



Food Fraud: What You Don't Know *Can* Hurt You

Speakers: Karen Everstine, Ph.D. & Jorge Acosta
July 20, 2016



Today's Speakers



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Agenda

- USP Background
- What is food fraud?
- Food Fraud Regulatory Requirements
- Tools and Strategies to Reduce your Risk
- Your Best Line of Defense
- Q & A

USP Background



USP Mission: To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods



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	Is the ingredient what it purports to be?	Is enough of the ingredient present?	Are levels of impurities appropriately controlled?

USP's Food Program



Advancing science-based standards, tools, and services to improve confidence in the global food supply chain

What is food fraud?



Food Fraud: How does it occur?



- Dilution/substitution
 - Misrepresentation of geographic, botanical, animal, varietal origin
 - Use of non-food-grade substances
- Artificial enhancement
 - Color additives
 - Protein content
 - Organoleptic qualities
- Misrepresentation of production practices
- Misrepresentation of nutritional content
- Use of non-declared, unapproved, or banned pesticides, antibiotics, fungicides, etc.
- Removal of authentic constituents

Food Fraud: How does it occur?

- Melamine adulteration of both wheat gluten and dairy products (2007-2008)
- Adulteration of cooking oils with *Argemone mexicana* oil (1998)
- Sudan I in chili powder (2005) and lead oxide in paprika (1994)
- Peanut in ground cumin (2014-15)



Food Fraud: Examples

Ground Cumin

Origin: unknown

Contains:

Tartrazine
Acid Black 1
Orange II

CFIA Lab results:

4.2 ppm Tartrazine
2.3 ppm Acid Black 1
2.6 ppm Orange II



Cumin Powder

Origin: unknown

Contains:

Peanut allergen
@
11,700 ppm



Candy Coated Seeds

Origin: Pakistan

Rhodamine B

Detected by LC/MS/MS
method
(targeted method)
LC/MS/MS Sensitivity
Parts Per Billion or
Parts Per Trillion



Saffron Flower (Kasubha)

Origin: Phillippines

Contains:

Acid Orange II
Metanil Yellow & Sudan I

Also acid dyes:

E124 Ponceau 4R,
E126 Ponceau 6R



Allura Red AC
Erythrosine
Tartrazine
Sunset Yellow

Ponceau 4R

Rhodamine B
Auramine O
Orange II
Acid Blue 1
Crystal Violet
Brilliant Green

Flourescent Brightener?



Paprika

Adulterated with dye

Adulterated with annatto



Food Fraud: Global Problem

- Occurs frequently, but actual prevalence unknown
- Usually not detected, as low as 4% of the time (Gee et al 2014)
- Potential for significant **public health harm** when perpetrators make mistakes
- Potential for significant **financial harm** when fraud is discovered
- Erodes consumer confidence



Food Fraud Regulatory Requirements



What is food fraud?

- British Retail Consortium (BRC) definition:
 - **Fraudulent and intentional substitution, dilution or addition** to a product or raw material, or misrepresentation of the product or material, **for the purpose of financial gain**, by increasing the apparent value of the product or reducing the cost of its production
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Final Rule definition:
 - 21 CFR 117.130 (2) (iii) – Hazard may be intentionally introduced for purposes of economic gain



FDA Regulations

- Economically Motivated Adulteration (EMA) of spices with toxic colorants
 - 79 FR 58524 at 58550–58551
 - Dyes containing lead added to spices
 - Lead chromate to enhance turmeric color
 - Lead oxide to paprika – Hungary 1995
 - Sudan I to Chili Powder – UK 2005
- Milk with melamine – 6 dead infants and >290,000 ill
- Required to assess risk of ingredients



FDA Regulations

- 21 CFR 117.130
- Beyond misbranding and adulteration provisions of FD&C Act
- Limited to hazards with a pattern of economically motivated adulteration in the past
- Only products that can cause illness or injury
- Typically managed by a Supply-Chain Preventive Control
 - i.e. Testing by supplier or receiving company

GFSI/BRC Requirements

- BRC Food Issue 7 – Section 5.4 Product Authenticity
- Access on historical and developing threats to the supply chain
- Vulnerability Assessment for raw materials or groups
 - Historical evidence
 - Economic factors
 - Ease of access to raw materials through supply chain
 - Routine testing sophistication
 - Nature of raw materials
- Based on risk – assurance and/or testing must be in place



Comparison: FDA vs BRC Requirements



- BRC requires us to consider quality, legality, and food safety implications
 - Standards of Identity
 - Economic purposes



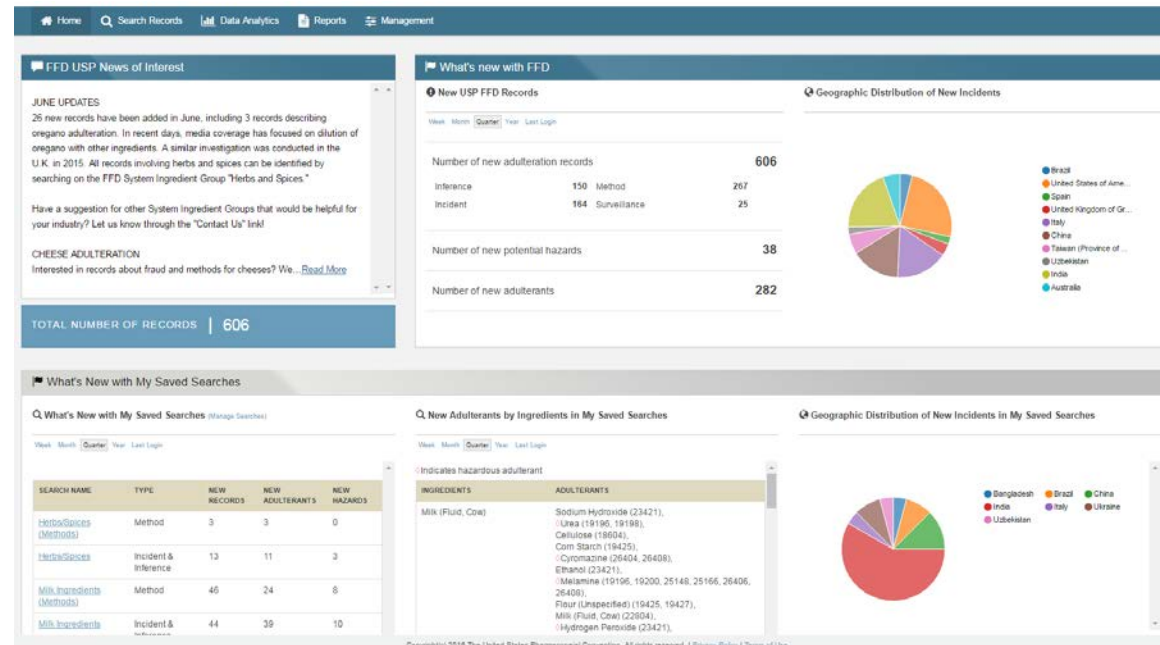
- FDA's main concern is when potential fraud situations have food safety implications
 - Standards of Identity not necessarily a food safety implications
 - Might have other legal implications

Tools and Strategies to Reduce your Risk



Food Fraud Database (FFD 2.0)

- Expanded record types
- User-friendly online interface
- Broad and flexible search capabilities
- Dashboard feature with alerts
- Automated analytics
- Report generator
- Real-time updates



Food Fraud – Historical Data

By JIM AXELROD, EMILY RAND / CBS NEWS / February 29, 2016, 7:11 PM

FDA: Listeria found at cheese plant with mislabeled products

2 Comments / 391 Shares / Tweet / Stumble / Email

PITTSBURGH -- If you love cheese, this news was pretty unappetizing -- **some Parmesan cheese actually contains wood pulp.**

Then last Friday, an executive at a Pennsylvania food company **pleaded guilty** to selling cheese that had no relation to what was on the label. CBS News decided to investigate.



David Hickton / CBS NEWS

You would think when FDA investigators found Castle Cheese marketing a product as 100 percent Parmesan cheese that is actually zero percent Parmesan, the company has a problem.

"The product that they were marketing and which was on the label was not what they were selling," said U.S. attorney David Hickton.

Hickton brought the case against Castle Cheese outside of Pittsburgh after an FDA inspection in 2012 found the company's Parmesan was actually a mixture of cheaper cheeses like Swiss and Cheddar, and in one case, an "unknown ingredient."

"Advertising it as Parmesan and Romano and putting in something else so the supplier could make more money, that's just clearly fraud on the consumer," Hickton said.

media report ➡ fraud incident

Food Fraud – Historical Data

Advanced Pharmaceutical Bulletin

Adv Pharm Bull, 2014, 4(4), 359-362
doi: 10.5681/apb.2014.052
http://apb.tbzmed.ac.ir

Research Article

Amino Acid Profile as a Feasible Tool for Determination of the Authenticity of Fruit Juices

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Keywords:
· Fruit juice
· Amino acid
· HPLC
· Adulteration
· Authenticity

Abstract
Purpose: Fruit juice is a nutrient rich food product with a direct connection to public health. The purpose of this research was to determine the amino acid profile of juices and provide a quick and accurate indicator for determining their authenticity.
Methods: The method of analysis was HPLC with fluorescence detector and pre-column derivatization by orthophthalaldehyde (OPA). Sixty-six samples of fruit juices were analyzed, and fourteen amino acids were identified and determined in the sampled fruit juices. The fruit samples used for this analysis were apples, oranges, cherry, pineapple, mango, apricot, pomegranate, peach and grapes.
Results: The results showed that 32% of samples tested in this study had a lower concentrate percentage as compared to that of their labels and/or other possible authenticity problems in the manufacturing process. The following samples showed probable adulteration: four cherry juice samples, two pomegranate juice samples, one mango, three grape, four peach, seven orange, two apple and one apricot juice samples.
Conclusion: In general, determining the amount of amino acids and comparing sample amino acids profiles with the standard values seems to be an indicator for quality control. This method can provide the regulatory agencies with a tool, to help produce a healthier juice. The aim of this study is the analytical control of the fruit juice composition is becoming an important issue, and HPLC can provide an important and essential tool for more accurate research as well as for routine analysis.

Introduction
The fruit juice industry is one of the most important agricultural businesses in the world. There are many advantages interrelated with the manufacturing of this food. Fruits are perishable items and their harvest is seasonal, but the consumption of these fruit has been made available throughout the year with the processing technologies we use today. The juices of these fruits and its concentrates have become a valuable semi-finished product. A large variety of fruits are used for commercial manufacturing of fruit juice, such as the orange, apple, peach, pomegranate, apricot, pineapple and grapes. The detection of adulteration requires a clear definition of what in fact constitutes a juice. The authentication of


on the profile analysis, e.g., sugars, amino acids, carotenoids, flavonoids, organic acids and others. There are many known classes of juice adulteration in today's manufacturing process. The most frequent types of adulteration include a simple dilution with water, by the addition of natural constituents from juices. As well as from other sources such as the addition of sugar syrup, which decreases the total amino acid value; additionally the use of constituents not naturally present in the juice such as colorants and the addition of inexpensive juice from other types of a lesser expensive fruit. More sophisticated forms of adulteration consists in the use of in- expensive amino

Scholarly
publication



fraud inference
method information

Food Fraud – Historical Data



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration

College Park, MD

Dates:

April 2012-September 2013

Projects:

FY12-CFSAN Sampling for Seafood Species Labeling in Wholesale Seafood

FY13-CFSAN Sampling for Seafood Species Labeling in Wholesale Seafood

FY13-CFSAN Sampling for Seafood Species Labeling in Imported Seafood

BACKGROUND

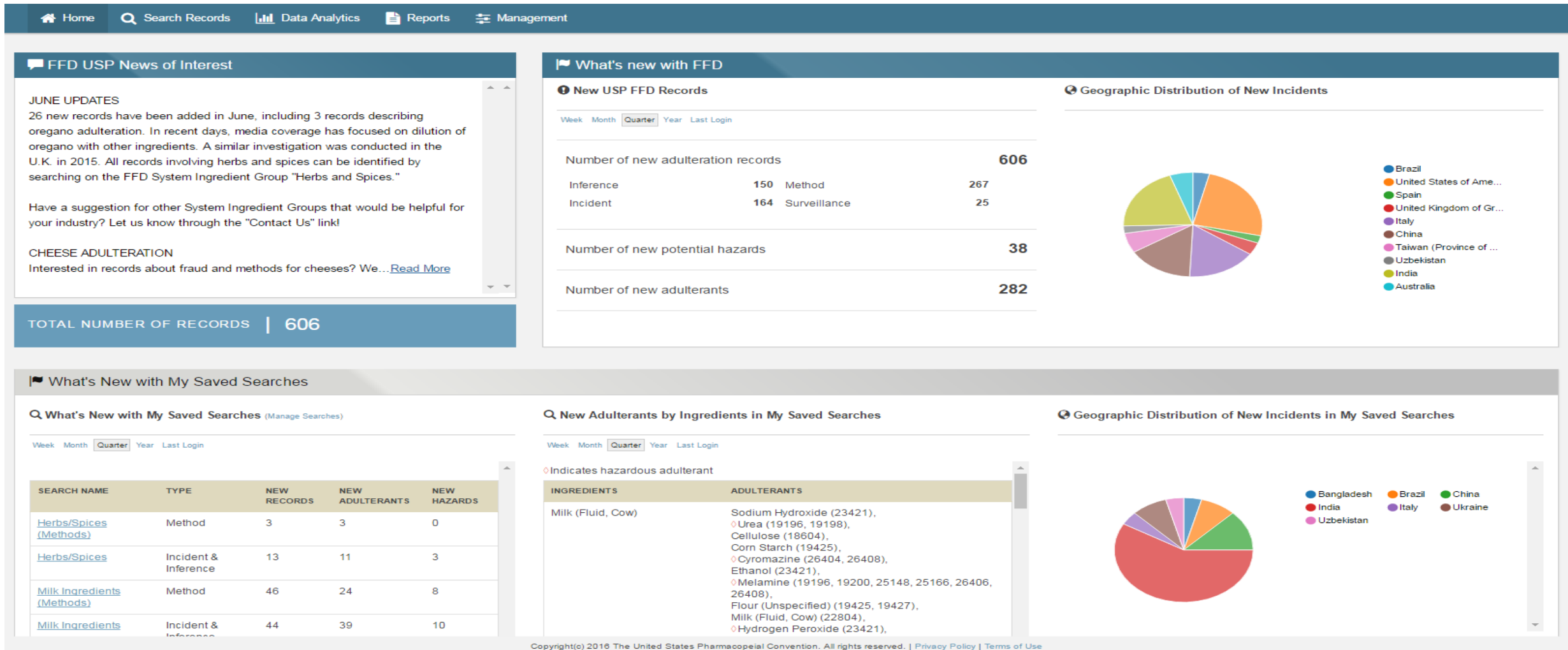
All FDA regulated products are required to be labeled in a manner that is truthful and not misleading. One aspect of truthful labeling is identifying seafood species by their acceptable market names. [The Seafood List - FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce](#) was developed to provide guidance to industry about what FDA considers to be acceptable market names for seafood sold in interstate commerce and to assist manufacturers in labeling seafood products. Incorrect use of an established acceptable market name, which causes the labeling to be false and/or misleading, can result in the product being misbranded under [section 403\(a\)\(1\)](#) of the Federal Food Drug and Cosmetic (FD&C) Act (21 U.S.C. 343(a)(1)). In recent years there have been a number of reports of seafood in the U.S. being labeled with an incorrect market name. In response to these reports FDA began conducting [DNA testing](#) on fish that have a history of being misidentified, in an effort to determine the accuracy of the market names on their labels. To date FDA's testing has focused primarily on fish collected from the U.S. wholesale distribution chain, prior to the point of retail sale, and to a limited extent on seafood collected at the point of import. FDA will use the results from this testing to help guide future sampling, enforcement, and education efforts designed to ensure that seafood offered in the U.S. market is labeled with an acceptable market name for the species.

OVERALL SUMMARY FOR THREE SAMPLING EFFORTS FOR SEAFOOD SPECIES LABELING PERFORMED IN FY 2012-2013

In FY 2012-2013, three sampling efforts were performed to assess the accuracy of seafood species labeling. This sampling focused primarily on products from the U.S. wholesale

Market-based
sampling → fraud
surveillance

FFD 2.0 – Dashboard Feature with Alerts



FFD 2.0 – Broad and Flexible Search Capabilities

Home

Search Records

Data Analytics

Reports

Management

Narrow Results

✕ clear selected filters

Ingredients:

Milk (Fluid, Cow) (20)

Cheese (Sheep's Milk) (3)

Mozzarella Cheese (Buffalo) (3)

see all

Adulterants:

Milk (Fluid, Cow) (10)

Water (8)

Melamine (5)

see all

Hazards:

Yes (14)

No (0)

Unknown (33)

Regulatory Classifications:

Year Ended/Reported:

Reference Publication Year:

Reference Types:

Produced Locations:

Distributed Locations:

Deaths:

Illnesses:

Export Records

	INGREDIENT11	INGREDIENT SYNONYMS	ADULTERANTS	RECORD TYPE11	PRODUCED LOCATION	DISTRIBUTED LOCATIONS	YEAR11	PUBLICATION YEAR11	CREATION DATE11
<div>Details</div> <div>Select</div>	Milk (Fluid, Cow)	Bovine Milk, Whole Cow's Milk	Melamine	Incident	China	China	2007 - 2008	2008, 2009, 2016	06/07/2016

Details for Incident 21524

Ingredient Name: Milk (Fluid, Cow)

Reg. Classification: Food Ingredient

Ingredient Synonyms: Bovine Milk, Whole Cow's Milk

USP ID:

CAS#: 8049-98-7

INS#:

UNII#: 917J3173FT

Adulterant Name: Melamine

Adulterant Synonyms: 1,3,5-Triazine-2,4,6-triamine, 2,4,6-Triamino-s-triazine, Cyanuramide, Cyanurotriamide, Cyanurotriamine

CAS#: 108-78-1

Hazard: Yes

Concentrations Detected:

Reasons for Adulteration: Artificial enhancement (protein)

Year Began: 2007

Year Ended/Reported: 2008

Produced Location: China

Distributed Locations: China

Weight of Evidence: High

Weight of Evidence Notes: The World Health Organization referred to the incident as one of the largest food safety events it has had to deal with in recent years, and that the crisis of confidence among Chinese consumers would be hard to overcome. A spokesman said the scale of the problem proved it was "clearly not an isolated accident, [but] a large-scale intentional activity to deceive consumers for simple, basic, short-term profits."

Creation Date: 06/07/2016

Health Outcomes:

DEATH	ILLNESS	LOCATION
6	300000	China

References:

FDA Issues Warning About Baby Formula from China

Chapman, L. (2008, September 12). FDA Issues Warning About Baby Formula from China. Retrieved May 12, 2016, from <http://www.findingdulcinea.com/news/health/September-October-08/FDA-Issues-Warning-About-Baby-Formula-from-China.html>

ID: 21376

Type: Media

Year Published: 2008

Reference URL:

<http://www.findingdulcinea.com/news/health/September-October-08/FDA-Issues-Warning-About-Baby-Formula-from-China.html>

DOI:

Sanlu's melamine-tainted milk crisis in China

Lu, J., Tao, Z., & Woo, C. H. (2009). Sanlu's melamine-tainted milk crisis in China. Harvard Business Review C, 439, 1-24.

ID: 21408

Type: Scholarly

Year Published: 2009


Reference URL:

<https://yellowrabbittales.files.wordpress.com/2014/01/china-baby-milk-case-study.pdf>

DOI:

Melamine Scandal Widens

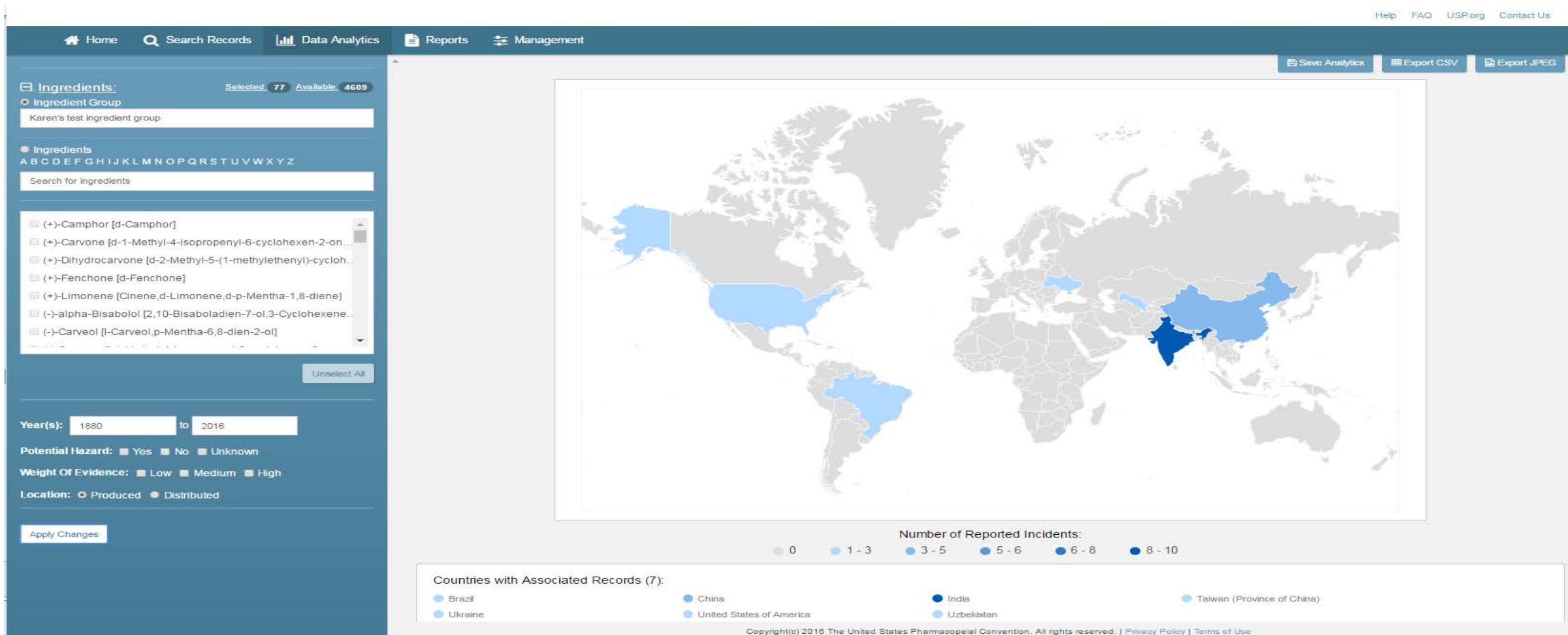
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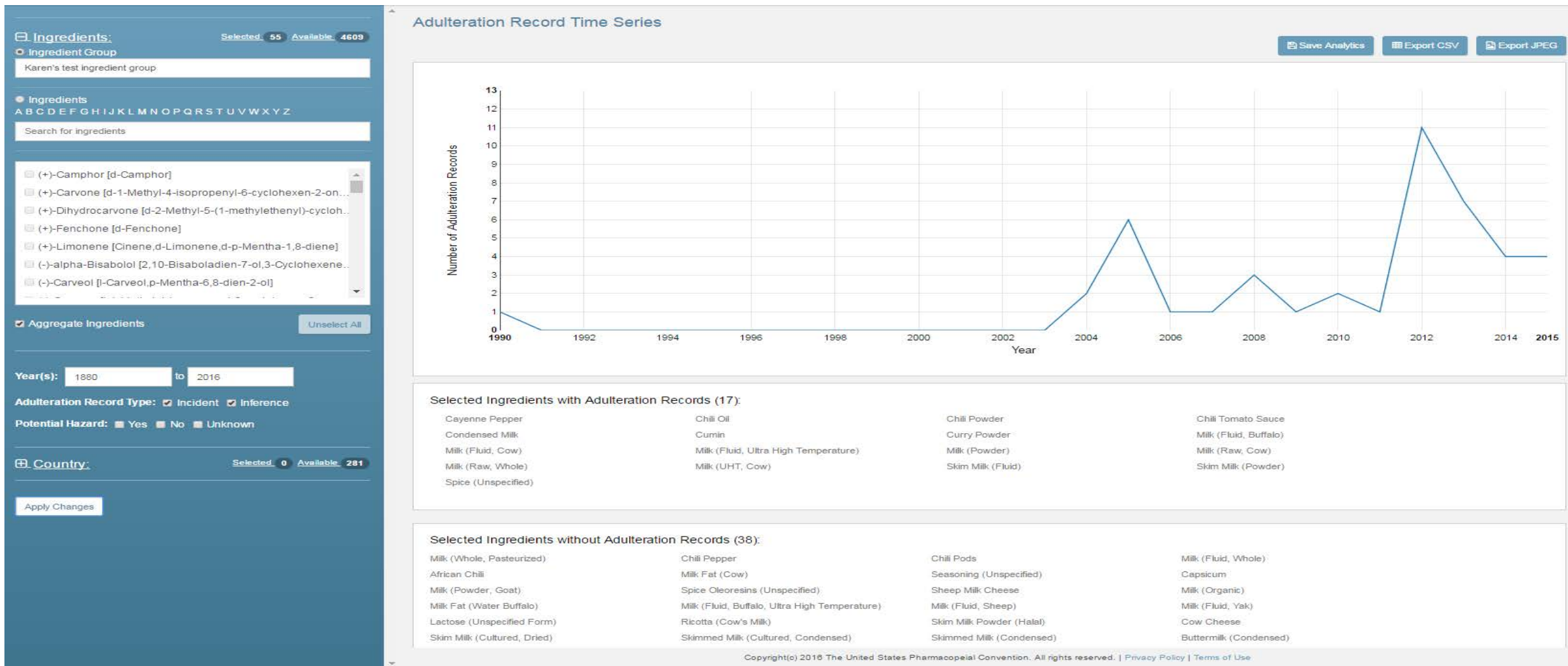
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FFD 2.0 – Automated Analytics



FFD 2.0 – Automated Analytics



What is an economically motivated hazard?

- Which food fraud adulterants are “known or reasonably foreseeable?”
- What is a “pattern of economically motivated adulteration in the past?”
- **Which adulterants are potentially hazardous (economically motivated hazard)?**



Hazards Identification Expert Panel

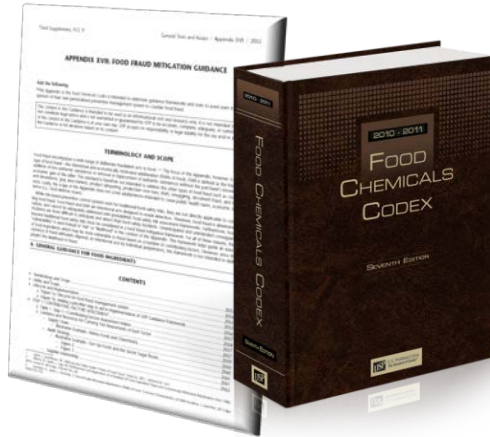
FFD 2.0 EMA Hazards Identification Report

Ingredient Name	Ingredient Synonyms	Potentially Hazardous Adulterants Associated With Incidents (Record IDs)	Potentially Hazardous Adulterants Associated With Inferences (Record IDs)
Milk (Fluid, Cow)	<ul style="list-style-type: none"> Whole Cow's Milk 	<ul style="list-style-type: none"> Melamine [China] (21524) Urea [Pakistan] (20697) Hydrogen Peroxide [Brazil] (23421) Water (Non-Potable) [India] (22960) Hydrolyzed Leather Protein [China] (13381, 13359) 	<ul style="list-style-type: none"> Cyromazine (26408) Synthetic Milk (Nonspecific) (26605) Melamine (26408, 19196, 25166) Urea (19196)
Milk Fat (Cow)	<ul style="list-style-type: none"> Milk Fat (Bovine) 	<ul style="list-style-type: none"> Urea [India] (25387) 	None
Milk (Raw, Whole)	<ul style="list-style-type: none"> Milk (Unpasteurized) 	None	<ul style="list-style-type: none"> Urea (30757)
Skim Milk (Powder)	<ul style="list-style-type: none"> Anhydrous Skim Milk De-Fatted Skim Milk Powder Dehydrated Skim Milk Dehydrated Skimmed Milk 	<ul style="list-style-type: none"> Melamine [China] (14965) 	<ul style="list-style-type: none"> Cyromazine (26160) Triuret (26160) Dicyandiamide (26160) Amidinourea (26160) Urea (26160)

Potentially hazardous adulterants were not currently identified among incident and inference records within the USP Food Fraud Database for the following ingredients:

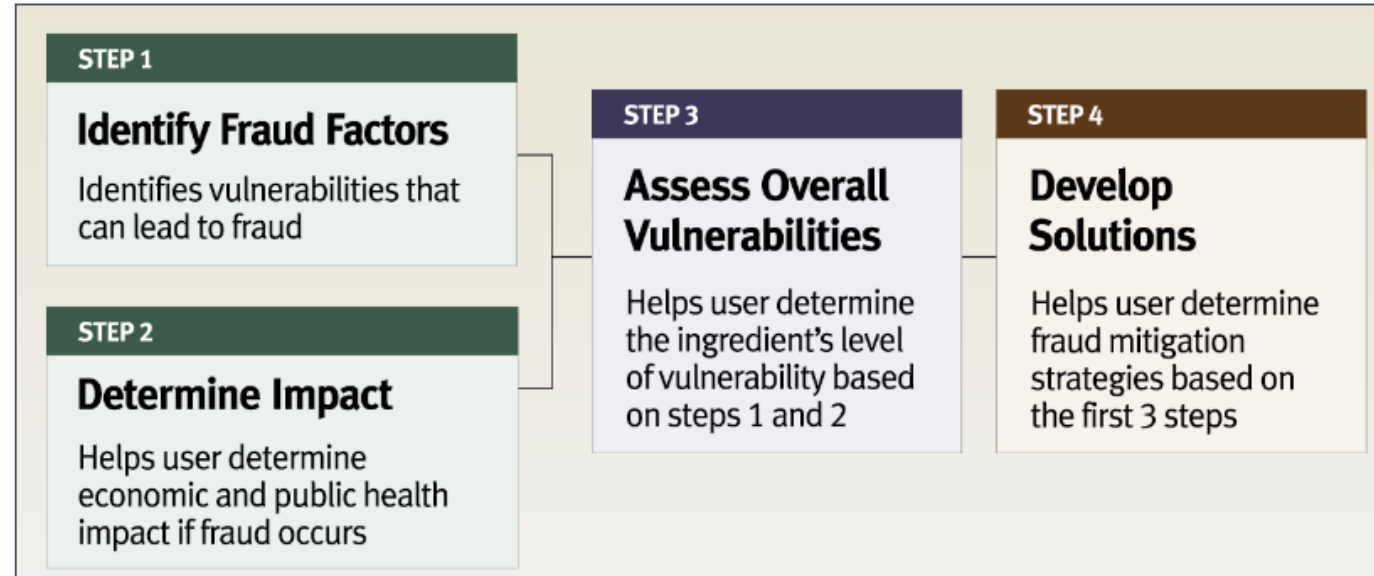
Lactose (Unspecified Form), Milk (Fluid, Ultra High Temperature), Milk Protein (Dried), Milk (Organic), Milk (Fluid, Goat), Buttermilk, Cattle Milk Process Residue, Sirene Cheese (Cow's Milk), Skim Milk (Cultured, Dried), Skimmed Milk (Cultured, Condensed), Skimmed Milk (Condensed), Ricotta (Cow's Milk), Buttermilk (Condensed), Cattle Milk Protein (Dehydrated), Condensed Cultured Skim Milk, Condensed Milk, Condensed Skimmed Milk, Cow's Milk Cheese, Chocolate Milk (Dried), Milk (Fluid, Whole), Milk (Raw, Cow), Milk (Whole, Pasteurized), Skim Milk Powder (Halal), Cream (Cow's Milk), Milk (Fluid, Bovine), Evaporated Milk

USP Food Fraud Mitigation Guidance



USP Food Fraud Mitigation Guidance
www.foodfraud.org

Framework for how to design your own tailored food fraud mitigation system and control plan based on both **vulnerability** and **impact** assessments



USP Food Fraud Mitigation Guidance – The Complete Picture

Combine vulnerability and impacts assessments to create an “overall” risk score, which can then be used to inform decisions around mitigation

	Low		Moderate		High
Food Safety	Food Grade - Known Safe	Food Grade - No Known Risks	Food Grade - Known Sub-Population Risks	Non-Food/Non-Food Grade - Unknown Risks	Non-Food/Non-Food Grade - Known Risks
Economic Impact	No Significant Balance Sheet Impact	Operational Risk			Enterprise Risk
Potential Multipliers					
Focused Consumption	No Focused Consumption	Temporally Focused	Low Level	Potential Target Populations	At-Risk Populations
Nutritional Sufficiency	No Sufficiency Impacts		Important Micro-Nutrient Food	Core Food For a Sub-population	Primary/Critical Sub-Population Food
Public Confidence	Specific food	Specific Commodity	Industry Sector	Industry Wide	Authorities & Industry

		Contribution to Vulnerability				
		Low		Medium		High
Controllable factors	Supply chain	X				
	Audit strategy			X		
	Supplier relationship	X				
	History of issues		X			
	Testing frequency			X		
	Methods & specs			X		
Uncontrollable factors	Geopolitical considerations	X				
	Economic anomalies		X			
	Fraud history	X				

		Contributing Factors (Composite of Step 1)				
		Low		Moderate		High
Potential Impact (Composite of Step 2)	Low Economic	New controls optional	New controls optional	New controls optional	New controls optional	New controls should be considered
	Medium Economic	New controls optional	New controls should be considered	New controls should be considered	New controls should be considered	New controls strongly recommended
	Low Public Health/High Economic	New controls optional	New controls should be considered	New controls should be considered	New controls strongly recommended	New controls strongly recommended
	Moderate Public Health/High Economic	New controls optional	New controls should be considered	New controls strongly recommended	New controls strongly recommended	New controls strongly recommended
	High Public Health/High Economic	New controls optional	New controls strongly recommended	New controls strongly recommended	New controls strongly recommended	New controls strongly recommended

FFD 2.0 and Food Fraud Vulnerability Tools

- SSAFE Food Fraud Vulnerability Assessment Tool¹:
 - “Free tool with a clear, robust, and effective methodology to help food companies undertake food fraud vulnerability assessments.”
- GMA/Battelle EMAAlert²:
 - “Software tool that enables food manufacturers to rapidly analyze and understand EMA vulnerabilities”
- USP Food Fraud Mitigation Guidance³:
 - “Comprehensive, practical four-step approach to help perform a vulnerability assessment and develop a customized food fraud mitigation plan.”

Data on historical food fraud trends is a key component of any food fraud mitigation plan

¹<http://www.ssafe-food.org/our-projects/>

²<http://www.battelle.org/our-work/national-security/cbrne-defense/threat-assessment/emaalert>

³<http://www.foodfraud.org>

Acknowledgments

>60 Expert Volunteers Supporting USP's Food Program

- USP Food Ingredients Expert Committee
- USP Olive Oil Authenticity and Quality Expert Panel
- USP Food Adulterants Hazards Identification Expert Panel
- USP Food Adulteration Expert Panel
- USP Non-Targeted Methods for Milk Ingredients Expert Panel



How To Engage with USP

- **Volunteer** as an expert
- **Sponsor** new and revised standards
- **Comment** on proposed standards
- **Attend** USP workshops and related events
- **Subscribe** to the Food Fraud Database (foodfraud.org)
- **Contact** USP to learn about training and advising services (foods@usp.org)

Adulteration and Fraud in Food Ingredients and Dietary Supplements Workshop

Download the Adulteration Workshop Program

Date: December 3–4, 2015; USP, Rockville, MD

Co-sponsored by the American Botanical Council and the Food Protection and Defense Institute.



Your Best Line of Defense

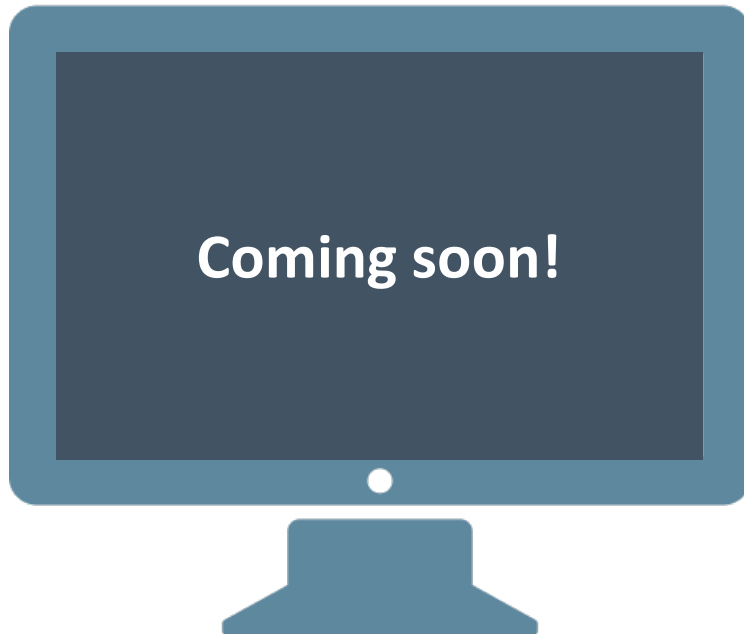


Employees Are your Best Line of Defense

- Learning:
 - Consistency
 - Ensure employees know what food fraud is so they will speak up when they see something concerning
- Communications:
 - Drive retention through reinforcement
- Performance:
 - Coach and observe employee behavior on the production floor



New Alchemy Food Fraud Course



- Introduces basic economic motivators of food fraud
- Provides examples of different types of food fraud
- Explores the employee's role in preventing food fraud
- Available by end of year

Food Defense: How to Comply with FSMA's New Intentional Adulteration Rule

Date: Wednesday, August 17th | 12:00-1:00 pm CT

Speakers: John W. Larkin, Ph.D. (Food Protection and Defense Institute) & Holly Mockus (Alchemy)

FSMA's Intentional Adulteration final rule was published on May 26. Also referred to as the "food defense rule," it is intended to protect the food supply from potential large-scale public harm that could threaten consumers and put your bottom line at risk. The rule requires facilities to create a written food defense plan in which they must identify areas of their operation vulnerable to intentional adulteration and devise strategies to mitigate that risk. Do you have a robust food defense plan in place that demonstrates your facility is adequately protected? Join this webinar to learn about the final rule, what it means for your facility, and how to build your food defense plan to comply.

Learning Objectives:

- Explore food defense and why it is important
- Find out what FSMA's new intentional adulteration final rule requires of food manufacturers
- Receive tips on how to build a strong food defense plan in order to comply
- Learn how your frontline is your best defense



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Q&A



THANK YOU

Karen Everstine, PhD, MPH, REHS

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