

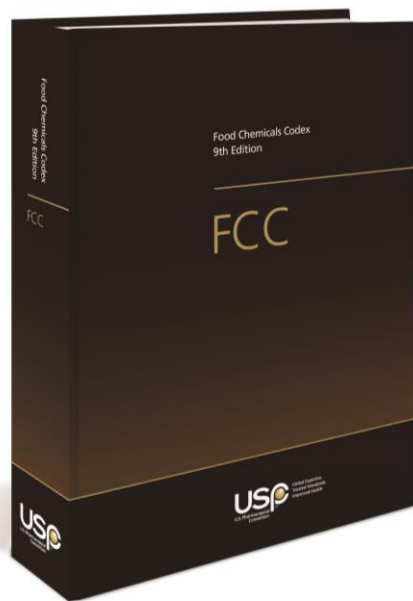
Food Fraud: The Role of Standards and the Litigation Implications

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September 14, 2017

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.

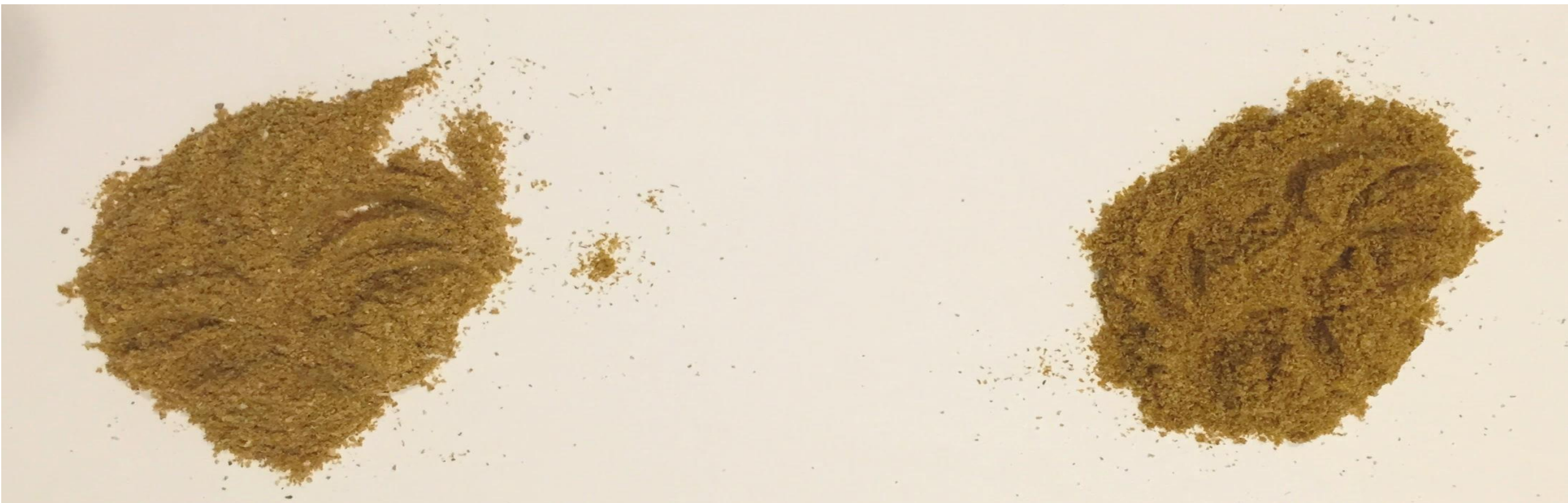


Authentic peppercorns



Adulterated peppercorns

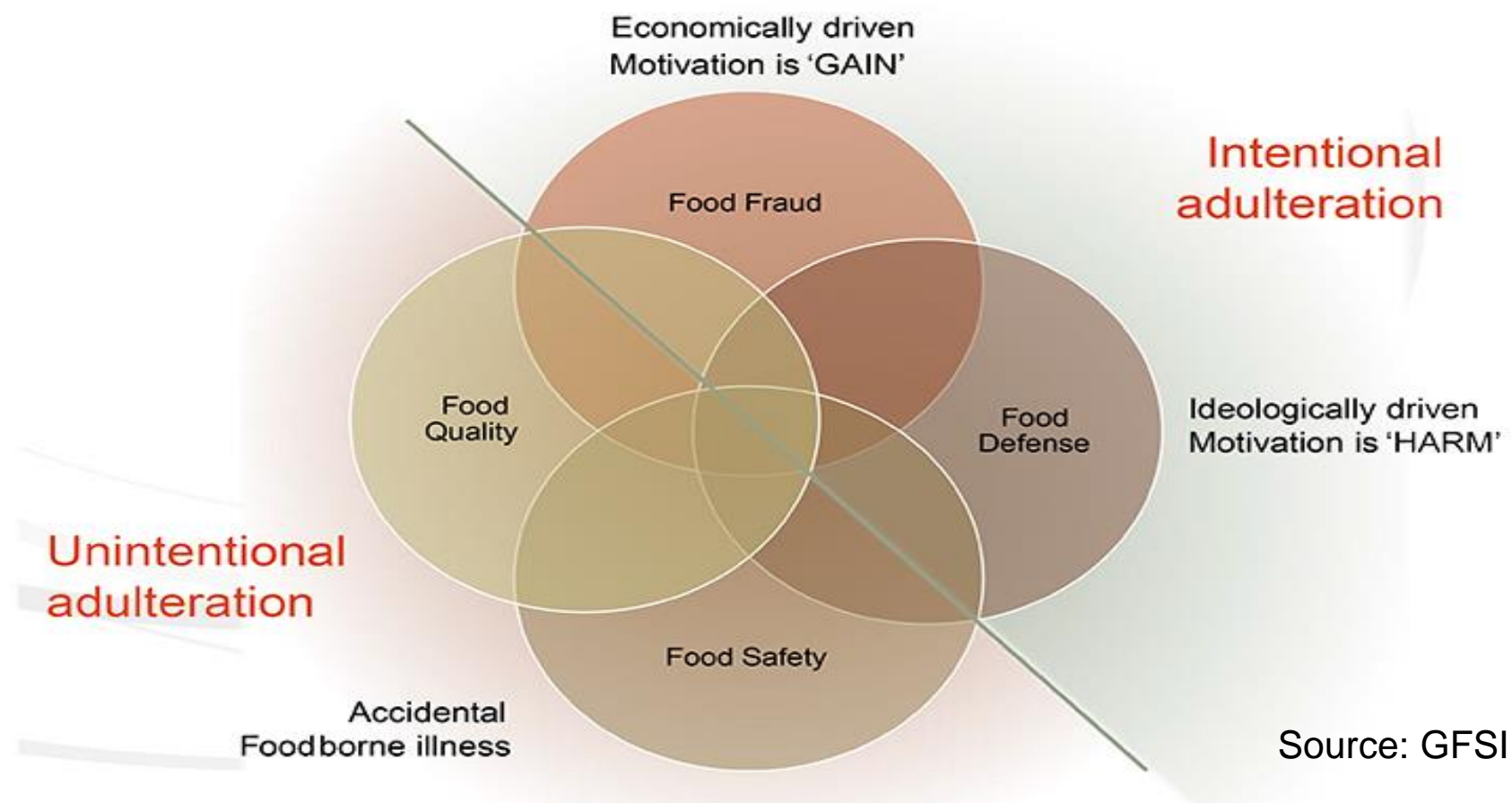
25% Papaya Seeds



Adulterated cumin
20% Peanut shells

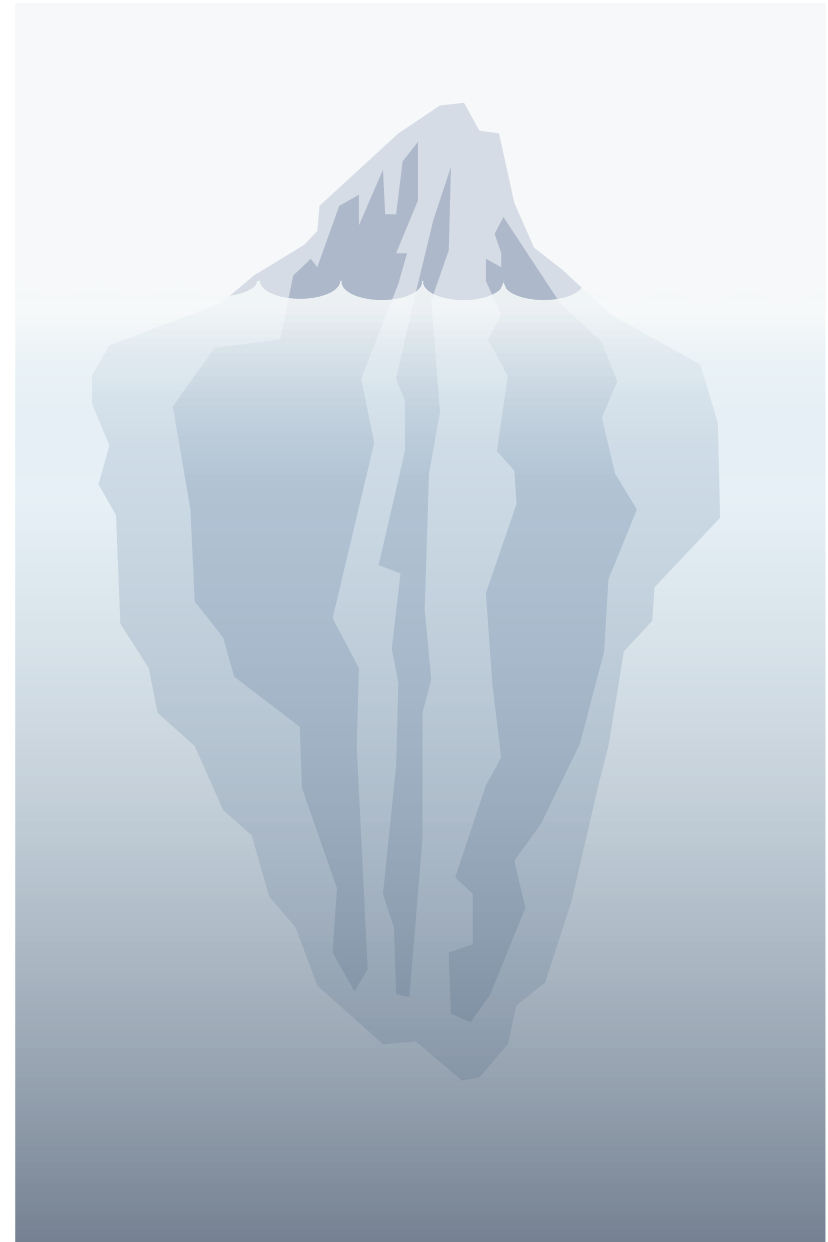
Authentic cumin

Intentional vs. Unintentional Adulteration

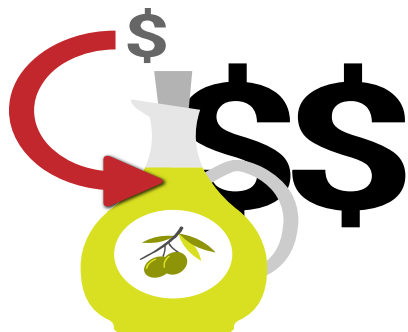


Food Fraud – Prevalence

- 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)



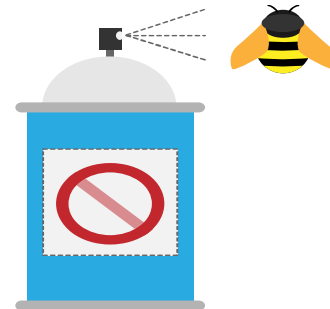
Food Fraud – Types



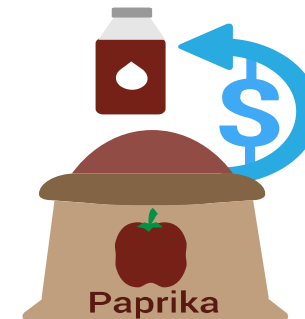
Dilution or Substitution



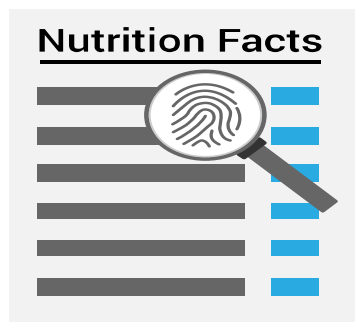
Artificial enhancement



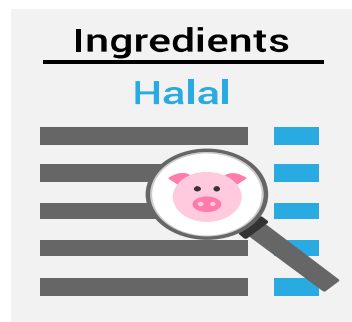
Use of undeclared, unapproved, or banned biocides



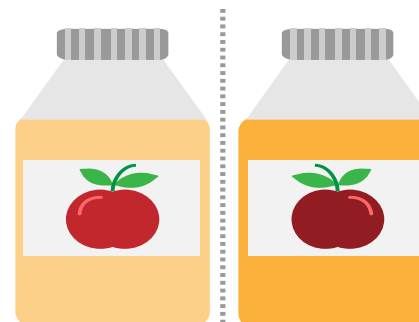
Removal of authentic constituents



Misrepresentation of nutritional value



Fraudulent labeling claims

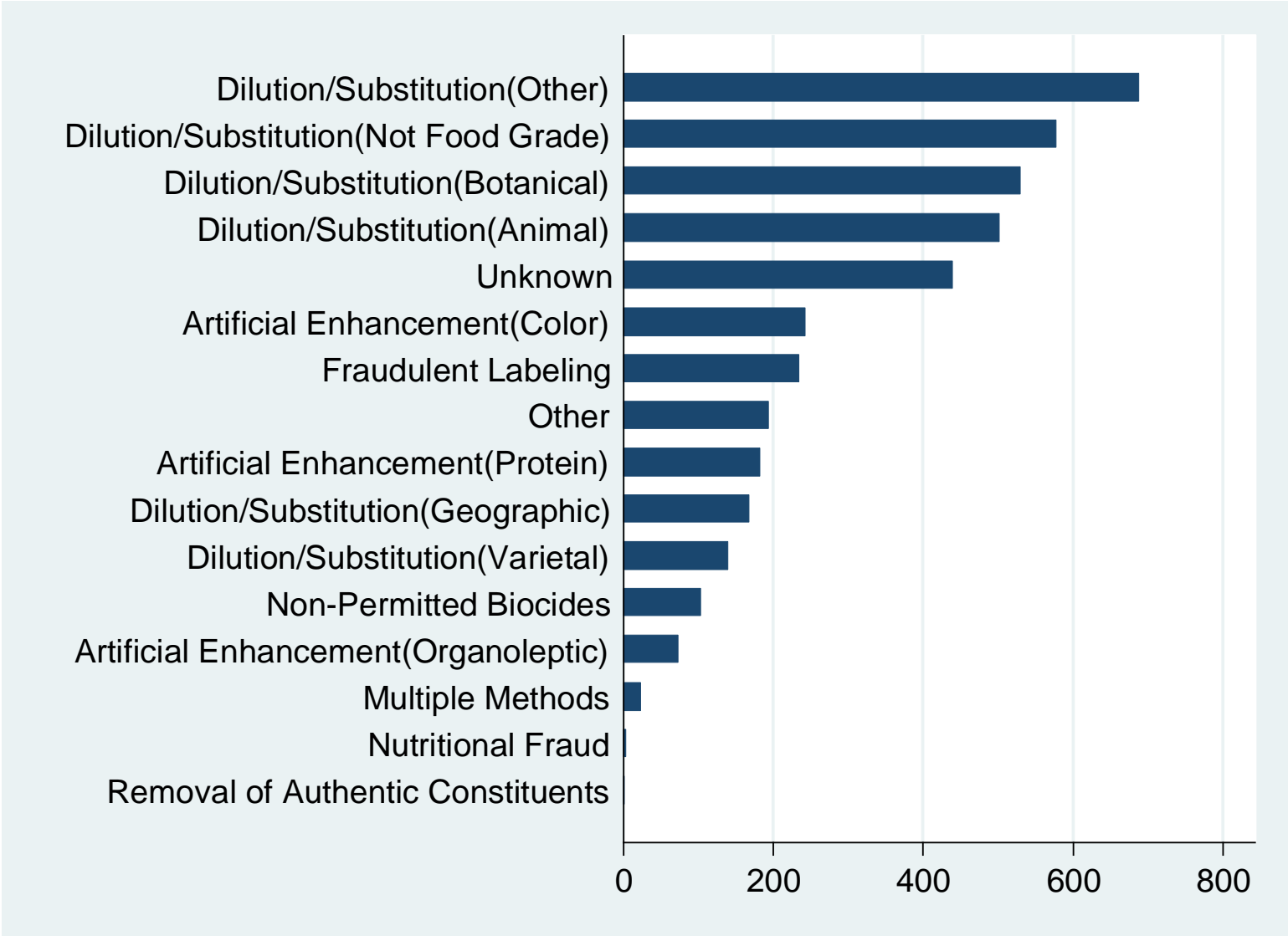


Formulation of a fraudulent product



Counterfeits, theft overruns gray markets

Food Fraud – Data Trends (Type)



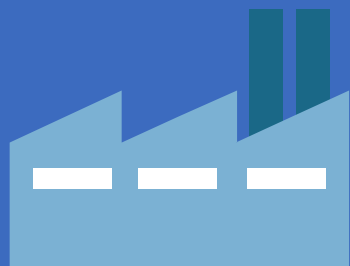
Source: USP Food Fraud Database v2.0

N=3321 incident and inference reports

Data captured 6/27/2017

Food Fraud – Impact

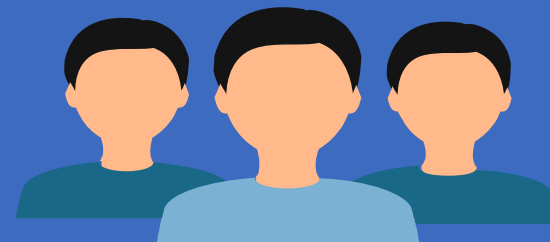
AFFECTED PARTIES



**FOOD
INDUSTRY**



GOVERNMENT



CONSUMER

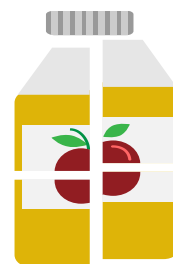
IMPACT



Economic



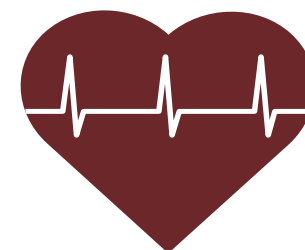
Compliance



**Brand
Damage**

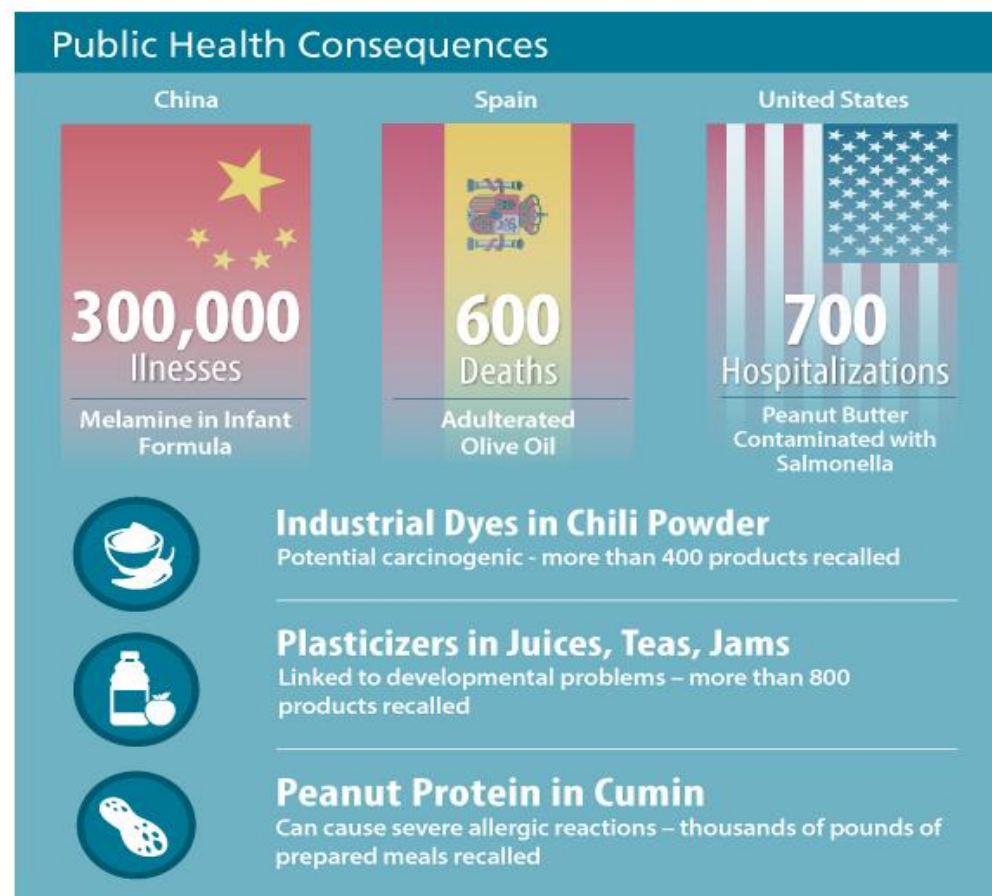


**Consumer
Confidence**



Public Health
(In some cases)

Food Fraud – Public Health Impact



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



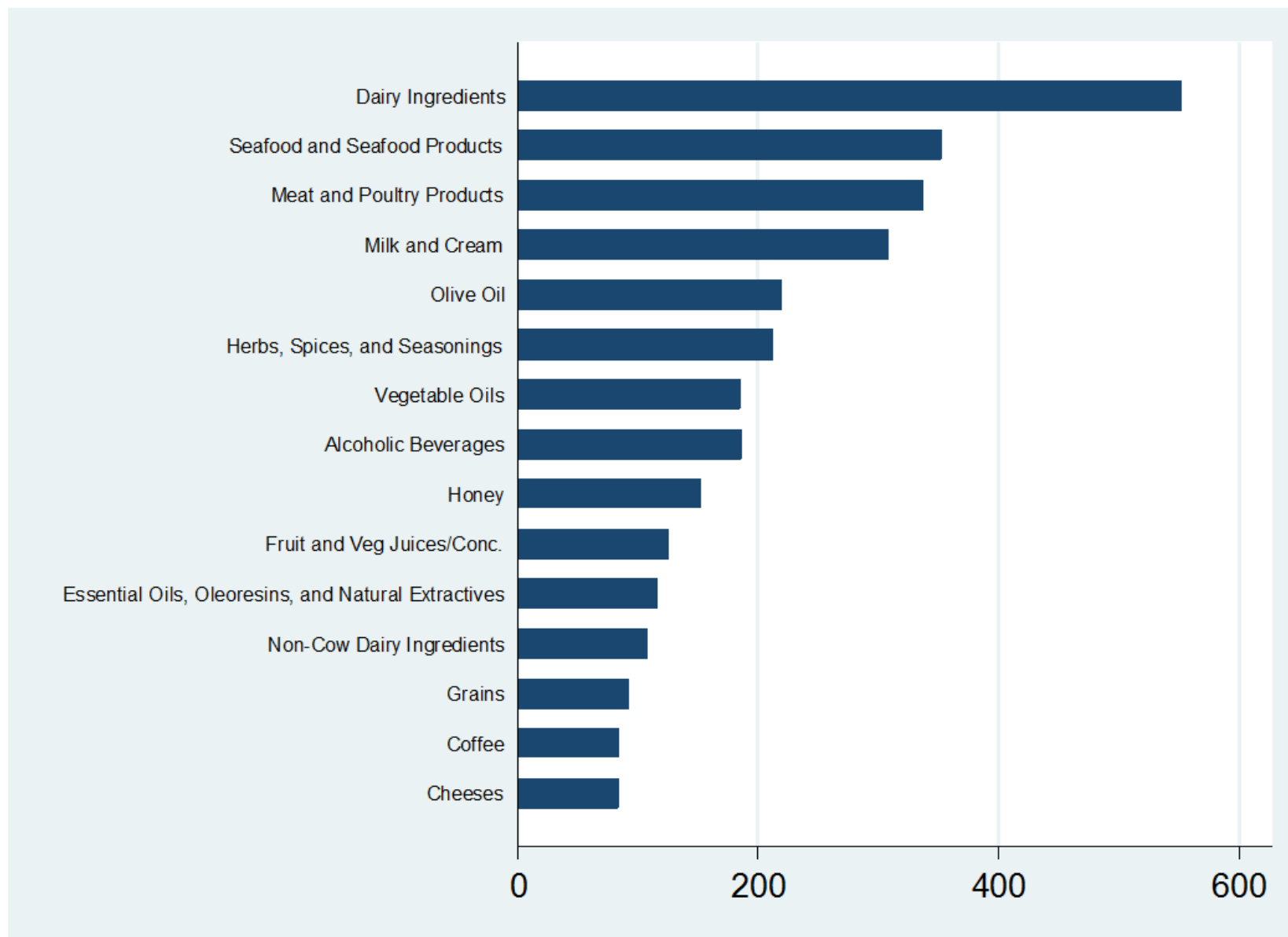
Olive oil
Cooking oils
Apple juice
Orange juice
Pomegranate juice
Honey
Maple syrup
Infant formula
Milk
Butter
Wine
Liquor
Vanilla Extract
Chicken



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)



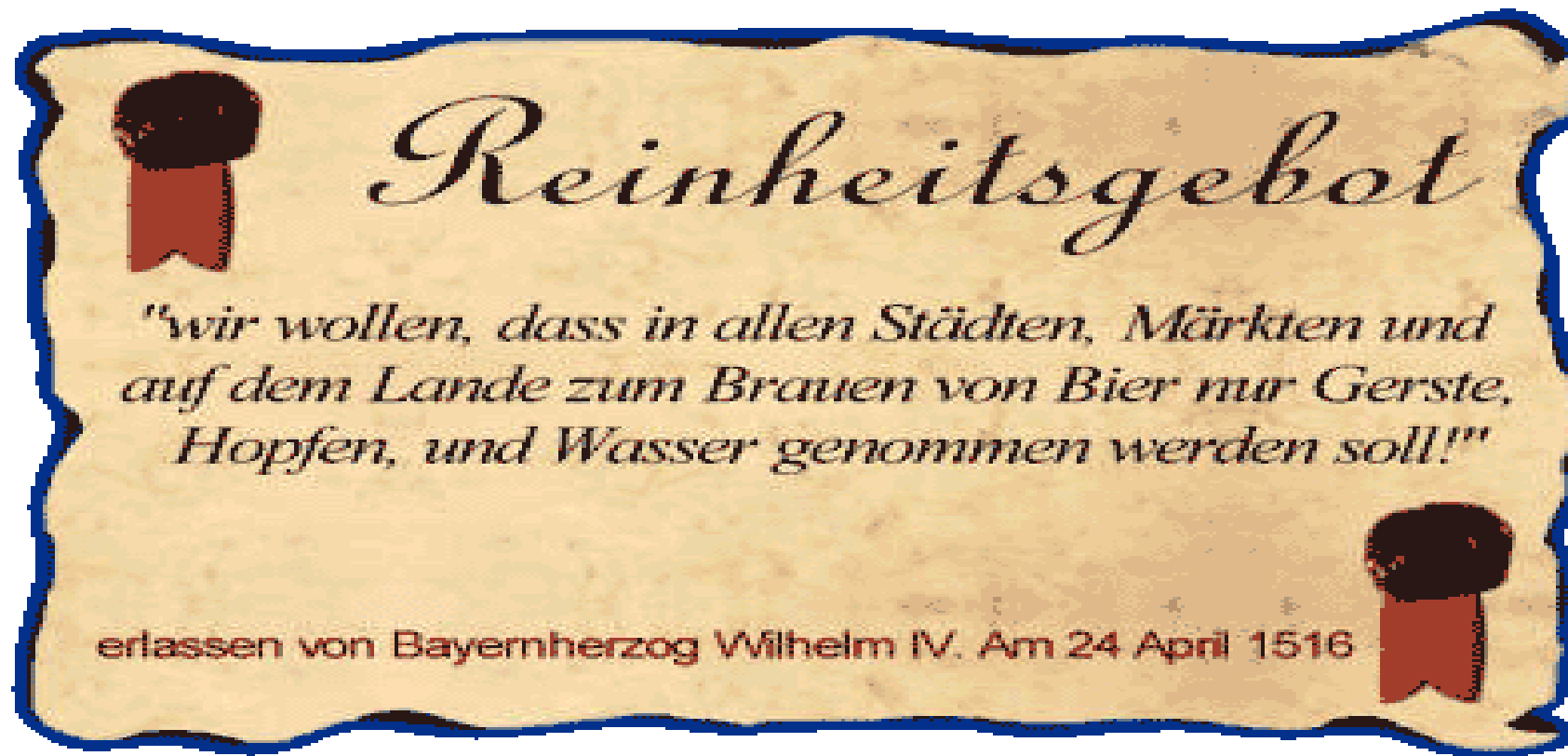
Source: USP Food Fraud Database v2.0

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:



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.

80 Fed. Reg. 55907, 55912 (Sept. 17, 2015)

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:

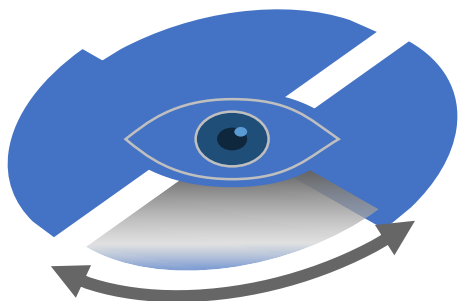
- (i) The hazard occurs naturally;
- (ii) The hazard may be unintentionally introduced; or
- (iii) The hazard may be intentionally introduced for purposes of economic gain.”**

21 CFR 117.130(a)(2)(iii)

GFSI Food Fraud Requirements

Clause Name	Requirement
Food Fraud Vulnerability Assessment	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.
Food Fraud Vulnerability Control Plan	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.

Food Fraud Requires a Different Approach

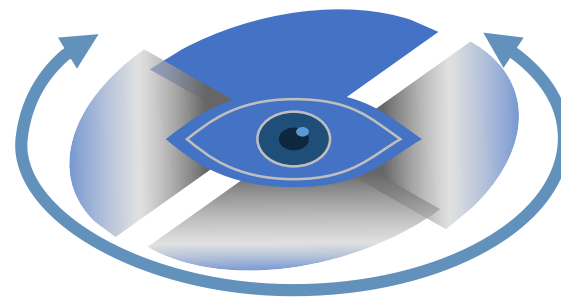


Unintentional
Food Safety
Threats



Risk
Assessment
+
Preventive
Controls

VS



Intentional
Food Fraud
Threats



Vulnerability Assessment
+
Mitigation
(Control Plan)

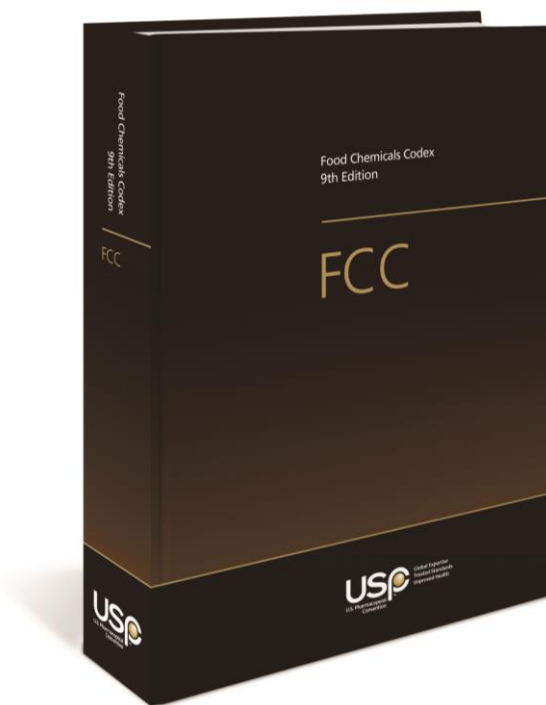
Food Fraud Mitigation Guidance



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

Compendial Standards	Identity	Strength	Quality/Purity
<ul style="list-style-type: none">▶ Set standards for identity, strength, quality and purity▶ Help ensure the right dosage▶ Help prevent economically-motivated adulteration	<ul style="list-style-type: none">▶ Is the ingredient what it purports to be?	<ul style="list-style-type: none">▶ Is enough of the ingredient present?	<ul style="list-style-type: none">▶ Are levels of impurities, particularly toxic impurities, appropriately controlled?

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>
- FPGI Database – <https://foodprotection.umn.edu/>
- GMA/Battelle EMAIert – <https://emailert.org/>
- SSAFE Food Fraud Vulnerability Assessment – <http://www.ssafe-food.org/>
- USP Food Fraud Database – <http://www.foodfraud.org/>
- USP Food Fraud Mitigation Guidance – <http://www.usp.org/food/food-fraud-mitigation-guidance>

Olive Oil and Food Fraud

FDLI, Food Advertising, Labeling and Litigation Conference

Paul Miller

Extra Virgin Alliance, Australian Olive Association

September 14 2017

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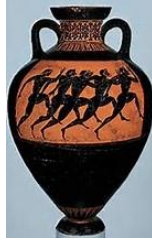
September 14 2017

paul@oilmiller.com

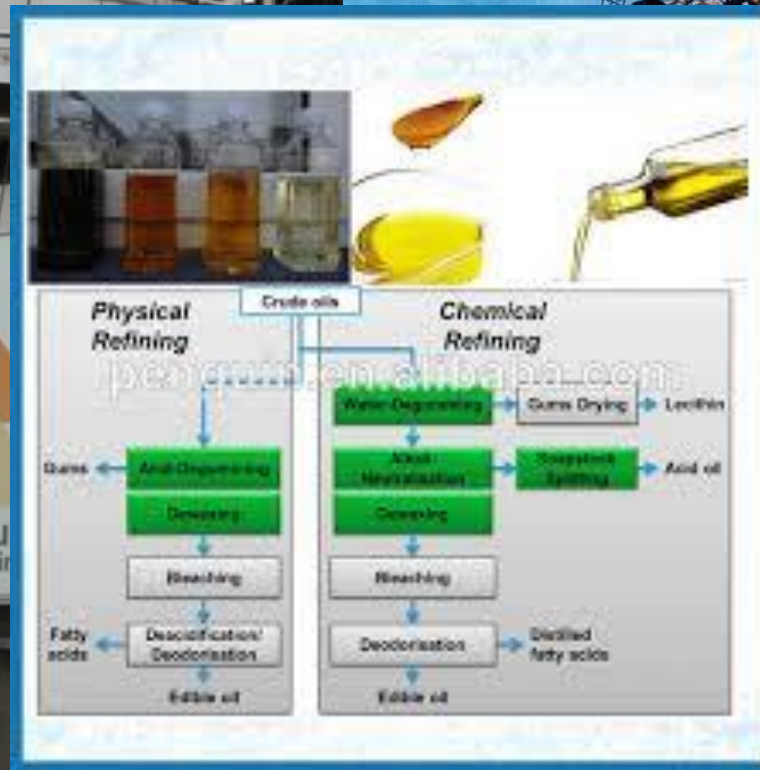
Olive Oil and Food Fraud - outline

- 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)

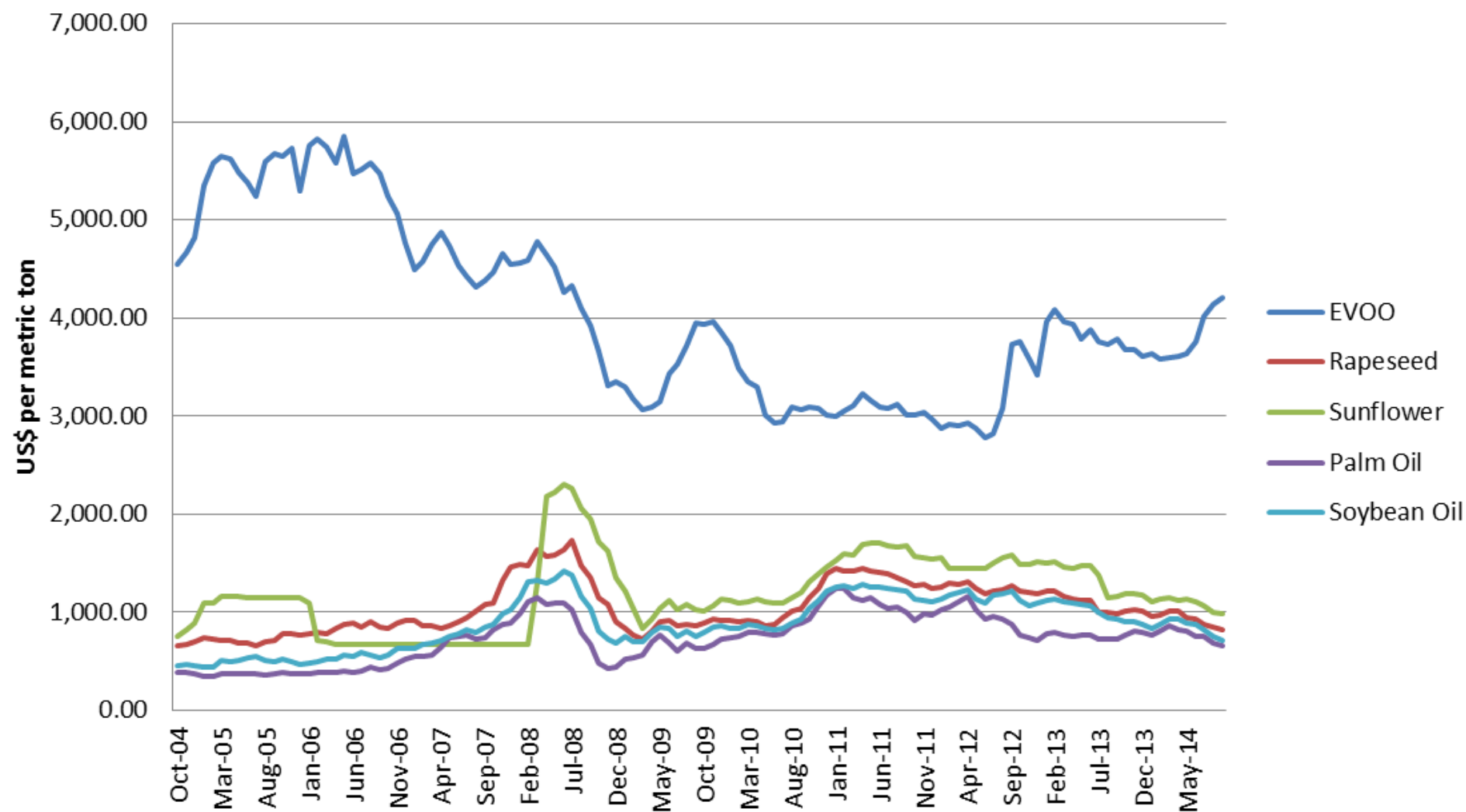
For The Consumer

- 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



Bulk extra virgin olive oil prices and bulk seed oils - Oct 2004 - Sept 2014

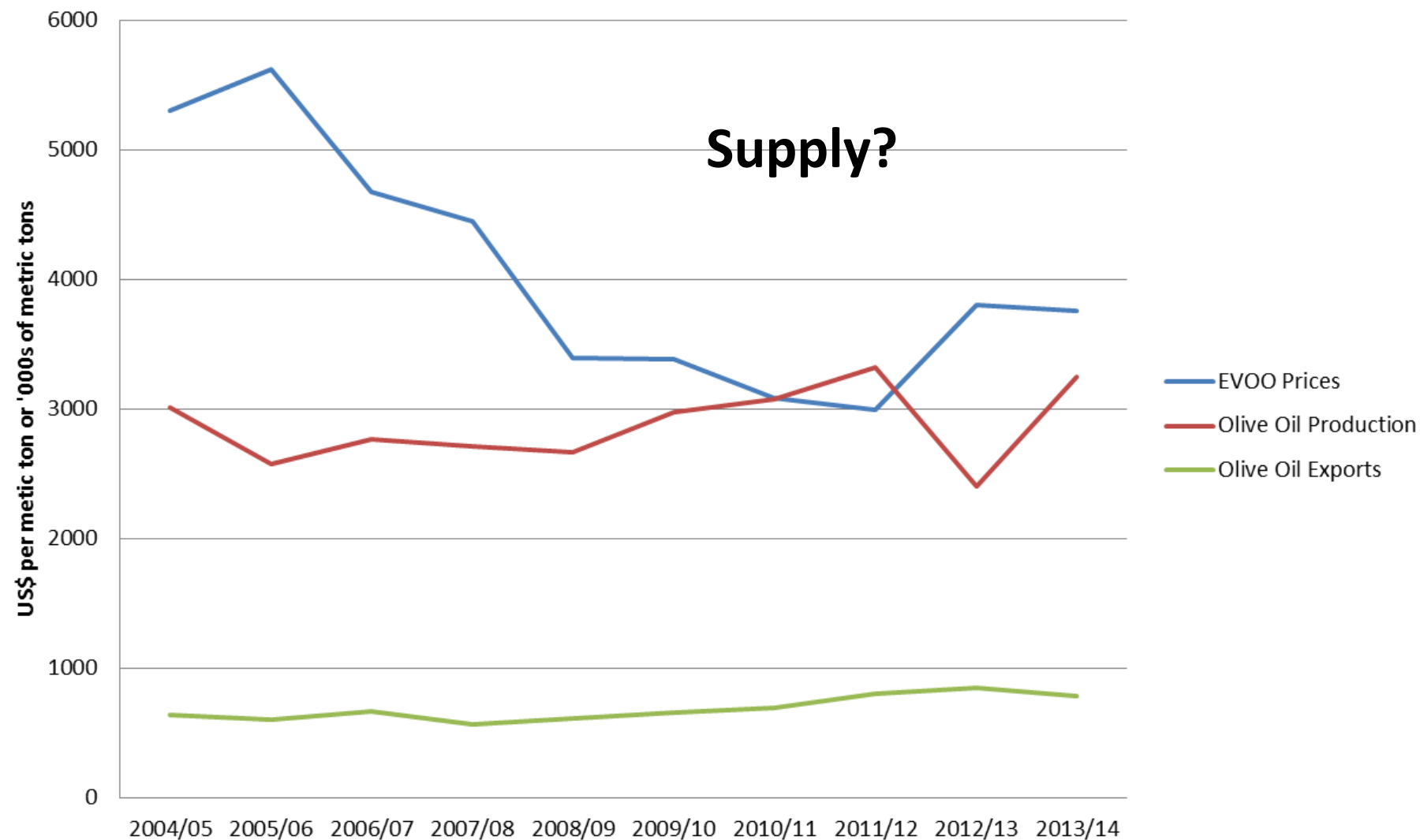


What caused this?

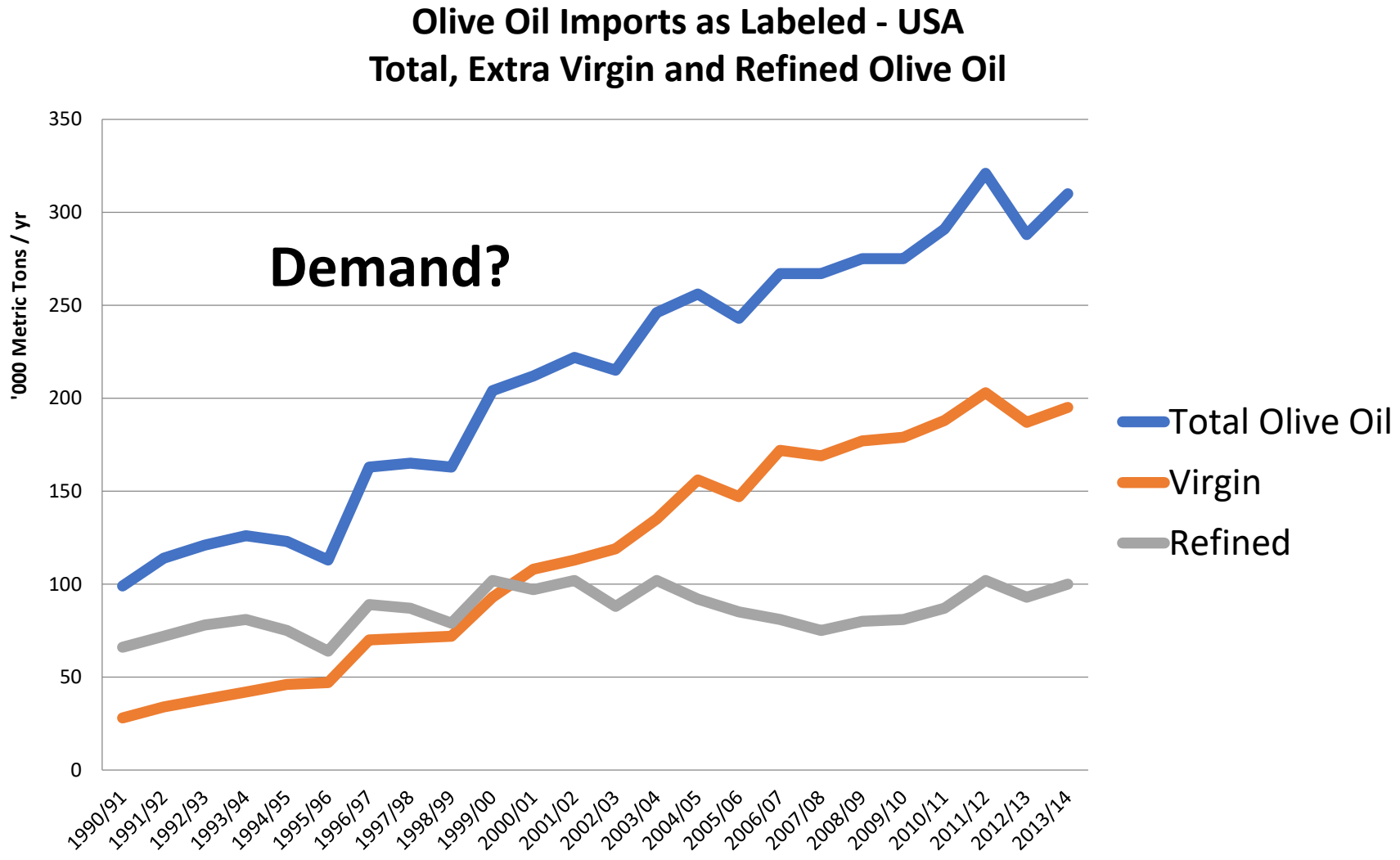
The decade to 2014

- 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, IOC and USDA

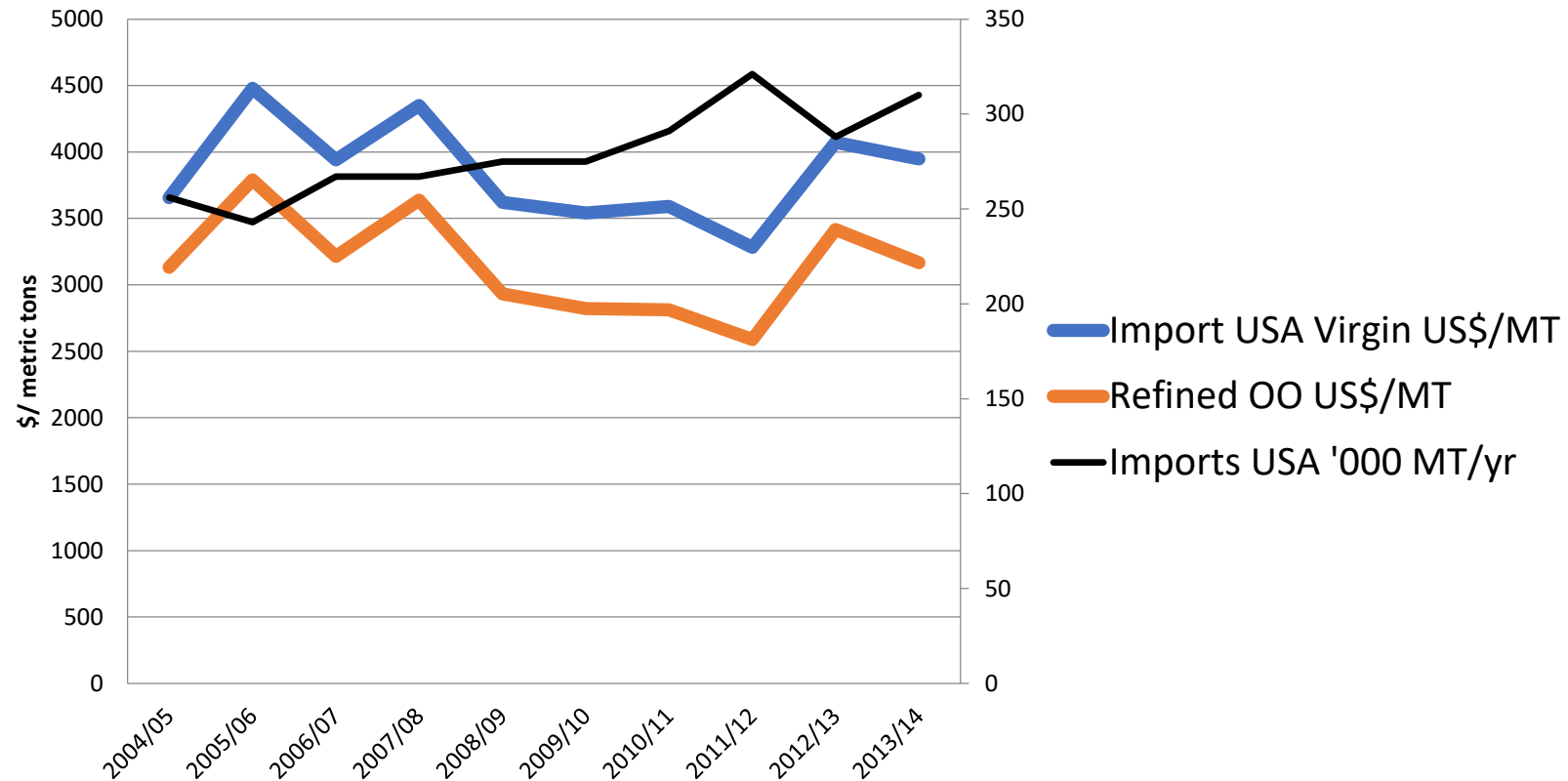
Extra virgin olive oil bulk prices, world olive oil production and world olive oil exports



Trend to extra virgin in the USA - naturally



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:

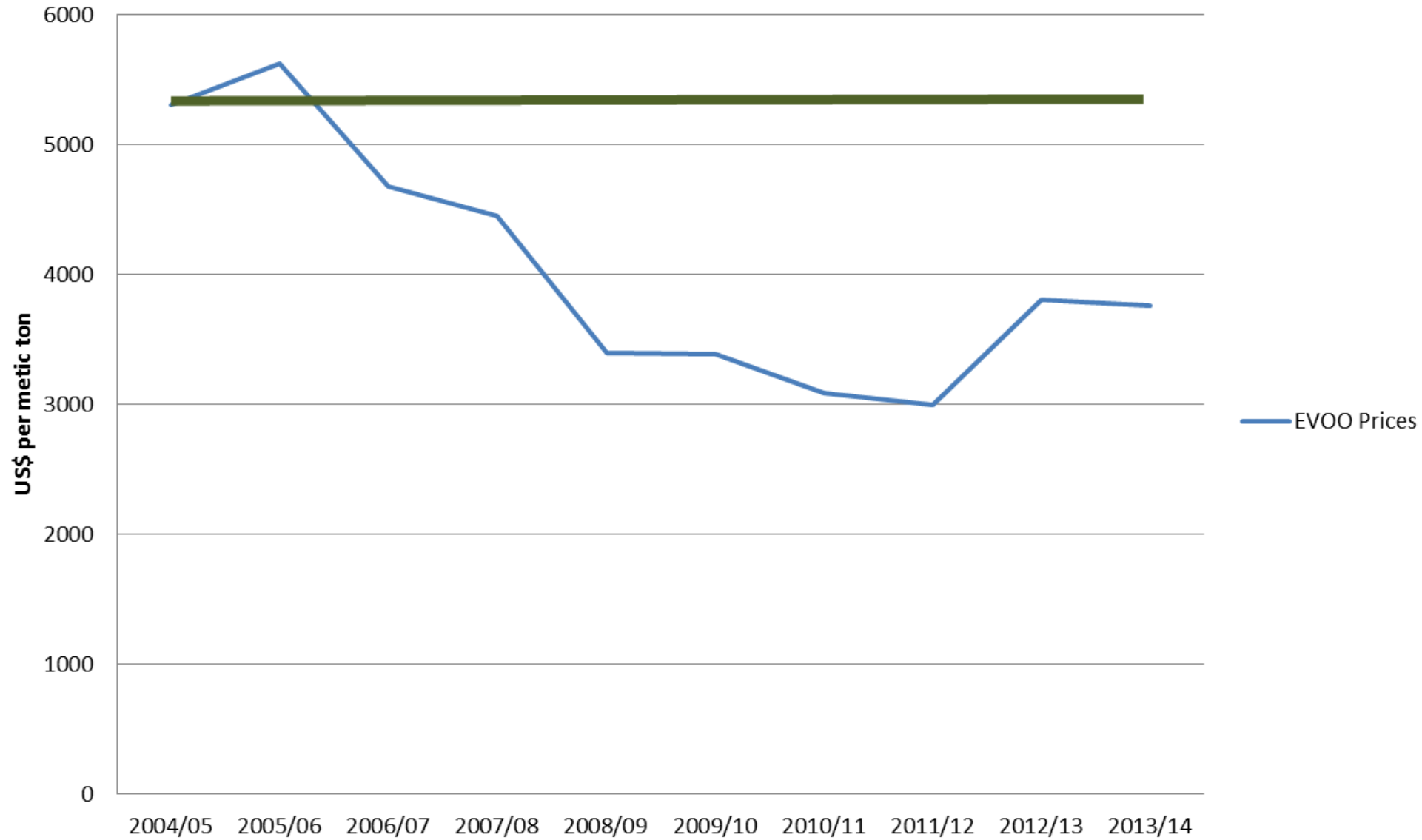
this price fall was mainly as a result of the “race to the bottom” caused by competition using falsely labeled products sold for lower and lower prices

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?

- The health outcomes are better from extra virgin than refined olive oils – both from quality within the product and in interactions with food - Covas M-I, et al. 2006, Minor components of olive oil: evidence to date of health benefits in humans. Nutrition Reviews v64 pp20-30. Covas MI, Nyyssonen K, Poulsen HE, et al. 2006, The effect of polyphenols in olive oil on heart disease risk factors: a randomized trial. Ann Intern Med v 145 pp333-41;
- **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

Food Fraud and "Economically Motivated Adulteration" of Food and Food Ingredients

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 defraud the European Union's farm support program, which subsidizes olive oil, as part of the Common Agricultural Policy (CAP). In some cases an alternate seed or nut oil may be sold as or thinned out with hazelnut, soybean, corn, peanut, sunflower, safflower, walnut, vegetable, canola, or palm oil, and in one case, lard. Some combinations contained no olive oil. The use of nut or legume oils could pose a problem for those with certain food allergies. In rare cases, non-food-grade oil may be added, such as rapeseed.

Fish and Seafood. Some higher-value fish and seafood are replaced with cheaper, more abundant fish. A report by Oceana found that fish samples purchased at grocery stores, restaurants, and sushi bars in major cities were often mislabeled, including red snapper (actually tilefish); white tuna and butterfish (actually escolar); wild Alaskan salmon (actually farmed Atlantic salmon); caviar (actually catfish roe); and monkfish (puffer fish). Other types of substitutions have involved halibut, sole, grouper, and striped bass. Some substitutions have involved fish or seafood associated with certain types of fish poisoning or allergens. Other substitutions are intended to evade import and other restrictions.

Milk and Milk-based Products. Milk from bovine cows has had milk from other types of animals, such as sheep, buffalo, and goats-antelopes, added to it, but also adulterated with reconstituted milk powder, urea, and rennet, among other products (oil, detergent, caustic soda, sugar, salt, and skim milk powder). Adulterated milk may also be watered down and then supplemented with melamine to artificially raise the apparent protein content and hide dilution. Melamine, an organic base chemical, is widely used in plastics, adhesives, and other consumer products, and is known to pose a public health threat. Adulterated milk might also be added into infant formula and other milk-based products. Baby formula is a common target for retail theft, often by tampering with the sell-by codes to move expired product.

Honey, Maple Syrup, and Other Natural Sweeteners. Honey might have added sugar syrup, corn syrup, fructose, glucose, high-fructose corn syrup, and beet sugar, without being disclosed on the label. Honey from a "non-authentic geographic origin" is also common, such as cases where honey from China is transshipped through another Asian country and falsely sold as honey from the second country—usually to avoid higher customs duties and tariffs that would be imposed on honey from China. Some of this honey might also contain unapproved antibiotics or other additives and heavy metals. Maple syrup is sometimes thinned out with sugar or corn syrup.

Fruit Juice. Juices might be watered down, or a more expensive juice (such as from pomegranates or other "super" fruit) might be cut with a cheaper juice (such as apple or grape juice). Some juice may be only water, dye, and sugary flavorings, although fruit is the listed ingredient on the label. Orange juice has been shown to sometimes contain added unlisted lemon juice, mandarin juice, grapefruit juice, high fructose corn syrup, paprika extract, and beet sugar. Apple juice has been shown to have added unlisted grape juice, high fructose corn syrup, pear juice, pineapple juice, raisin sweetener, fig juice, fructose, and malic acid.

Coffee and Tea. Ground coffee might be cut with leaves and twigs, as well as roasted corn, ground roasted barley, and roasted ground parchment. Instant coffee may include chicory, cereals, caramel, more parchment, starch, malt, and figs. Tea may contain leaves from other plants, color additives, and colored saw dust.

Spices. Saffron is the world's most expensive spice, and has been found to have added glycerin, sandalwood dust, tartrazine (a yellow dye), barium sulfate, and borax. Ground black pepper has been shown to have added starch, papaya seeds, buckwheat, flour, twigs, and millet. Vanilla extract, turmeric, star anise, paprika, and chili powder are other spices prone to fraud. Sudan red dyes have been used to color paprika, chili powders, and curries, but are also known carcinogens and are banned for use in foods.

Organic Foods and Products. Using fraudulent certification to market, label, or sell non-organic (conventionally produced) agricultural products as USDA-certified "organic" is a violation of U.S. law and federal National Organic Program (NOP) regulations. Products fraudulently labeled as "organic" have been detected by USDA for a range of foods and food ingredients from both domestic and international suppliers.

Clouding agents. "Clouding agents" or food processing aids "to enhance the appeal or utility of a food or food component," such as palm oil and other allowed food ingredients, are often used in fruit juices, jams, and other foods. Of particular concern is the fraudulent replacement or addition of the plasticizer Di(2-ethylhexyl) phthalate (DEHP) and other related phthalates, as a substitute for other ingredients. DEHP may also be used in food contact materials, such as seals and packaging. DEHP is associated with public health risks, including cancer and reproductive concerns.

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



JRC Food Fraud Monthly Report



European
Commission



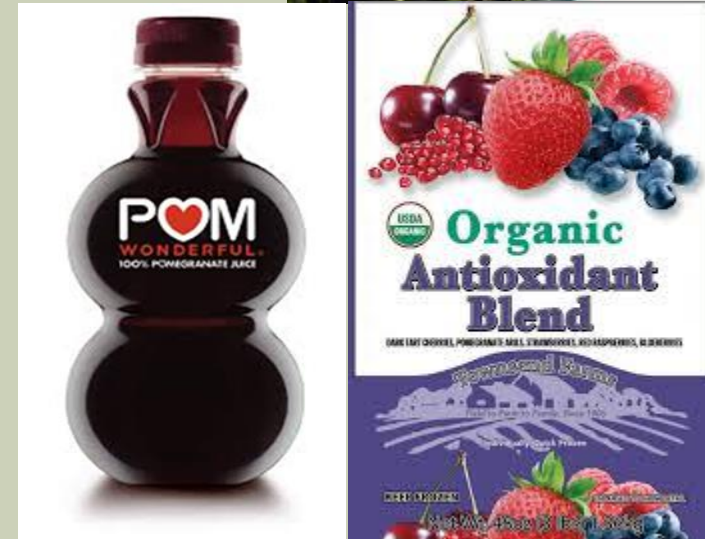
SOME REAL PROBLEMS

- 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**



PROBLEMS IN TRACING

Exhibit 7 – Illustrative supply chain for canned tuna

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

Supply chain for canned tuna



Source: <http://www.ilo.org/public/english/dialogue/sector/techmeet/tmfe07/tmfe-r.pdf>

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



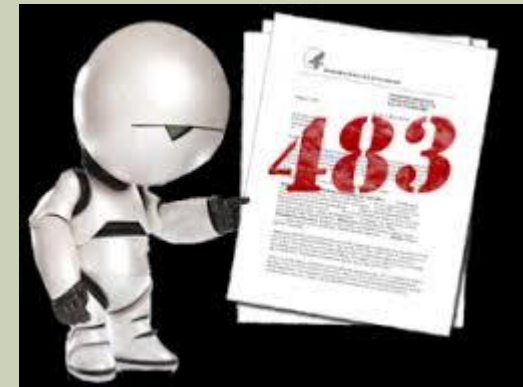
LEGAL REMEDIES

■ 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

