USP Mission

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

Who We Are and Where We Work

- Founded in 1820, nonprofit, private, independent and self-funded
- Focused on quality standards to protect the public's health
- More than 1,000 employees worldwide

- Headquarters in Rockville, MD near Washington, DC, NIH and FDA
- Laboratory facilities in U.S., India, China, Brazil and Ghana
- Offices in Switzerland, Ethiopia, Indonesia, the Philippines and Nigeria

- Work with more than 900 volunteers from industry, academia and government to develop standards that help protect public health
- Internationally recognized and globally focused

What We Do

PHARMACEUTICALS

Nearly 200 years of ensuring trust and confidence among patients and providers

FOOD INGREDIENTS

Globalization means food supplies today face greater risks

HEALTHCARE QUALITY

Ongoing transformation in health delivery reveals additional needs for standards setting

DIETARY SUPPLEMENTS & HERBAL MEDICINES

Explosive industry growth demands a focus on quality to ensure consumer confidence and safety
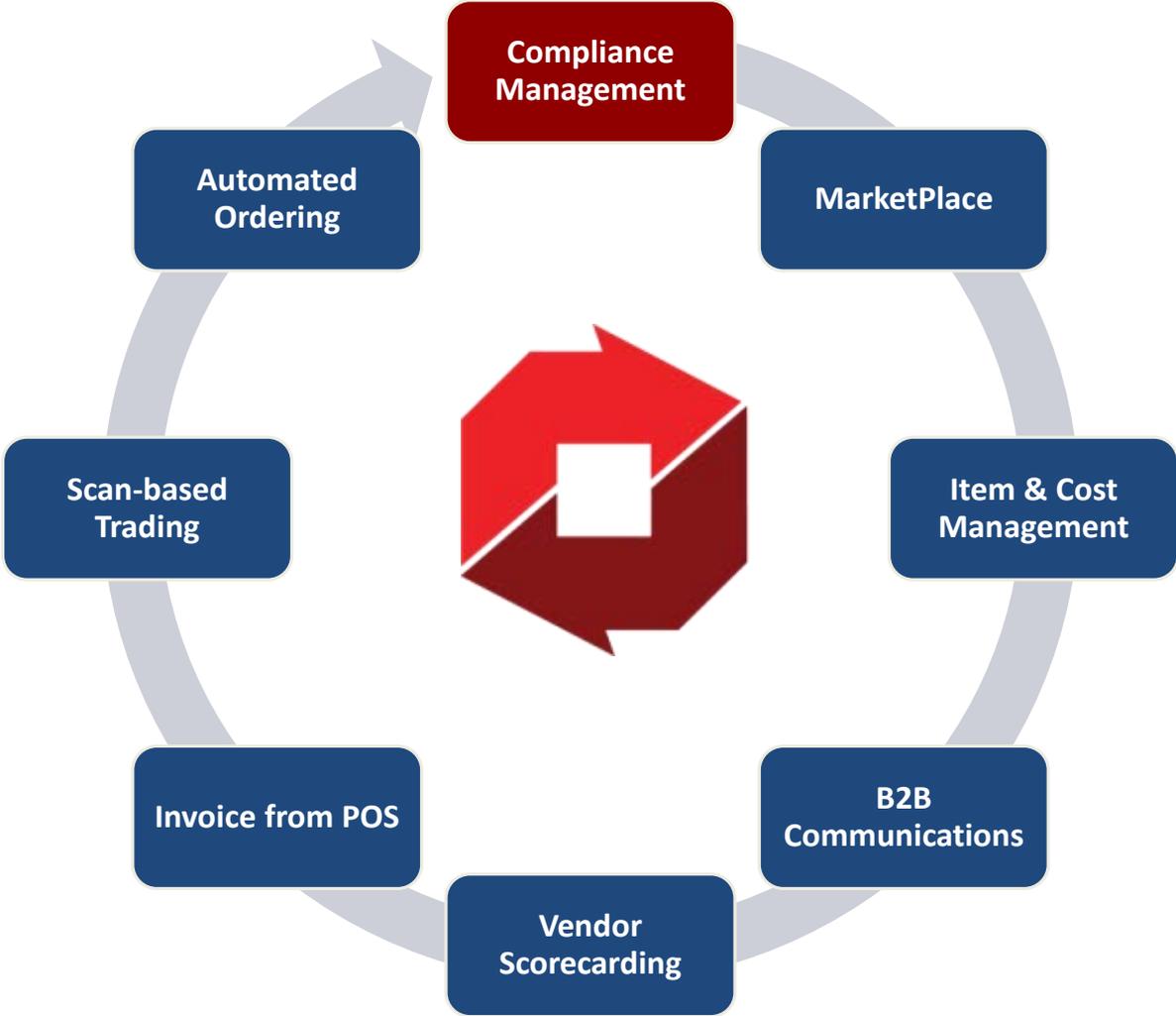
GLOBAL PUBLIC HEALTH

Combating substandard and counterfeit medicines in under-resourced countries around the globe

USP Approach to Developing Solutions

Science-Based…Informed and Approved by Independent Experts

Over 60 Expert Volunteers Support USP's Food Program

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

USP Food Safety and Integrity Solutions

Food Chemicals Codex & Reference Materials

Food Fraud Database

Food Fraud Mitigation Services

The ReposiTrak Platform

Compliance Management

MarketPlace

Automated Ordering

Item & Cost Management

Scan-based Trading

B2B Communications

Invoice from POS

Vendor Scorecarding

ReposiTrak
Trusted Brand Protection

PARK CITY
GROUP
Sell More - Stock Less - See Everything

1

Unmatched Industry Endorsements

"ReposiTrak augments our food and drug safety efforts…with a **proven, comprehensive and easy-to-implement solution** that **doesn't require systems changes** and is extremely cost effective."
– *Hilary Thesmar, PhD, RD, CFS FMI VP for Food Safety Programs*

"We see the ReposiTrak system becoming an **industry standard** for the retail supply chain, helping all trading partners **meet the new federal food safety requirements**, reducing unsalable products and keeping the end consumer healthy."
--*Francis Cameron, President & CEO of ROFDA*

"We were looking for a technology partner to help us **raise the bar** not only with our data management and reporting, but also with upgrades to all of our user interfaces. It made perfect sense to partner with ReposiTrak because of their **experience in the industry** and technical capabilities."
--*Robert Garfield, Senior Vice President, SQFI*

"ReposiTrak is a **pioneering innovator** in delivering robust retail management software solutions for our rapidly changing industry. This technology will equip our members with a toolbox for success in a constantly evolving marketplace. We are thrilled to partner with ReposiTrak as we continue to advance and expand our ecosystem."
--*Patrick Spear, president and CEO of GMDC*

The Industry's Only Dedicated Success Team

- Our software is excellent, but it only works if your supply chain partners adopt it

- It takes up to 20 "touches" by phone, e-mail and mail on average to get a vendor compliant

- We have a full-time, U.S. based Customer Success Team who follow-up with all of your vendors to ensure adoption and compliance with your requirements

ReposiTrak
Trusted Brand Protection

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G R O U P
Sell More - Stock Less - See Everything

All Three Types of Risk | Controlled

We understand that your responsibility goes beyond regulatory to include financial and brand risk

Supplier: Please select Supplier ...

Document Category: All

Type to search

All
Risk Management
Legal
Regulatory
Informational

Document:

Status:

Partner

Competitive Treat Maker (118699)   MISSING

Filter By

Supplier: Please select Supplier ...

Document Category: Regulatory

Document: Third Party Audit Certificate

Status: All

Additional Filters

Documents

Document	Partner	Status	Effective Period
Third Party Audit Certificate for facility LexiTreats1 - Morgantown	Competitive Treat Maker (118699)	Missing	N/A	Action▾
Third Party Audit Certificate for facility CSHQ1 - CurlySue Facility HQ	Curly Sue Doodle Beds (118658)	Missing	N/A	Action▾
Third Party Audit Certificate for facility LexiTreats1 - Morgantown	Lexi's Treats (118496)	Missing	N/A	Action▾
Third Party Audit Certificate for facility P1 - My Treats Distribution Plant	My Treats (118670)	Compliant	03/01/2017 12/31/2018	Action▾
Third Party Audit Certificate for facility P2 - My Treats Manufacturing Plant	My Treats (118670)	Compliant	03/01/2017 12/31/2018	Action▾

ReposiTrak
Trusted Brand Protection

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Complete Document Management Automation

Your customized requirements are automatically shared with your vendors.

They upload the documents (not you!) directly online – we'll make any phone calls or send any emails necessary to speed compliance.

Filter By

Document Category:	All with Exceptions	
Document:	All with Exceptions	☑ Required Documents Only
Status:	All with Exceptions	

Documents

Document	Status	Effective Period	Partner	
Food Quality Plan for facility P1 - My Treats Distribution Plant	Missing	N/A	The Treat Shoppe (118371)	Action▾
Food Quality Plan for facility P2 - My Treats Manufacturing Plant	Missing	N/A	The Treat Shoppe (118371)	Action▾
Third Party Audit for facility P1 - My Treats Distribution Plant	Specs not met	03/01/2017 03/01/2018	The Treat Shoppe (118371)	Action▾
Third Party Audit for facility P2 - My Treats Manufacturing Plant	Specs not met	03/01/2017 03/01/2018	The Treat Shoppe (118371)	Action▾

		Effective Period	
	Compliant	09/01/2016 N/A	Action▾
ts (118509)	Compliant	09/01/2016 N/A	Action▾
18670)	Compliant	03/01/2017 N/A	Action▾
ats (118540)	Compliant	09/02/2016 N/A	Action▾
Company (118558)	Compliant	10/11/2017 N/A	Action▾

ReposiTrak
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Fast & Accurate Document Verification

26% of the documents are not authentic. The system automatically verifies and alerts both you and your vendor.
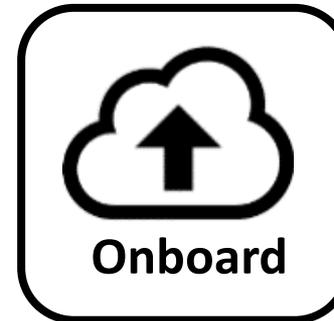
You'll Be Up & Running In 30 Days

- **Cloud-based, no IT Support needed**
- **You define your requirements**
  - We'll provide Best Practices
- **Self-enrollment**
  - Create profile
  - Upload required documents
- **Your Account Manager will be assigned**
- **Your compliance results will improve**

ReposiTrak MarketPlace

Make compliance work for you...

Search

Curate

Onboard

Order

Questions? Our ReposiTrak Team is Here to Help

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Food Fraud Compliance Requirements:
as of January 1, 2018

ReposiTrak and USP: Food Fraud Vulnerability Assessment and Mitigation Planning

January 24, 2018 – 1 to 2pm ET

John Spink, PhD

Director & Assistant Professor, Food Fraud Initiative
College of Veterinary Medicine/ Food Safety

WWW.FoodFraud.MSU.edu   Twitter @FoodFraud   and #FoodFraud

MSU Food Fraud Think Tank
Brand Owner and Manufacturer

- Support the FFI mission to standardized prevention practices

- Help lead strategy and policy.

- Internal and external leadership.

- Deliverables:
  - Expanded engagement such as CODEX, ISO, etc.
  - Food Fraud Audit Guide MOOC
  - Expanded on-line, on-demand resource such as YouTube
  - Food Fraud Initiative Reports
  - Industry benchmarking surveys

Food Fraud Curriculum

FREE

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

- Free, open, online, open to everyone, includes a 'certificate of completion'
- **Food Fraud Overview MOOC –** May & November
- **Food Fraud Audit Guide MOOC –** Oct, Dec, Jan, etc.
- *Food Defense Audit Guide MOOC – Open to Public January 20, Feb, etc.*

Executive Education (Short-Course)

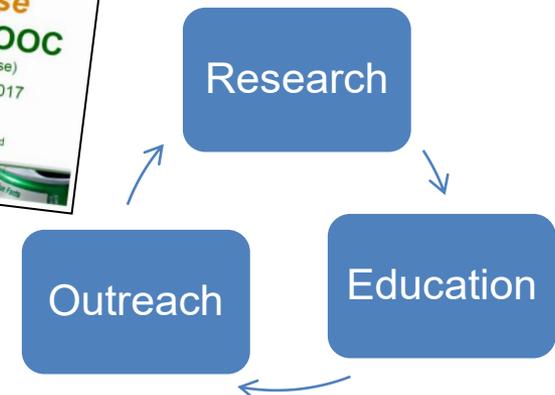- Food Fraud Strategy, Quantifying Food Risk with Vulnerably Assessments

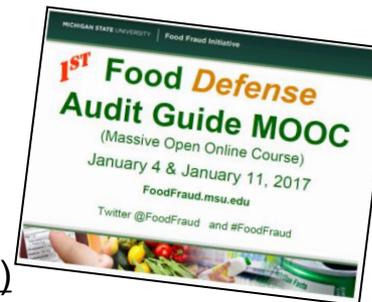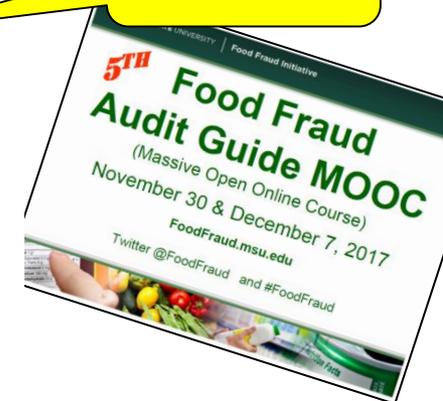**Graduate Courses** (Online, Three Credits)

- Anti-Counterfeit & Product Protection (Food Fraud)
- Quantifying Food Risk (including Food Fraud)
- Global Food Safety (including Food Fraud)
- Food Protection and Defense (Packaging Module)
- Packaging for Food Safety

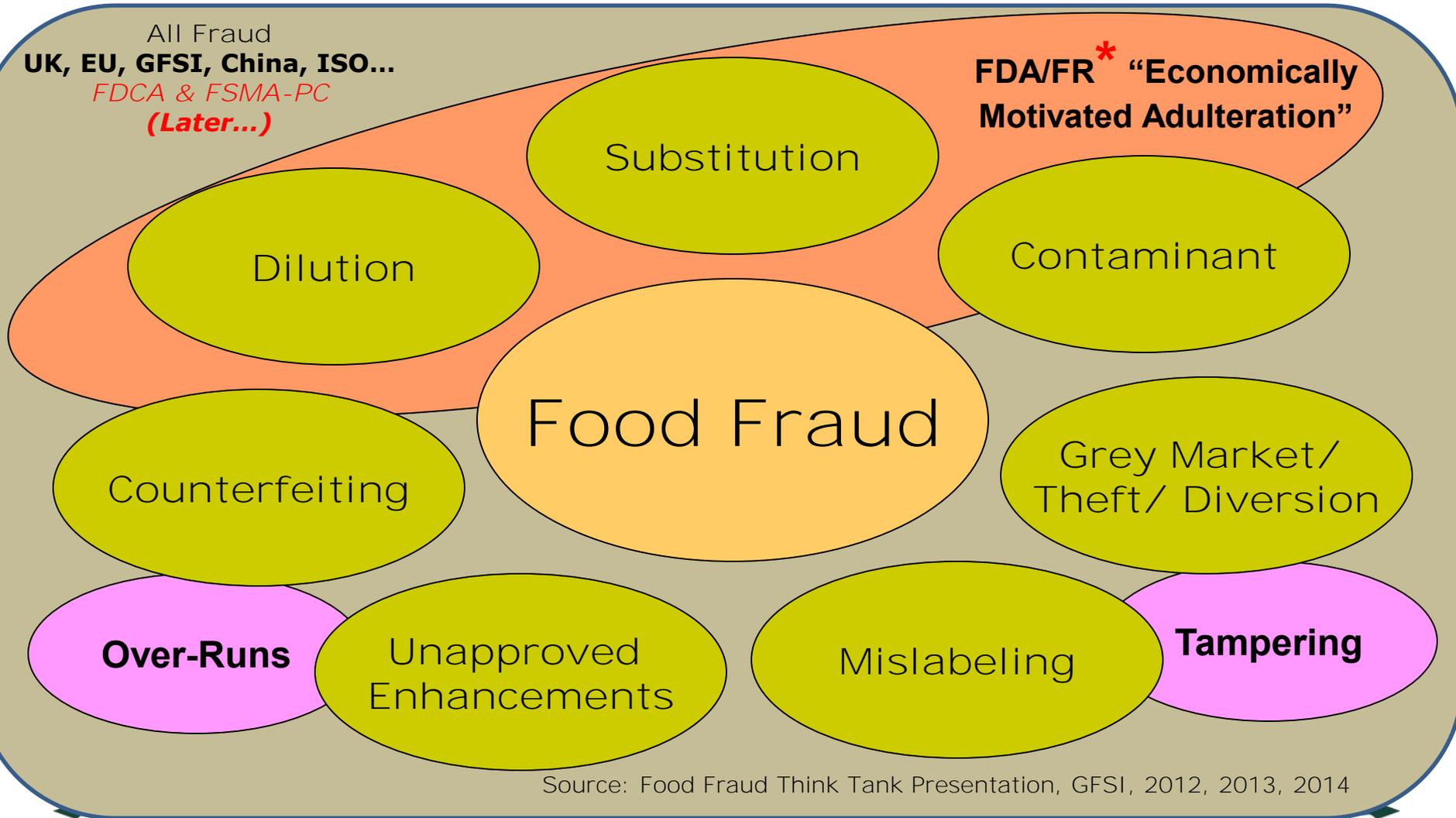**Graduate Certificate** (Online, Four Courses Each)

- Certificate in Food Fraud Prevention (Food Safety)

Master of Science in Food Safety (Online)

- **www.online.FoodSafety.msu.edu**

5TH **Food Fraud Audit Guide MOOC** (Massive Open Online Course) November 30 & December 7, 2017 FoodFraud.msu.edu Twitter @FoodFraud and #FoodFraud

1ST **Food Defense Audit Guide MOOC** (Massive Open Online Course) January 4 & January 11, 2017 FoodFraud.msu.edu Twitter @FoodFraud and #FoodFraud

Research

Outreach

Education

What is Food Fraud?

All Fraud
UK, EU, GFSI, China, ISO...
FDCA & FSMA-PC
(Later...)

FDA/FR* "Economically Motivated Adulteration"**

Substitution

Dilution

Contaminant

Food Fraud

Counterfeiting

Grey Market/ Theft/ Diversion

Over-Runs

Unapproved Enhancements

Mislabeling

Tampering

Source: Food Fraud Think Tank Presentation, GFSI, 2012, 2013, 2014

The Food Risk Matrix

Prevent by Understanding the Motivation

Food Quality	Food Fraud	Motivation Gain: Economic
Food Safety	Food Defense Wide-scale Terrorism	Harm: Public Health, Economic, or Terror
Unintentional	Intentional	
Action		

Source: Adapted from: Spink (2006), The Counterfeit Food and Beverage Threat, Association of Food and Drug Officials (AFDO), Annual Meeting 2006; Spink, J. & Moyer, DC (2011) Defining the Public Health Threat of Food Fraud, Journal of Food Science, November 2011

GFSI Conference 3/2014

Approach to Food Fraud Prevention

Food Safety Management System

Food Safety	Food Defence	Food Fraud
HACCP Hazards	**TACCP** Threats	**VACCP** Vulnerabilities
Prevention of unintentional / accidental adulteration • Science based • Food borne illness	Prevention of intentional adulteration • Behaviourally or ideologically motivated	Prevention of intentional adulteration • Economically motivated
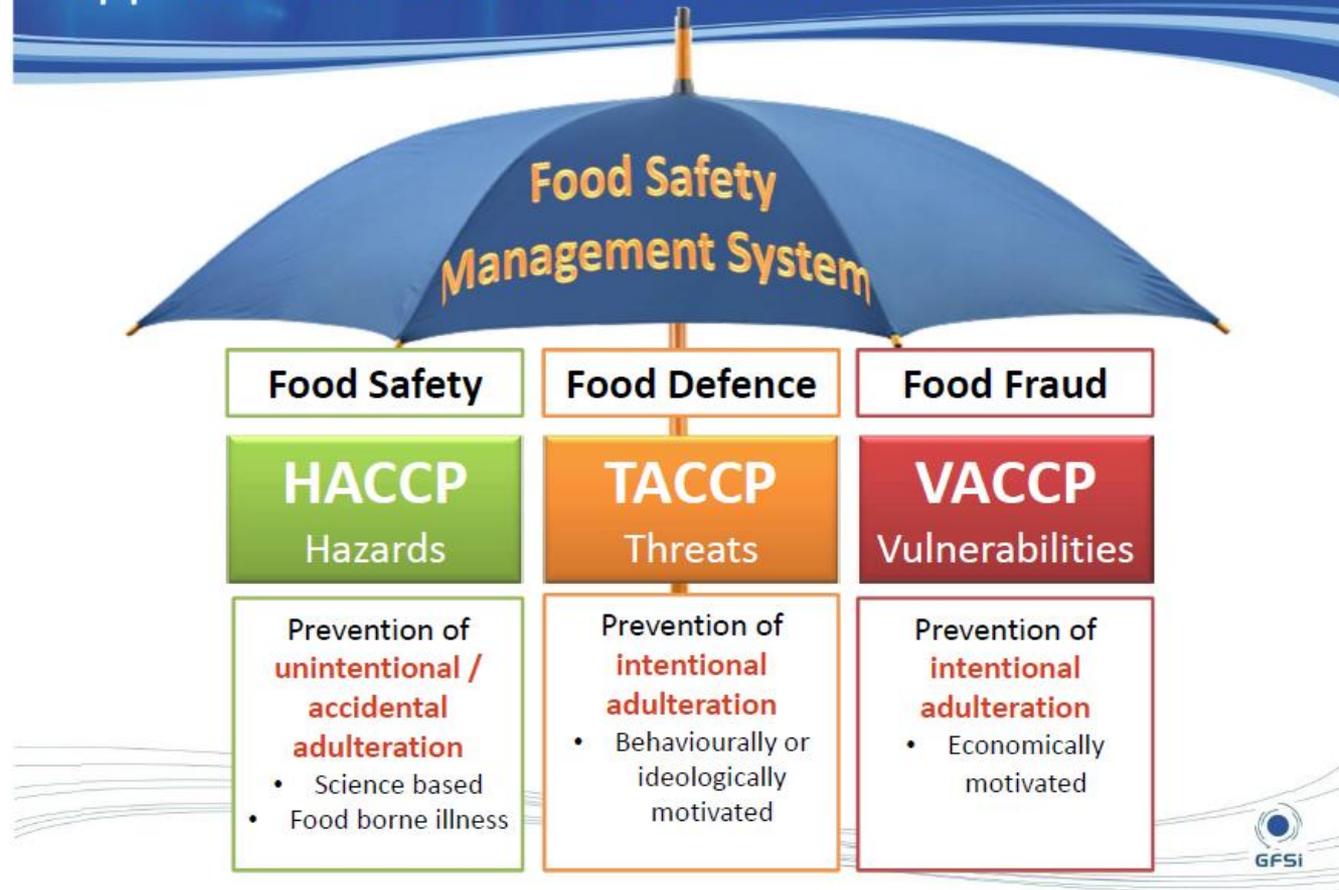
REVIEW: GFSI Issue 7 Published Food Fraud Terms

FFVA

FSM AI 21 Food fraud vulnerability assessment

- The standard shall require that the organisation has a **documented food fraud vulnerability assessment procedure** in place to identify potential vulnerability and prioritise food fraud mitigation measures.

FFPS

FSM AI 22.1 Food fraud mitigation plan

- The standard shall require that the organisation has a **documented plan** in place that specifies the measures the organisation has **implemented to mitigate** the public health risks from the **identified food fraud vulnerabilities**.

+Details

FSM AI 22.2 Food fraud mitigation plan

- The standard shall require that the organization's Food fraud mitigation plan **shall cover the relevant GFSI scope** and shall be supported by the organisation's Food Safety Management System.

> Every 'vulnerability' does *NOT* need a control plan – e.g. meteor.

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.

FFVA: Rank

FFPS: Method

Food Fraud Compliance Requirements: Scope

"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. Implement a Food Fraud Prevention Strategy (Y/N)

4. Written (Y/N)

5. Minimally conduct an annual Food Fraud Incident Review (Y/N)

6. Note: Address all types of Food Fraud (Y/N)

7. 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/
- **New Food 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 – OK! Optimal!

- The formal and official process has started…

Approval = ACTION

Create Document

Document to Auditor

Q: YES OR NO?

Takeaways: Focus on…

- Preventing all Food Fraud
    - not only adulterant-substances

- All compliance
    - not just FSMA-PC, FSMA, FDCA, or Securities Laws

- Reducing recall potential
    - do your job… your CFO and Board of Directors care

- Reducing liability
    - Corporate, legal, regulatory, and overall

MSU Engagement 2018

	Outcome	Benefit	Commitment
Graduate Course	Share your knowledge and set direction of research	Plus **Graduate Certificate in Food Fraud Prevention**	14 Weeks, online, May to August, ~$2200
Executive Education	Share your knowledge and set direction of research	Develop the internal talent to support initiatives in the AC space, meet other thought leaders ("invitation only" sessions for brand owners)	2 Days on-campus ($1950) Feb 20-23, 2018 (22-23 FFIS) Fall 2018, TBD
Multi-Client Studies	Research the why's of AC/D, understand underlying drivers	Uncovering the drivers may lead to new strategies to combat Counterfeiting	Teleconference Meetings with option for on-campus e.g. Veterinary and Animal Product Fraud
MOOC	Engage global network of Food Fraud thinkers..	Two, 2-hour on-line webinar format with assessment. Students earn an MSU "credential".	Overview: May & Nov. FF Audit Guide: Monthly Food Defense Audit Guide: Jan, Mar, +

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Acknowledgements

- **MSU Veterinary Medicine:** Dean Christopher Brown, Chair Dan Grooms, Chair Ray Geor, Dr. Wilson Rumbeiha, Cindy Wilson, Dean John Baker
- **MSU Global:** Associate Provost/ Executive Director Christine Geith, Jerry Rhead, Gwyn Shelle, Lauren Zavala, Associate Provost/ EVP Dr. Karen Klomparens, Rashad Muhammad
- **Queens's University Belfast (UK):** Professor & Director Christopher Elliott, Dr. Moira Dean, Dr. Michael Hollis
- **MSU Online Master's of Science in Food Safety:** Director Melinda Wilkins, Ex-Director Julie Funk, Kristi Denbrock, Heather Ricks, Peggy Trommater, Heidi Chen, Dr. Gary Ades, Chair Ray Goer
- **MSU Food Science:** Chair Fred Derksen, Les Bourquin, Bradley Marks, Felicia Wu, VP of Research Ian Gray, David Ortega, Gale Strasburg
- **MSU Program in Public Health:** Director Michael Rip and Douglas C Moyer
- **MSU NFSTC:** Dr. Scott Winterstein, Trent Wakenight,, Dr. Kevin Walker, Sandy Enness, Jen Sysak, Dr. Rick Foster, to name a few critical contributors and supporters.
- **MSU Food Safety Policy Center:** Dr. Ewen Todd
- **MSU School of Packaging:** Dr. Bruce Harte, Dr. Robb Clarke, Dr. Laura Bix, Dr. Paul Singh, Dr. Diana Twede, Dr. Gary Burgess, Dr. Harold Hughes, Dr. Mark Uebersax, Dennis Young, and Director Joseph Hotchkiss
- **MSU Communication Arts/ Consumer Behavior:** Dr. Maria Lapinski and Dr. Nora Rifon
- **MSU Criminal Justice:** Dr. Jeremy Wilson, Director Ed McGarrell, Dr. Justin Heinonen, Roy Fenoff, Zoltan Fejas, Barbara Sayre, and Sara Heeg
- **MSU Supply Chain Management:** Dr. Cheryl Speier, Dr. Ken Boyer, Dr. John MacDonald, Chair David Closs, Dr. Stan Griffis, Dr. Judy Whipple
- **MSU College Social Science:** Dean Marietta Baba and Assoc Dean Chris Maxwell
- **MSU College of Law:** Dr. Neil Fortin and Dr. Peter Yu
- **MSU Libraries:** Anita Ezzo, Nancy Lucas, Kara Gust
- **MSU International Programs:** Dr. Mary Anne Walker, Dr. John Whimms
- **State of Michigan's Ag & Food Protection Strategy Steering Committee:** Dr. John Tilden, Brad Deacon, Gerald Wojtala, Byron Beerbower
- **The Citadel:** Dr. Roy Fenoff

Discussion

John Spink, PhD

SpinkJ@msu.edu

Twitter: Food Fraud and #FoodFraud
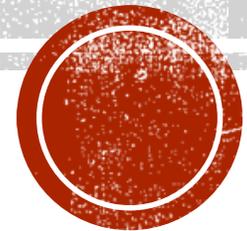
www.FoodFraud.msu.edu

Video on YouTube: Search "Food Fraud" and "MSU"

FOOD FRAUD: THE PATH TO COMPLIANCE

ReposiTrak and USP: Food Fraud Vulnerability Assessment and Mitigation Planning

January 24, 2018 – 1 to 2pm ET

Neil Bogart, AVP Quality Systems
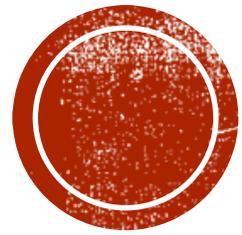
RED DIAMOND: COFFEE, TEA

- Founded in 1906 on Morris Ave in Birmingham, AL

- Fourth Generation Family Owned

- Rich Heritage of Innovation

Wholesale Section of Morris Ave. on a busy day, Birmingham, Ala.

RED DIAMOND: STILL GROWING TODAY

- New ~85 acre campus in St. Clair County in 2008

- Operates 3 distinct business divisions

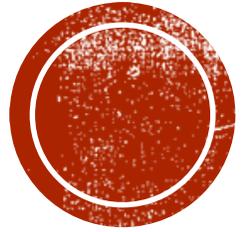- Distribution footprint in 48 states

FOOD FRAUD

Our journey

METHOD USED

http://www.usp.org/foods/food-fraud-mitigation-services

PRE-SCREENING

PRE-SCREENING

- Where do I start? (The prescreening)
  - Vendors
    - How many do we have and who are they?
    - What are the risks introduced by each vendor?
      - Are they GFSI Compliant?
      - Have you reviewed their history?
        - Recalls
        - Withdrawals
      - Have you reviewed their vendor approval program?
   - Are they compliant with your vendor approval program?

PRE-SCREENING

- We use ReposiTrak® to manage our vendors and their documents.
  - Review of compliance easier
    - Dashboards and exception alerts
  - New vendor approval process is faster
    - E-sign negates need to print, sign, scan and send back
  - Auto review verifies document contents vs. supplier submissions
    - For example, minimum level of insurance coverage
  - Categorization of vendors and their document requirements
    - By risk level (High, Medium, Low) and if a co-packer

PRE-SCREENING

Dashboard
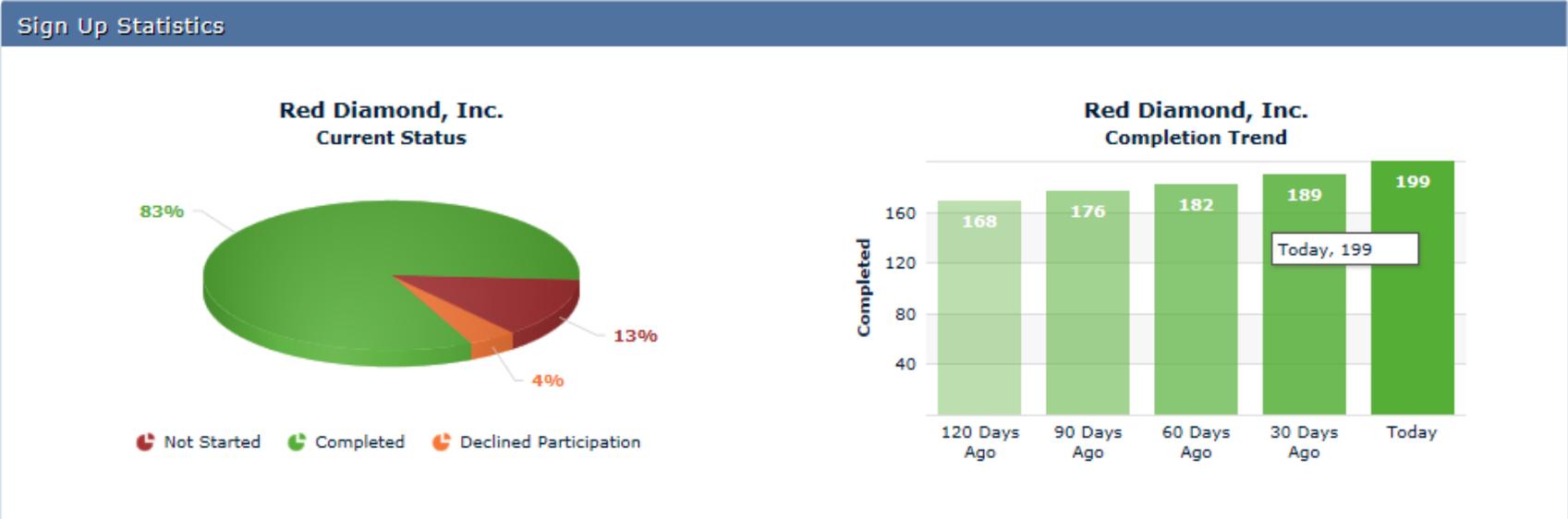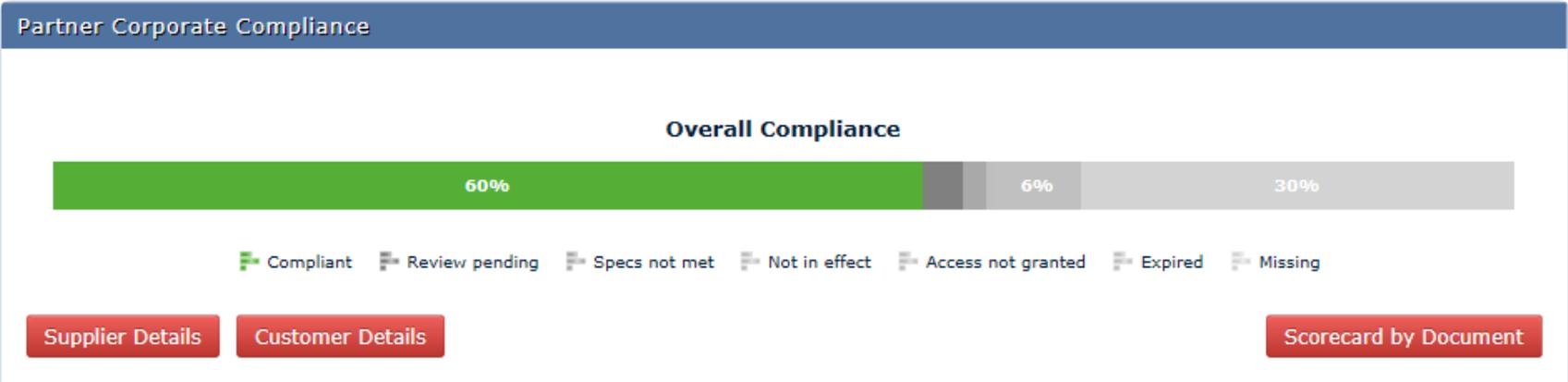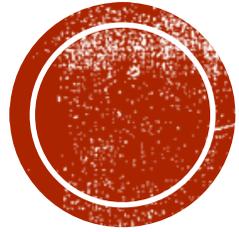
VULNERABILITY & RISK ASSESSMENT

VULNERABILITY & RISK ASSESSMENT

- Once you have identified your "high risk" suppliers
  - Identify those ingredients that could have a large affect in your day-to-day business
  - Then identify which of those ingredients could have the highest potential of fraud:
    - Recalls
    - Withdrawals
    - Import Alerts
    - Trade organizations
    - Reportable Food Registry
   - USP Food Fraud Database - subscription

VULNERABILITY & RISK ASSESSMENT

- We use USPs Food Fraud Database
  - Makes it easier to look up your items
  - Faster than having to go through all the other recommended sources for information on fraud
  - You can set up notifications on if something on your list changes
    - Saves time on the question:
      - How often should I review my products for fraud?
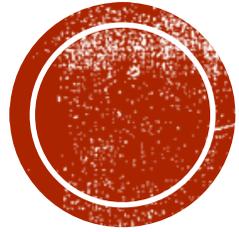
OVERALL RISK

OVERALL RISK

- How does the potential fraud risk your business?
  - Is all fraud a risk to your business? (Yes / No)
  - Does the fraud you have found necessitate a mitigation plan?
    - Do not let emotions get in the way of your decision making
    - Use FMEA form to determine if you really need to mitigate the risk
      - How often does it happen?
      - Can you catch it in your testing protocol?
      - Has the fraud been detrimental to human health?
        - Grass clippings in tea
        - Peanut shells in cumin

OVERALL RISK: FMEA

- Determine how serious each effect is "S"
  - 1-10

- For each failure, determine root cause - - Root-Cause-Analysis (RCA)
  - 5-Whys or Fishbone

- For each cause, determine the occurrence rating "O"
  - 1-10

- For each cause, identify current process controls
  - Tests, procedures, or mechanisms

OVERALL RISK: FMEA

- For each control, determine the detection rating "D"
  - 1 (always detected) to 10 (never detected)
  - Estimates how well the controls can detect either the cause or its failure after they have happened, but prior to customer receipt

- Is failure mode associated with a critical characteristic?
  - Is a "Mitigation Plan" needed?
    - If severity is 9 or 10 and detection rating is above a 3.
  - "Y" or "N"

OVERALL RISK: FMEA

- Calculating risk priority number (RPN) = S (seriousness) x O (occurrence) x D (detection)
- Calculating criticality (CRIT) = S X O
  - These numbers provide guidance for ranking potential failures in the order they should be addressed
- Identify corrective actions
  - Design or process change lowering severity or occurrence
  - Maybe additional controls to improve detection
- List who is responsible and due date
- After a predetermined time, reanalyze new S, O, D ratings and new RPNs.
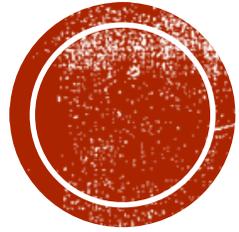
OVERALLOVERALL RISK: FMEA RISK

Function	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s) of Failure (RCA)	O	Failure Mode Needs Critical Characteristic (CCP) S = 9 or 10 D = >3 "Y" or "N"	Current Process Control(s)	D	RPN	CRIT	Recommendation(s)	Responsible Party & Target Completion Date	Action Result(s)						
													Action Taken	S	O	D	RPN	CRIT	Analysis Date

OVERALL RISK: FMEA

Function	Potential Failure Mode	Potential Effects(s) of Failure	S	Potential Cause(s) of Failure	O	Current Process Controls	D	RPN	CRIT	Recommended Action(s)	Responsibility and Target Completion Date	Action Results					
												Action Taken	S	O	D	RPN	CRIT
Dispense amount of cash requested by customer	Does not dispense cash	Customer very dissatisfied Incorrect entry to demand deposit system Discrepancy in cash balancing	8	Out of cash	5	Internal low-cash alert	5	200	**40**								
				Machine jams	3	Internal jam alert	10	240	24								
				Power failure during transaction	2	None	10	160	16								
	Dispenses too much cash	Bank loses money Discrepancy in cash balancing	6	Bills stuck together	2	Loading procedure (riffle ends of stack)	7	84	12								
				Denominations in wrong trays	3	Two-person visual verification	4	72	18								
	Takes too long to dispense cash	Customer somewhat annoyed	3	Heavy computer network traffic	7	None	10	210	21								
				Power interruption during transaction	2	None	10	60	6								

ECONOMICALLY MOTIVATED ADULTERATION (EMA) – MITIGATION PLAN

EMA MITIGATION PLAN

- We found it necessary to test our coffee and tea

- To determine if our products were free of adulteration, we chose DNA – whole genome sequencing
  - Results:
    - So far we have tested the tea
      - Other plant based materials?
        - Are they EMA and are they detrimental to human health - - NO
      - When do you choose to move forward with other testing?
        - Concentration of other materials
          - GCMS?
            HPLC?
    - How often should we test?

- POINT OF DIMINISHING RETURNS?????