adulterated / Misbranded Food is a Crime
- 21 U.S.C. § 333(a)(1) = Misdemeanor
 - First time offense and
 - No actual knowledge of adulteration / misbranding
- 21 U.S.C. § 333(a)(2) = Felony
 - If Repeat Offense or
 - Actual knowledge of adulteration / misbranding
- Individual Criminal Liability under the “Park Doctrine”



RECENT EXAMPLES





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