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U.S. Pharmacopeial Convention

USP Tools for Food Fraud Prevention and Mitigation

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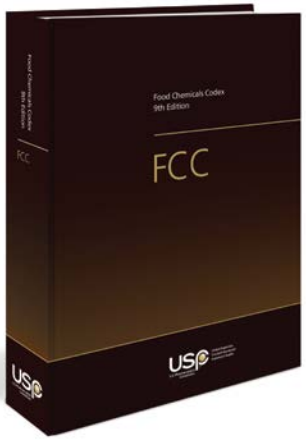
USP's Food Focus: Ingredients

USP MISSION

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



USP U.S. Pharmacopeial Convention Food Fraud Database

Food Fraud: Global Problem

THE TIMES OF INDIA

70% of milk in Delhi, country is adulterated

Kounteya Sinha, TNN | Jan 10, 2012, 02.33AM IST

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NEW DELHI: Beware, your daily glass of good health could actually
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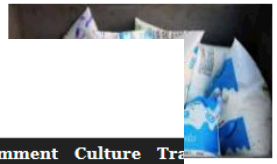

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Food dye scare sparks largest recall in history

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Walkers Worcester s

By David Derby
12:01AM GMT 22 I

The worst food s
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OVER 2,500 TONS SEIZED IN EUROPOL'S MASSIVE FAKE FOOD OPERATION

Posted on Feb 17, 2015 by Hanna Daych

Europol seizing record numbers of illegal drinks (Europol/Twitter)

GLOBAL EXPERTISE

Europol has forcibly seized over 2,500 tons of fake and below-standard food from 47 countries through a joint operation with international policing agency Interpol dubbed "Operation Opson IV."

Bloomberg Business

The Honey Launderers: Uncovering the Largest Food Fraud in U.S. History

By Susan Berfield | September 19, 2013

SEND TO kindle

Magnus von Buddenbrock and Stefanie Giesselbach arrived in Chicago in 2006
full of hope. H
they had both
assignments a
family-owned
based in Ham
had joined AL
its founder, Al

The New York Times

Asia Pacific

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH SPORTS OPINION
AFRICA AMERICAS ASIA PACIFIC EUROPE MIDDLE EAST

Asia Food Tainting Spreads, Leading to Recall in U.S.

Nicky Loh/Reuters

Products from the Mr. Brown brand in the King Car Food warehouse in Taoyuan, Taiwan. A nondairy creamer made in China, used in the products, was found to be contaminated.

Consequences of Food Fraud

Always: Cheats consumers

When discovered: Significant costs for food producers; Erodes consumer confidence

Gone wrong: Introduces food safety hazards

Food Fraud Is Hard to Predict

Criminal “designs” adulterant to evade existing QA system

QA system reacts by developing new tests

Industry and regulators alike need a way to predict food fraud so they can apply risk-based prevention

Reality for Industry and Regulators

Where to focus ?

Advances Towards Prevention # 1

Understanding the Past

"Neither a wise man nor a brave man lies down on the tracks of history to wait for the train of the future to run over him." ~Dwight D. Eisenhower

USP Food Fraud Database

Since 2012, the first public database on food fraud

USP Food Fraud Database

www.foodfraud.org

> 2,000 records

By ingredient information on:

- Fraud history
- Potential hazards
- Available detection methods

USP Food Fraud Database

R: Concise Reviews in Food Science

Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010

Jeffrey C. Moore, John Spink, and Markus Lipp

Abstract: Food ingredient fraud and economically motivated adulteration are emerging risks, but a comprehensive compilation of information about known problematic ingredients and detection methods does not currently exist. The objectives of this research were to collect such information from publicly available articles in scholarly journals and general media, organize into a database, and review and analyze the data to identify trends. The results summarized are a database that will be published in the US Pharmacopeial Convention's *Food Chemicals Codex*, 8th edition, and includes 1305 records, including 1000 records with analytical methods collected from 677 references. Olive oil, milk, honey, and saffron were the most common targets for adulteration reported in scholarly journals, and potentially harmful issues identified include spices diluted with lead chromate and lead tetraoxide, substitution of Chinese star anise with toxic Japanese star anise, and melamine adulteration of high protein content foods. High-performance liquid chromatography and infrared spectroscopy were the most common analytical detection procedures, and chemometrics data analysis was used in a large number of reports. Future expansion of this database will include additional publically available articles published before 1980 and in other languages, as well as data outside the public domain. The authors recommend in-depth analyses of individual incidents.

Keywords: analytical procedures, economically motivated adulteration, *Food Chemicals Codex*, food fraud, food ingredients

Practical Application: This report describes the development and application of a database of food ingredient fraud issues from publicly available references. The database provides baseline information and data useful to governments, agencies, and individual companies assessing the risks of specific products produced in specific regions as well as products distributed and sold in other regions. In addition, the report describes current analytical technologies for detecting food fraud and identifies trends and developments.

Moore et al. 2012. Journal of Food Science. 77(4): R118-126

FSMA and EMA

Facilities are required to consider economically motivated adulteration (EMA) as part of their hazard analysis with focus on:

- "Known or reasonably foreseeable hazards"
  =Pattern/history of adulteration
- "If they affect the safety of the food"
  =Reasonably likely to cause illness or injury

Utility of USP FF Database

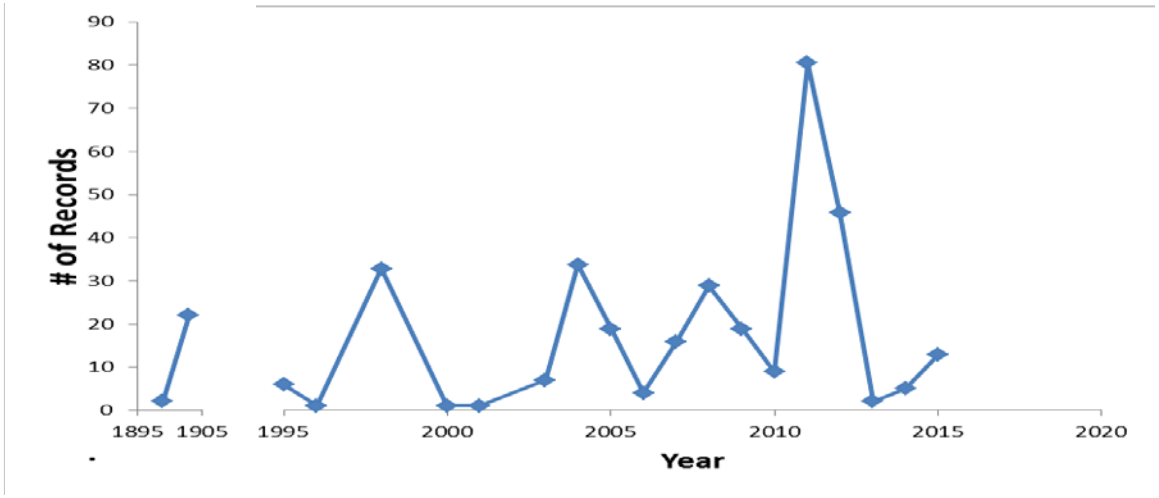
EMA hazard requiring PC?

- **Maltodextrin**: No history/pattern (0 records; 0 adulterants)

Likely no

- **Spices**: Clear pattern/history (350 records and 223 adulterants)
  - 35 unique adulterants (representing 24% of records) that pose potential safety concerns, e.g., industrial dyes, lead compounds, nut materials

Potentially yes



Next Steps for USP Database

- Significant upgrade planned for 2016 and beyond
  - New customizable dashboard interface with data analytics
  - Adding information on potential safety issues for adulterants
  - Geospatial - surveillance information
  - New record types and fields

Advances Towards Prevention # 2

- ***Needs***:
  - What's next after EMA hazards requiring PC are identified

  OR

  - Where to start if going above and beyond FSMA requirements (e.g. GFSI requirements for food fraud)

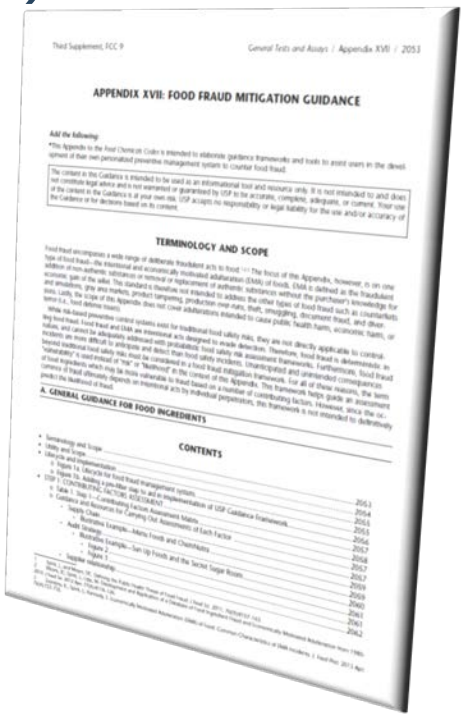
- ***Solution:***
  - A vulnerability assessment and control plan approach

USP Guidance on Food Fraud Mitigation

- Aim: Guidance to help organizations develop their own ***action oriented*** fraud mitigation system(s) to identify riskiest ingredients and develop appropriate control plan(s)

- Focus:
  - –Ingredients; EMA

- Published: Sept. 1, 2015
  - –3rd Supplement to USP's Food Chemicals Codex



APPENDIX XVII: FOOD FRAUD MITIGATION GUIDANCE

TERMINOLOGY AND SCOPE

A. GENERAL GUIDANCE FOR FOOD INGREDIENTS

CONTENTS

USP Food Fraud Mitigation Guidance Approach

Ingredient by ingredient…..

Vulnerabilities characterization

1. Contributing factors assessment
2. Impacts assessment
3. Combining 1 & 2

4. Mitigation strategy development

Step 1: Contributing Factors

	Contributing Factor	Contribution to Vulnerability: Low[4]	Medium-Low[4]	Medium[4]	Medium-High[4]	High[4]
Controllable factors	Supply chain	Firm vertically integrated	Supplier vertically integrated	Supplier manufactures	Upstream supplier manufactures	Open market
	Audit strategy	Robust, onsite, with numerous anti-fraud measures	Robust, onsite, with limited anti-fraud measures	Immature, onsite, no antifraud measures	Currently developing an onsite audit strategy	No onsite audits
	Supplier relationship	Trusted supplier and previously purchased ingredient(s)	Trusted supplier and new ingredient	Established supplier and some relationship	Established supplier and no prior relationship	Unestablished supplier and no prior relationship
	History of supplier quality & safety issues	No known issues	Few minor issues, quickly resolved	Recurrent issues or resolution concerns	Multiple persistent issues; some evidence of inadequate controls	Strong evidence of quality or safety concerns; inadequate controls
	Testing frequency	Intensive-every lot independently tested by buyer	Random lots independently tested by buyer	Independent testing done at yearly or other limited intervals as part of supplier qualification	No independent testing done, reliance on Certificate of Analysis	COA either not present or not specific to lot/ shipment. No independent testing
	Susceptibility of QA methods and specs	Methods are very selective/ specific; specifications only allow for natural variability.	Methods are selective/ specific; specifications allow for natural and analytical variability.	Methods are selective but not specific; specifications reflect same.	Methods are of limited selectivity/ specificity; specifications reflect same	Methods are not selective or specific; specifications ranges are broader than ideal
Uncontrollable factors	Geopolitcal consideratons	Ingredient is a single component sourced from a single geographic origin of low concern	Several components sourced from geographic origin(s) of low concern	Single component; originated or transited through regions with some geopolitical concerns	Several components; some originated or transited through regions with some geopolitical concerns	One or more components originated or transited through one or more regions exhibiting several characteristics of geopolitical concern
	Fraud history	No or few known reports; no substantiating evidence	Moderate volume of reports; no substantiating evidence	Numerous reports; limited substantiating evidence	High volume of reports; some substantiating evidence	High volume of reports; good substantiating evidence
	Economic anomalies	Nothing unusual	Isolated anomalies	Frequent but unrelated anomalies	Common but focused anomalies	Common and broad anomalies

Step 1: Contributing Factors

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Uncontrollable factors	Economic anomalies	Nothing unusual	Isolated anomalies	Frequent but unrelated anomalies	Common but focused anomalies	Common and broad anomalies

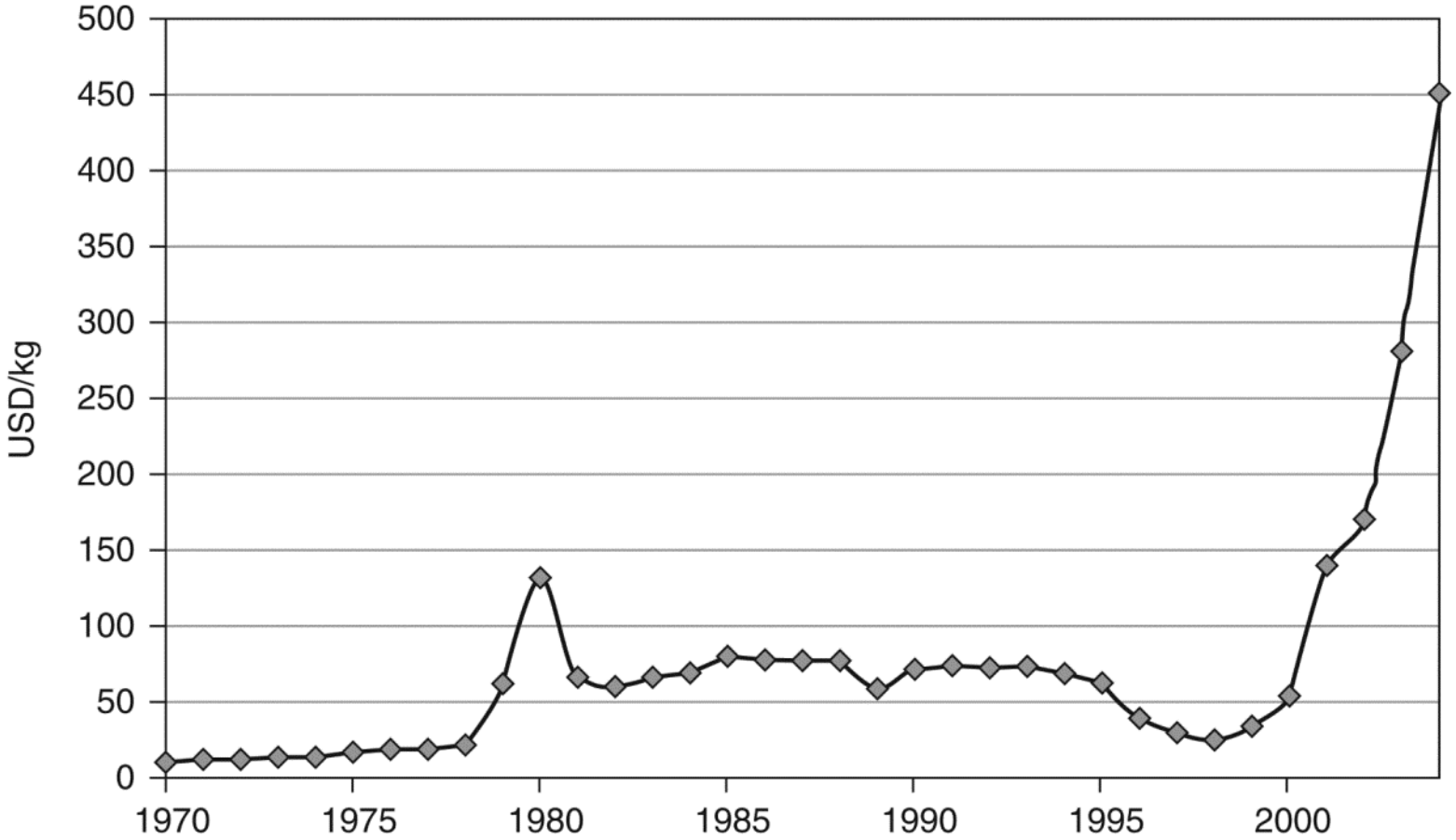
Pomegranate Juice

High

Step 1: Contributing Factors

Contributing Factor	Contribution to Vulnerability				
	Low[4]	Medium-Low[4]	Medium[4]	Medium-High[4]	High[4]
Supply chain	Firm vertically integrated	Supplier vertically integrated	Supplier manufactures	Upstream supplier manufactures	Open market

World vanilla prices: 1970–2004



ctors	Economic anomalies	Nothing unusual	Isolated anomalies	Frequent but unrelated anomalies	Common but focused anomalies	Common and broad anomalies

Step 2: Impacts Assessment

Identify known and potential adulterants

	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

Step 3: Overall Fraud Vulnerabilities Characterization

Example: Hypothetical Maltodextrin

Step 1

	Factor	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		
	Geopolitical considerations	X				
Uncontrollable factors	Economic anomalies		X			
	Fraud history	X				

Step 2

	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

Potential Impact (Composite of Step 2)	Contributing Factors (Composite of Step 1): Low		Moderate		High
Low Economic	New co… optional	…controls …nal	New controls optional	New controls optional	New controls should be considered
Mo… Economic	New co… optional	…controls …ould 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

Step 3: Overall Fraud Vulnerabilities Characterization

Example: Hypothetical Spice

Step 1

	Factor	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	
	Geopolitical considerations				X	
Uncontrollable factors	Economic anomalies				X	
	Fraud history				X	

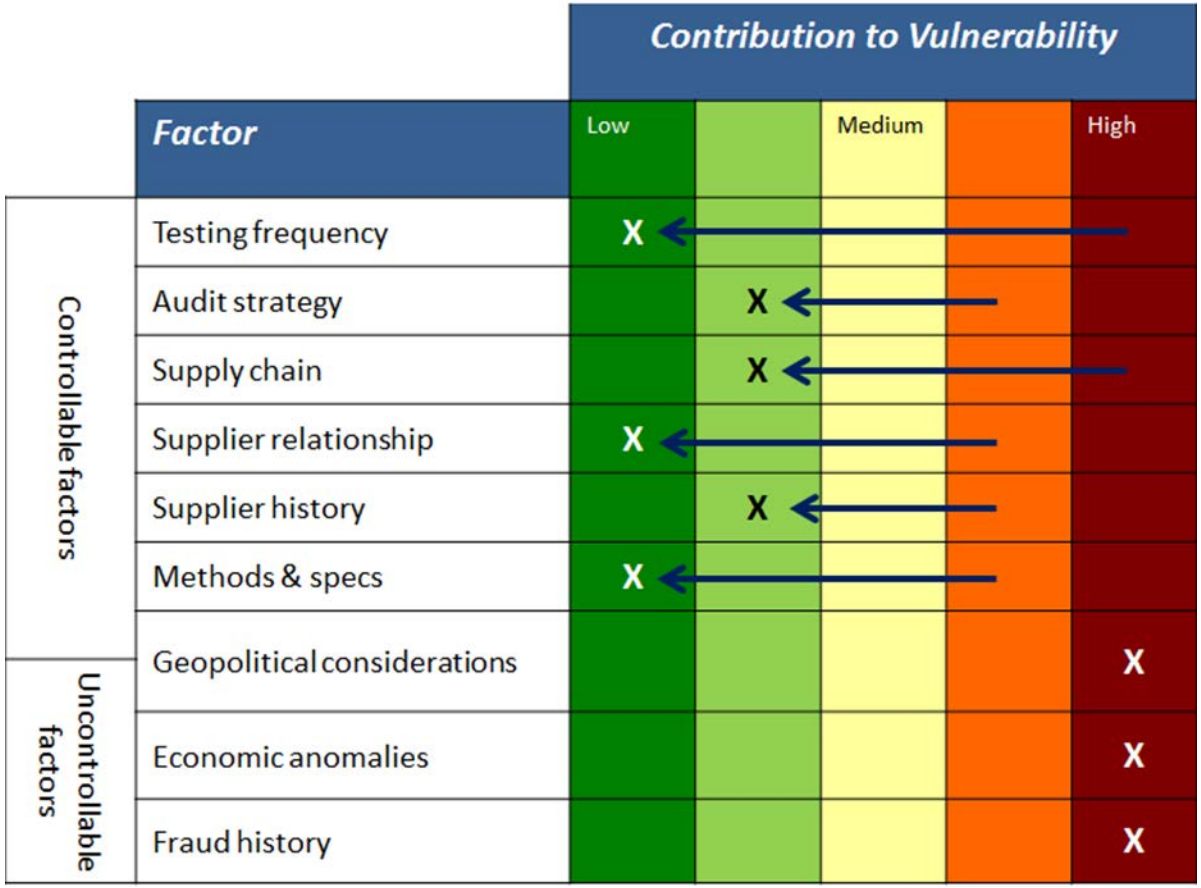
Step 2

	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

Potential Impact (Composite of Step 2)	Contributing Factors (Composite of Step 1): Low		Moderate		High
Low Economic	New controls optional	New controls optional	New controls optional	New controls optional	New controls should be considered
Moderate 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 should be considered	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

Step 4: Developing a Mitigation Strategy

- Question: Are my the identified vulnerabilities acceptable? If not, how do I prevent or control them?



USP Testing Standards on Spice Adulteration

- Analytical standard projects in USP's pipeline
  - Non-targeted methods for dyes in spices
  - Targeted/confirmatory screening methods for dyes in spices
- Monographs for spice oleoresins and other natural colors
- Seeking your feedback and collaboration

Conclusions

- Two USP tools to help industry deal with EMA/fraud in context of FSMA and GFSI
  - USP Food Fraud Database (freely available at www.foodfraud.org)
  - USP Food Fraud Mitigation Guidance (purchase a copy of USP's Food Chemicals Codex, www.usp.org)
- New analytical tools in development at USP to help detect adulteration in spices and natural colors

Upcoming USP Events on Adulteration

USP- Rockville, MD

Training course on USP Food Fraud Mitigation: Dec. 2, 2015

Workshop on Food and Supplement Adulteration: Dec. 3-4, 2015

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USP's Expert Panel on Food Ingredients Intentional Adulterants

•Paul Brent, Ph.D., Retired (FSANZ)
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•Henry B. Chin, Ph.D. Retired (Coca-Cola)
•Jon DeVries, Ph.D. Retired (General Mills / Medallion Labs)
•Karen D. Everstine, Ph.D. National Center for Food Protection and Defense – U. Minnesota
•Shaun Kennedy, University of Minnesota–Twin Cities Campus
•Petra Lutter, Ph.D., Nestlé Research Center
•Richard A. Myers, Ph.D., Kemin Industries
•John Spink, Ph.D., Michigan State University
•Saskia van Ruth, Ph.D. RIKILT, Wageningen University and Research Centre
•Carl Winter, Ph.D. UC Davis
•Yongning Wu, Ph.D., M.D., China National Center for Food Safety Risk Assessment
•Liangli Yu, Ph.D. , University and Maryland and Shanghai Jiao Tong University
•Daniel Folmer, Ph.D., US FDA
•R. Duane Satzger, Ph.D., US FDA
•Jennifer Thomas, J.D., US FDA
•Robin Churchill MSc. PhD., Health Canada