Food Fraud: The Role of Standards and the Litigation Implications

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USP & Food Quality

- Founded in 1820, USP is an independent nonprofit organization with the goal of improving global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods

- USP develops standards and resources that regulators, manufacturers, and retailers can use to help ensure food safety and integrity
• What is Food Fraud?
  • Definition
  • Impact
  • Examples

• Food Fraud and the Regulatory Environment

• Food Fraud and the Role of Standards

• Food Fraud Resource Overview
Food Fraud – Definition

The intentional misrepresentation of the true identity or contents of a food ingredient or product for **economic gain**.

Authentic peppercorns

Adulterated peppercorns
25% Papaya Seeds
Adulterated cumin
20% Peanut shells

Authentic cumin
Intentional vs. Unintentional Adulteration

Economically driven
Motivation is ‘GAIN’

Intentional
adulteration

Ideologically driven
Motivation is ‘HARM’

Source: GFSI

FDLI
Food Fraud – Prevalence

• True prevalence unknown – estimates indicate up to 10%

• Detected at rates as low as 4% of the time (Gee, 2014)

• Early cases date back thousands of years (CRS, 2014)
Food Fraud – Types

- Dilution or Substitution
- Artificial enhancement
- Use of undeclared, unapproved, or banned biocides
- Removal of authentic constituents
- Misrepresentation of nutritional value
- Fraudulent labeling claims
- Formulation of a fraudulent product
- Counterfeits, theft overruns, gray markets

Source: USP Food Fraud Database v2.0
Food Fraud – Data Trends (Type)

Source: USP Food Fraud Database v2.0

N=3321 incident and inference reports

Data captured 6/27/2017
Food Fraud – Impact

**Affected Parties**
- Food Industry
- Government
- Consumer

**Impact**
- Economic
- Compliance
- Brand Damage
- Consumer Confidence
- Public Health (in some cases)
Food Fraud – Public Health Impact

Public Health Consequences

- **China**: 300,000 Illnesses from Melamine in Infant Formula
- **Spain**: 600 Deaths from Adulterated Olive Oil
- **United States**: 700 Hospitalizations from Peanut Butter Contaminated with Salmonella

**Industrial Dyes in Chili Powder**
Potential carcinogenic - more than 400 products recalled

**Plasticizers in Juices, Teas, Jams**
Linked to developmental problems - more than 800 products recalled

**Peanut Protein in Cumin**
Can cause severe allergic reactions – thousands of pounds of prepared meals recalled
Food Fraud – Widely Publicized Examples

- Infant formula (melamine crisis)
- Extra virgin olive oil (sunflower and other oils)
- European horse meat scandal
- Vodka (methanol)
- Spices
  - Cumin (peanut shells?)
  - Oregano (olive leaves, sumac leaves, etc.)
Food Fraud – Sampling of Known Events

- Olive oil
- Cooking oils
- Apple juice
- Orange juice
- Pomegranate juice
- Honey
- Maple syrup
- Infant formula
- Milk
- Butter
- Wine
- Liquor
- Vanilla Extract
- Chicken
- Shrimp
- Rice
- Ground Beef
- Vegetable proteins
- Candies & Sweets
- Organic produce
- Tomato paste
- Spices
- Tea
- Coffee
- Flour
- Liquid Eggs
- Fish
Food Fraud – Data Trends (Ingredient Groups)

Source: USP Food Fraud Database v2.0

N=3321 incident and inference reports

Data captured 6/27/2017
Food Fraud and the Regulatory Environment

German Beer Purity Law dating back to 1516:

**Reinheitsgebot**

"Wir wollen, dass in allen Städten, Märkten und auf dem Lande zum Brauen von Bier nur Gerste, Hopfen, und Wasser genommen werden soll!"

erlassen von Bayernherzog Wilhelm IV. Am 24 April 1516
FSMA Requirements Specific to Food Fraud

FDA Food Safety Modernization Act (FSMA) Preventive Controls Final Rule:

The hazard analysis must consider hazards that may be present in the food because they occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain. We continue to believe that hazards that may be intentionally introduced for economic gain will need preventive controls in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past. Economically motivated adulteration that affects product integrity or quality, for example, but not food safety, is out of the scope of this rule.

FSMA Preventive Controls Regulations

As part of the required hazard analysis, hazard identification “must consider…

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

(i) The hazard occurs naturally;
(ii) The hazard may be unintentionally introduced; or
(iii) The hazard may be intentionally introduced for purposes of economic gain.”

21 CFR 117.130(a)(2)(iii)
# GFSI Food Fraud Requirements

<table>
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<tr>
<th>Clause Name</th>
<th>Requirement</th>
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<tbody>
<tr>
<td>Food Fraud Vulnerability Assessment</td>
<td>The standard shall require that the organisation have a documented food fraud vulnerability assessment in place to identify potential vulnerability and prioritise food fraud vulnerability control measures.</td>
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<tr>
<td>Food Fraud Vulnerability Control Plan</td>
<td>The standard shall require that the organisation have a documented plan in place that specifies the control measures the organisation has implemented to minimize the public health risks from the identified food fraud vulnerabilities.</td>
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Food Fraud Requires a Different Approach

Unintentional Food Safety Threats
- Risk Assessment
- Preventive Controls

Intentional Food Fraud Threats
- Vulnerability Assessment
- Mitigation (Control Plan)
Food Fraud Mitigation Guidance

Source: USP Food Fraud Mitigation Guidance
Food Fraud and the Role of Standards

*Food Chemicals Codex (FCC)*

- Internationally recognized testing methods, specifications, and supporting reference materials for food ingredients
  - Promotes uniformity of quality and added assurance of safety and integrity
  - Defines “food-grade”
  - Where applicable, utilizes USP Reference Standards
  - Widely used in buyer/seller agreements
FCC Coverage

- # of Monographs: ~1200
- # of Reference Materials: ~500 multiuse + ~250 food-specific
- Types of ingredients
  - Food additives, food colors, substances generally recognized as safe (GRAS)
  - Processing aids, such as enzymes, extraction solvents, filter media, and boiler water additives
  - Foods, such as sugar, salt, edible oils
  - Functional food ingredients
  - Complex food ingredients/commodities (juices, high value oils, etc.)
FCC in U.S. & International Law

- In U.S., a food shall be deemed to be misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations [FD&C Act 403(g)(3)]

- FCC standard is required when FDA has specifically adopted that standard in a regulation and food is marketed on the basis of that regulation

- FCC is incorporated by reference in FDA’s food additive regulations (~200); 7th Edition is incorporated by reference

- FCC standards are generally accepted by industry and FDA in the absence of regulatory standard

- FCC standards recognized by international regulatory bodies, including in Canada, Australia, New Zealand, and Brazil
The Benefit of Compendial Standards

<table>
<thead>
<tr>
<th>Compendial Standards</th>
<th>Identity</th>
<th>Strength</th>
<th>Quality/Purity</th>
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<tr>
<td>Set standards for identity, strength, quality and purity</td>
<td>Is the ingredient what it purports to be?</td>
<td>Is enough of the ingredient present?</td>
<td>Are levels of impurities, particularly toxic impurities, appropriately controlled?</td>
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<td>Help ensure the right dosage</td>
<td></td>
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<tr>
<td>Help prevent economically-motivated adulteration</td>
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Compendial standards give regulators and the food industry a “common tongue” in which to discuss food quality. Based in science and paired with validated methods, compendial standards provide benchmarks against which food quality issues can be measured.
Food Fraud Resource Overview

Many resources available to help the food industry combat food fraud:

- FERA Horizon Scan – [http://fera.co.uk/knowledge-solutions/horizonscan.cfm](http://fera.co.uk/knowledge-solutions/horizonscan.cfm)
- FPDI Database – [https://foodprotection.umn.edu/](https://foodprotection.umn.edu/)
- GMA/Battelle EMAAlert – [https://emalert.org/](https://emalert.org/)
Olive Oil and Food Fraud

FDLI, Food Advertising, Labeling and Litigation Conference

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Olive Oil and Food Fraud - outline

• A brief history - leading to today’s categories of olive oil
• A decade of disaster – 2004-2014
• The effects and costs of olive oil fraud
• Is there hope? Recent changes, business models, standards development
• The opportunities and benefits
In the beginning......
there was olive oil & lamp oil
Then came industrial food-oil refining.
Then improved mechanical extraction of virgin olive oils

• From traditional hydraulic press

• To mechanical crushers, malaxers, centrifugal decanters and separators
Extra virgin for sure –
more than ever before, nearly 30%
of production
Current categories for the supply chain – 2 (8?) Categories of olive oil

1. Extra Virgin
2. Virgin
3. Lampante (Crude)

- VIRGIN
  (natural, oil as it comes from olive)

4. Refined Olive Oil
5. Olive Oil
6. Crude Olive Pomace Oil
7. Refined Olive Pomace Oil
8. Olive Pomace Oil

- Refined
  (manufactured industrial)
For The Consumer

• Extra Virgin Olive Oil
• Virgin Olive Oil
• Olive Oil
• Light olive oil (and extra lite)
• Pure olive oil
• Pomace olive oil

• Assuming that products are as labeled
Bulk extra virgin olive oil prices and food price indices - Oct 2004 - Sept 2014
What caused this?

The decade to 2014

• Questions – was this reduction in olive oil prices simply an effect of supply and demand?

• What about refined olive oil?

• Sources - Index Mundi [www.indexmundi.com](http://www.indexmundi.com), IOC and USDA
Extra virgin olive oil bulk prices, world olive oil production and world olive oil exports

Supply?
Trend to extra virgin in the USA - naturally

Olive Oil Imports as Labeled - USA
Total, Extra Virgin and Refined Olive Oil

Demand?
Price comparison refined v virgin olive oil imports USA - 10 years to 2014

Note: US import data now separates Extra Virgin
In 2013/2014 95% of volume of Virgin category was reported as Extra Virgin
The causes, effects and costs of olive oil fraud

The decade to 2014

• Supply and demand factors were not the cause of the decline in prices

• During this period pricing indicates that refined olive oil was substitutable for extra virgin olive oil – despite clear differences in demand
The causes, effects and costs of olive oil fraud

The decade to 2014

My experience plus discussions with executives in many olive oil companies including the biggest traders:

this price fall was mainly as a result of the “race to the bottom” caused by competition using falsely labeled products sold for lower and lower prices
The effects and costs of olive oil fraud

The decade to 2014

• What is the scale of the losses in value for the olive oil trade?

• For extra virgin olive oil, for exports, for all olive oil?

• The assumption here - and the reality usually is - that prices follow each other globally
Extra virgin olive oil bulk prices - what if they stayed at the October 2004 level
The effects and costs of olive oil fraud

• The decade to 2014 – the calculated wholesale $ value of lost prices
• If we consider evoo as 50% of exports the loss is US$ 4.5 billion
• If we consider all evoo (25% of all olive oil) the loss is US$ 9.3 billion
• If we consider all olive oil the loss is US$ 37.1 billion
Adding insult to injury

• The decade to 2014 – the calculated $ value of lost wholesale prices at least several US$ billions, plus consumers unknowingly cheated

• During this time the EU paid over € 25 billion in subsidies to the EU olive sector

• (At least in part) the EU consumers paid for being defrauded - twice
The effects and costs of olive oil fraud

• Counter-factual modeling could be used to better understand the effects of this destruction of value in the whole supply chain

• During this time, for the first time, olive oil became a loss-leader in supermarkets (like Coca Cola and washing detergent)

• The olive industry in the Mediterranean has employed less and less qualified people – positive change is now difficult

• I have observed what I believed to be good companies cheating to survive and living off subsidies – many of them
The effects and costs of olive oil fraud

- The endemic olive oil fraud has permeated attitudes and activities throughout the sector – poor farming, corrupt and criminal trade, complacent regulators, bad sometimes fraudulent science, false advertising – at a large social and financial cost.

- Consumers everywhere have missed out on the benefits of what they believed were healthy products when they purchased them – a health cost?
Is there hope for olive oil?

• Yes

• The downward race seems to be abating.
• There are new business models developing - $ from quality!
• Supported by EU concerns about the social costs and reputational damage, perhaps the bottoming out of a long process, plus a weather events since 2015 causing a sharp fall in supply as a catalyst for action
Changes in business models

• The business focus of major olive oil companies has been on reducing costs and offering lower prices – meeting standards was often ignored, manipulated or corrupted

• A new focus on creating value through quality and authenticity is emerging – suddenly there are $s in olive oil quality – and we are starting to see the results in food shops

• Other factors include – news about food frauds, young consumers, social media, consumer publicity, e-commerce....... and some legal action
EU labelling changes - 2012

(a) extra virgin olive oil:

‘superior category olive oil obtained directly from olives and solely by mechanical means’;

(b) virgin olive oil:

‘olive oil obtained directly from olives and solely by mechanical means’;

(c) olive oil composed of refined olive oils and virgin olive oils:

‘oil comprising exclusively olive oils that have undergone refining and oils obtained directly from olives’;
Is there hope for olive oil?

• The recent Australian experience, from one olive oil market to two markets, consumers beginning to get it and receive value for money

• But at what cost?
Is there hope for olive oil?

• A few regulations with standards are enforced – Canada, parts of the EU, China (but standards vary and have been corrupted)
• Parts of the trade are adopting advanced product specifications and monitoring - ahead of standards
• Consumers are being educated
• A few court cases exist
• FDA is taking interest
• USP is independently developing a standard of identity for olive oil as an ingredient that may have an impact on the trade
Why does olive oil quality matter?


- **See also the work of Dr Mary Flynn, Brown University Medical School, Providence, Rhode Island, USA.**

- The culinary outcomes are better from real extra virgin olive oil – sublime in some cases

- Note that 50% of extra virgin olive oil sold in China is used externally for skin care – the phenols in virgin oils are important for this use
The opportunity

A reflection - what I was advised in 2002 v the Australian market in 2017
Thank you
PROBLEMS IN FOOD FRAUD
LEGAL PERSPECTIVE

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PROBLEMS IN DEFINITION

- Terminology
  - Quality
  - Authenticity
  - Adulteration
  - Food Fraud
  - Substitution
  - Economically Motivated Adulteration
SO WHAT IS THE PROBLEM?

- Extra Virgin Olive Oil
  - You should care
- Cumin
  - You must care
- 100% Parmesan Cheese
  - Do you care?
- Honey?
- Country of origin labeling?
TOP TEN LIST

Leading Food Categories with Reported Cases of Food Fraud

Olive Oil: Olive oil is often substituted with a lower cost alternative, whether it is regular olive oil instead of higher-priced extra virgin olive oil or a less expensive variety from Greece or Turkey, instead of from Italy as the label claims. In such cases the fraud was associated with efforts to deflect the European Union's farm support program, which subsidizes olive oil, as part of the Common Agricultural Policy (CAP). In some cases an aromatic seal or nut oil may be used as or mixed out with tampons, sepulchres, corns, gynecias, endosperms, wheat, rice, vegetables, canola, or other cheaper feed-grade oils. Also, legal and regulatory problems for those who use it in cooking, it is an effective means for mass-producing corporate food products, and its use is common in the retail. Always look for a label that states "extra virgin" or "cold pressed."

Fish and Seafood: Some higher-value fish and seafood are replaced with cheaper, more abundant fish. A report by United States Food and Drug Administration (FDA) researchers indicated that fish and seafood are among the most commonly adulterated food items, with tilapia being the most common fish used in the replacement of salmon and other higher-priced fish. Also, the mislabeling of fish and seafood can occur at the processing stage, where fish and seafood are mixed, sorted, or blended with other less expensive fish or seafood.

Wheat and Wheat Products: Wheat flour has been found to be substituted with cheaper rice flour, corn flour, or other less expensive flours. Also, flour is often substituted with rice, potato, or other less expensive starches. In some cases, wheat flour is mixed with rice flour to create a product that is labeled as "organic." This practice is often used to make bread or other baked goods that are marketed as healthy and nutritious.

Honey: Mislabeling of honey can occur with the substitution of cheaper, more abundant honey with less expensive, similarly flavored products. In some cases, honey is mixed with other sweeteners, such as sugar or fructose. Also, some honey may be blended with other ingredients, such as essences or other extracts, to create a product that is labeled as "honey.

Maple Syrup: Maple syrup is often substituted with cheaper, more abundant syrups, such as corn syrup or sugar syrups. In some cases, maple syrup may be blended with other syrups to create a product that is labeled as "maple syrup."

Fruit Juices: Fruit juices are often substituted with cheaper, more abundant juices, such as apple or grape juice. Also, some juices may be blended with other ingredients, such as essences or other extracts, to create a product that is labeled as "fruit juice."

Coffee and Tea: Ground coffee is often substituted with cheaper, more abundant coffee beans, such as chicory, yerba mate, or guarana. Also, some coffee may be blended with other ingredients, such as essences or other extracts, to create a product that is labeled as "coffee."

Organic Foods and Products: Organic foods and products are often substituted with cheaper, more abundant foods, such as non-organic produce or foods that are not certified as organic. Also, some organic products may be blended with other ingredients, such as essences or other extracts, to create a product that is labeled as "organic."

Cloning agents: Cloning agents or food-processing aids “to enhance the appeal or utility of a food or food component,” such as pastes and other similar food-added ingredients, are often used in plant juices, jams, and other food products. Also, some cloning agents may be used in the production of organic foods, to enhance the appearance or safety of the food product. These agents may be blended with other ingredients, such as essences or other extracts, to create a product that is labeled as "organic."

Source: CRS compilation from information reported by USDA, Michigan State University, NCPPO and researchers at the University of Minnesota, Oregon, Consumers Union, Food Chemical News, and the Food Institute. Unless otherwise indicated, "adulteration" and "misbranding" of foods is prohibited under various FDA and USDA laws.
SOME REAL PROBLEMS

- Businesses Get Ripped Off
- Damage To Reputation
- Consumer Get Ripped Off
- Consumers Don’t Get Nutrition
- Expenses Of Recall
- Authenticity/Supplier Litigation
- Regulatory Enforcement
- FDA Criminal Enforcement
NOT A VICTIMLESS SITUATION

- **Big Loss of Business**
  - $10B to $15B per year (GMA)
  - Harm to Reputation

- **Product Categories Can Be Damaged**
  - Italian Wines 1980’s
  - Extra Virgin Olive Oil

- **Food Safety**
  - Undisclosed Allergens
    - Cumin
  - Hazard Analysis
    - Pomegranate juice
LIABILITY EXPOSURE FACED BY COMPANIES

- Recalls
  - Cumin

- Competitors
  - Lanham Act
  - POM v. Coke

- Supplier Litigation
- Class Actions
- Attorneys General
Exhibit 7 – Illustrative supply chain for canned tuna

Products often traverse complex global supply chains to reach U.S. consumers.

Source: http://www.fda.gov/food/foodborneillness/ucm124087.htm#toc1
OTHER COUNTRIES TAKE THIS MORE SERIOUSLY

- **EU**
  - Top Ten List
  - Government enforcement actions (e.g. seizures)

- **Canada**
  - FSIA Testing/Enforcement

- **UK**
  - Food Fraud Advisory Unit

- **China**
  - Melamine scandal
  - Food fraud = food safety
SOURCES OF FOOD FRAUD LAW

- **State/Federal Consumer Deception Statutes**
  - Unfair Competition Law
  - Lanham Act

- **State Standards of Identity**
  - Cal. Statutory Definition of Olive Oil
  - CDFA Regulations

- **USDA Regulations**
  - Grades of Olive Oil
  - Fish Origin Labeling

- **FDA Regulations**
  - Intentional Adulteration
  - Economically Motivated Adulteration
  - Standards of Identity
SELECT PROBLEMS IN FOOD FRAUD LAW

- State/Federal Consumer Deception Statutes
  - Have To Prove Consumer Deception
    - Very hard to convince a jury
    - Very expensive
    - Regulatory non-compliance does not work
  - Need A Standard
    - State statutory definition
    - Federal or state regulatory standard of identity
    - USDA grading guidelines
    - USP standards
    - Industry Standards
    - Expert Testimony
SELECT PROBLEMS IN FOOD FRAUD LAW

- Economically Motivated Adulteration
  - Part of FSMA
  - Required research
  - Fraudsters can hurt people
  - FDA Import Alerts
  - Other Food Fraud Databases
    - USP
    - Michigan State University
    - EFSA
LEGAL REMEDIES

- **Damages/Injunctive Relief in Private Litigation**
  - Consumer Attorney Issues
  - Competitor Actions
  - Supplier Actions
  - Attorneys General

- **Regulatory Enforcement Actions**
  - Product Seizures
  - Import Alerts
  - Warning Letters
  - Finding of FSMA Non-Compliance
LARGER REMEDIES

- **Power of Retailers**
  - LIDL/Costco – Extra Virgin Olive Oil

- **Know Your Supplier Deeply**

- **Comply With EMA Provisions Of FSMA**

- **Enforce Your Rights Against Suppliers By Contract**

- **Consumer Education/Sell Way Your To The Truth**
COMBATTING FOOD FRAUD

- Litigation
- Retailer Programs
- Third-Party Accreditation
- FSMA Compliance
- GFSI Mitigation Measures
- Insurance?
COMBATTING FOOD FRAUD

- USP Guidelines
- Food Fraud Databases
  - www.foodshield.org
  - USP
- Supply Chain Analysis
  - Attorneys, Industry Consultants, Scientists
  - Risk Assessment and Mitigation
  - Proper Tests, Protocol