



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

**CONTACT :**

+1.949.218.4830

[jennifer.frankenberg@trivista.com](mailto:jennifer.frankenberg@trivista.com)

**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

**CONTACT :**

+1.434.977.2582

[jneale@mcguirewoods.com](mailto:jneale@mcguirewoods.com)

**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.

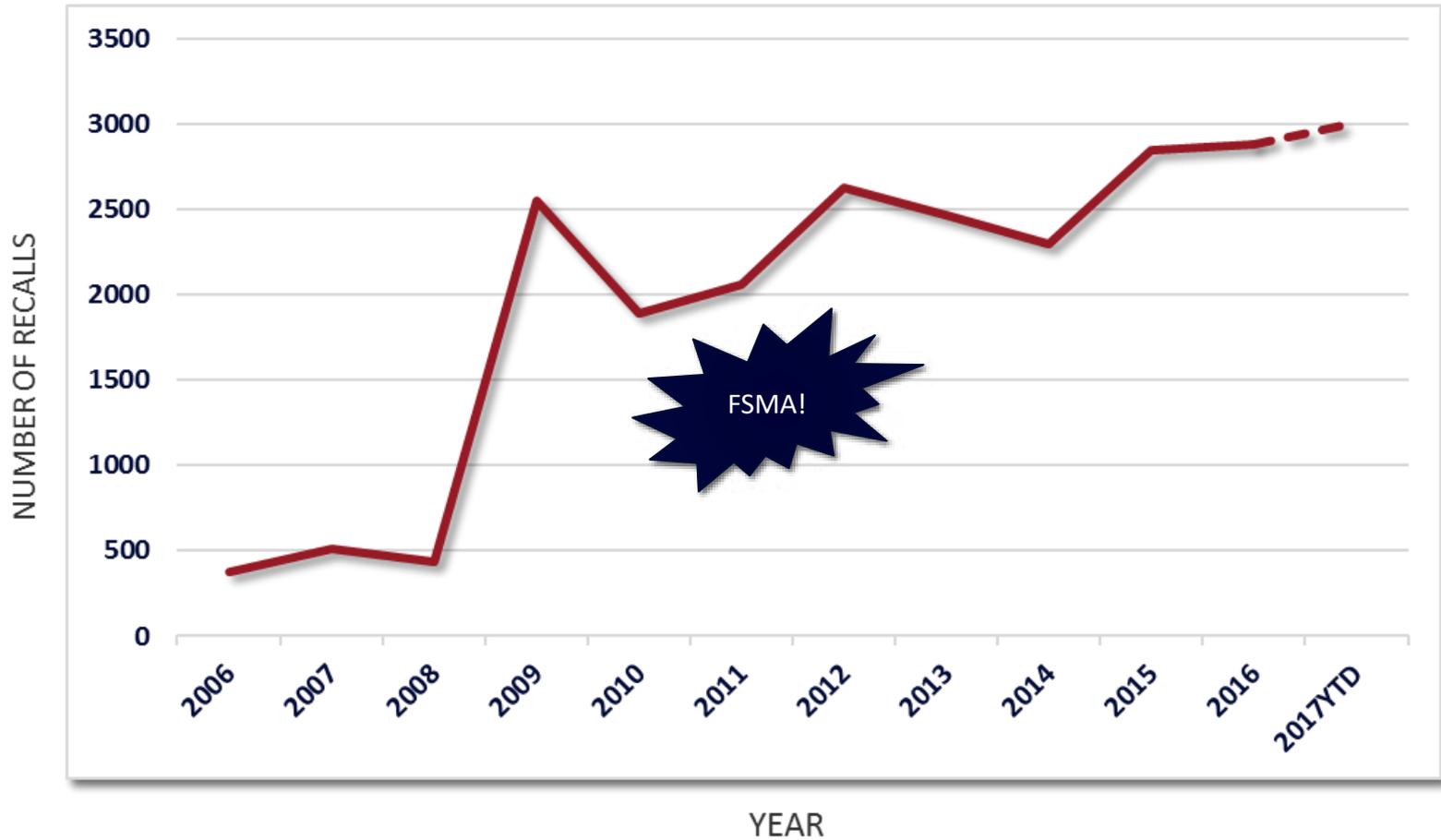
- **Topps** Liquidates Company after Massive Beef Recall
  - PE-backed
- *Detour Bar Maker, **Forward Foods**, Files Bankruptcy on Peanut Recall*
  - PE-backed
- *Massive Chicken Recall Puts \$2B Transaction on Hold*
  - **AdvancePierre** deal postponed following a USDA recall of 1.7 million pounds of 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 3<sup>rd</sup> 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



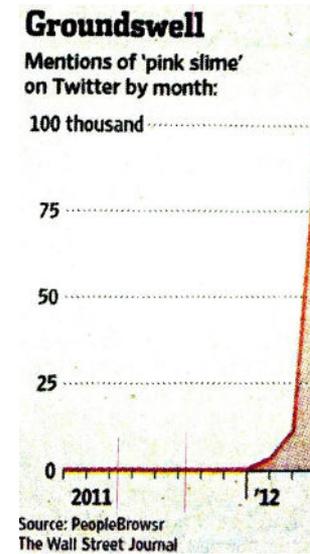
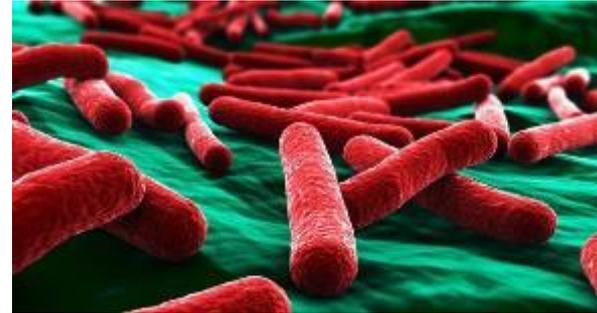
Figure 1: The “Big Eight” Allergens: Tree Nuts, Peanuts, Soy, Egg, Milk, Fish, Wheat and Shellfish.

**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](http://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





**TriVista**

**MCGUIREWOODS**

**Jennifer Frankenberg, Vice President**

**TRIVISTA**

[jennifer.frankenberg@trivista.com](mailto:jennifer.frankenberg@trivista.com)

+1.949.218.4830

**Jim Neale, Partner**

**MCGUIRE WOODS, LLP**

[jneale@mcguirewoods.com](mailto:jneale@mcguirewoods.com)

+1.434.977.2582

(888) 694 - 1484 [WWW.TRIVISTA.COM](http://WWW.TRIVISTA.COM) [INFO@TRIVISTA.COM](mailto:INFO@TRIVISTA.COM)