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)
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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 biosecurity, 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 multinational 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

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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 anywhere 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


Mercury Adulteration
Addison seafood distributor fined for mislabeling fish, shrimp

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

By LEONARD BUDEL
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.
Melamine in wheat gluten 2007

Melamine Pet Food Recall of 2007

On March 16, 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. FDA found contaminants 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, Chinese nationals and the businesses they operated under their executive officers were indicted by a federal grand jury for the illegal importation of melamine into the United States that was used as a contaminant in pet food.

Press Releases

- Charges Filed in Contaminated Pet Food
- FDA Investigation Leads to Several Indictments
- Pet Products Recalled
- Pet Food Recall Update
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 1,000 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

- 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

Massive cumin recalls for peanut/almond allergens
A Reminder that Food Fraud...
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.”
**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 SARBOX) 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Know your suppliers</strong></td>
<td>- Who’s in it? How complex? Sole/unknown sources? How monitor / verify compliance?</td>
</tr>
<tr>
<td><strong>Understand sector vulnerabilities</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Risk forecasting</strong></td>
<td>- Leverage internal and external data (complaints, broker intel, repositories, etc.)</td>
</tr>
<tr>
<td><strong>Limit intermediaries</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **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 (e.g., 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

Establish a Food Fraud committee

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

Perform broad vulnerability assessment

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

Establish internal working groups

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

Enhancement of existing programs

• 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

Program maintenance and continuous improvement

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

Continuous improvement: re-evaluate the vulnerability assessment
## Vulnerability Risk Assessment Heat Map

The table below represents the risk assessment grid using a color-coded system.

<table>
<thead>
<tr>
<th>Consequences</th>
<th>Very unlikely</th>
<th>Unlikely</th>
<th>Fairly likely</th>
<th>Likely</th>
<th>Very likely/ certain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Significant</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td></td>
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</tbody>
</table>

### 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

Where are we now?

Better

Good

Where do we want to be?

Best in Class

Compliance

Private Standards

Industry Leading Practice
## Maturity Model Example

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
<th>Level 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>• There is no Strategy</td>
<td>• Strategy is department-centric/not integrated into enterprise-risk management program.</td>
<td>• 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.</td>
<td>• department leadership and department-based goals with significant cross departmental interaction and support (e.g. with Marketing, R&amp;D, Procurement, etc.) actively engaged with some aspects of Food Safety/Food Fraud strategy execution.</td>
<td>• 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</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Corporate Policy</th>
<th>Supplier Specific</th>
<th>Uncontrollable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit Strategy</td>
<td>Supply Chain Structure</td>
<td>Geopolitical Considerations</td>
</tr>
<tr>
<td>Susceptibility of QA</td>
<td>Supplier Relationship</td>
<td>Fraud History</td>
</tr>
<tr>
<td>Methods &amp; Specs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testing Frequency</td>
<td>Supplier Regulator, Safety &amp; Quality History</td>
<td>Economic Anomalies</td>
</tr>
</tbody>
</table>

### Impact Multipliers

- Food Safety
- Focused Consumption
- Economic Impact
- Customer & Consumer (Public) Confidence
Questions?

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