

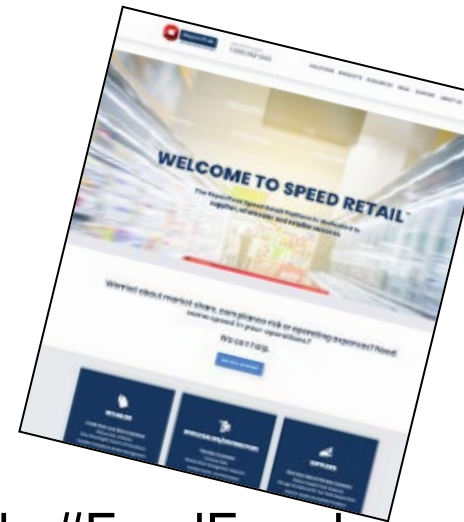
# *Quarterly Trends Update: Food Fraud Compliance for US Laws & Food Laws: 2019-Q2*

Webinar: Wednesday, June 20, 2019, Seattle  
2:00 to 3:00 PM ET

John Spink, PhD & Douglas C Moyer, PhD

Director & Assistant Professor, Food Fraud Initiative

[WWW.FoodFraudPrevention.com](http://WWW.FoodFraudPrevention.com) Twitter @FoodFraud #FoodFraud



# Food Fraud Curriculum

## Massive Open Online Course (MOOC – free, open, online)

- With a **'certificate of completion'** based on an **assessment**
  - On-demand, monthly instances, Ten Contact Hours
1. Food Fraud Overview MOOC
  2. Food Fraud Audit Guide MOOC
  3. Food Defense Audit Guide MOOC
  4. Training: FF VACCP (Vulnerability Assessment & Food Fraud Prevention Strategy)

## Conference (High-level update on key topics)

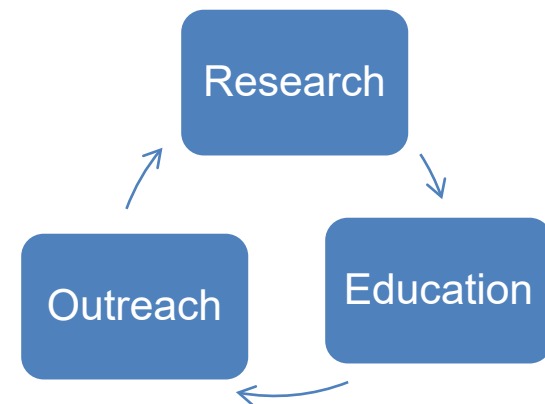
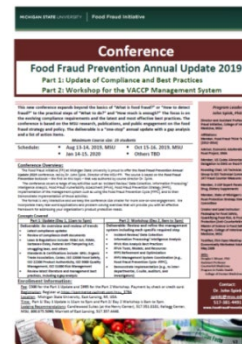
- **Food Fraud Prevention Annual Update 2019 & Workshop**
  - Aug 13-14 & Oct 15-16

## Executive Education (In-depth education)

- **Food Fraud Management Strategy & FFVA Workshop**
  - Sept 10-11-12, 2019 & Feb 4-5-6, 2020

## Textbook: Food Fraud Prevention

- Release August 3, 2019



# Quarterly Trends Update Webinars Series

- 2018-3Q
- Non-conformity

- 2018-4Q
- GFSI FF Document

- 2019-1Q
- Managing information
- FFPC



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**Quarterly Trends Update: Food Fraud Compliance and the Implications to Your Business: 3Q-2018**

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**Quarterly Trends Update: Food Fraud Compliance and the GFSI Food Fraud Technical Document / 4Q-2018**

Webinar: Wednesday, December 12, 2018  
1:00 to 2:00 PM ET

John Spink, PhD & Douglas C Moyer, PhD  
Director & Assistant Professor, Food Fraud Initiative  
College of Veterinary Medicine, Food Safety

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**FSSC 22000**

**FSSC 22000 and Food Fraud Prevention**

Jacqueline Southey, FSSC 22000 US Liaison  
Food Safety Summit, May 30, 2018

**FSSC 5/9/2018**

**Food Fraud Requirements**

The requirement shall have an assessment and implemented vulnerability assessment procedure as a plan that:

- identify potential vulnerabilities
- develop control measures and
- monitor them across the supply chain

**FSSC 22000 FF & FD Guidance documents**

Voluntary support document including:

- Background
- Definitions
- Requirements
- Implementation
- Team and training
- Auditing
- References

**Non Conformity Grading – FF & FD**

- Critical NC
  - FF and FD requirements are completely ignored; no risk assessment done, no plan and not embedded in FSMS. A direct food safety impact observed and/or certification integrity at stake.
- Major NC
  - FF and FD requirements are completely ignored; no risk assessment done, no plan and not embedded in FSMS.
- Minor NC
  - FF and FD requirements considered but the design is incomplete and/or execution not effective and/or not fully embedded in FSMS.

[FoodFraud.msu.edu](http://FoodFraud.msu.edu) © 2018 York Partners LLC

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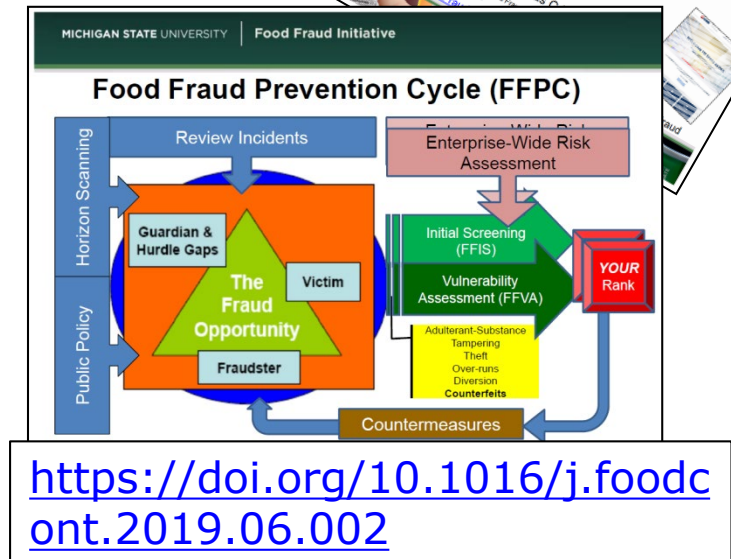
**GFSI Announcement 5/9/2018**

- Food fraud review:
- Blog, Technical Report

**TACKLING FOOD FRAUD THROUGH FOOD SAFETY MANAGEMENT SYSTEMS**

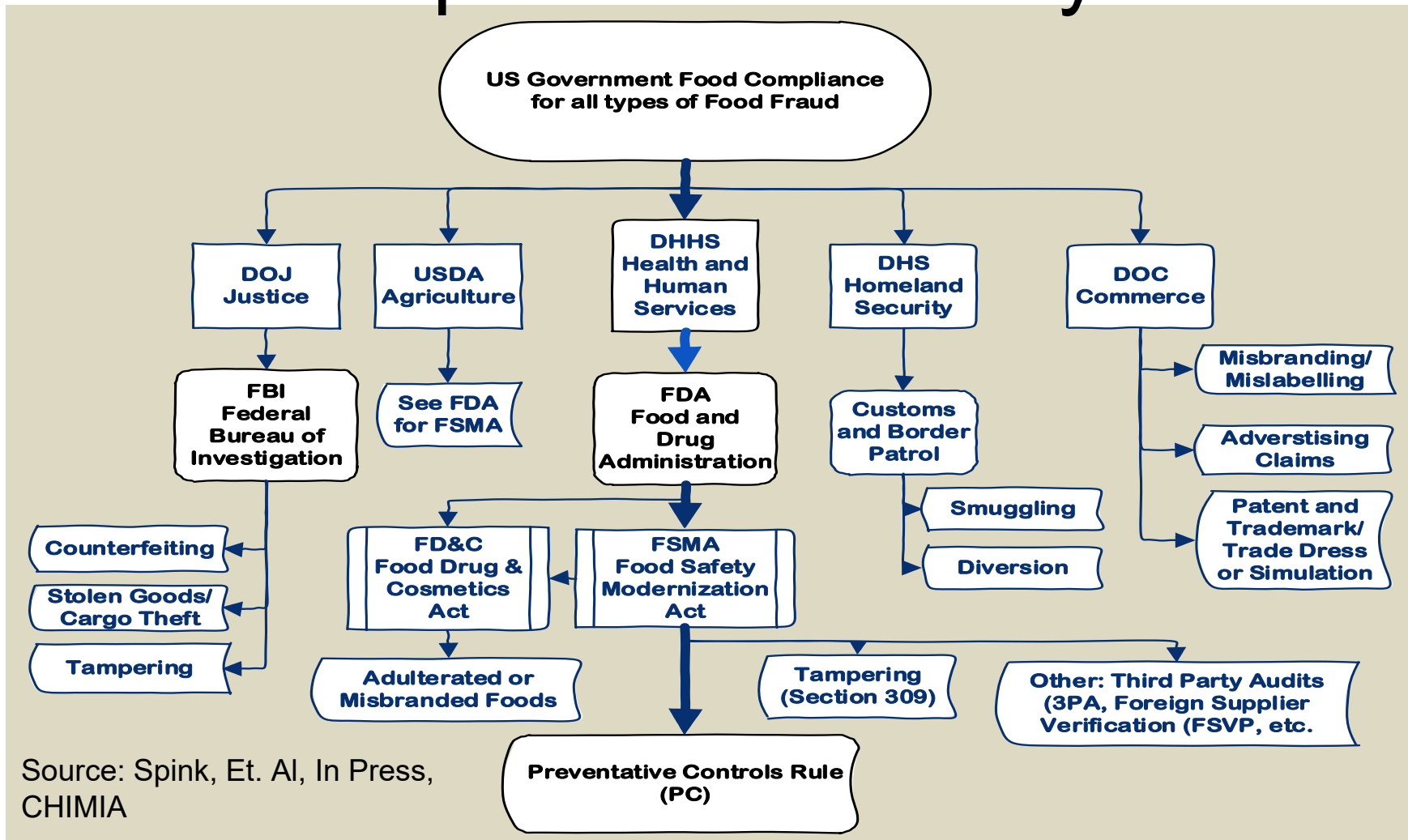
[http://www.mygfsi.com/files/Technical\\_Documents/201805-food-fraud-technical-document-final.pdf](http://www.mygfsi.com/files/Technical_Documents/201805-food-fraud-technical-document-final.pdf)

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# US LAWS

# Compliance Hierarchy...



Source: Spink, Et. Al, In Press, CHIMIA



# Legal Issues... Complexity...

- National Laws vs. International Standards
- FD&C
  - Adulterated Foods
  - Misbranded Foods
- Intellectual Property
- Consumer Product Safety
- Criminal Statutes vs. Civil Actions
- Customs Agencies or Import Alerts
- Multi-Layer Crime Fighting/ De-confliction
- *Naim: Beyond Governments...*



# US FOOD LAWS

# Food Fraud Compliance Requirements: Dates

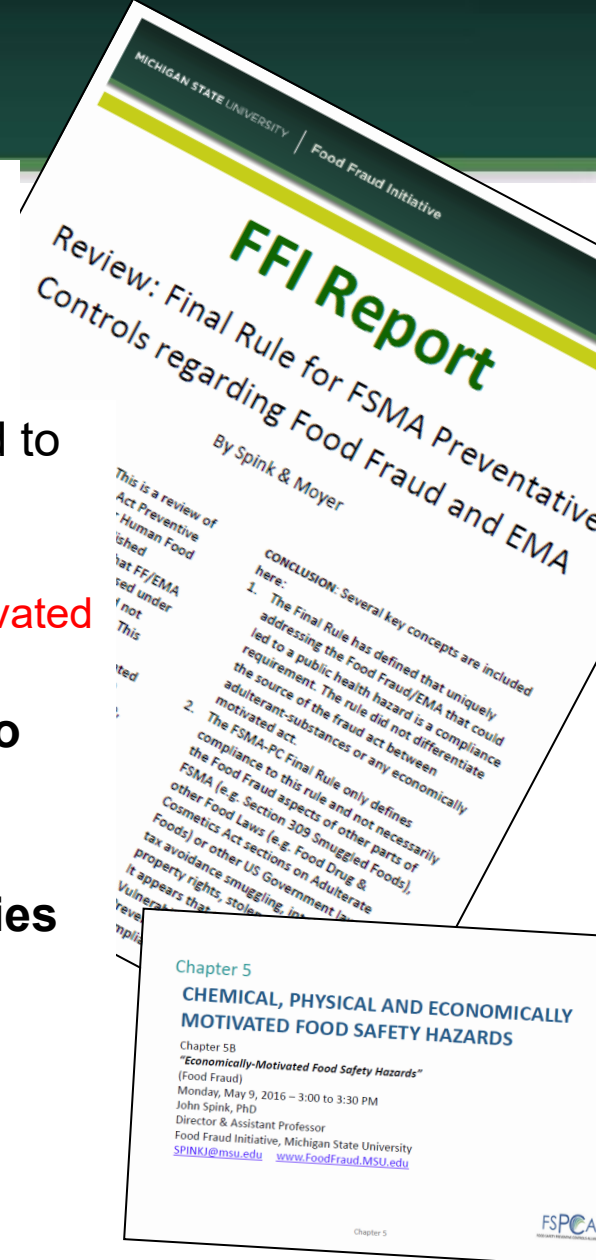
- GSFI (FSSC, SQF, BRC, IFS, etc.) – January **2018**
  - Food Fraud Vulnerability Assessment (all fraud)
  - Food Fraud Prevention Strategy (all products)
  - **No documents = audit non-conformance**
- GFSI – Some mentions (BRC, IFS, etc.) – July 2015
- FSMA-Preventive Controls – September **2016**
  - **“The hazard analysis must be written regardless of its outcome” [21CFR507.33 (a)(2)]**
  - **“The hazard may be intentionally introduced for purposes of economic gain.” (iii)**
- Food Drug & Cosmetics Act & Adulterated Foods – **1938**
  - **Adulterated Foods**
  - **Misbranded Foods**
  - **+ others such as Sec. 301 Smuggling**
- Sarbanes-Oxley Act – **2002** and 2007
- ISO 22000: now added note of Food Fraud and Food Defense
- ISO 12931, 22380, 27000, 28000, etc.: Product Fraud
- Codex Alimentarius: Food Fraud being defined with a management system



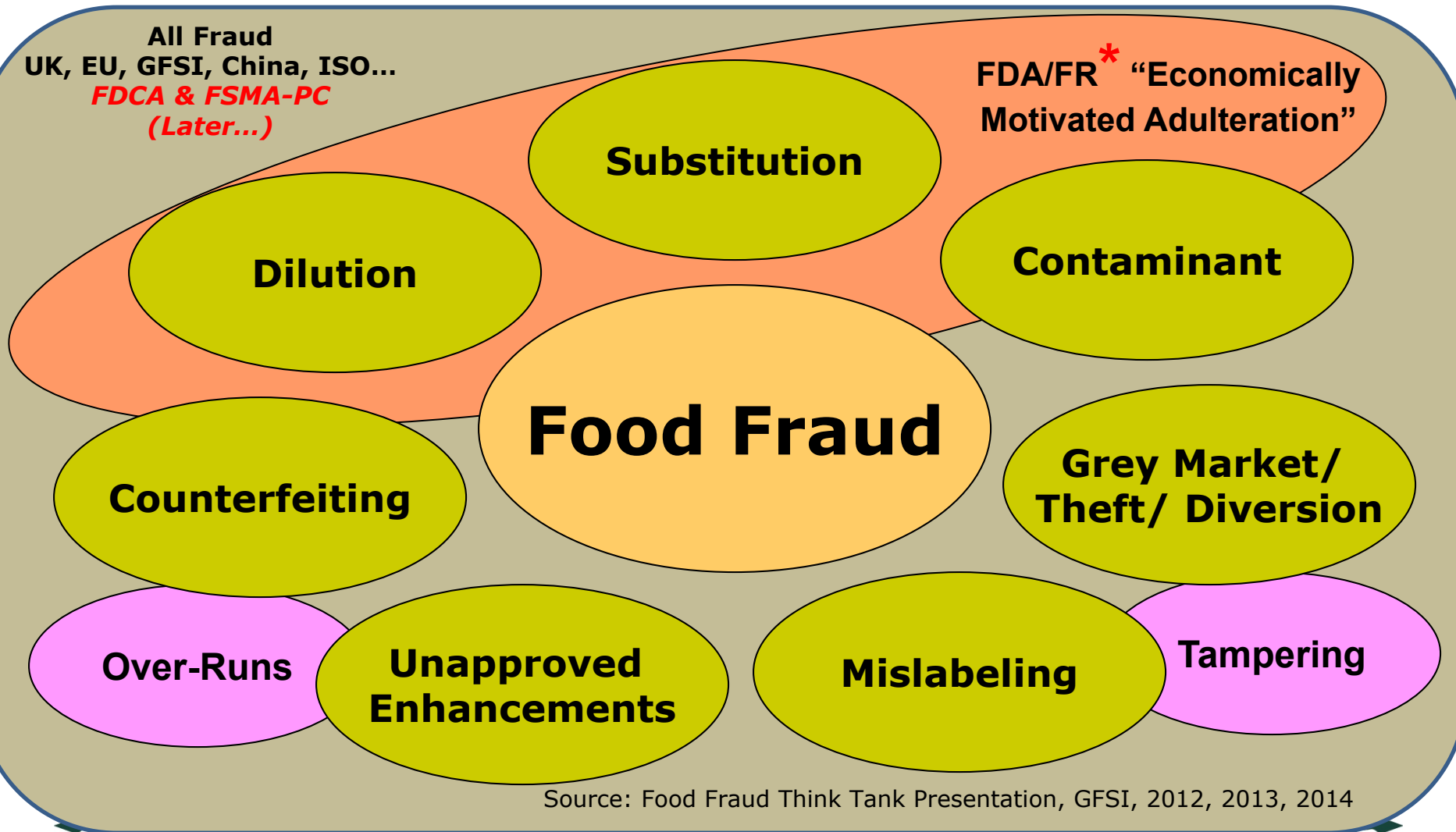
# FSMA Food Fraud/ EMA Preventive Controls Rule

1. Uniquely addressing Food Fraud/EMA that could lead to a public health hazard is a compliance requirement.
  - The rule did **not** differentiate the source of the fraud act between adulterant-substances or any economically motivated act.
2. The FSMA-PC Final Rule only defines compliance to this rule
3. It appears that current broad Food Fraud Vulnerability Assessment and Food Fraud Prevention Plan activities will lead to compliance with FSMA-PC for EMA/FF.
  - 1. Unique **Hazard** Assessment
  - 2. Address **Hazard** (Prevention Plan)

<http://foodfraud.msu.edu/wp-content/uploads/2015/09/FDA-FSMA-ERM-FRN-draft-rulemaking-2015-v12-formatted.pdf>



# What is Food Fraud?



# Current FDA Thinking: FDCA, Dr. Ostroff, Apr 5 & Oct 30, 2017

- All types of Food Fraud are illegal.
  - FDCA: Adulterated Foods, Misbranded Foods
- To determine “hazards that require a preventive control”, an assessment for all types of fraud is needed.
- Addressing Food Fraud is NOT covered in the FDA Food Defense plans.
- <http://foodfraud.msu.edu/2017/11/06/updated-comments-from-fda-presentation-on-food-fraud-and-economically-motivated-adulteration-fda-deputy-commissioner-for-foods-dr-stephen-ostroff/>





# Current FDA Thinking: FDCA, Dr. Ostroff, Apr 5 & Oct 30, 2017

“In circumstances where no regulatory agency has limited resources, where and how does EMA fit into a list of priorities?” Response: public health hazards

- Used the Food Risk Matrix to define the differences in food risks.
- Product in commerce
- Cited FDA definition of EMA then presented the Food, Drug & Cosmetics Act “Regulatory Response”:
- “Adulterated foods”
  - Section 402 (a) of the FD&C Act (21 USC 342): “If it bears or contains any poisonous or deleterious substance which may render it injurious to health.
  - Section 402 (b): “if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substances has been substituted wholly or in part...; or if damage or inferiority has been concealed... or if any substance has been added thereto or mixed or packed therewith, so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better of greater value than it is.”
- “Misbranding”
  - Section 403(b) of the FD&C Act (21 USC 343 (B)): “offered for sale under the name of another food.”
  - Section 403(a): “labeling is false or misleading”
  - Section 403(i): ingredient labeling”
- **Reference:** Ostroff, Steven (2017). A regulator’s view on preventing and mitigating economic adulteration of food, Presentation at the Food Fraud Conference, Quebec City, April 5, 2017, Acting Commissioner of the FDA and Deputy Commissioner for Foods and Veterinary Medicine

# ‘ § 342. Adulterated food

- A food shall be deemed to be adulterated—
  - ‘(a) Poisonous, insanitary, etc., ingredients
- ‘(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health.
- ‘(2) if it bears or contains any added poisonous or added deleterious substance ...
- ‘(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; ...
- ‘(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; ...
- ‘<(3) if damage or inferiority has been concealed in any manner; or
- ‘< If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381(a) of this title, ...

# § 343. Misbranded food

- A food shall be deemed to be misbranded—
- '(a) False or misleading label
- '(b) Offer for sale under another name (of another food)
- '(c) Imitation of another food
- '(e) Package form
  - <(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, [...]
- '(f) Prominence of information on label
- '(g) Representation as to definition and standard of identity
- '(h) Representation as to standards of quality and fill of container
- '(i) Label where no representation as to definition and standard of identity
- '(k) Artificial flavoring, artificial coloring, or chemical preservatives (... , unless it bears labeling stating that fact...)
- '(l) Pesticide chemicals on raw agricultural commodities (... , unless it bears labeling stating that fact...)
- '(m) Color additives
- '(n) Packaging or labeling of drugs in violation of regulations
- '(q) Nutrition information
- '(u) Ginseng
  - <If it purports to be or is represented as ginseng unless it is an herb or herbal ingredient derived from a plant classified within the genus Panax.
- '(v) Failure to label; health threat
- '(w) Major food allergen labeling requirements

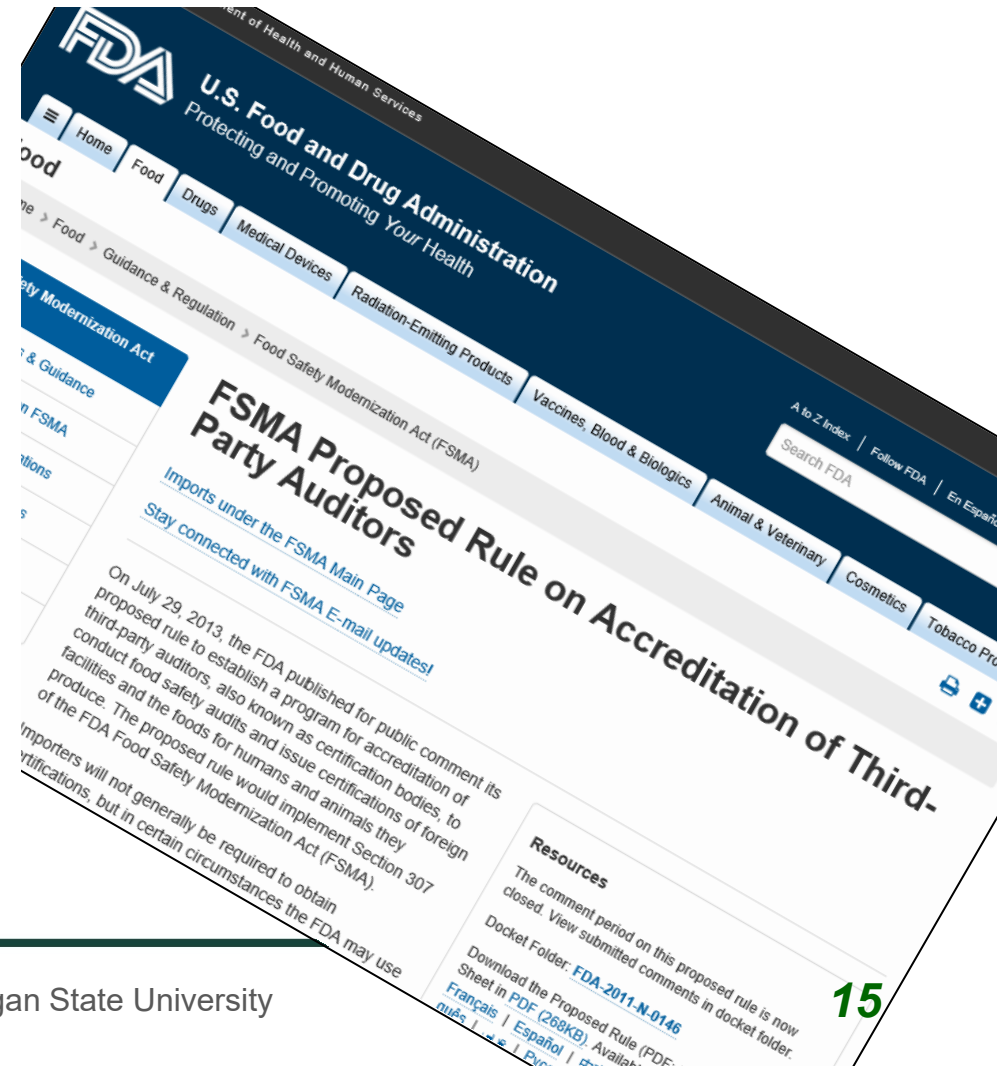


# FSMA and Third-Party Audits

Michael Taylor, Office of Foods, FDA,  
November 2014

## Opportunities for Collaboration and Progress on Verification

- “So, one of the most important questions we are grappling with at FDA is how we can enhance our role in verification and strengthen our **public and private partnerships** to better assure consumers that our food safety systems are working. ... “
- “First, in our domestic inspection and compliance program, our focus will be on achieving and verifying that **private food safety management systems** are working effectively to prevent problems. ... “
- “Second, **private verification and audit activities** already play a central role in food safety systems, ...”
- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm421685.htm>



# US INTELLECTUAL PROPERTY RIGHTS LAWS

# Financial Reporting

## e.g. Sarbanes-Oxley

- Regulatory compliance for securities and financial report – e.g. public companies
- The Board expects the CEO/CFO to control -- or mention -- **all** risks that are outside the '*risk appetite*.'
- CEO/CFO expects the same of the SVP/VPs... and them to YOU.
  - Inherent risks – not new
  - Increased scrutiny and liability... read the news

# Intellectual Property Rights Law

- Trademarks
  - Trade Dress
- Patents
  - Three types of patents are recognized: utility patent, design patent, and plant patent. Including “trade dress.”
- Copyrights
- Trade Secrets
  - “Shelf-life of secrets”

Note: All consumer product fraud is not an IP infringement... maybe not even a civil violation... or considered unethical?

**Trade dress** -- The distinctive packaging or design of a product that promotes the product and distinguishes it from other products in the marketplace -- for example, the shape of Frangelico liqueur bottles. Trade dress can be protected under [trademark](#) law if a showing can be made that the average consumer would likely be confused as to product origin if another product were allowed to appear in similar dress.

# IPR Law

## What is US IP Law

- The counterfeit trademark crime is set out at 18 U.S.C. 2320 ;
- Criminal infringement of copyrighted works is set out at 17 U.S.C. 506(a) and 18 U.S.C. 2319;
- The counterfeit labeling provision is set out at 18 U.S.C. 2318;
- Theft of trade secrets [is] prohibited by 18 U.S.C. 1831 and 1832
- Also,
- The Anti-Counterfeiting Consumer Protection Act has applied the RICO Act (The Racketeer Influenced and Corrupt Organizations Act) to counterfeit crimes (18 USC Sec. 1963, 2006).
- (StopFakes.gov, US Department of Commerce, 2007)

# US DOJ/ FDA-OCI

- Goal: high conviction rate, not to trial; 93% don't go to court
- 1001 – False Statements
- 371 – Conspiracy (“no interest”)
- 1341 – Mail Fraud/ 1343 – Wired Fraud (“interest”)
- 2320 – Trafficking in Counterfeit Goods
- 545 – Smuggling goods into the USA (20 years each count)
- 21 USC 342 Adulterated foods/ 343 Misbranded foods
- Others: 541 Entry of goods falsely classified, 542 Entry of goods by means of false statement, 548 Removing or repacking goods in warehouses, 2461c, 982(a2), 853 (p), 982 (b1)... see 21 USC 333 Penalties/
- Felony:
  - 10 years per count, 3 shipping containers?
  - “no mens rea” (“the intention or knowledge of wrongdoing that constitutes part of a crime, as opposed to the action or conduct of the accused”) = strict liability
  - Willful blindness... ignorance? “red flags can prove knowledge”



# INFORMATION AS TRANSPARENCY AND ACCOUNTABILITY

Some basic questions should be asked before selecting new countermeasures when assessing the overall risk. There are basic work processes that could reduce the risk in the first place:

- Know Your Supply Chain [17]
  - Do you know where you buy your supplies?
  - Do you know where they buy their supplies?
  - Do you formalize your relationships?
  - Do you trust but verify?
  - How much information do you supply others?
  - Do you have long term contracts?
- Know Your Channel(s) [17]
  - Do you know where your products are headed?
  - Do you monitor where your products have been?
  - Do those two statements match? Do you know?
  - How many countries do you serve?
  - Have you seen your products distributed?

Spink, J. Chapter 9: Overview of the Selection of Strategic Authentication and Tracing Programmes, Book: Fake Medicines Volume I: Economics and Policy, Editors: Werthheimer and Park, 2011 [In Press]

# US FOOD LAWS AND RECORDKEEPING

# SEC. 204. ENHANCING TRACKING AND TRACING OF FOOD AND RECORDKEEPING

- (e) Evaluation and Recommendations-
- (1) REPORT- Not later than 1 year after the effective date of the final rule promulgated under subsection (d)(1), the Comptroller General of the United States shall submit to Congress a report, taking into consideration the costs of compliance and other regulatory burdens on small businesses and Federal, State, and local food safety practices and requirements, that evaluates the public health benefits and risks, if any, of limiting--
- (A) the product tracing requirements under subsection (d) to foods identified under paragraph (2) of such subsection, including whether such requirements provide adequate assurance of traceability in the event of intentional adulteration, including by acts of terrorism; and
- (B) the participation of restaurants in the recordkeeping requirements.

**SSSSSSOOOOO WHAT???**

# Required Documents

- Food Fraud Vulnerability Assessment
  - Clarify details: at least annual, etc.
- Food Fraud Prevention Strategy
  - Clarify details: covers all fraud and all products, etc.

Plus:  
FF  
Policy

FFVA:  
Rank

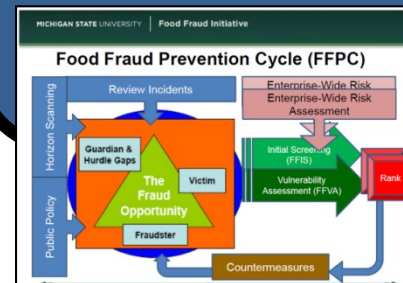
FFPS:  
Method

Plus:  
FF Audit  
Results

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Case Study: Corporate Risk Map

	Likelihood	VH	H	M	L	VL	Detail
Consequence		1	2	3	4	5	Incoming 1-VH*M: xxx 2-VH*M: yyy Outgoing A-VH*M: zzz B-VH-M: aaa D-VH-L: bbb
VERY HIGH	A						
HIGH	B						
MEDIUM	C						2,A 1,B
LOW	D						4,E,F H
VERY LOW	E						3





# Food Fraud Compliance Requirements: Scope

3  
NEW

“Food Fraud Compliance Requirements — The general compliance requirements for Food Fraud prevention are:

1. Conduct a Food Fraud Vulnerability Assessment (Y/N)
2. Written (Y/N)
3. Create a Food Fraud Prevention Strategy (Y/N)
4. Written (Y/N)
5. **<NEW> Demonstrate Implementation (Y/N)**
6. **<NEW> Executive Level Sign-off (Y/N)**
7. Minimally conduct an annual Food Fraud Incident Review (Y/N)
8. **<NEW> Method to review your incidents and general market incidents (Y/N)**
9. Note: Address all types of Food Fraud (Y/N)
10. Note: Address all products from both incoming goods (e.g., ingredients) and outgoing goods (e.g., finished goods) through to the consumer.” (Y/N)

Reference:

Food Safety Magazine, Feb 2017, “Food Fraud Vulnerability Assessment and Prefilter for FSMA, GFSI and SOX Requirements”, <http://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-fraud-vulnerability-assessment-and-prefilter-for-fsma-gfsi-and-sox-requirements/>

Food Safety Magazine, Feb 2017, “Food Fraud Prevention – how to start and how much is enough?”, <http://www.newfoodmagazine.com/33890/new-food-magazine/past-issues/issue-1-2017/issue-1-2017-digital-version/>



# “Just a Check Box” – yes and no

- There is often a criticism that some audits are just a checkbox – did it, check.
- Is this OK for Food Fraud? For this stage right now?
- **YES!!!!**
- The formal and official process has started



**Q: YES OR NO?**

# Acknowledgements

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- **The Citadel:** Dr. Roy Fenoff

# Discussion

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MOOC programs: [www.FoodFraud.msu.edu/mooc/](http://www.FoodFraud.msu.edu/mooc/)