



Understanding Types of Food Fraud Risk

Part 3 of 5

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Food Fraud PDG Chair: Neil Bogart, Food & Beverage - Area
Technical Support – Ecolab

Food Fraud PDG Vice Chair: Karen Everstine, PhD, Senior
Manager, Scientific Affairs – Decernis

- Part 1: A Strategic Approach to Operationalize Food Fraud Mitigation (held on 2/20/19)
- Part 2: Challenges Identified with Food Fraud Implementation (held on 4/2/19)
- **Part 3: Understanding Types of Risk (Regulatory, Operational, Enterprise)**
- Part 4: Emerging Food Categories (scheduled for 6/11/19)
- Part 5: Ecommerce, Counterfeit, and Labeling (scheduled for 6/27/19)



Shaun Kennedy

**Director and Adjunct Associate Professor
The Food System Institute and the University of Minnesota**

Shaun Kennedy is an Associate Professor in the Department of Veterinary Population Medicine at the University of Minnesota. He has also served as the Director of the National Center for Food Protection and Defense (NCFPD), a Department of Homeland Security Center of Excellence, and the Associate Director for the Center for Animal Health and Food Safety. Shaun's research focuses on food system bio-security, food safety and food defense and he has authored leading articles and book chapters on both. He has served on the US Pharmacopia Intentional Adulterants Expert Panel and is a scientific advisor to food firms, national laboratories and regulatory authorities. Shaun provided the inaugural lecture in the FDA's Chief Scientist Lecture series and received the FDA Commissioner's Special Citation for advancing food defense.



Melanie Neumann

**Executive Vice President and General Counsel
Neumann Risk Services, A Matrix Sciences Company**

Melanie combines food safety and regulatory expertise with her legal expertise to build and deliver uniquely comprehensive solutions to her clients. Melanie has applied her unique qualifications inside large multi-national companies, in legal practice and in large and boutique consulting practices, sharing her insight and expertise in risk mitigation, risk management, recall and crisis management and regulatory compliance to help clients address the challenges posed by global trade in a challenging and dynamically changing regulatory environment and manage the impact on producing safe food. Melanie is a graduate of Mitchell-Hamline Law School, practicing food law and regulatory compliance for 20 years, and also holds an M.S. in Food Safety from Michigan State University. She is an adjunct professor at Michigan State and Northeastern University. Melanie is focused on the strategic development of services to ensure that our clients are able to manage the legal, regulatory and technical challenges in bringing safe food to market.

Understanding Types of Food Fraud Risk

Shaun Kennedy

Director, The Food System Institute

Adjunct Associate Professor, Veterinary

Population Medicine, University of Minnesota

28 – May - 2019



Food Safety vs. Food Fraud Risk

- Food safety deals with *Known or reasonably foreseeable hazards*
 - Hazard that is known to be, or has the potential to be, associated with the facility or the food
 - The risk has an inherent probability of occurring
- Food fraud deals with intentional adulteration for economic gain
 - The risk has no inherent probability, it instead represents an implicit vulnerability



Inherently Different Risk Types

- Probabilistic (stochastic) risks have
 - A knowable, non-zero distribution of results
 - The result distribution can be shifted by external forces
- Deterministic risks have
 - A fixed probability in the absence of an external force
 - A different fixed probability in the presence of an external force



Food Fraud Risk Conundrum

- The probability of the risk occurring is zero under normal operations
- The probability becomes 1.0 once a person commits the fraud
- The range of downside risks is as broad as for food safety, but with less ability to control the magnitude of the consequence
 - Justifying investment to prevent something that shouldn't happen but, if it did happen, would be really bad difficult



Type of Business Risk from Food Fraud - Simplified

- Balance sheet risk
 - Over payment for an ingredient
 - Disposal of raw materials
 - Cost of alternative materials
 - New testing requirements
 - Recall costs
 - Cost to retain customers
 - Supply chain shifts that increase cost



Type of Business Risk from Food Fraud - Simplified

- Operating risk
 - Requires a recall
 - Disrupts sourcing and customers
 - Negative impacts to organization operations beyond just the economic impacts
- Reputational risk
 - Standing with customers tarnished
 - Brand equity negatively impacted due to consumer loss of confidence
 - Regulatory compliance posture weakened leading to higher scrutiny



Type of Business Risk from Food Fraud - Simplified

- Regulatory/criminal risk
 - Violation of one or more regulatory requirements leads to fines and mandatory compliance actions
 - Violation can extend from regulatory to criminal depending on the type of fraud
- But – it's never that simple
 - There is usually a little bit of each in any fraud event



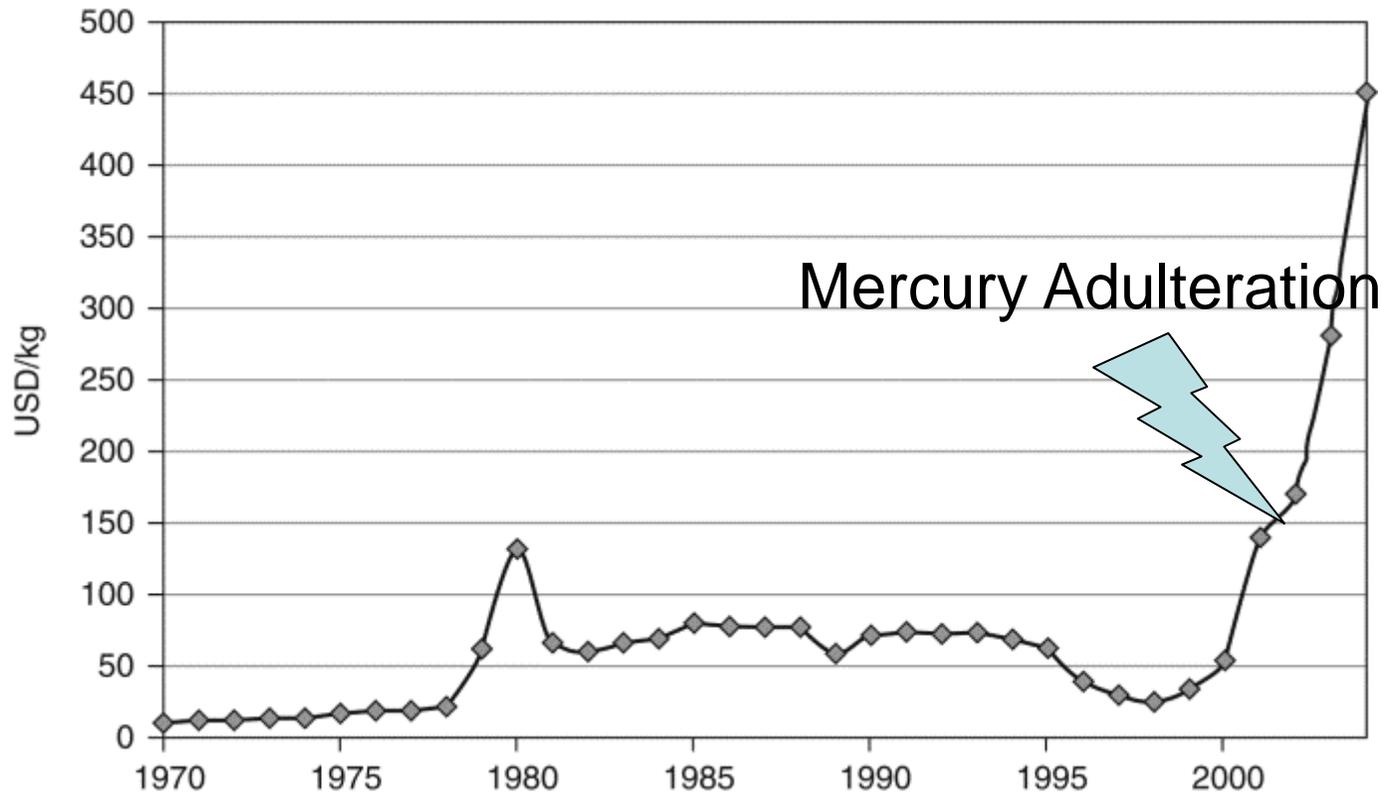
Differentiating Consequences

- Operational risks are any where the consequences of it occurring are a manageable balance sheet event
 - Customers may leave, consumers may shift preferences, regulatory scrutiny may increase but the firm survives
- Enterprise risks go beyond the balance sheet and threaten the very existence of the firm
 - Recovery may not be achievable



Balance Sheet Example

World vanilla prices: 1970–2004



Regulatory/Criminal Risk

Addison seafood distributor fined
for mislabeling fish, shrimp

Posted: Aug 07, 2013 3:37 PM CDT

Updated: Aug 21, 2013 3:37 PM CDT

The owner of a west suburban Seafood distribution company was fined \$100,000 and sentenced to five years' probation Wednesday for mislabeling some fish as more expensive grades and misstating the weight of frozen shrimp to charge customers more.

. . . . Bruno, the president and owner of Gourmet Express Marketing, Inc., admitted he mislabeled and sold swai as "catfish" and perch as "red snapper" or "pacific snapper," the U.S. Attorney's office said. He also misstated the weight of ice-glazed shrimp.



BUSINESS/ECONOMICS

Beech-Nut reels from juice scandal

By Gail Appleson
Reuters News Service

NEW YORK, Reuter — The president of Beech-Nut Nutrition Co. said the nation's second-largest baby food maker now has the difficult task of rebuilding a reputation tarnished by the company's distribution of phony apple juice in the early 1980s.

"I don't know how many people are aware it's something in the

past," Richard Theuer told Reuters in a telephone interview Friday. "Feeding babies is a sacred trust. The articles that I've seen have hurt our reputation. Our responsibility now is to dedicate ourselves to rebuilding that reputation."

Last week, a federal jury in Brooklyn convicted two former senior executives of Beech-Nut for intentionally distributing millions of bottles of sugar water and calling it "100 percent apple juice." Fort Washington, Pa.-based Beech-Nut is a subsidiary of the Swiss-based Nestle food conglomerate.

Theuer, who holds a doctorate degree in biochemistry and nutrition, said it is important that people realize the events described in the indictments occurred in the early 1980s.

Last November, Beech-Nut pleaded guilty to 215 criminal counts of intentionally selling adulterated and misbranded juices from 1981 to 1983. The company paid a \$2 million

food and drug laws enacted 50 years ago — and paid \$140,000 to cover the costs of the Food and Drug Administration.

The apple juice scandal came to light when a former Beech-Nut employee became suspicious that the firm was distributing fake apple juice. He informed company officials, but they did nothing.

Jérôme LiCari, Beech-Nut's former director of research and development, quit his job in 1982 and a year later penned an anonymous letter to the Food and Drug Administration. In the letter, LiCari charged that Beech-Nut and its top officials had long known that the company's apple juice for babies was actually sugar water with flavoring.

LiCari testified in federal court that Niels Hoyvald, the company's president and chief executive officer, and John Lavery, its vice president of operations, had refused to act on his worries that the product was

LiCari is now director of clinical research for the Sandoz Nutrition Corp. in Minneapolis.

His testimony and his letter, which spurred a federal investigation that began in 1982, led to the convictions this week of Hoyvald and Lavery for illegally distributing the phony apple juice over a five-year period to 20 states, Puerto Rico, the Virgin Islands and five foreign countries.

Hoyvald, 54, a resident of Lebanon, N.J., was found guilty of 351 felony counts and faces up to three years in prison for each count and maximum fines totaling \$3.5 million.

Lavery, 56, of Schenectady, N.Y., was convicted of 448 criminal charges — including one conspiracy count, 18 mail fraud charges and 429 violations of the Food Act. The conspiracy and mail fraud charges carry maximum prison terms of five years; the food violations, three years. He could be fined up to \$4.5

Fake apple juice 1982

MONEY MARKET MUTUAL FUNDS

Funds with assets of \$100 million or more available to individual investors. For period ended Feb. 18, 1988.

Fund	Assets \$ million	Avg 7-day 7-day	
		return days	yield %
Alex. Brown Gov't. Series	241.8	47	8.1
Alex. Brown Prime	883.5	36	8.4
Alvarado Group			
Capital Res.	1,274.4	58	8.2
Gov't. Res.	307.1	81	8.0

COLLECTIONS > APPLE JUICE

Beech-Nut Is Fined \$2 Million for Sale Of Fake Apple Juice

By LEONARD BUDER
Published: November 14, 1987

The Beech-Nut Nutrition Corporation pleaded guilty yesterday to Federal charges that it had sold phony apple juice intended for babies and agreed to pay a \$2 million fine.

The corporation also agreed, as part of a plea arrangement with the Government, to pay \$140,000 in investigative costs to the Food and Drug Administration. Beech-Nut, a subsidiary of Nestle S.A. of Switzerland, is the second-largest maker of baby food products in the United States after the Gerber Products Company.

"We believe that Beech-Nut's fine represents the largest fine ever paid under the Food, Drug and Cosmetic Act by at least sixfold since the act's enactment in 1938," Richard K. Willard, the Assistant Attorney General in charge of the civil division, said in Washington.

Lo

Times.com



Melamine in wheat gluten 2007



FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Bi

Animal & Veterinary

Home Animal & Veterinary Safety & Health Recalls & Withdrawals

Safety & Health

- Recalls & Withdrawals
- Enrofloxacin for Poultry
- Melamine Pet Food Recall of 2007**
- Withdrawal of New Animal Drug Application Process

Resources for You

- Search for Pet Food Recalls
- Consumer Complaint Coordinators
- Melamine Pet Food Recall - Frequently Asked Questions

Melamine Pet Food Recall of 2007

On March 15, 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. FDA found contaminant in vegetable proteins imported into the United States from China and used as ingredients in pet food.

A portion of the tainted pet food was used to produce farm animal feed and fish feed. FDA and the U.S. Department of Agriculture discovered that some animals that ate the tainted feed had been processed into human food. Government scientists have determined that there is very low risk to human health from consuming food from animals that ate tainted feed. All tainted pet food, animal and fish feed, and vegetable proteins continue to be recalled and destroyed.

As a result of FDA and USDA's comprehensive investigation, several Chinese nationals and the businesses they operated, including the executive officer, were indicted by a federal grand jury in the United States that were found to have introduced wheat gluten into the United States that was contaminated with melamine.

Press Releases

- Charges Filed in Contaminated Pet Food
- FDA Investigation Leads to Several Indictments in Pet Food



Risk Types Along the Supply Chain

Coal Purification Plant

Xuzhou Anying Biologic Technology Development

Suzhou Textiles, Silk, Light & Industrial Products

ChemNutra

Stephen & Sally Qing Miller

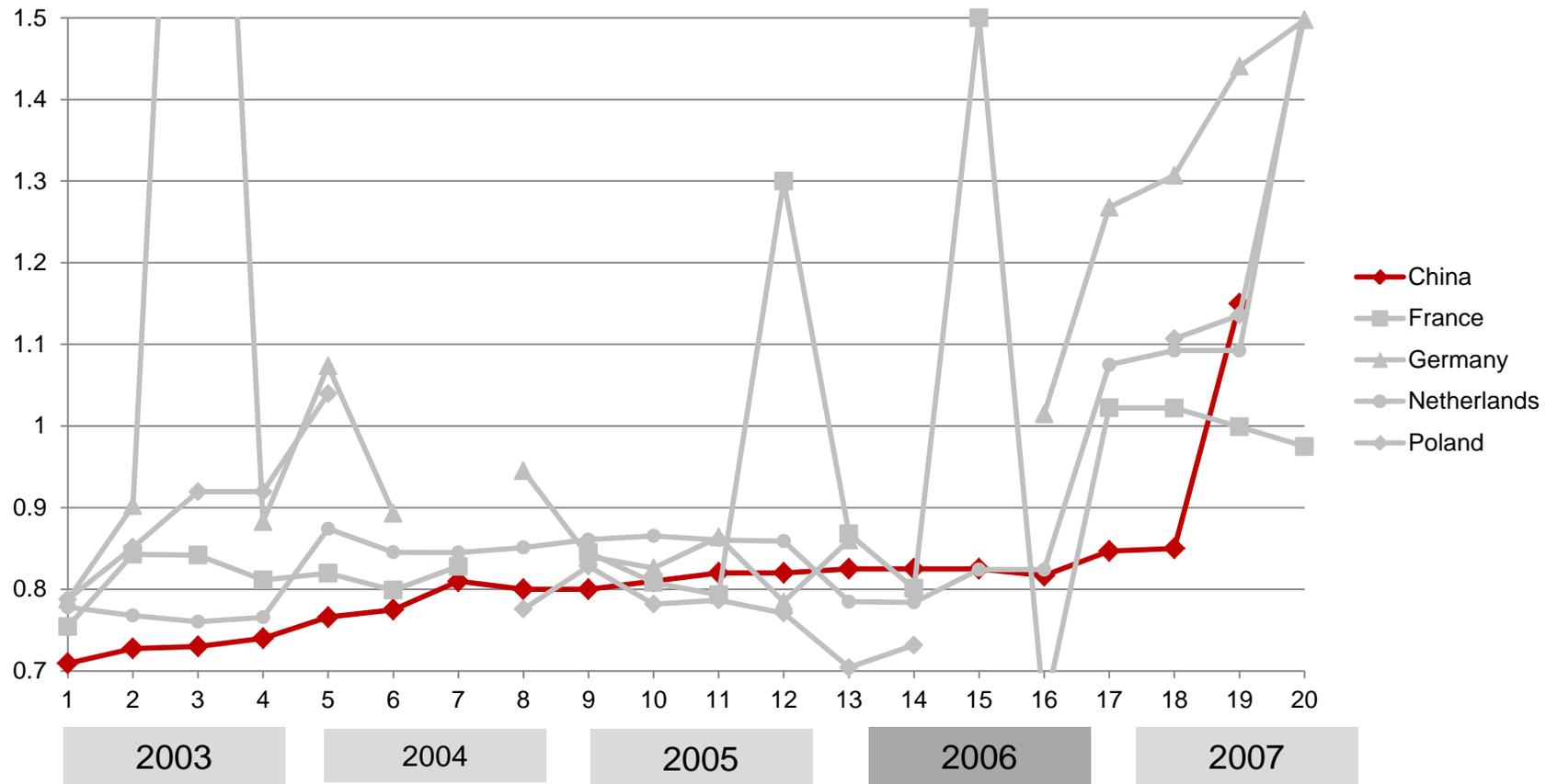


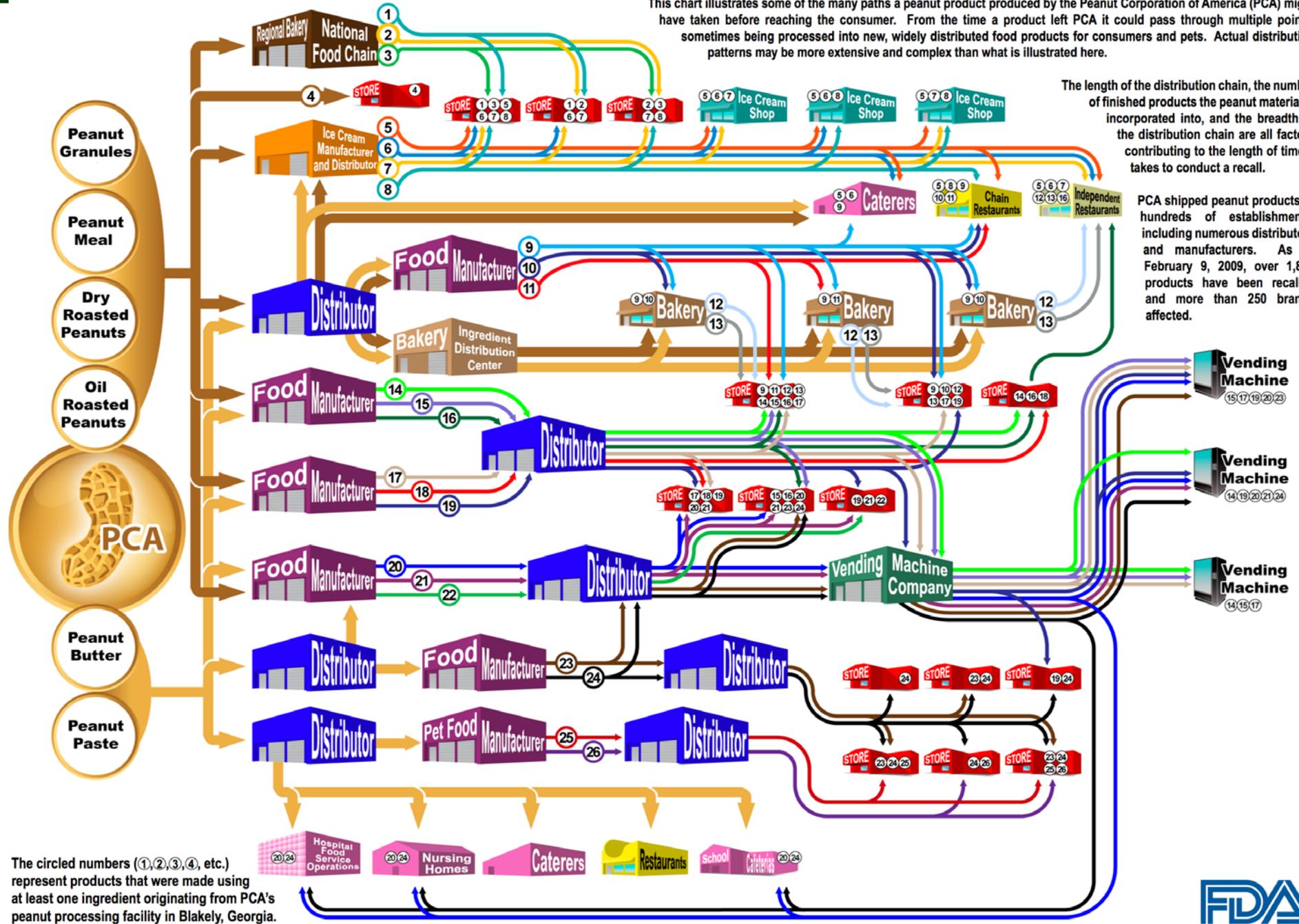
Nearly 100 pet food brands

The food industry



Wheat Gluten Price by Country (GATS)





This chart illustrates some of the many paths a peanut product produced by the Peanut Corporation of America (PCA) might have taken before reaching the consumer. From the time a product left PCA it could pass through multiple points, sometimes being processed into new, widely distributed food products for consumers and pets. Actual distribution patterns may be more extensive and complex than what is illustrated here.

The length of the distribution chain, the number of finished products the peanut material is incorporated into, and the breadth of the distribution chain are all factors contributing to the length of time it takes to conduct a recall.

PCA shipped peanut products to hundreds of establishments, including numerous distributors and manufacturers. As of February 9, 2009, over 1,800 products have been recalled and more than 250 brands affected.

The circled numbers (1, 2, 3, 4, etc.) represent products that were made using at least one ingredient originating from PCA's peanut processing facility in Blakely, Georgia.

Risk Types Along the Supply Chain

- PCA's actions brought enterprise risk leading to bankruptcy
- Leadership complicity yields life, near life and 5 year prison terms
- >360 companies had to manage recalls
- Peanut butter companies saw >20% loss in sales – even though many not impacted directly
- Peanut industry hit \$1B
- Traceability aspects of FSMA



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Food Fraud: Managing This Emerging Risk & Evolving Requirements

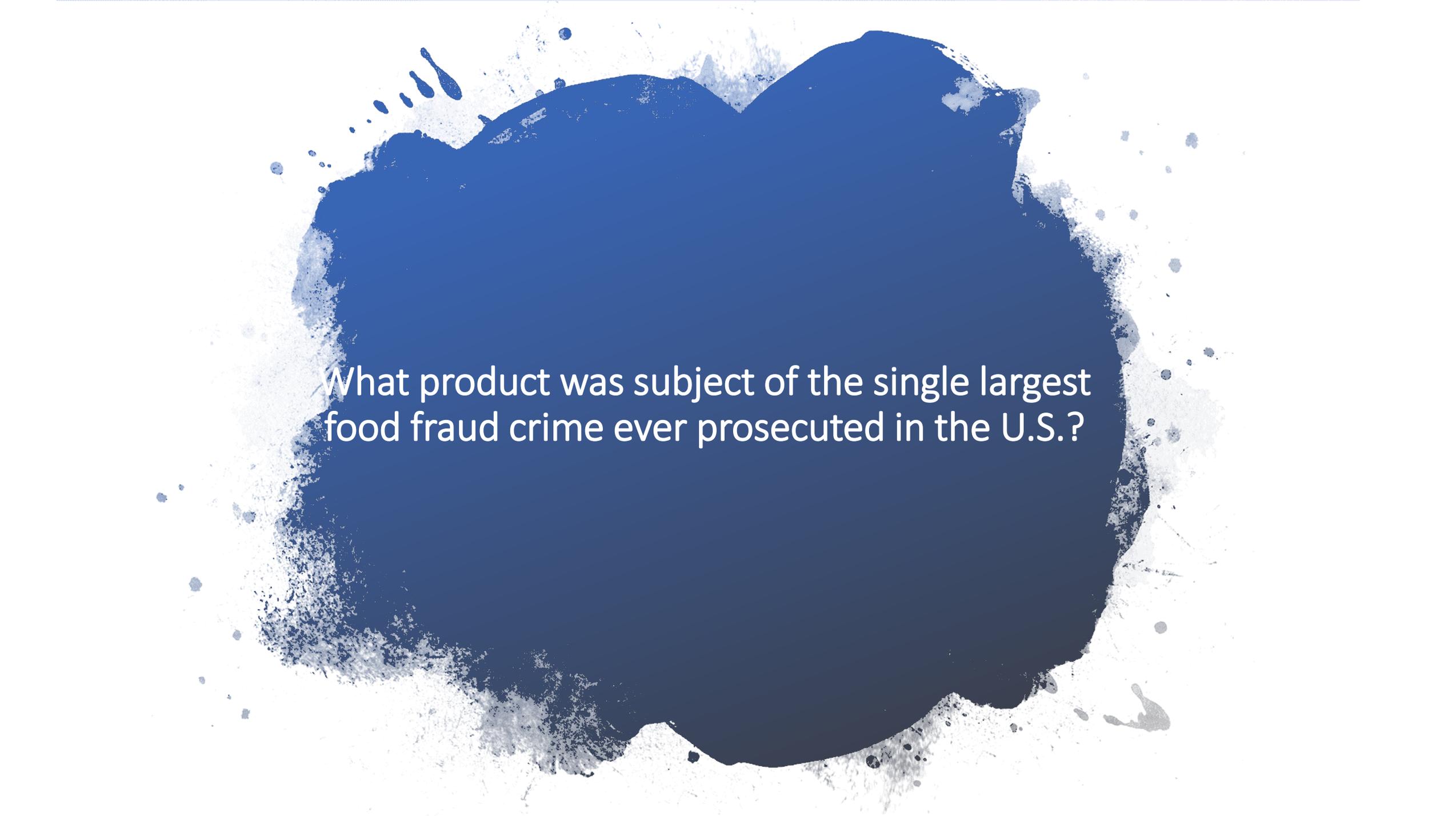
Melanie Neumann, J.D., M.S.

President, Neumann Risk Services, LLC

EVP, Matrix Sciences

Founder Neumann Risk Services





What product was subject of the single largest food fraud crime ever prosecuted in the U.S.?

“HoneyGate”

- Crime “Ring”
- 7 Years
- 80 Million Dollars
- Chinese Honey
- Often adulterated
- 2016: 42M pounds seized Miami



Unintended Food Safety Consequences



**Massive cumin recalls for
peanut /almond allergens**

- Cumin spice recall
- Expensive spice
- Ground peanut shells and almond shells to create cumin appearance
- Supplier charged more \$\$ for lesser valuable product
- Caused a food safety issue-- undeclared allergen
- Class 1 recalls conducted by supply chain recipients
- Market result: Increased supplier controls / spice testing

A Reminder that Food Fraud...



FSMA PC Human Food Rule/ Hazard Analysis



Hazard analysis (21 CFR 117.130):

(a)

(1) you must conduct a hazard analysis to identify and evaluate... known or reasonably foreseeable hazards...”

(2) The hazard analysis must be written ***regardless of its outcome***”

(b) The hazard identification must consider:

(2) **Known or reasonably foreseeable hazards** that may be present in the food for any of the following reasons:

(ii) The hazard may be unintentionally introduced; or”

(iii) The hazard may be intentionally introduced for purposes of ***economic gain***.”



What's the Difference between Food Fraud and Intentional Adulteration ? (The IA Rule ?)

The FDA explains why food fraud is not included in the Intentional Adulteration (FSMA-IA) rule even though it is an “intentional” act.

- “The goal of the final rule on intentional adulteration is to prevent acts intended to cause **wide-scale harm** to **public health**, including acts of terrorism targeting the food supply.”



GFSI Definitions

Food Fraud:

A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labeling, product information or false or misleading statements made about a product for economic gain that *could* impact consumer health.

Food Fraud Vulnerability:

Susceptibility or exposure to a Food Fraud risk, which is regarded as a gap or deficiency that could place consumer health at risk if not addressed.

GFSI Benchmark Requirements

FSM AI 21 Food fraud vulnerability assessment

- The standard shall require that the organization has a **documented food fraud vulnerability assessment procedure** in place to identify potential vulnerability and prioritize food fraud mitigation measures.

FSM AI 22.1 Food fraud mitigation plan

- The standard shall require that the organization has a **documented plan** in place that specifies the measures the organization has **implemented to mitigate** the public health risks from the **identified food fraud vulnerabilities**.

FSM AI 22.2 Food fraud mitigation plan

- The standard shall require that the organization's Food fraud mitigation plan **shall cover the relevant GFSI scope** and shall be supported by the organization's Food Safety Management System.

Other Regulations



- **The Sarbanes-Oxley Act of 2002** (i.e., SOX or SARBBOX) requires U.S. corporations to **report all types of business fraud that could lead to a negative impact on the corporation.** Food Fraud incidents create a risk to food manufacturers' and retailers' revenue. Such risk must be managed within a threshold or reported as required within the SOX regulation.
- **The Federal Anti-tampering Act of 1983** (FATA, 18 USC 1365). The FATA **classified tampering** — which includes a type of Food Fraud — **within Crimes and Criminal Procedures** and Chapter 65 on Malicious Mischief. Under the Act, tampering is **a felony punishable by fine and imprisonment with a possible life sentence if a death occurs.**



Opportunities, Motivations and Risk Mitigation Strategies / Controls



Opportunities

- **Supply & Demand**
- **Knowledge & capability** to adulterate
- **Knowledge & capability** to detect fraud
- **Access** to production areas / transportation / receiving activities
- **Historical evidence** of fraud
- **Lack of Transparency** across supply chain
- **Complex supply chain**



Motivations/Contributing Factors

- Economic value of product
- Ethical business culture of supplier
- Corruption level of country of origin
- Competition in supply chain sector
- Financial health of supplier
- Organizational structure

Mitigation strategies

Know your suppliers

- Who's in it? How complex? Sole/unknown sources? How monitor / verify compliance?

Understand sector vulnerabilities

Risk forecasting

- Leverage internal and external data (complaints, broker intel, repositories, etc.)

Limit intermediaries

Enhance detection

- Define ingredient standards/ specifications
- Define test methods
 - Simple/low cost to advanced analytical testing
- Test close to the source
- Conduct verification testing
- Risk-based frequency

Manage as Enterprise Risk

Deterrent Strategies / Controls

Implement Rigorous Supplier Approval Program

- Ensure food fraud is included in your program
- Trust but verify
- Educate
- Share near misses

Testing

- Who performs? How often
- Identify test methods

Contracts

- Explicitly Prohibit in multiple areas/ways (eg substitution, additions, diversion, spot buys, etc.)
- Require advance written notice and approval before spec/formulation changes
- Include food fraud/adulteration for economic gain as a basis for rejection; trigger for supplier termination/indemnification, etc.

Tell your suppliers you are watching!

- The risk of getting caught is a significant deterrent!

Program Maintenance and Communications

- **Internal Policies and Communication**

- Communicate Food Fraud program to senior management
- Incorporate Food Fraud into existing policies (Corporate and Quality policies)

- **External Policies and Communication**

- Incorporate Food Fraud clauses into next version of your Supplier and Coman Contracts/Expectations Manuals
- Develop specific communications to external stakeholders

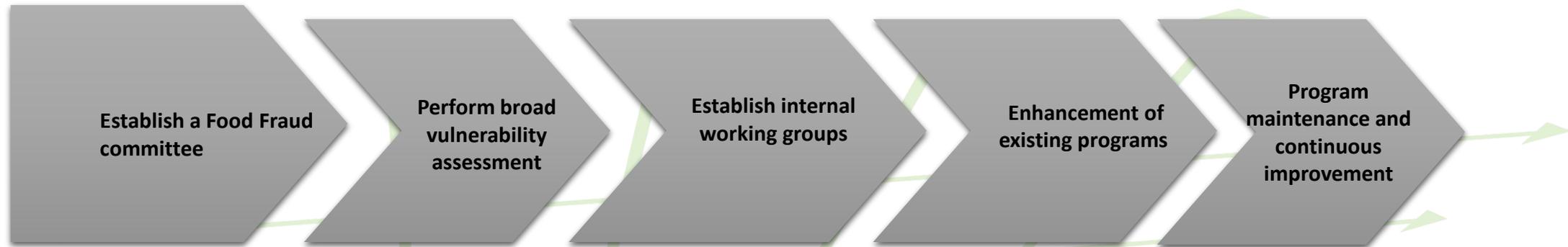
- **Leverage Existing Data & Benchmark**

- Use industry acknowledged tool, process, and/or expert for vulnerability assessment
- Benchmark with peer companies

- **Monitor / Horizon Scanning**

- systematically and continuously monitor main food fraud databases/alert systems
- Define roles and responsibilities for periodically scanning these tools

ERM Implementation Road Map



- Multi-functional group established (Quality, Procurement, Security, Business integrity, Finance, Legal)

- Corporate level, top-down initial vulnerability assessment
- Create corporate food fraud policy/prevention strategy

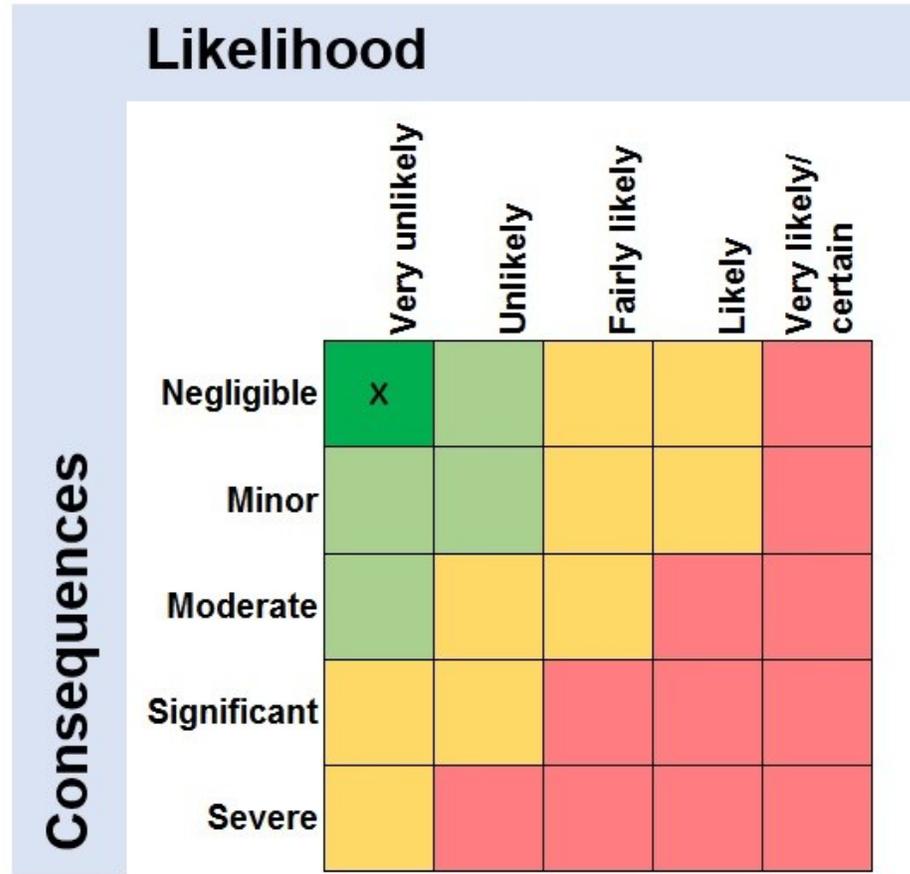
- Raw and packaging materials
- Policies and communication
- High risk areas
- Counterfeiting

- Consider full vulnerability assessment
- Evaluation of existing programs in place (global and regional).
- Identify risks on ERM risk map
- Implement controls for high and very high risk
- Enhance existing programs

- Quarterly meeting of Food Fraud committee.
- Continuously monitor & external benchmark

Continuous improvement: re-evaluate the vulnerability assessment

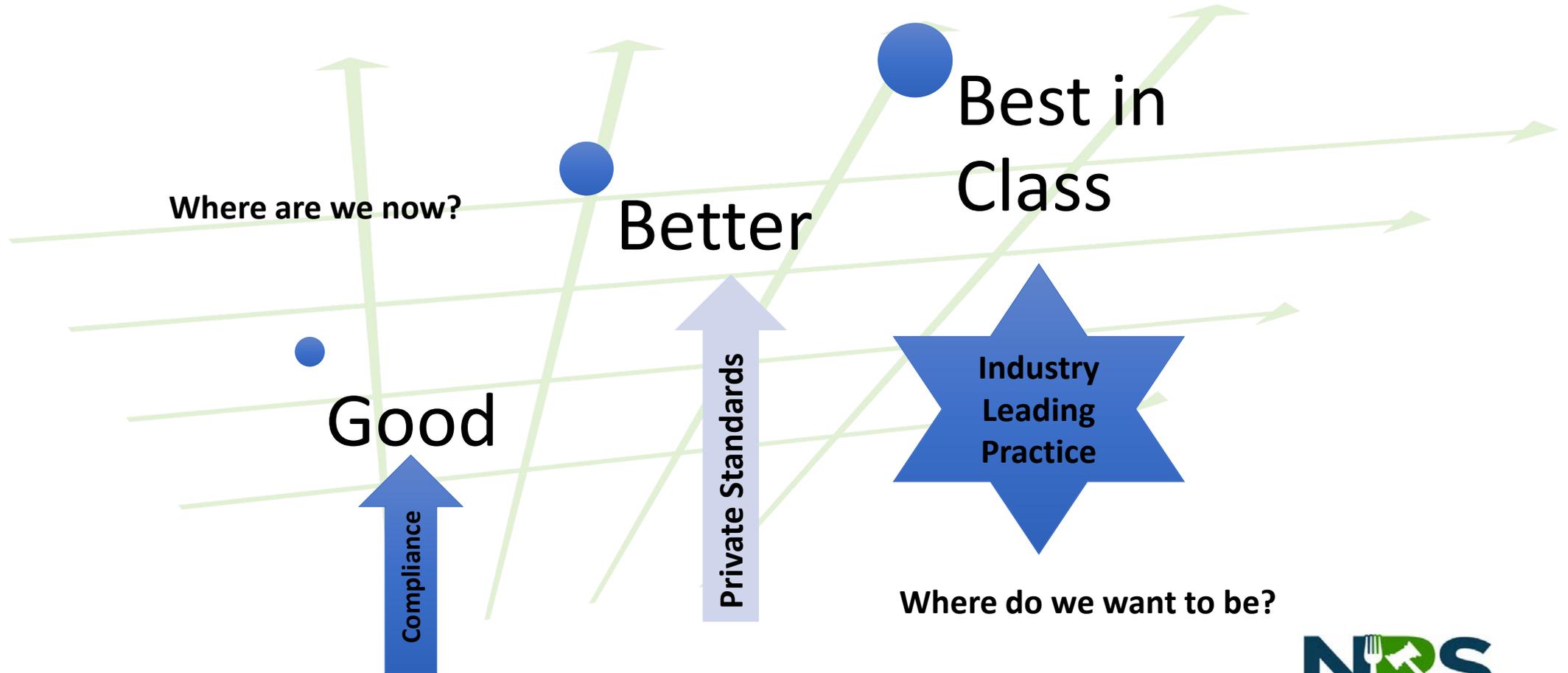
Vulnerability Risk Assessment Heat Map



Key
 Red areas = high risk; urgent action is required and regular monitoring may be needed
 Yellow areas = medium risk: action is needed with occasional monitoring to mitigate the risk
 Green areas = low risk



Guard Against Complacency: Using a Risk Maturity Model



Maturity Model Example



FSQA / Food Fraud Strategy is Aligned With Company ERM Strategy

ENCE

Level 1	Level 2	Level 3	Level 4	Level 5
<ul style="list-style-type: none"> There is no Strategy 	<ul style="list-style-type: none"> Strategy is department-centric/not integrated into enterprise-risk management program. department leadership and department-based goals rather than cross departmental programs or goals. 	<ul style="list-style-type: none"> strategy is department-centric yet is recognized as an important, foundational risk to the company while not elevated as part of the enterprise-risk management program. department leadership and department-based goals with some limited cross departmental interaction (e.g. with Marketing, Procurement) with some aspects of strategy execution. 	<ul style="list-style-type: none"> department leadership and department-based goals with significant cross departmental interaction and support (e.g. with Marketing, R&D, Procurement, etc.) actively engaged with some aspects of Food Safety/Food Fraud strategy execution. 	<ul style="list-style-type: none"> strategy originates with FSQA and other key departments yet is backed by C Suite and aligned with corporate mission/vision and corporate enterprise risk management (ERM) strategy Management commits to institutionalizing strategy into ERM strategy/program company-wide

Implementation Challenges



- Lack of participation from needed functions
 - Many people take a “it won’t happen here” approach
- Trying to do too many things at once
- Not doing enough (e.g. missing diversion, counterfeiting risk, FFVA not broad enough)
- Assuming that you can do the Food Fraud work in a short time
- Completing your vulnerability assessment and then not doing anything with it

Thank you!

Questions?

Contact mneumann@matrixsciences.com

Practical Hazard Assessment

- USP Food Fraud Mitigation Guidance a reasonable starting point
 - Developed by a volunteer panel of experts for broad industry use
 - Outlines a process, not a specific set of tools
- Multiple resources are available for fraud history (Decernis), horizon scanning (Leatherhead), scoring approaches (SSAFE, GMA)
- Main thing is to simplify the front end



Breaking Down The Criteria

Corporate Policy	Supplier Specific	Uncontrollable
Audit Strategy	Supply Chain Structure	Geopolitical Considerations
Susceptibility of QA Methods & Specs	Supplier Relationship	Fraud History
Testing Frequency	Supplier Regulator, Safety & Quality History	Economic Anomalies
Impact Multipliers		
Food Safety		
Focused Consumption		
Economic Impact		
Customer & Consumer (Public) Confidence		



Questions?

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