Economically Motivated Adulteration (Food Fraud)

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Agenda

- ~~Background~~
- Definitions/Terminology
- What The Industry Has Done
- Why FSMA Matters
- Food Fraud Prevention
- Creating a Vulnerability Assessment Tool
- Key Takeaways

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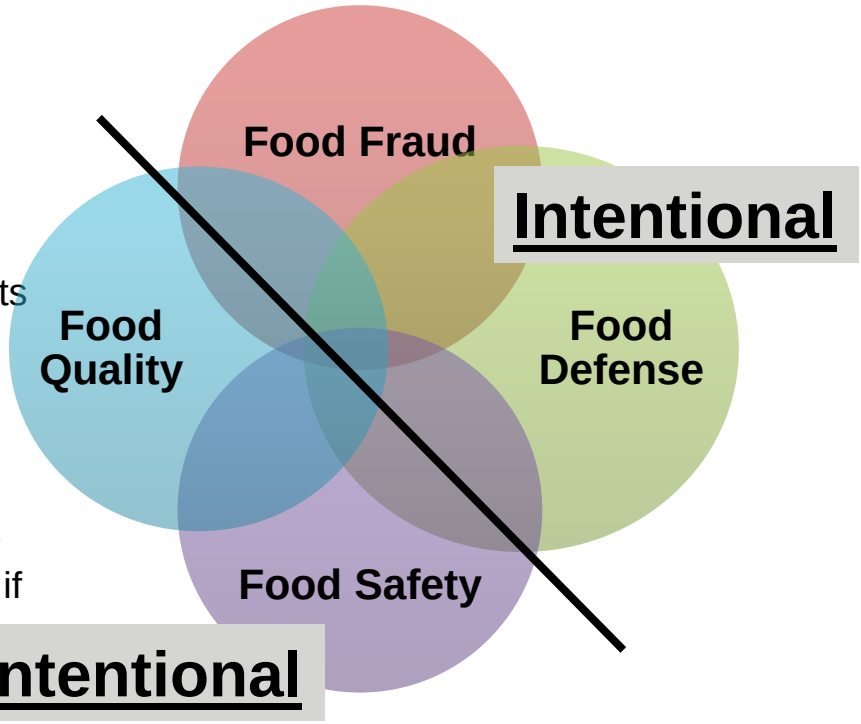
Definitions

Food Fraud*

A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labelling, or false or misleading statements made about a product for economic gain.



Vulnerability

Susceptibility or exposure to a risk. A weakness or a deficiency that could lead to negative consequences if not addressed.

Authenticity

Food that is authentic, i.e. that is proven to be genuine, true and real and meets previously established specifications.

Integrity

The quality of being honest and fair; the state of being complete or whole.

** Source: J. Spink & D.C. Moyer, (2011) Journal of Food Science, 76(9), 157-163*

Terminology

- Sunflower oil partially substituted with mineral oil
- Hydrolyzed leather protein in milk

- Watered down products using non-potable / unsafe water
- Olive oil diluted with lampante oil

- Melamine added to enhance protein value
- Use of unauthorized additives (Sudan dyes in spices)

- Copies of popular foods - not produced with acceptable safety assurances.

- Poultry injected with hormones to conceal disease
- Harmful food colouring applied to fresh fruit to cover defects

- Sale of excess unreported product

- False expiry, provenance
- Toxic Japanese star anise labeled as Chinese star anise
- Mislabeled recycled cooking oil

Food Industry Efforts

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GMA Economic Adulteration WG

Identified WG Priorities:

- **Increase industry awareness**
- **Stakeholder collaboration**
  - NMSU Predict (Bob Silver)
  - A-CAPPP MSU (John Spink)
  - NCFPD UMN (Amy Kircher, Karen Everstine)
  - USP (Jeff Moore)
  - ☞ Roundtable meetings
  - ☞ Information sharing: actual incidents, potential incidents, sharing analytical info/methods
- **Alignment of Industry/Academia/Government**
- **Alignment of analytical vendors**

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GMA EA WG – Awareness/Education

- **Published AT Kearney/GMA Science Education Foundation Report in 2010 –**
  - **"Consumer Product Fraud: Deterrence and Detection"**
  - **http://www.gmaonline.org/downloads/wygwam/consumerproductfraud.pdf**
- **Held a webinar Oct 2010**
  - **Strategies for Managing Risk**
  - **Case studies**

CONSUMER PRODUCT FRAUD: DETERRENCE AND DETECTION

Strengthening Collaboration to Advance Brand Integrity and Product Safety

2010

ATKEARNEY

in association with

GMA
The Association of Food, Beverage and Consumer Products Companies

GMA
Science and Education Foundation®

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Estimated Cost of Inaction – Aggregate Industry Impact

Figures from Preceding Cases		
Market	**Incident**	**Cost of Inaction**
Pet Food (US)	Melamine	$2.4 B
Toys (US)	Lead Paint	$0.9 B
Toothpaste (US)	Diethyl Glycol	$0.1 B
Total 2007		**$3.4 B**
Milk (China)	Melamine	$10 B
Peanut (US)	Salmonella	$1.5 B
Pharma (Global)	Heparin	$0.1 B
Total 2008/2009		**$11.6 B**

X

Assumptions on yearly EA cases	
Impact of incident	**# of cases with comparable cost impact(1)**
High	1
Medium	5
Low	10
	16
High	1
Medium	5
Low	10
	16

=

Estimated yearly cost to the market
$2.4 B
$4.5 B
$1.0 B
$7.9 B
$10 B
$7.5 B
$1.0 B
$18.5 B

Sources: FDA, CDC, http://www.mondaq.com/article.asp?articleid=57594, Incident Repository, A.T. Kearney analysis
Notes: (1) Assumption on comparable cases considers that not all economic adulteration cases are reported publicly

Standards

PAS 96: 2014

- Provides guidance on approaches and procedures to improve resilience to deliberate attack
- Combines Food Defense and Food Fraud (EMA)
- Introduces a new risk management methodology – Threat Assessment Critical Control Point (TACCP)

Department for Environment Food & Rural Affairs

Food Standards Agency
food.gov.uk

bsi.

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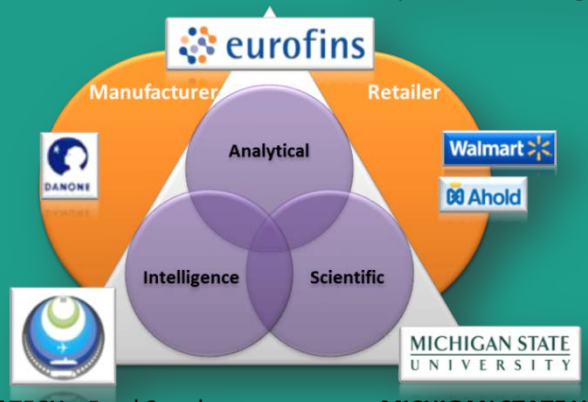
GFSI – Food Fraud

Food Fraud Think Tank

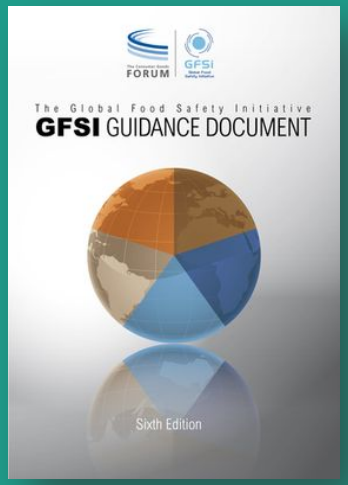
New concept for GFSI

EUROFINS – Early Warning Analytical Methodologies



INSCATECH– Food Supply Chain Protection Solution

MICHIGAN STATE UNIVERSITY– Food Fraud Initiative



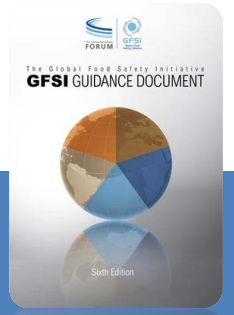
2012

2013

2014

2015

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. This plan shall cover the relevant GFSI scope and shall be supported by the organisation's Food Safety Management System.

GFSI Food Fraud Strategic Plan

Incorporation in GFSI Guidance Document Vs. 7 (2016)

Incorporation in Food Safety Management Schemes

Implementation and execution in companies' FS Management System

Certification via third party audits

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FSMA

Things that might have seemed like just a good idea before, are now required under the law, will require records to support compliance, and those records are going to be available to FDA

FSMA – Economically Motivated Adulteration

FDA decided to include EMA under Preventive Control Rules

- Best addressed with a hazard analysis-type approach (versus a vulnerability approach)
- Believes that some EMA events are “known or reasonably forseeable”
- Facilities must consider EMA as part of their Hazard Analysis (“hazards that may be intentionally introduced for purposes of economic gain”)

Designing a Food Fraud Protection Plan

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Food Fraud Prevention

Vulnerability Assessments

- Supply Chain Mapping
  - Socio-economic
  - Behavioural
  - Geo-political
  - Historical

Vulnerability Control Plan

- Monitoring strategy
- Origin/Label verification
- Specification management
- Supplier audits
- Analytical testing strategy
- Anti-counterfeit technologies

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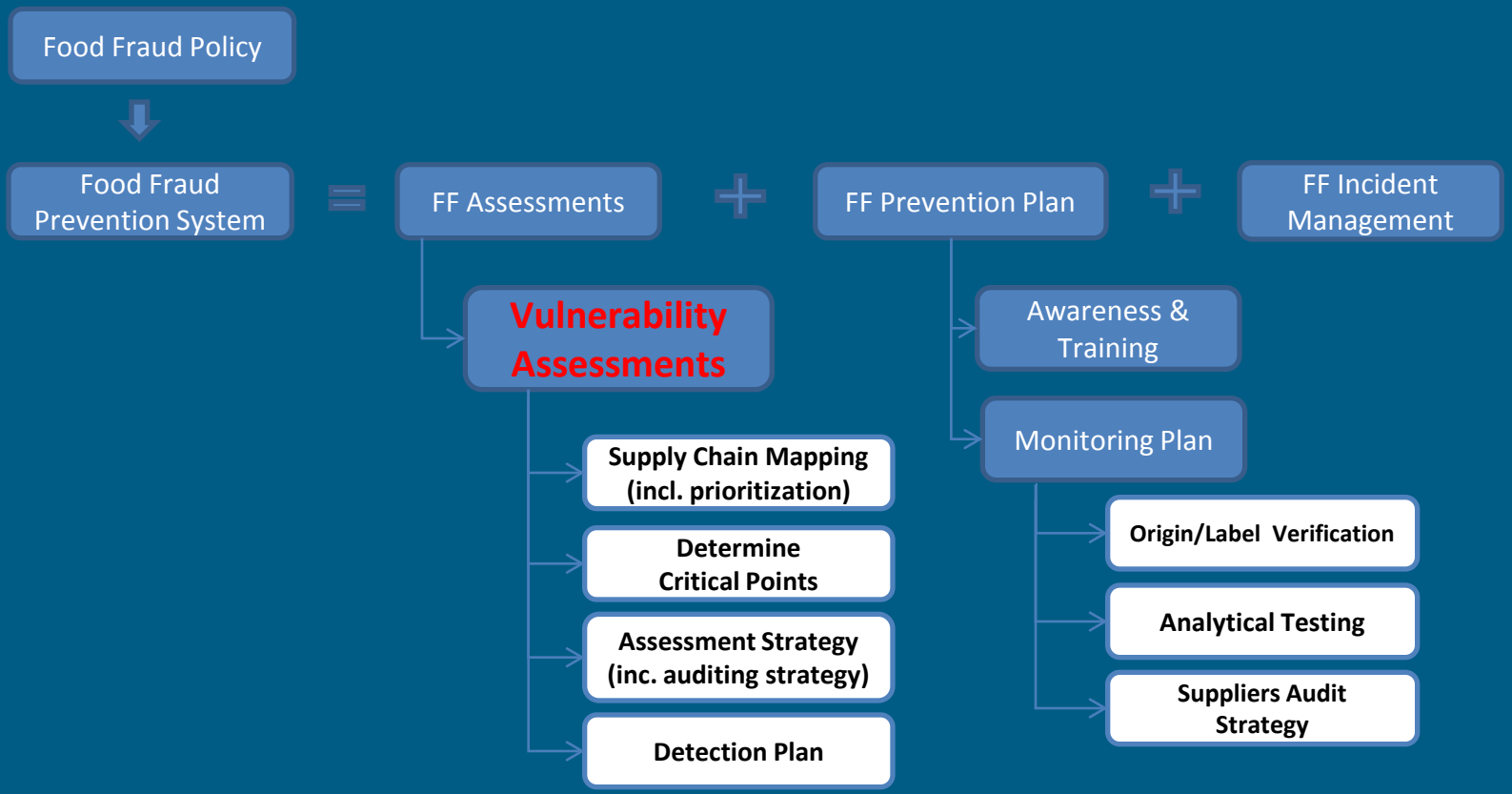
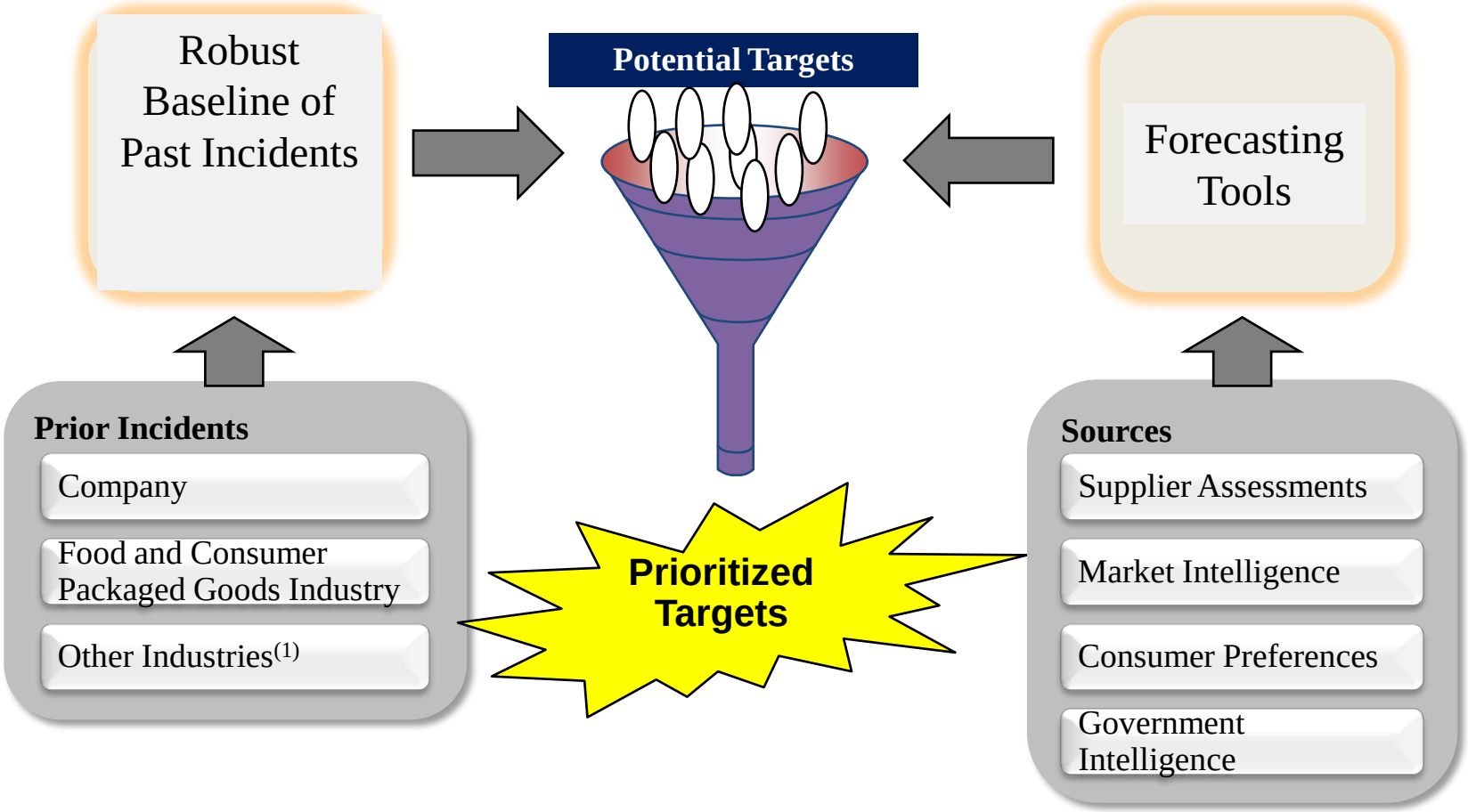
Key Elements of Food Fraud Protection



Identification and Prioritization



Note: (1) Other industries may include pharma, chemicals, automotive, etc.
Source: A.T. Kearney analysis, 2009

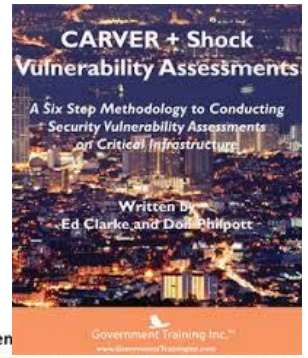
Creating a Vulnerability Assessment Tool

EMA Vulnerability Assessment Tool

GOAL: Develop a tool *similar* to "Carver + Shock" that quantitatively assess vulnerability of supply chains to EMA

Design a tool that integrates data streams with input from multiple subject matter experts that:

- **uses surveillance/historical data**
- **incorporates "real-time" environmental events**
- **considers criminalistics approach**
- **involves predictive modeling**



☞ **resulting in quantitative vulnerability risk determinations**

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EMA Vulnerability Assessment Tool

GOAL: Develop a tool similar to "Carver + Shock" to quantitatively assess vulnerability of supply chains to EMA

Will need to define key elements that drive EMA:

- Economic
  - Product value
  - Volume
  - Scarcity
- Ease
  - Testing
  - Governance
  - Inherent properties
- Cultural
  - Historic
  - Sourcing/origination

Must also consider:

- Dynamic vs Static
- Weighting Factors

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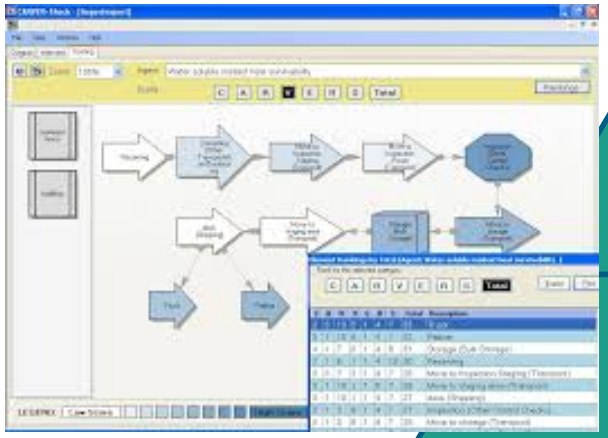
GMA EA WG – Designing the blueprint



Integrate information
into EMA Vulnerability Assessment Model

Capture trend analysis
information that helps to **predict** vulnerabilities
e.g., trade flow, economic information, climate change
Consider various models

NCFPD EMA Database Info
Utilize US Pharmacopeia Resource
FCC Monograph Evaluation
Open Source Info

Key Attributes of the Tool

- User friendly interface
- Easily accessible with various devices
- Incorporate a range of user inputs regarding threat attributes
- Output should be quantitative vs qualitative
- Graphical display and intuitive
- Securely protects user identity and data inputs
- Needs to be predictive and not just regurgitate historical events
- Quantifiable outputs that are actionable

EMA Vulnerability Assessment Tool

Status Update:

- **Designed blueprint for EMA Vulnerability Assessment Tool**
- **Sent out RFP to solicit vendors to develop Model**
- **Selected vendor/negotiated contract**
- **Validate the tool**
  - **Supply chain's known high risk foods (e.g., fruit juice, olive oil, etc.)**
  - **Ensure usefulness in the supply chain**
- **Make tool available for utilization across food industry**

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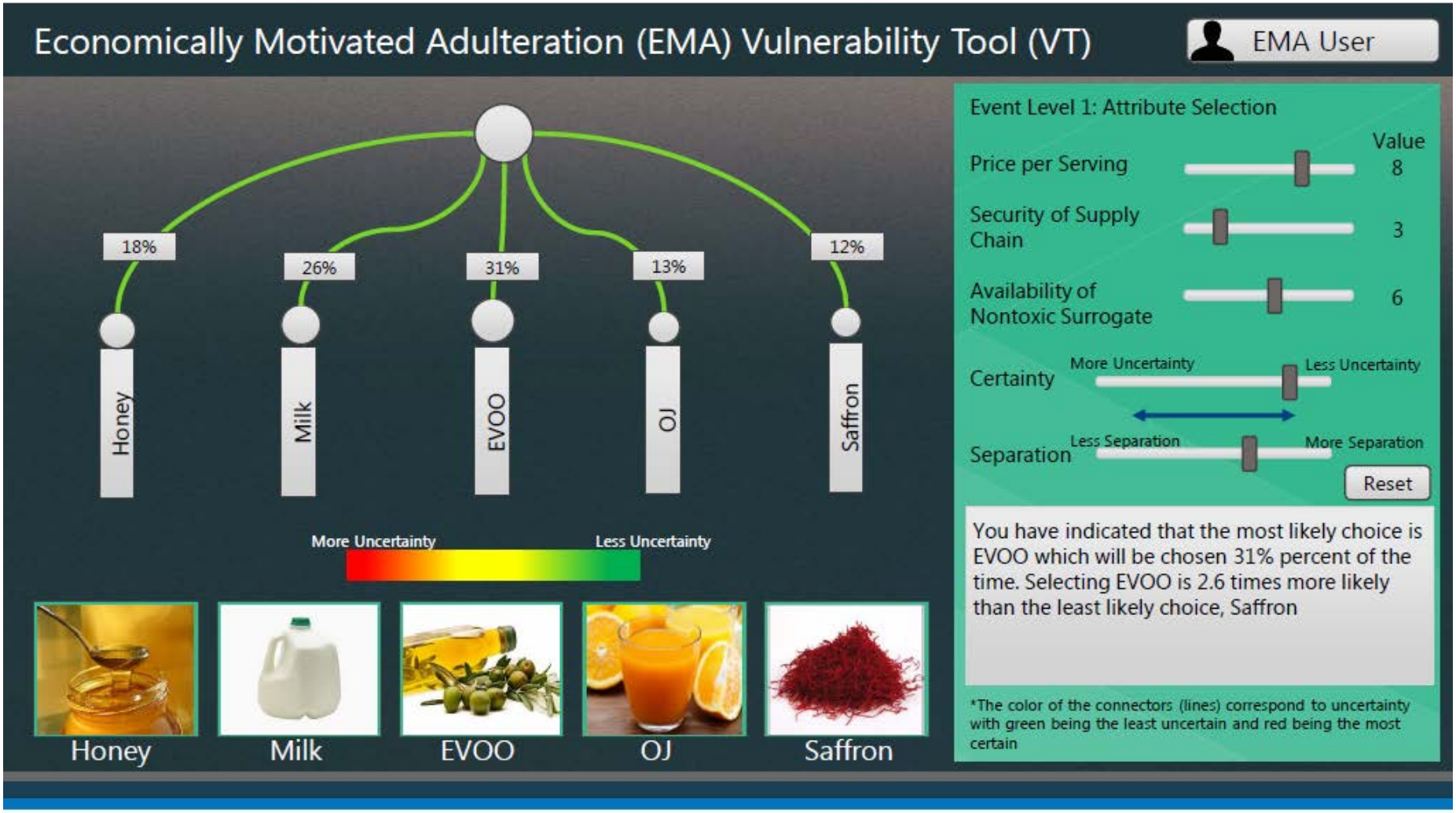
Example Visual of Tool



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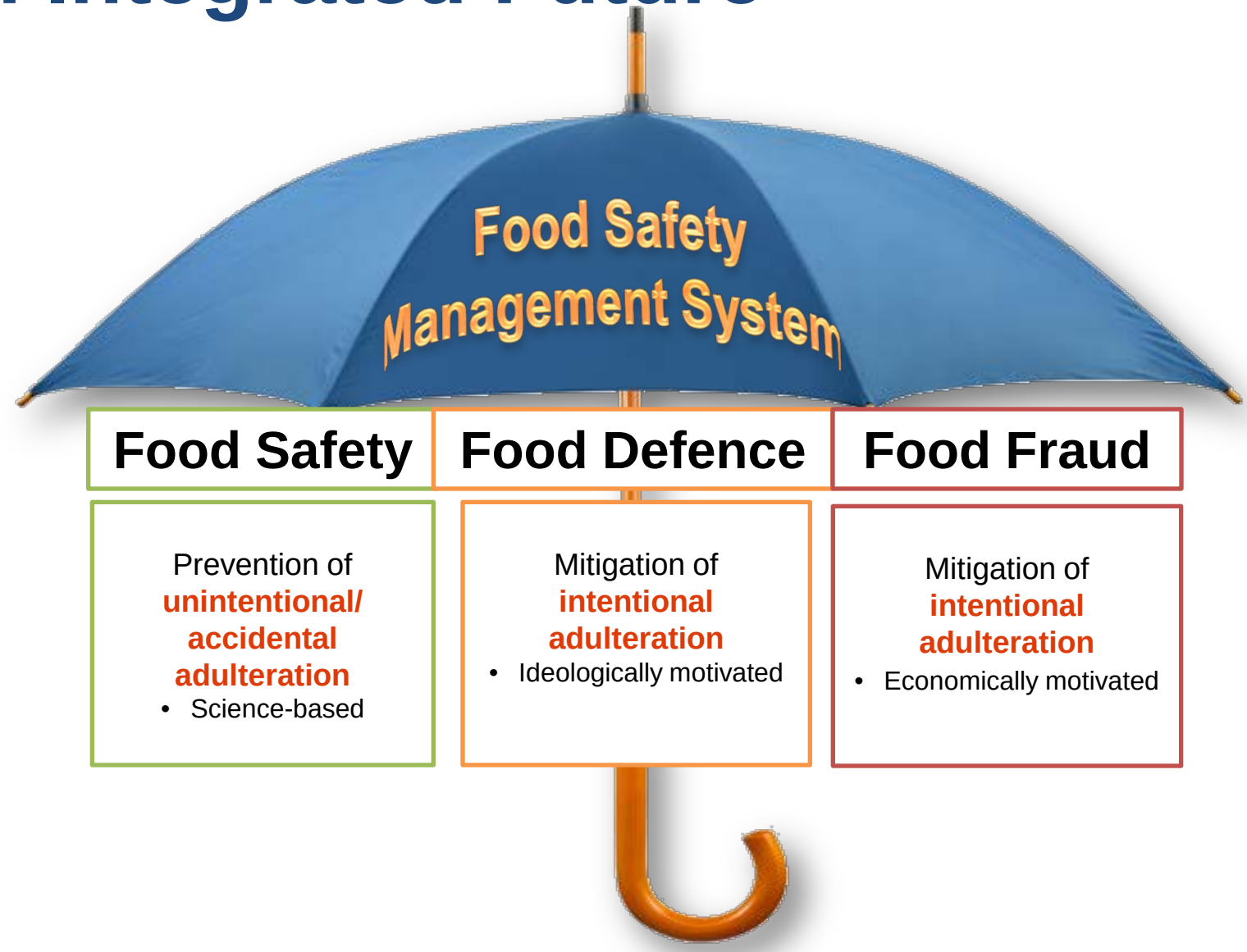
An Integrated Future



Food Safety	Food Defence	Food Fraud
Prevention of **unintentional/ accidental adulteration** • Science-based	Mitigation of **intentional adulteration** • Ideologically motivated	Mitigation of **intentional adulteration** • Economically motivated

Key Takeaways

- **Need to develop EMA Protection Plan**
- **Gain visibility of supply chain down through origination**
- **Perform vulnerability assessment**
- **Map supply chain vulnerability identifying key priorities for mitigation**
- **Trust but verify throughout the supply chain**

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Thank You