



FSPCA 2024 ANNUAL CONFERENCE

A GLOBAL COMMUNITY NAVIGATING
A CHANGING LANDSCAPE



WELCOME

JASON WAN, PHD
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)



OPENING REMARKS

BRIAN SCHANEBERG, PHD
INSTITUTE FOR FOOD SAFETY & HEALTH (IFSH)

WELCOME

2024 IFSH FSPCA Annual Meeting

November 19-20, 2024
Burr Ridge, IL

ILLINOIS TECH



State of the Institute

Agenda

- Membership
- Year-in-Review
- New NCFST / IFSH 5-Year Aims

Thank You Members

- **3A-Sanitary Standards, Inc.**
- Abbott Nutrition
- American Beverage Association
- Archer-Daniels-Midland Company
- bioMérieux
- Campden BRI
- Chicagoland Food and Beverage Network
- ConAgra Foods
- **Danone**
- Deibel Laboratories, Inc.
- Ecolab Inc.
- E&J Gallo Winery
- Eurofins
- McCormick FONA
- Good Foods Group
- Hormel Foods Corp.
- Lamb Weston
- Land O’Frost
- Mars Inc.
- National Dairy Council / Dairy Management Inc.
- Nestle USA
- Reckitt
- The Kraft Heinz Company
- Tilia Holdings LLC
- Unilever

Year-in-Review

Booth Update

INSTITUTE FOR
Food Safety



Research Capabilities

- Food Safety & Quality Evaluation
- Process Technology
- GMP, BSL 2&3 Pilot Plants
- Whole Genome Sequencing
- Allergen & Pathogen Testing
- Packaging Assessment
- Training & Certification

FOOD SAFETY
Food Defense

Science for the Real World



AND HEALTH
Nutrition



Clinical Trials

- Claims Validation
- Mechanism of Action
- Metabolomics & Metagenomics
- Precision Nutrition

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
Innovation Through Collaboration

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Sprout Safety Alliance



Jim Jones & Mike Cabonargi Visit



- IFSH member engagement session
- Past accomplishments and future vision
- A model of stakeholder engagement
- New Human Foods Program org Oct 1
- Final rule on agricultural water published
- Process for re-evaluation of food additives
- Healthy symbol, voluntary front-of-pack coming

Some Research Highlights

- Viral and bacterial microbiomes of leafy greens and herbs
- Dry-heat treatment on sprout seeds
- *C. botulinum* and toxin production in plant-based meat alternative products
- PIF *Cronobacter* desiccation and sanitizer stress, population dynamics
- Undeclared allergens in peanut, nut and seed butters and pastes; cross-contact risks
- Nanoparticle, contaminants and food contact research
- PT of SARS-CoV-2 omicron variant detection in veterinary diagnostic laboratories
 - **FDA Group Recognition (Crosscutting) Honor Award: “For outstanding achievement, collaboration, and extraordinary efforts to address the post-pandemic needs of veterinary diagnostics in SARS-CoV-2 testing”**
- Quantitative assessment of *Listeria monocytogenes* in queso fresco cheese
- Plant-milk nutrient bioavailability

Future Aims

FY2024 Congressional Appropriations

areas of interest

- **New Approach Methods** with a goal to reduce animal testing and advance alternative methods in a measurable and impactful way through the IFSH coordinated Food Toxicology Public-Private Partnership
- The **New Era of Smarter Food Safety** through data to identify and predict vulnerabilities in the nation's food supply chain
- Outreach to **Small Farmers** through relevant training services
- **Plant Based Product Labeling** assessment through consumer studies to better understand consumers' attitudes, beliefs, perceptions, feelings, and motivations relative to product composition, health attributes, and terms used on labeling
- Support the **Traceability Rule** through the development of educational and training materials

Areas of Funding Interest

- Sprout Safety Alliance and Curriculum update
- Cold Grown Sprouts
- Genome Trkr and WGS Outreach
- PIF Safety
- Emerging chemicals and toxic elements, PFAS
- Improving quality of data through applied research that informs prevention strategies
- **Food Traceability Curriculum development and launch**
- High Pathogenic Avian Influenza in dairy: sample blinding, raw milk surveillance, other processing technologies
- PFAS market basket sample blinding
- PT/MV Program
- Support of research associates (post-masters / post-doc)

Other Activities

- Launch an IFSH Faculty Advisory Council
- Expand industry member portfolio
- Develop cleaning / sanitation training curriculum
- Build a certification program as a credential in Preventive Controls for Humans Food
- Evaluate partnerships with NIST and AOAC
- Continue the production of clinical research meals in the GMP certified food processing pilot plant in support of the NIH Common Fund's Nutrition for Precision Health, powered by the All of Us Research Program
- Support FDA in Highly Pathogenic Avian Influenza research
- Add *Brucella* spp. and *Coxiella burnetti* to the list of agents for research in the BSL2/3 Select Agent suite

Thank You



KEYNOTE SPEAKER

ERIK P. METTLER

U.S. FOOD AND DRUG ADMINISTRATION (FDA)



FSPCA OPERATIONAL HIGHLIGHTS

JASON WAN, PHD
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

KATHY GOMBAS
FSMA SOLUTIONS



FSPCA Operational Highlights 2024

www.fspca.net

Jason Wan, Ph.D.
Director – FSPCA
Associate Director - IFSH

FSPCA

- **Established in Dec. 2011 with FDA FSMA funding, now self-sustaining**
- **VISION:** Be the internationally recognized trusted source for training programs and outreach for the prevention-oriented standards of the U.S. Food Safety Modernization Act (FSMA).
- **MISSION:** Assist the human and animal food industry and related entities in building food safety capacity through education, training and outreach with an emphasis on small-, and medium-sized businesses.

FSPCA Activity

- Develop Standardized/Core Curriculum on FSMA Training
- Develop and Implement Policies and Procedures
 - Policies, Protocols, Procedures, Value Propositions, MOUs
- Develop Train-the-Trainer Programs and Conduct Lead Instructor Courses
- Conduct Outreach Programs
 - Technical Assistance Network
 - International Outreach Activities

FSPCA Standardized/Core Curricula

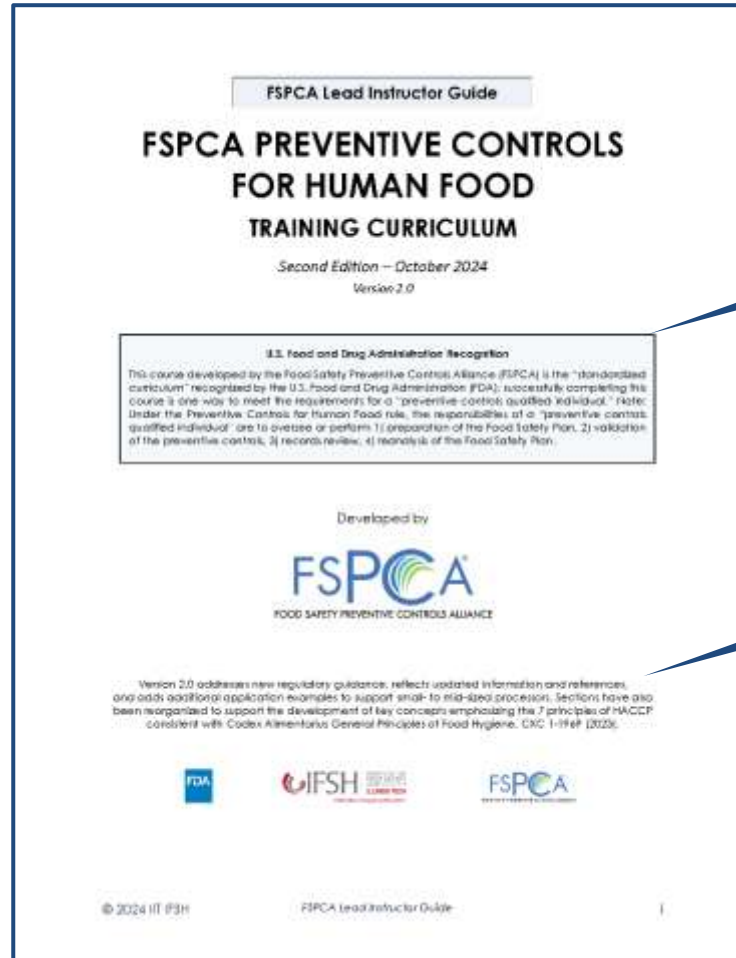
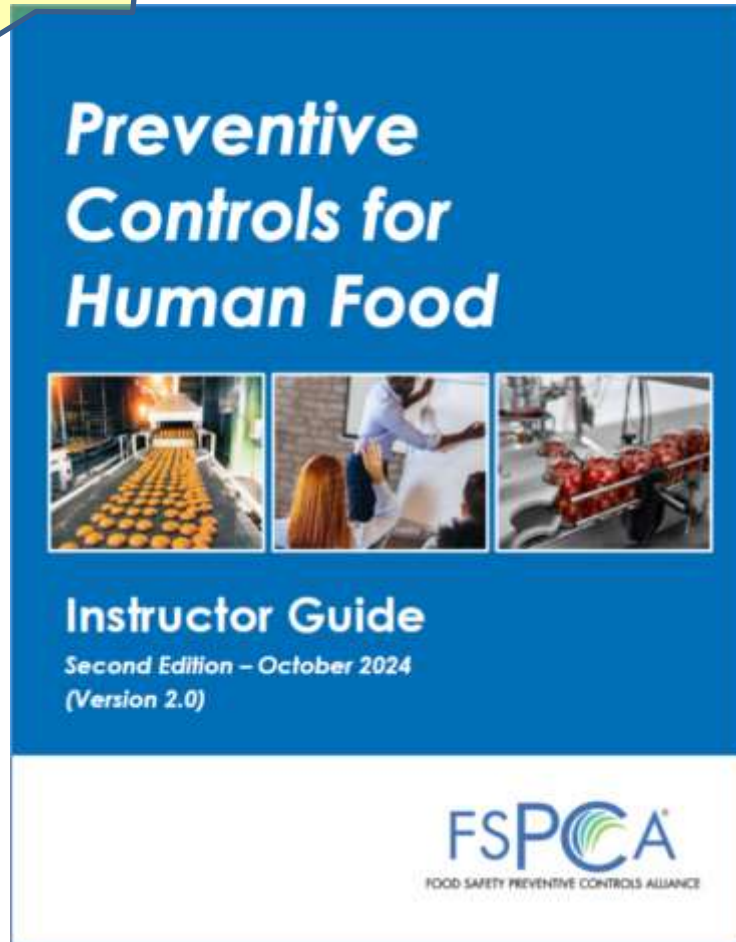


All FSPCA Participants Manuals are publicly available on the FSPCA website

In development – Food Traceability core curriculum

NEW

PCHF V2.0 Recognized by FDA as Standardized Curriculum



FDA Recognition as Standardized Curriculum for PCQI Training

Consistent with Codex Alimentarius General Principles of Food Hygiene CXC 1-1969 (2023)

FSPCA Food Traceability Rule Core Curriculum

- Food Traceability Rule and relevance to food industry
- FTR curriculum team established in October 2023
- First draft curriculum completed in July 2024
- FTR curriculum walkthrough at FDA Rockville July 29-Aug 2, 2024
- Estimated completion date May 2025
- FTR Lead Instructor courses and participant courses start from July 2025



2023 FSPCA Lead Instructor Courses

- **Virtual Human Food Lead Instructor Course**
 - April 10-14, 2023
 - June 19-23, 2023
 - August 14-18, 2023
- **In-Person Animal Food Lead Instructor Course**
 - November 28- 30, 2023, IFSH
- **Virtual FSVP Combination Course**
 - December 11-15, 2023
- **Virtual IAVA Combination Course**
 - October 31 – November 1, 2023 (Participant portion) and November 7 – 8, 2023 (Lead Instructor portion)



2024 FSPCA Lead Instructor Courses

- **Virtual Animal Food Lead Instructor Course**
 - June 24-28
- **Virtual IAVA Combination Course**
 - August 7 - 6, 2024 (Participant portion) and August 13 – 14, 2024 (Lead Instructor portion)
- **Virtual/In-person Human Food V2.0 LIRT Course**
 - Oct 29, 2024
 - Oct 30, 2024
 - Oct 31, 2024
 - Nov 6, 2024
 - Nov 6-7, 2024
 - Nov 12-13, 2024
 - Nov 18, 2024 (three concurrent in-person sessions)
 - 20 more LIRT courses for remainder of 2024 Calendar Year

FSPCA Annual Conferences



FSPCA AC 2023 (October 17-18)
Marriott Chicago Southwest, Burr Ridge, IL



FSPCA Webinars 2024

Dates	Webinar Topic	Audience
February 22	Updates to FDA's Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Spotlight on Appendix 1	Open to the Public
February 29	Animal Food Rule Inspectional Findings and Supplemental Resources for FSPCA Animal Food Lead Instructors	FSPCA Animal Food Lead Instructors
April 9	Food Traceability Rule Awareness for Industry Module Webinar	FSPCA Lead Instructors
April 11	Seminario web gratuito sobre el módulo de conocimiento de las reglas de trazabilidad de alimentos de la FSPCA para la industria (En español)	FSPCA Lead Instructors
December 12	How to Be Ready for a Recall: Working with FDA and Preparing for the Unexpected	Open to the Public

FSPCA Training Metrics

Metrics

(as of October 1, 2024)

154

FSPCA
Lead Instructor
courses completed

3149

Successfully trained
Lead Instructors from
79 countries

18484

FSPCA
participant courses
delivered by
FSPCA Lead Instructors

213821

Personnel from 143
countries have been
trained on FSMA
regulations

[ALL METRICS](#)

2024 Annual Conference Program Highlights

- Keynote Presentation - Erik P. Mettler, Assistant Commissioner for Integration, FDA Human Foods Program;
- Launch of the Preventive Controls for Human Food Version 2.0 curriculum;
- Highlights from FDA senior officials on FSMA inspections;
- Insights from industry leaders and FSMA Regional Centers
- Updates on FSMA training curricula; including Food Traceability
- FSPCA Award and Recognition presentation
- Interactive networking forums

THANK YOU!

- FSPCA EAB Members
- Committee Members
- TOTs, LIRT Trainers
- Lead Instructors
- Volunteers
- All Stakeholders and Members of FSPCA Community
- All of You



FSPCA STRATEIC PLAN

KATHY GOMBAS

FSPCA EXECUTIVE ADVISORY BOARD CHAIR

FSPCA Strategic Plan

Vision: Be an internationally recognized trusted source for training programs and outreach for the prevention-oriented standards of the US Food Safety Modernization Act (FSMA).

Mission: Assist the human and animal food industry and related entities in building food safety capacity through education, training and outreach with an emphasis on small and medium-sized businesses.

Core Values:

People: We foster a community that values respect, inclusivity, & transparency.

Collaboration: We develop trusted & strategic relationships with stakeholders worldwide.

Excellence: We deliver the highest quality curricula recognized by FDA, with personal & professional integrity.

Evolve: We innovate to proactively & continually adapt to stakeholder needs.

FSPCA Strategic Framework

GOAL 1	Attract, develop, recognize, and support volunteers and lead instructors	
OUTCOME	Sustain and support volunteer base <ul style="list-style-type: none"> • Create greater awareness of volunteer activities • Create recognition and appreciation process for significant volunteer contributions 	<ul style="list-style-type: none"> • Quarterly Newsletter; Website; E-blasts; LinkedIn • FSPCA Annual Awards and Recognition Program
	Sustain and support lead instructors <ul style="list-style-type: none"> • Design and make networking opportunities available • Plan and implement continuing education opportunities • Increase awareness of current advertising and other resources in Lead Instructor Portals 	Annual Conference; Private Chatter Group; Lead Instructor Webinars ; PCHF LI V2.0 Portal
	Maintain and expand diversity of volunteers and lead instructors	Online FSPCA Volunteer Interest Form



LinkedIn Data from May 1 to November 1:

- New followers: **2,846** (total 10,690)
- Organic impressions with content: **88,682**
- Members reached with content: **49,303**
- Engagement rate: **8.4%** (1% to 4% considered good, 148.7% vs. competitors)

Upcoming FSPCA Webinars

2024 - 2025	Topic	Presenter(s)	Invitees
Dec 12	How to Be Ready for the First 24 Hours of a Recall	Amy Philpott – PR Solutions; Trinh Nguyen, FDA; Maile Gradison & Elizabeth Fawell, Hogan Lovells.	Open to Public
Jan TBD	Background on U.S. Food Safety System	Juan Silva	PCHF LIs
Feb TBD	FDA Data Dashboards	FDA invited speaker	All LIs

FSPCA Strategic Framework

GOAL 2	Build and maintain strategic relationships	
OUTCOME	Evaluate existing FSPCA relationships to leverage past investments and explore new opportunities	FDA/FAS funding to support International V2.0 Lead Instructor Refresher Training
	Evaluate potential relationships that may provide new and additional value to the FSPCA	International Engagement

FSPCA Strategic Framework

<p>GOAL 3</p>	<p>Create responsible marketing and outreach strategies to promote products and services</p>	
<p>OUTCOME</p>	<p>Develop and implement an outreach and encouragement plan to attract new Lead Instructors and engage current Lead Instructors</p>	
	<p>Develop and execute a branding plan for promoting FSPCA products and services, including product updates and revisions</p>	
	<p>Develop a strategic communication plan to identify and attract stakeholders from human and animal food and related industries with an emphasis on small companies, importers, and other underserved stakeholders who are not yet utilizing FSPCA products and services</p>	<p>Small processors International engagement</p>
	<p>Support international community through exploration of an Information Exchange Platform to facilitate cross-communication between FSPCA and regional Points of Contact (liaisons, ambassadors) to listen to regional concerns and needs and provide solutions.</p>	<p>Launched Information Exchange Pilot Program in Latin America</p> 

FSPCA Strategic Framework

GOAL 5	Modify existing and develop new products and services to further the mission of FSPCA worldwide	
OUTCOME	Review and update curriculum to address regulatory and scientific changes, and facilitate rollout	<p>Preventive Controls for Human Food V2.0</p> <ul style="list-style-type: none"> • Lead Instructor Refresher Training – Launched October 2024 • Participant Courses – Start deliveries January 2025
	Establish a process to explore and evaluate additional value-added products and services, e.g., FSPCA Technical Assistance Network (TAN) Refresh	<p>FSPCA TAN Refresh – launched October 28 <i>Attend Day 2 of Conference to learn more!</i></p>
	Implement a system to identify and address stakeholder needs	
	Plan and prioritize the development of new products	<p>Food Traceability Core Curriculum – target launch March 2025</p>



FOOD TRACEABILITY RULE



PANELIST
MELINDA HAYMAN

U.S. FOOD AND DRUG
ADMINISTRATION (FDA)



PANELIST
LISA WEDDIG

NATIONAL FISHERIES
INSTITUTE (NFI)



PANELIST
HILARY THESMAR

THE FOOD INDUSTRY
ASSOCIATION (FMI)



PANELIST
MORGAN MADISON

FLORIDA FRUIT AND
VEGETABLE
ASSOCIATION



MODERATOR
JUAN SILVA

MISSISSIPPI STATE
UNIVERSITY

Highlights of the Food Traceability Final Rule: Requirements for Additional Traceability Records for Certain Foods

November 19, 2024
FSPCA Annual Conference

Melinda Hayman, Ph.D., Consumer Safety Officer
FDA Human Foods Program
Office of Compliance and Enforcement



Exemptions to the Food Traceability Rule

You are subject to the Food Traceability final rule, unless an exemption applies. To determine whether you may be exempt, please click on any of the following categories that may apply to you:

<input type="checkbox"/> Farms	<input type="checkbox"/> Certain types of processing
<input type="checkbox"/> Commercial rare agricultural commodities (RACCO)	<input type="checkbox"/> Personal consumption, eating, food for specific consumers
<input type="checkbox"/> Fishery means production facilities	<input type="checkbox"/> Other
<input type="checkbox"/> Retail food establishments (RFEs), restaurants	

What will the Food Traceability Rule require?



- New recordkeeping requirements.
 - Persons who manufacture, process, pack, or hold foods on the Food Traceability List.
- Covers the entire food supply chain.
- Includes both foreign and domestic entities.
- Full and partial exemptions may apply.

Compliance date

January 20, 2026

- Applies to all firms.
- Provides 3 years for covered entities to work with supply chain.
- We will educate before and while we regulate.
- Routine inspections under the rule will start in 2027.
- For-cause inspections will start at onset of compliance date.

Key Requirements of the Food Traceability Rule



- Traceability Plan
- Records of Critical Tracking Events (CTEs)
 - Specific Key Data Elements (KDEs) for each CTE
- Traceability lot code (TLC) and TLC source
- Records provided to FDA within 24 hours
- Records maintained for 2 years
- Electronic Sortable Spreadsheet (ESS) for outbreaks and recalls

FTR Implementation



Implementation Updates

- Developing of an internal FDA system to facilitate analysis of traceability information
- Developing approach/program for routine and for-cause inspections and overall compliance strategy
- Collaborating with State, Local, Tribal and Territorial partners
- Developing of regulator and industry training



FTR Resources

- Food Traceability Rule Preamble ([Federal Register](#))
 - Link directly to [codified](#)
- Food Traceability Final Rule [webpage](#)
- Translations
- Food Traceability List [webpage](#)
- Frequently Asked Questions ([FAQs](#))
- Food Traceability Final Rule [Webinar](#)
- Small Entities Compliance [Guide](#)
- Traceability Lot Code [webpage](#)
- Electronic Sortable Spreadsheet in [Excel™](#)
- Electronic Sortable Spreadsheet w/data in [Excel™](#)
- Critical Tracking Events and Key Data Elements [document](#)
- Exemptions [tool](#)

FTR Resources (cont.)

Supply Chain Examples

- Produce Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Additional Supply Chain Examples
 - [Various](#)
 - [Deli salads](#)
 - [Cheese](#)
 - [Sprouts](#)
 - [Seafood](#)

Questions?

- [FSMA Technical Assistance Network \(TAN\):](#)
- Access to Resources:





Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened	Tomatoes (fresh)
Cheese (made from pasteurized milk), soft ripened or semi-soft	Tropical tree fruits (fresh)
Cheese (made from unpasteurized milk), other than hard cheese	Fruits (fresh-cut)
Shell eggs	Vegetables (fresh-cut)
Nut butters	Finfish (histamine-producing species) (fresh, frozen, and previously frozen)
Cucumbers (fresh)	Finfish (species potentially contaminated with ciguatoxin) (fresh, frozen, and previously frozen)
Herbs (fresh)	Finfish, species not associated with histamine or ciguatoxin (fresh, frozen, and previously frozen)
Leafy greens (fresh)	Smoked finfish (refrigerated, frozen, and previously frozen)
Leafy greens (fresh-cut)	Crustaceans (fresh, frozen, and previously frozen)
Melons (fresh)	Molluscan shellfish, bivalves (fresh, frozen, and previously frozen)
Peppers (fresh)	Ready-to-eat deli salads (refrigerated)
Sprouts (fresh)	

Exemptions Tool

Exemptions to the Food Traceability Rule

You are subject to the Food Traceability final rule, *unless* an exemption applies. To determine whether you may be exempt, please click on any of the following categories that may apply to you:

Farms

Certain types of processing

Commingled raw agricultural commodities (RACs)

Personal consumption, holding food for specific consumers

Fishing vessels, molluscan shellfish

Other

Retail food establishments (RFEs), restaurants



Traceability Plan Example

Traceability Plan Example for Restaurants (continued)

Traceability Plan	Page 1 of 1	
BUSINESS NAME: Sammy's Sandwich Shoppe	ISSUE DATE	01/01/2028
ADDRESS: 123 Main Street, Anytown, CA 12345	SUPERSEDES	01/20/2026

Procedures to Maintain the Records

Hard copies of Invoices and Bills of Lading are scanned and stored in an electronic filing system located on our local computer system. Digital advance shipment notices that have been received are also maintained in an electronic filing system located on our local computer system. Records are maintained for two years.

Procedures to Identify FTL Foods

All suppliers to Sammy's Sandwich Shoppe are obligated by contract to identify FTL Foods on the records provided when shipments are received (either paper copies provided at receiving or electronically sent ahead of shipment receipt).

Assigning Traceability Lot Codes

We do not assign TLCs.

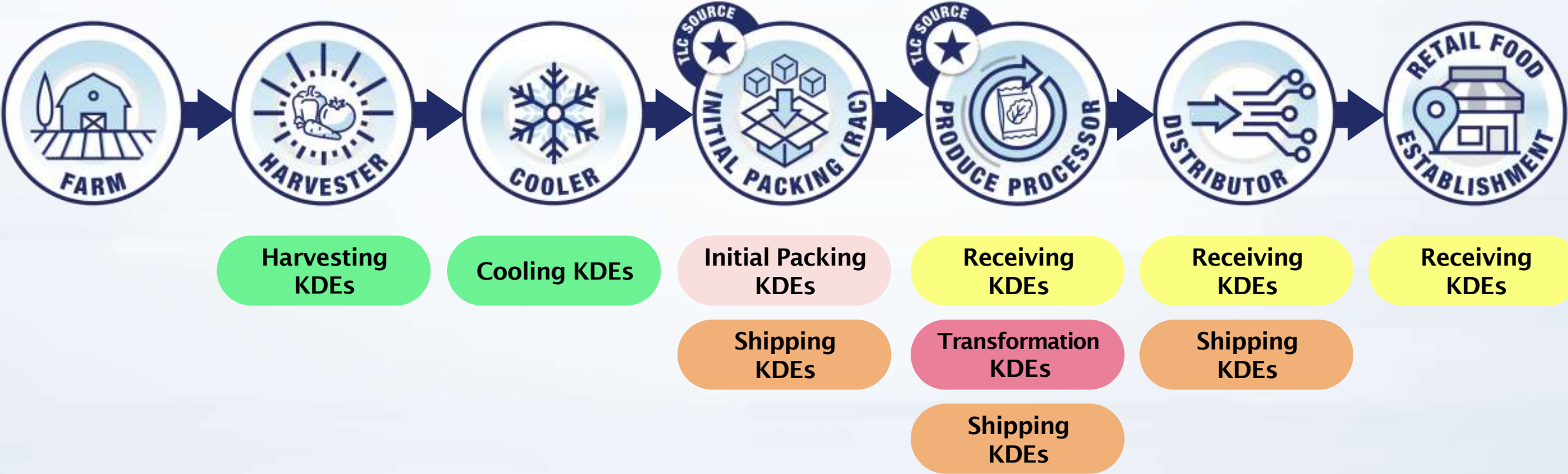
Point of Contact

Steve McGee, Manager, 456-789-1233

Traceability Plan Updates

This plan is reviewed annually as part of our management review of our food safety program, as well as whenever something changes in our traceability procedures. Each previous traceability plan is kept in a folder on our local computer system for at least two years after it is updated.

Supply Chain Example: Fresh Produce



Electronic Sortable Spreadsheet Example



<u>Location Description for the Immediate Subsequent Recipient (other than a transporter) - Business Name</u> (Name of the Company Operating the Location Receiving the Food)	<u>Location Description for the Immediate Subsequent Recipient (other than a transporter) - Phone Number</u> (Phone Number to Call the Location Receiving the Food)	<u>Location Description for the Immediate Subsequent Recipient (other than a transporter) - Street Address or Geographic Coordinates</u> (Street Address or Geographic Coordinates of the Actual Location Where the Food is Received)
Cathy's Cooler	+1.123.123.1231	123 Park Ave
Cathy's Cooler	+1.123.123.1231	123 Park Ave
Fresh Processor Plant #16	+1.114.114.1141	114 Hill St
Ca Mau Shrimp Farm - Cooling Shed	+84 99 999 88 33	123 Nguyen

What can industry do to get started?

1. Do you manufacture, process, pack or hold a food on the [Food Traceability List](#)?
2. Do [any exemptions apply](#) to your situation?
3. What [Critical Tracking Events \(CTEs\)](#) do you conduct?
4. What [Key Data Elements \(KDEs\)](#) do you already maintain? What additional KDEs do you need to maintain to be in compliance with the final rule?
5. Develop a [traceability plan](#).
6. Talk with your supply chain partners.
 - Understand the record keeping practices in your supply chains
 - Determine how best to communicate required information
 - Discuss potential solutions



FTR Training for Industry with FSPCA



Goals

- Provide an understanding of the rule
- Considerations for how to build a traceability program



Target Audience

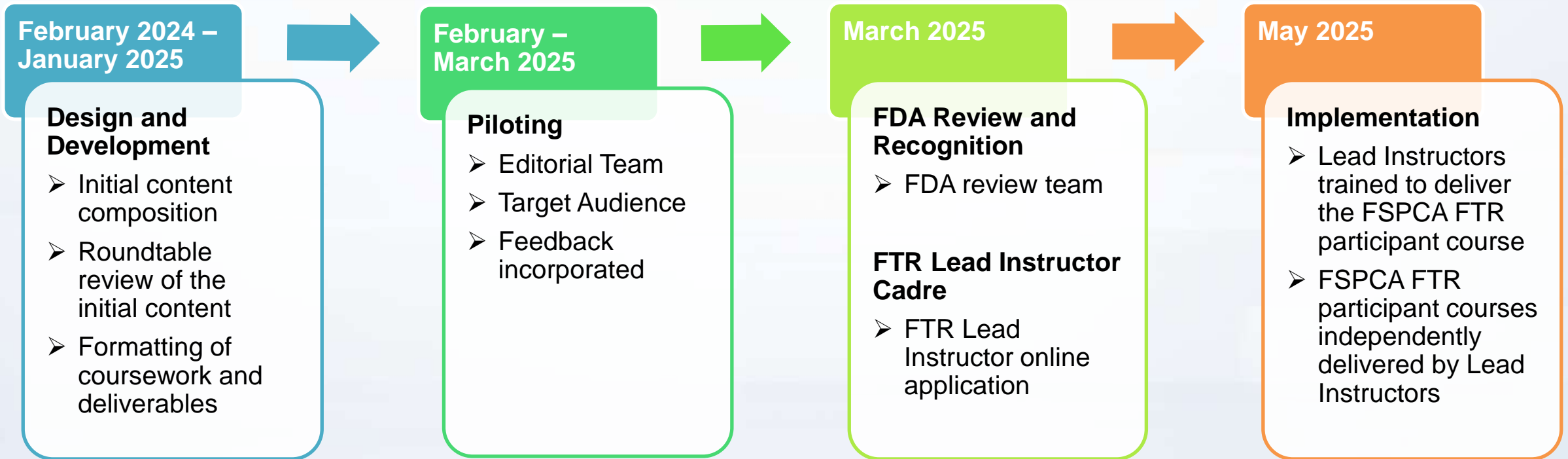
- All persons covered by the rule



Modality

- Train-the-trainer model
- Lead Instructors will deliver the training
- In person and virtual offerings

FTR Training Timeline



FTR Training Chapter Topics

- Introduction and Background
- Application of the Rule
- Critical Tracking Events and Key Data Elements
- Traceability Plan Requirements
- Recordkeeping Requirements
- Building a Traceability Program
- Data System Characteristics
- How Lot Codes Move through the Supply Chain

How to become a FTR Lead Instructor

- There are three overarching benchmarks against which FSPCA FTR Lead Instructor applicants will be evaluated. They are:
 - Food Safety Instructor Experience
 - Education
 - Work Experience
- The benchmarks are equally weighted and the specific criteria for each benchmark is being developed.
- Approved FTR Lead Instructor applicants must successfully complete an FTR Combination Course (participant and Lead Instructor course) to be eligible to register and deliver the FSPCA FTR participant courses

MAIN
CONFERENCE
ROOM

BREAKOUT SESSION: ASK AN EXPERT FDA PERSPECTIVES ON HUMAN FOOD



EXPERT
GLENN BASS

U.S. FOOD AND DRUG
ADMINISTRATION
(FDA)



MODERATOR/SCRIBE
LILLIAN HSU

U.S. FOOD AND DRUG
ADMINISTRATION
(FDA)

FSPCA

“Ask The Expert”



Glenn Bass
Deputy, Office of Human Food
Inspectorate, West
[*Glenn.Bass@FDA.HHS.GOV*](mailto:Glenn.Bass@FDA.HHS.GOV)
240-402-4894



Agenda

1

What's New in FSMA

2

New Model for Field Operations

3

New Model for Human Food Program

4

FDA Inspections by the Numbers

5

Report a Product Problem

6

Recalls



What's New in FSMA?



What's New in FSMA?

- [2024 Food Facility Biennial Registration Renewal](#) Period: 10/1/2024 through 12/31/2024
- [FDA Proposes to Exempt Certain Cottage Cheese From Traceability Requirements](#)
- [Final Rule: Pre-Harvest Agricultural Water](#)
- [Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food](#)
- [Fees: FY2025 User Fee Rates Under the Food Safety Modernization Act for the Voluntary Qualified Importer Program the Accredited Third-Party Certification Program](#)
- [FDA Concludes Voluntary Pilot Program to Evaluate Alignment of Third-Party Food Safety Standards with FSMA Rules](#)

Frequently Asked Questions on FSMA

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Food Safety
Modernization Act (FSMA)

Frequently Asked
Questions on FSMA

FSMA Rules & Guidance
for Industry

What's New in FSMA

[FSMA Training](#)

[FSMA Technical
Assistance Network \(TAN\)](#)

The following are questions and answers related to the Food Safety Modernization Act (FSMA).


For additional assistance with **human food** topics, [submit your question to the TAN](#) .

For additional assistance with **animal food** topics, email the [CVM TAN Mailbox](#).


Content current as of:
06/11/2024

Regulated Product(s)
Animal & Veterinary
Food & Beverages


Law(s) & Regulation(s)
Food Safety Modernization
Act

Dietary Supplements 


Enforcement 

Food Packaging Manufacturers 

Food Safety Plans 

Food Traceability Rule 

Foreign Supplier Verification Program (FSVP) 

Intentional Adulteration/Food Defense 

Laboratory Accreditation for Analyses of Foods (LAAF) 

Preventive Controls - General 



New Model for Field Operations

*The new Office of Inspections and Investigations
(OII)*

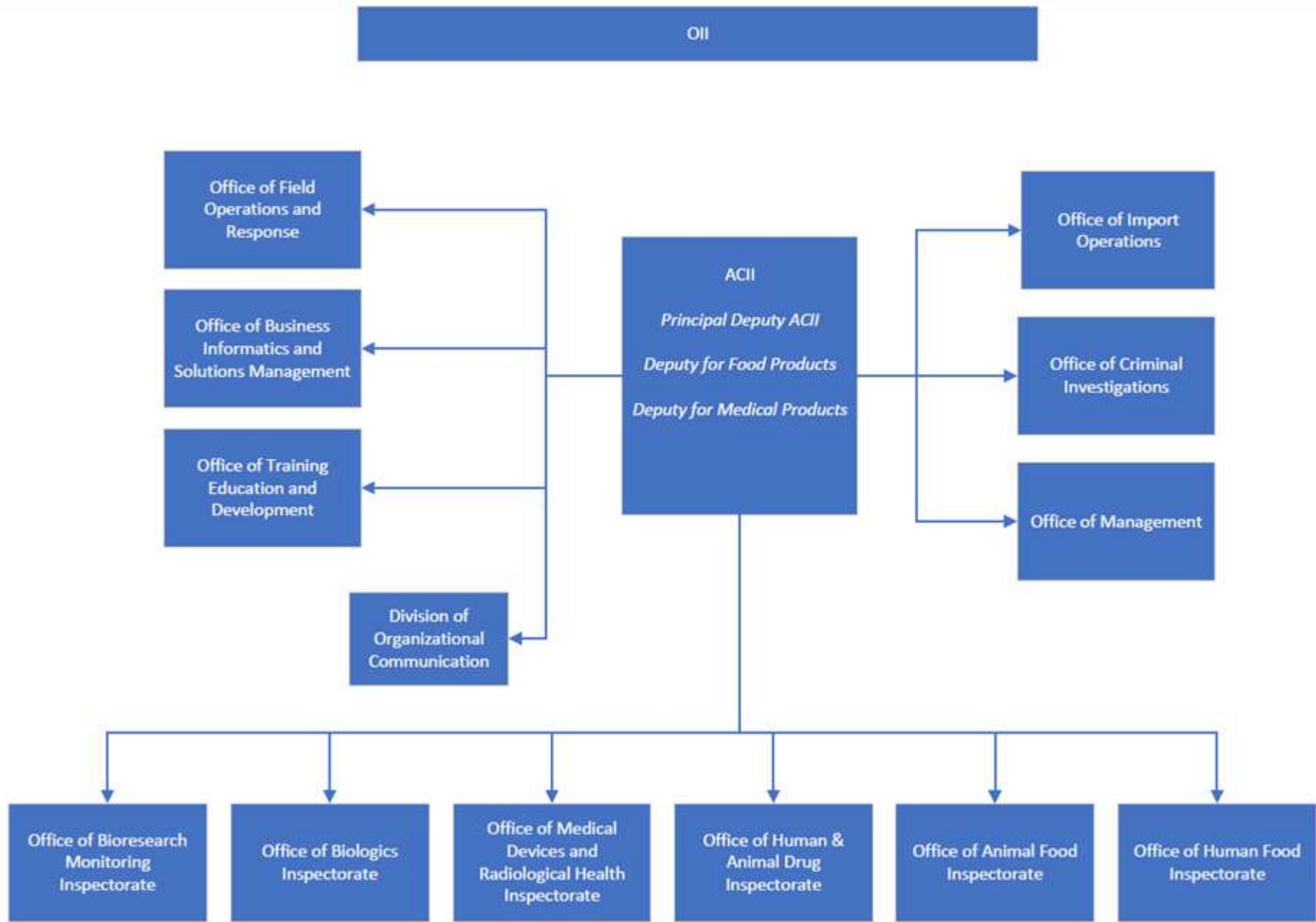


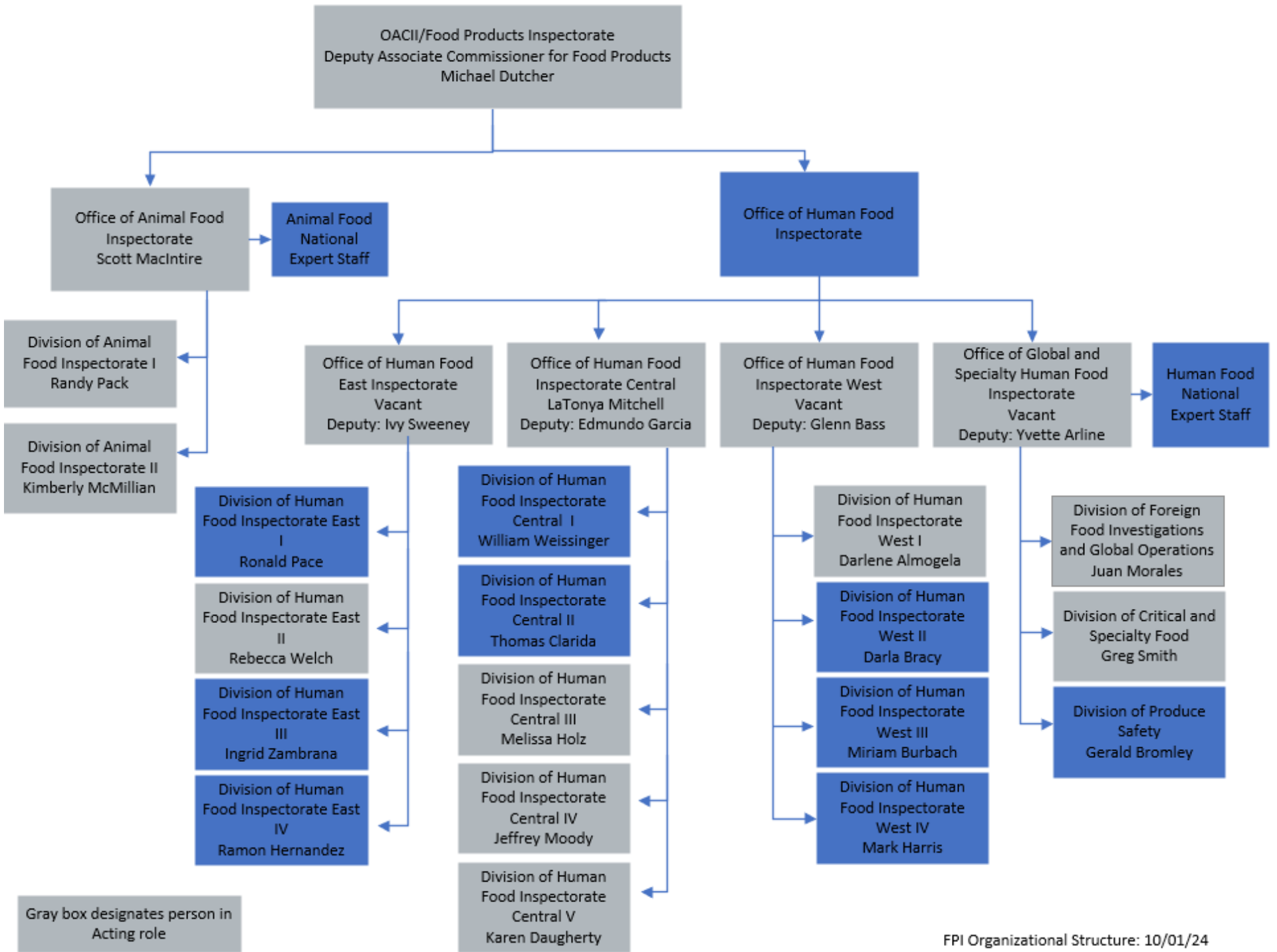
Legend:

Directly impacted by reorganization that took effect on Oct. 1, 2024 (i.e., shifts of functions, resources and/or personnel)

**Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations**







Gray box designates person in Acting role



Geographic Boundaries Overview



Office of Regulatory Affairs (ORA)

Office of Human and Animal Food Operations (OHAFO)



HAF Program Divisions

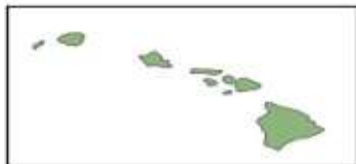
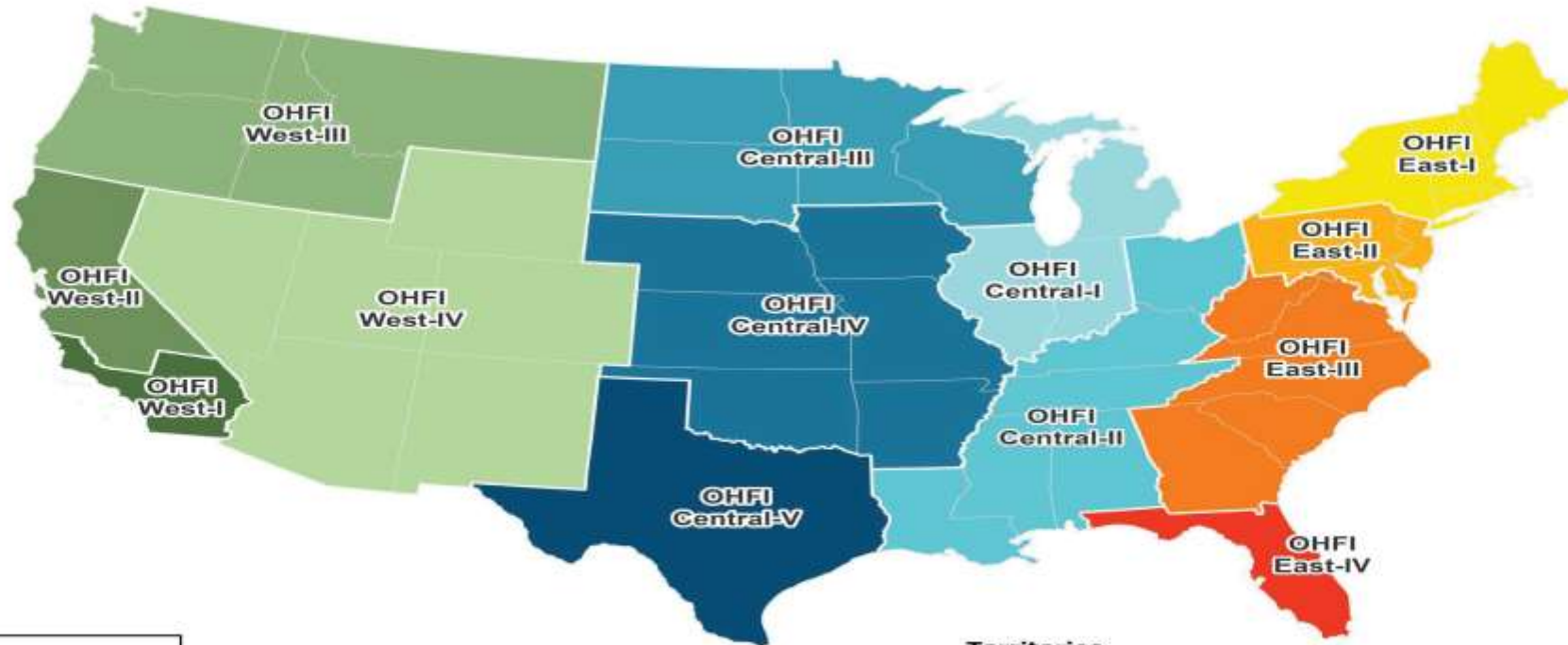
Division 1W (MIN)	Division 1E (NWE, NYK)
Division 2W (KAN)	Division 2E (BLT, NWJ, PHI)
Division 3W (DAL)	Division 3E (ATL)
Division 4W (DEN, LOS)	Division 4E (FLA, SJN)
Division 5W (LOS, SAN)	Division 5E (CIN, NOL)
Division 6W (SEA)	Division 6E (CHI, DET)
FDA Current Districts Boundaries	
Arizona State Boundaries	



Office of Inspections and Investigations



Office of Human Food Inspectorate (OHFI)



Territories

USVI
AS
GU
MP

OHFI Divisions	
East-I	Central-I
East-II	Central-II
East-III	Central-III
East-IV	Central-IV
	Central-V
	West-I
	West-II
	West-III
	West-IV
	State

Office of Human Food Inspectorate (OHFI)

Division Boundaries

New OII/OHFI Division	States	Districts
HFI East 1	CT, MA, ME, NH, NY, RI, VT	NWE-DO NYK-DO
HFI East 2	DE, NJ, PA, MD, DC	PHI-DO, NWJ-DO, BLT-DO
HFI East 3	VA, WV, GA, NC, SC	BLT-DO, ATL-DO
HFI East 4	FL, PR, VI	FLA-DO, SJN-DO
HFI Central 1	IL, IN, MI	CHI-DO DET-DO
HFI Central 2	OH, KY, TN, LA, AL, MS	CIN-DO, NOL-DO
HFI Central 3	WI, MN, ND, SD	MIN-DO
HFI Central 4	IA, KS, MO, NE, AR, OK	KAN-DO, DAL-DO
HFI Central 5	TX	DAL-DO
HFI West 1	Southern CA	LOS-DO
HFI West 2	Northern CA	SAN-DO
HFI West 3	AS, GU, MP, HI, AK, ID, MT, OR, WA	SAN-DO, SEA-DO
HFI West 4	AZ, NV, CO, UT, NM, WY	DEN-DO, SAN-DO, LOS-DO



New Model for Human Food Program Offices (HFPO)



Human Food Program Offices (HFP)

Office of
Compliance and
Enforcement

Office of Chemical
Safety, Dietary
Supplements and
Innovation

Nutrition Center of
Excellence

**Office of
Microbiological
Food Safety**

Office of
Enforcement (OE)

Office of
Surveillance
Strategy and Risk
Prioritization

Office of
Communication,
Education and
Engagement

Office of Quality
Assessment and
Management

Office of
Compliance
Intervention and
Consultation (OCIC)

**Office of Strategic
Programs**

Office of Integrated
Food Safety System
Partnerships

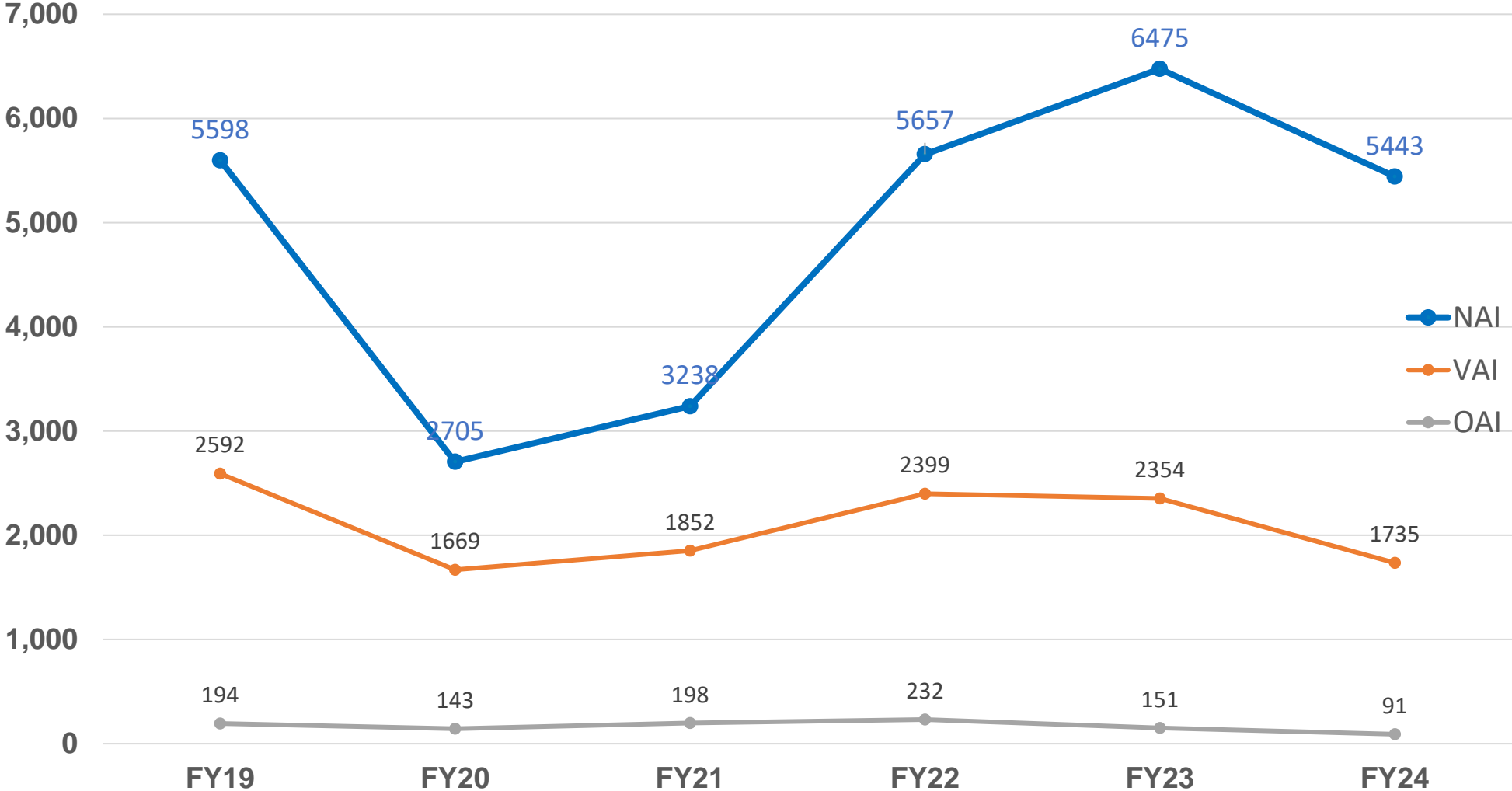
Office of Policy and
International
Engagement



FDA Inspections by the Numbers



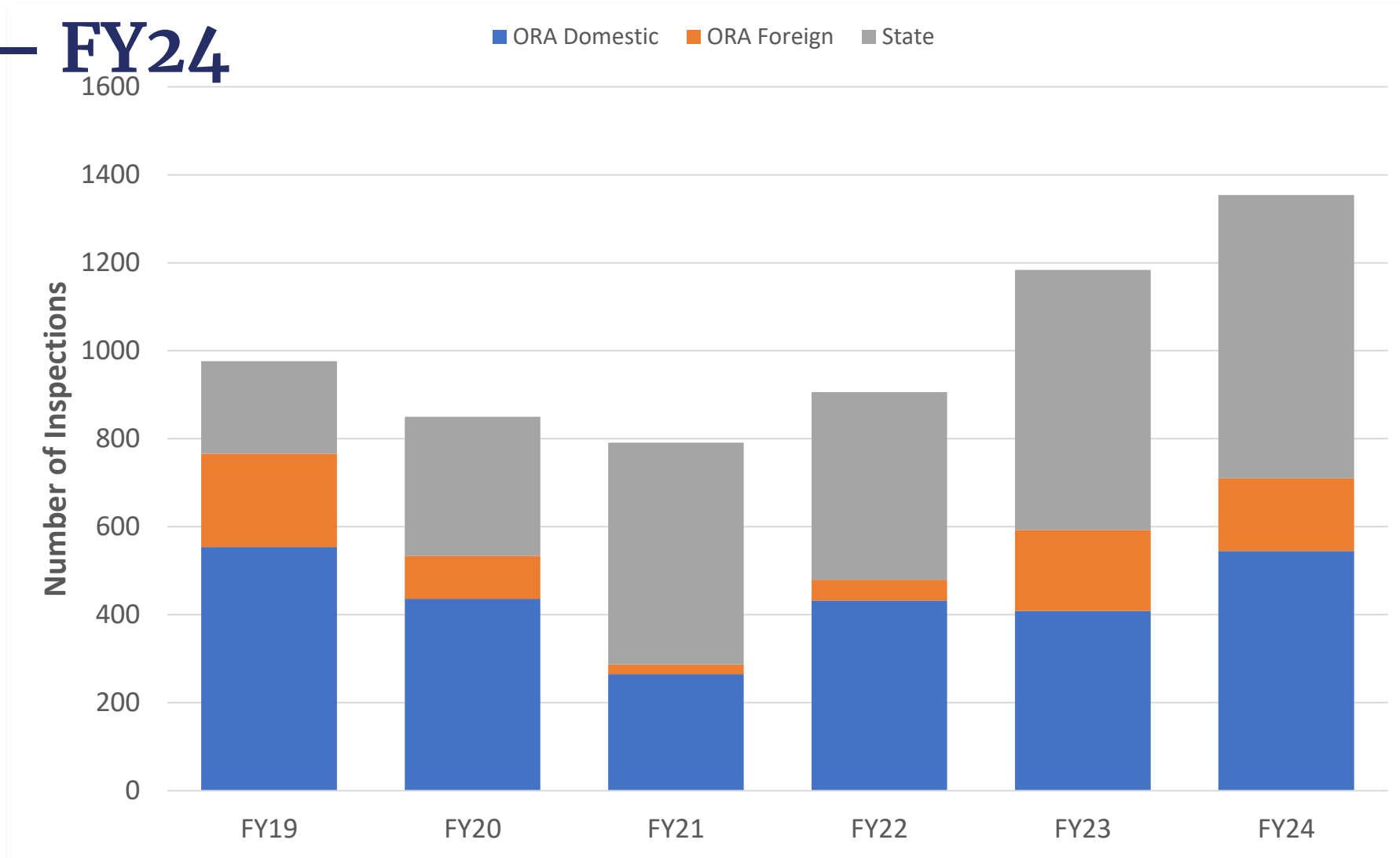
Food Inspections, FY19 – FY24



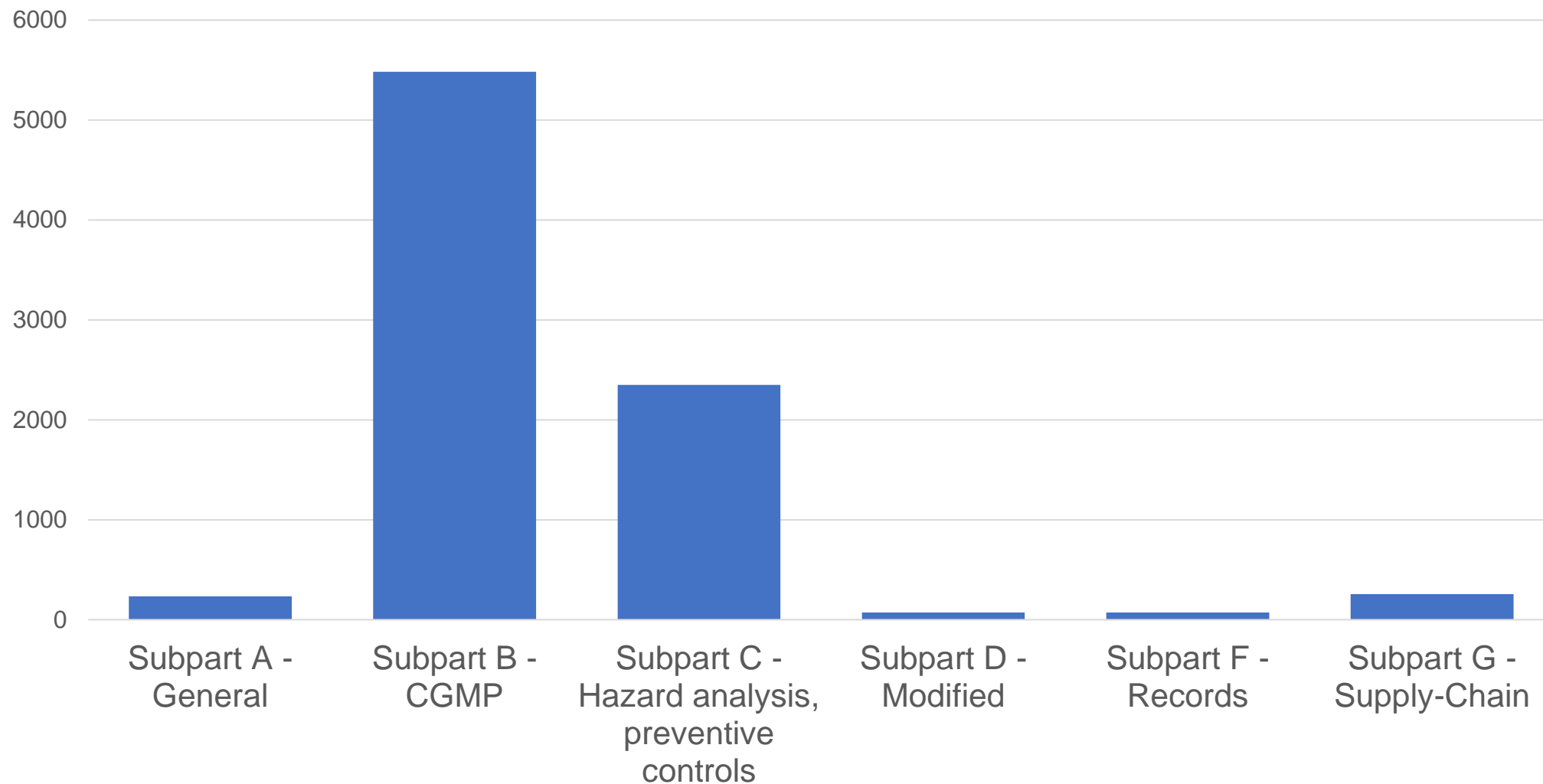
Preventive Controls Human Food, 21 CFR

117

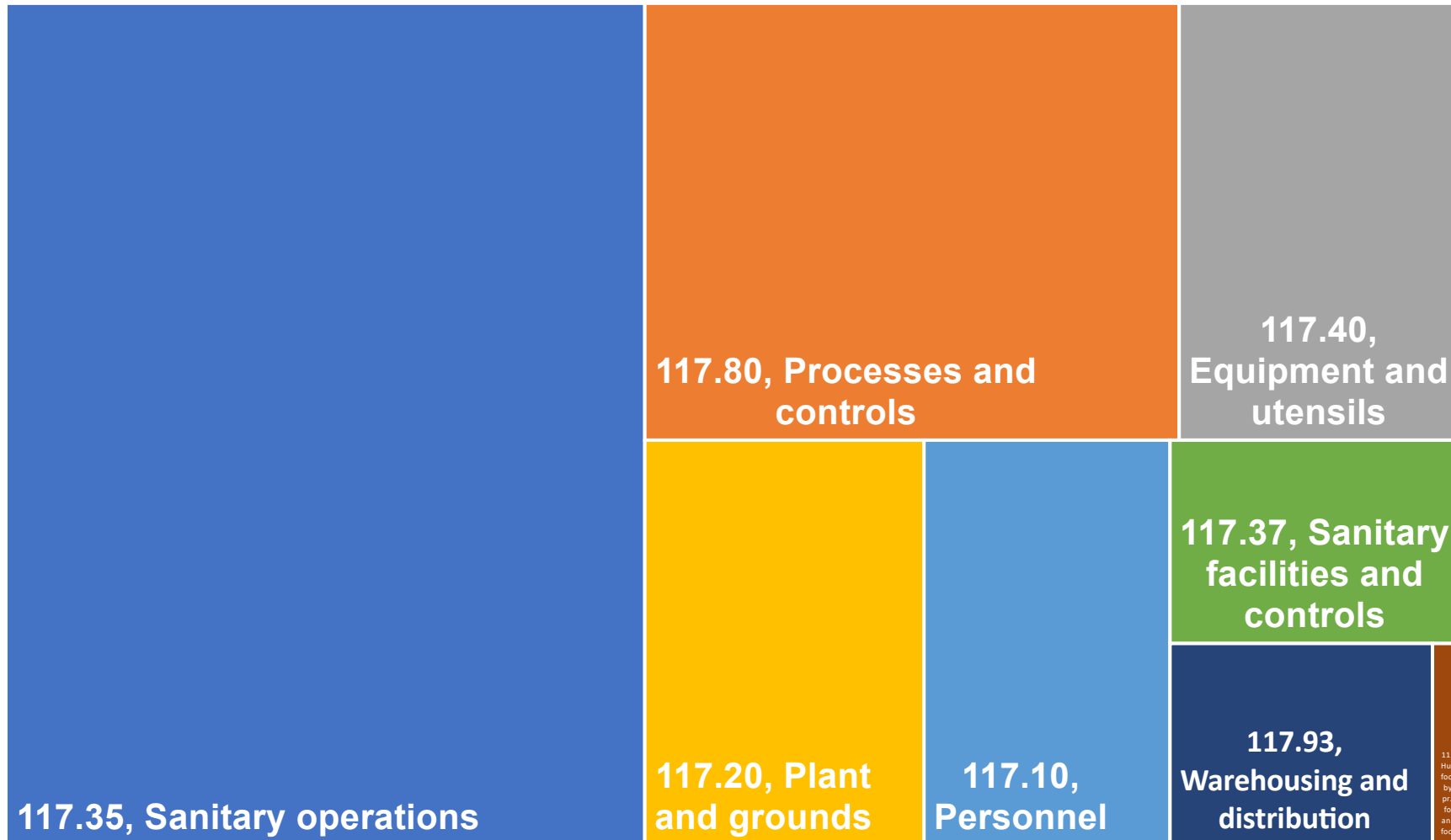
FY19 – FY24



Preventive Controls HF, 21 CFR 117 Observations, FY19 – FY24



Preventive Controls HF, 21 CFR 117 Subpart B Observations, FY19 – FY24



Operation Code	CITE ID	CFR/FDCA Number	SHORT DESCRIPTION	FULL LONG DESCRIPTION	COUNT
12	18141	21 CFR 117.35(a)	Sanitary operations - Plant maintenance	You did not maintain your plant [in a clean and sanitary condition] [in adequate repair]. Specifically, ***	317
12	18138	21 CFR 117.10	Personnel	You did not take a reasonable measure or precaution related to personnel practices. Specifically, ***	304
12	18145	21 CFR 117.35(c)	Pest control	You did not [exclude pests from your food plant] [use pesticides under precautions and restrictions] to protect against contamination of food. Specifically, ***	290
12	18161	21 CFR 117.80(c)	Manufacturing, processing, packing, holding - Controls	You did not conduct operations under conditions and controls necessary to minimize the potential for [growth or survival of microorganisms] [allergen cross-contact] [contamination of food] [deterioration of food]. Specifically, ***	258
12	18149	21 CFR 117.40	Equipment and utensils - Design and maintenance	Your equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against [allergen cross-contact] [contamination]. Specifically, ***	202
12	22717	21 CFR 117.130(a)(1)	Hazard analysis - Identification of hazard	Your hazard analysis did not identify a hazard that required a preventive control. Specifically, ***	198
12	18142	21 CFR 117.35(a)	Sanitary operations - Plant sanitation	You did not clean and sanitize your utensils or equipment in a manner that protects against [allergen cross-contact] [contamination]. Specifically, ***	160
12	18140	21 CFR 117.20(b)	Plant construction and design	Your plant was not [constructed] [designed] to facilitate maintenance and sanitary operations. Specifically, ***	149

Inspection Observations – Subpart B (GMP)

117.35 – Sanitary Operations

- Plastic container without label
- Extensive dough residues
- Significant rusting of metal
- Cleaned brush placed on floor, brush still heavily soiled
- Pest control live cats, cat excrement; live birds and bird feathers near uncovered tanks

Inspection Observations – Subpart B (GMP)

117.40 – Equipment and utensils

- Flaking and peeling paint exposed to food
- Shredder plate had pressure of metal-on-metal contact
- Not clean or sanitize to protect against allergen cross-contact (low sanitizer concentration)

Inspection Observations – Subpart B (GMP)

117.80 – Manufacturing, Processing, Packing Controls

- Apparent rodent excreta
- Environmental samples tested positive for *Listeria monocytogenes*
- Rust, corrosion, peeling paint above in-process, RTE product
- Did not maintain cold room or cooler to prevent condensation with in-progress products
- Repeat observations, exposed concrete throughout manufacturing area; liquid pooling on floor and equipment near in-process foods

Inspection Observations – Subpart C

(Hazard analysis and preventive controls)

117.130 – Hazard Analysis

- Repeat observation, hazard analysis did not identify a known or reasonable hazard that required a preventive control.
- Did not identify pathogen (*listeria monocytogenes*) as a hazard requiring a preventive control.
- Did not identify pathogens or recontamination with environmental pathogens as hazards requiring a preventive control.

Inspection Observations – Subpart C **(Hazard analysis and preventive controls)**

117.135 – Preventive Controls

- Did not implement your process preventive control and verification procedures. (temperatures, metal detection)

Inspection Observations – Subpart C

(Hazard analysis and preventive controls)

117.145 – Monitoring

- Repeat observation, did not establish and implement adequate written procedures for monitoring process controls. (metal, labeling – undeclared allergens, environmental pathogens).

Inspection Observations

Egregious Findings

Repeat observations, plant construction, sanitary operations, pest control (holes/cracks in equipment, building, gaps), pest harborage, accumulation of product, presence of live larvae, beetles, insects in product, presence of birds, feathers, bird carcass, rodent activity.

Examples of Voluntary Corrections

- Training of personnel.
- No longer handling product.
- Repaired or maintained equipment.
- Recall plan contained required elements.
- Monitoring records of calibrated devices.

Examples of Voluntary Corrections

- Environmental swabs negative of pathogens.
- Sanitation records and frequency of cleaning.
- Floors repaved and repaired that water could drain.
- Replaced previous equipment; designed to be cleaned and maintained.



Report a Product Problem

FDA's SmarHub



All Categories

Food

Infant Formula

Dietary Supplements

Human Drugs

Medical Devices

Vaccines, Blood, and
Biologics

Pet Foods/Treats and
Livestock Food

Veterinary/Animal
Drugs

Cosmetics

Tobacco Products

Other Safety Issues



Food?

[Report Here](#)



Infant Formula?

[Report Here](#)



Dietary Supplements?

[Report Here](#)



Human Drugs?

[Report Here](#)



Medical Devices?

[Report Here](#)



Vaccines, Blood &
Biologics?

[Report Here](#)



Recall Coordinators



Recall Coordinators

Office of Inspections and Investigations (OII)

Product Type	Division	Firm's State	Contact
Animal Foods	Animal Food Inspectorate	U.S.	Nina Patel oioafianimalfoodrecalls@fda.hhs.gov
Human Food	Human Food Inspectorate West I	Southern CA	Vacant oiihfwest1recalls@fda.hhs.gov
Human Food	Human Food Inspectorate West II	Northern CA	Vacant Email: oiihfwest2recalls@fda.hhs.gov
Human Food	Human Food Inspectorate West III	AK, HI, ID, MT, OR, WA, Guam, Commonwealth of the Northern Mariana Islands, American Samoa	Anh Trinh Nguyen oiihfwest3recalls@fda.hhs.gov
Human Food	Human Food Inspectorate West IV	AZ, CO, NM, NV, UT, WY	Vacant Email: oiihfwest4recalls@fda.hhs.gov

Human Food Inspectorate East, Biologics, Medical Devices, and Pharmaceuticals contacts here:
<https://www.fda.gov/safety/industry-guidance-recalls/oii-recall-coordinators>

Recall Point of Contacts

Office/Division	Recall Coordinators	Recall Email
HFI East 1	Randi-Lynn Bodoh and Melissa Henaghan	oihfeast1recalls@fda.hhs.gov
HFI East 2	Ruark Lanham	oihfeast2recalls@fda.hhs.gov
HFI East 3	Emma Nesbit	oihfeast3recalls@fda.hhs.gov
HFI East 4	Beira Montalvo	oihfeast4recalls@fda.hhs.gov
HFI Central 1	Michael Larson	oihfccentral2recalls@fda.hhs.gov
HFI Central 2	Vacancy (on boarding)	oihfccentral1recalls@fda.hhs.gov
HFI Central 3	Kristine Zuroski	oihfccentral3recalls@fda.hhs.gov
HFI Central 4	Jeannie Vonderbrink, Acting	oihfccentral4recalls@fda.hhs.gov
HFI Central 5	Brandi Williams	oihfccentral5recalls@fda.hhs.gov
HFI West 1	Vacancy (on boarding)	oihfwest1recalls@fda.hhs.gov
HFI West 2	Vacancy (on boarding)	oihfwest2recalls@fda.hhs.gov
HFI West 3	Anh Trinh Nguyen	oihfwest3recalls@fda.hhs.gov
HFI West 4	Vacancy (on boarding)	oihfwest4recalls@fda.hhs.gov
Animal Food Recalls	Nina Patel	oiioafianimalfoodrecalls@fda.hhs.gov



Training Update



Training Update



FD254 PC for Human Food –
FDA only course in Orlando,
FL, February 2025



Dietary Supplement Training
– OJE will be required for this
course starting with the
December 2024 course.

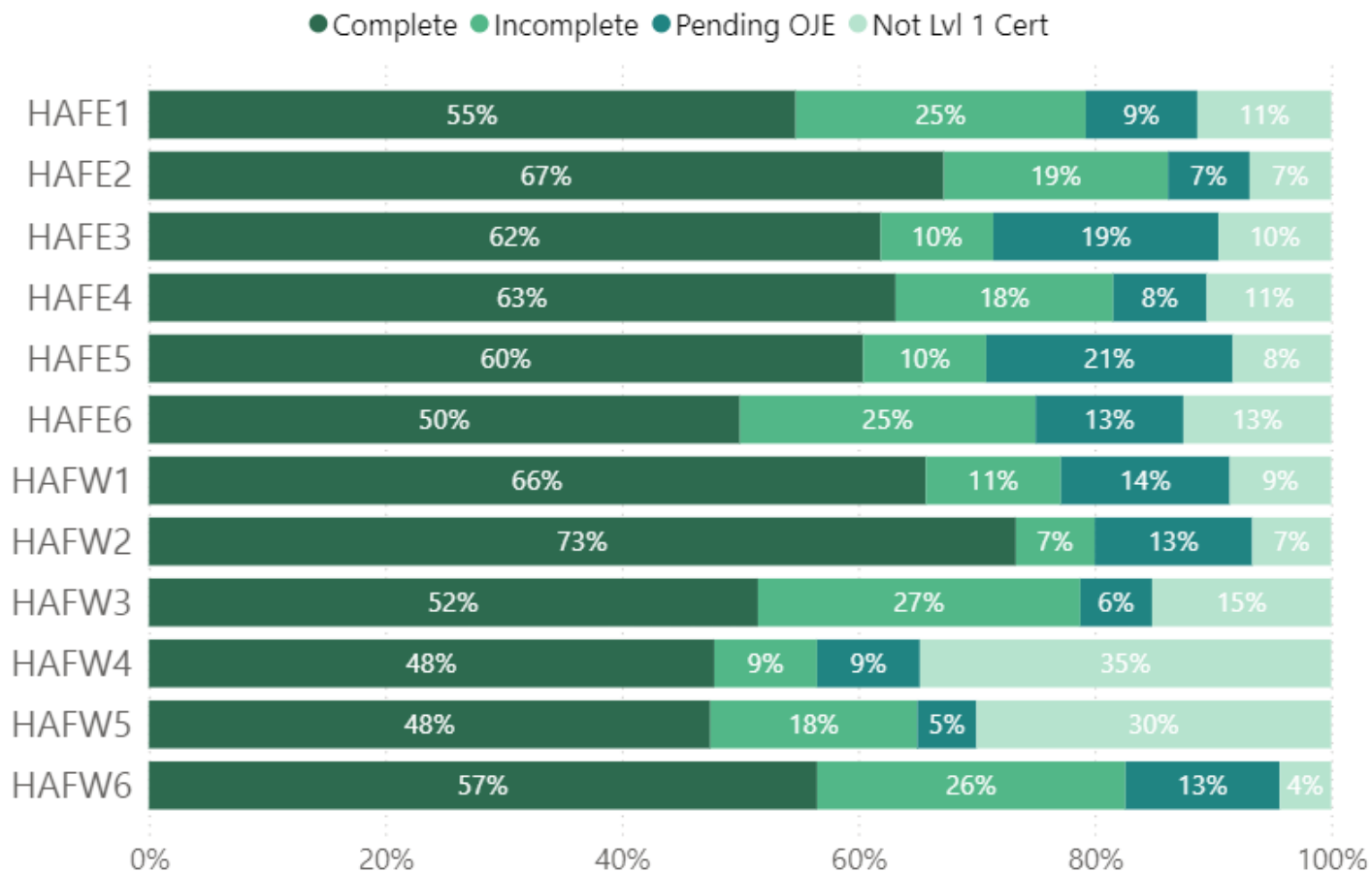
The Work Continues

Course

FD254-Preventive Control

Select a single course using the drop-down filter above

Number of CSOs with Selected Course(s) Complete



The Work Continues

FY 25
Priorities

2 Tier
Program

Revised
rTAN

Industry
Portal

KEEP MOVING THE CHEESE

**NOTHING
CHANGES**

IF

**NOTHING
CHANGES**

Thank You



Glenn Bass



Deputy Director



Office of Human Food
Inspectorate West



(OHFI-West)



Glenn.Bass@fda.hhs.gov



240-402-4894

**SALON
4**

BREAKOUT SESSION: ASK AN EXPERT FDA PERSPECTIVES ON ANIMAL FOOD



EXPERT
JENNIFER ABRAHAMZON
U.S. FOOD AND DRUG
ADMINISTRATION (FDA)



EXPERT
DAVID FAIRFIELD
NATIONAL GRAIN AND
FEED ASSOCIATION (NGFA)



MODERATOR/SCRIBE
CHRIS LINCECUM
COOPERATIVE FARMERS
ELEVATOR (CFE)

FDA Perspectives on Animal Food

Jennifer Abrahamzon

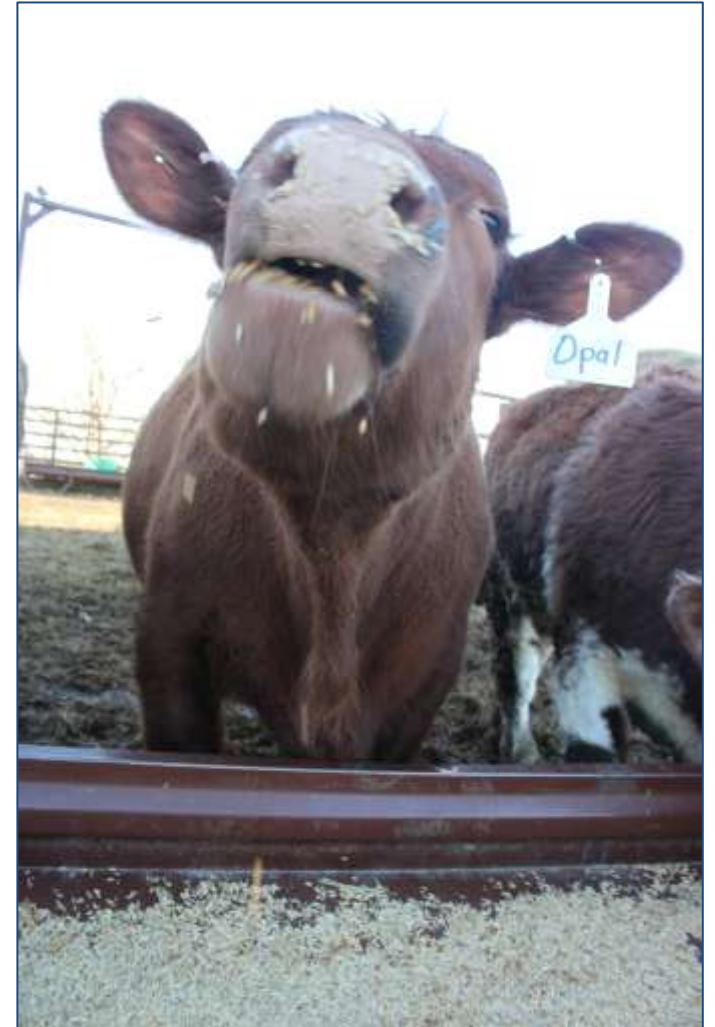
CVM Office of Surveillance and Compliance

November 19, 2024



Today's Menu

- FDA Perspectives
 - FDA Reorganization & Animal Food
 - Comprehensive Inspection & Compliance
 - Inspectional Updates
 - Animal Food Resources



FDA
Reorganization



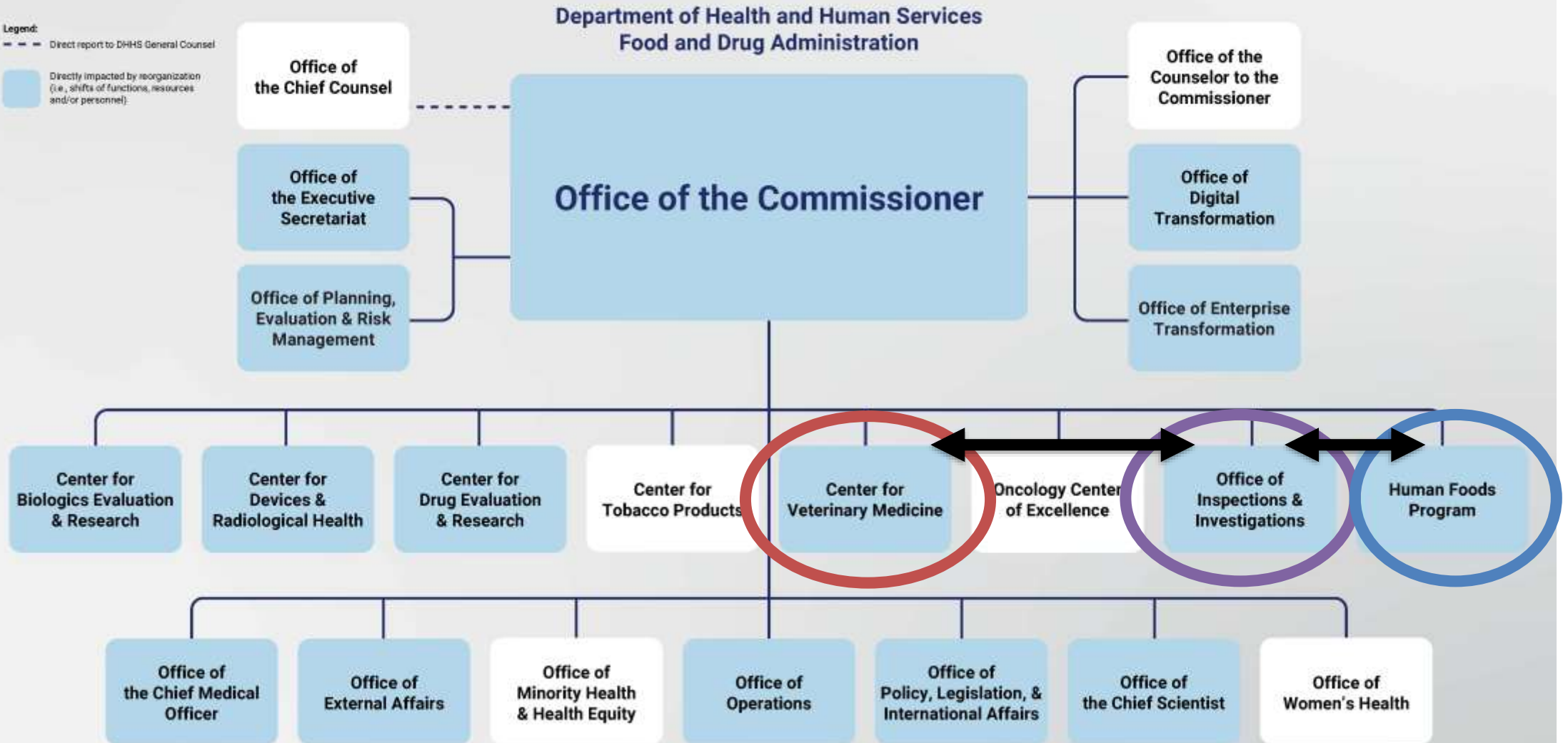
FDA Reorganization



Legend:

- - - Direct report to DHHS General Counsel

Directly impacted by reorganization (i.e., shifts of functions, resources and/or personnel).



[†]The elements of the reorganization are the same as those proposed in December 2023.

[‡]The changes reflected here will be implemented when all required reorganization steps have been met.

FDA Reorganization



Legend:
Directly impacted by reorganization (i.e., shifts of functions, resources and/or personnel)

Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations



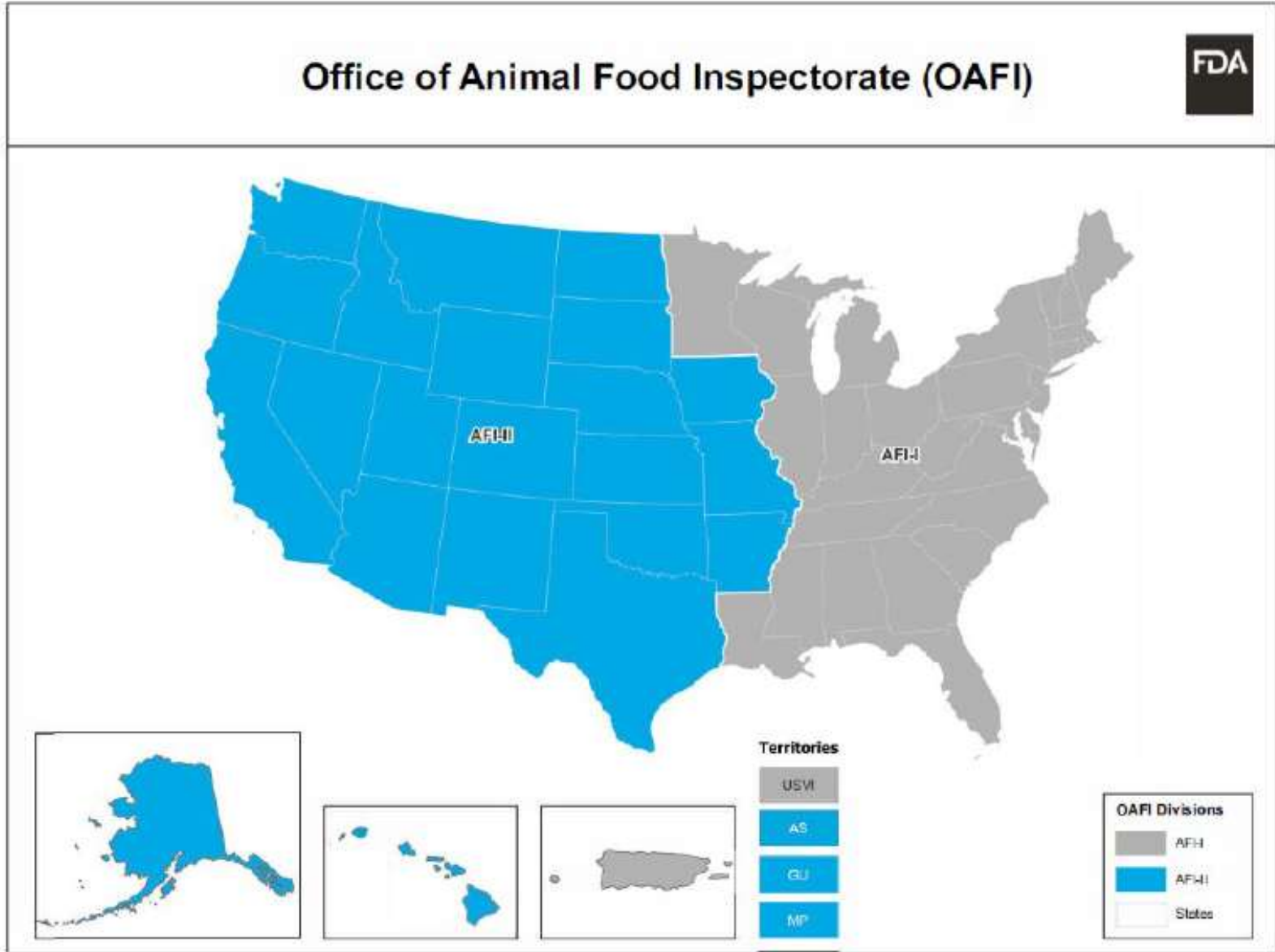
†The elements of the reorganization are the same as those proposed in December 2023.
†The changes reflected here will be implemented when all required reorganization steps have been met.

*Includes Division of Tobacco Inspectorate
**Includes specialized teams for products such as infant formula

What does this mean for you?

- Animal food investigators will only be performing animal food inspections
 - Office of Animal Food Inspectorate -> Animal Food East/West Divisions
 - Overall program coordination (workplanning, inspections, etc.)
 - POCs will change (expected on our website as implementation continues)
- Functions are shifting –
 - Many functions handled by your District Office will continue to be handled by the Office of Animal Food Inspectorate (e.g., inspections, sampling, etc.)
 - Some functions currently handled by your District Office will now be handled centrally, either CVM or OII (e.g., coordination of emergency response, recalls, complaints, post-inspection compliance activities)

FDA Reorganization



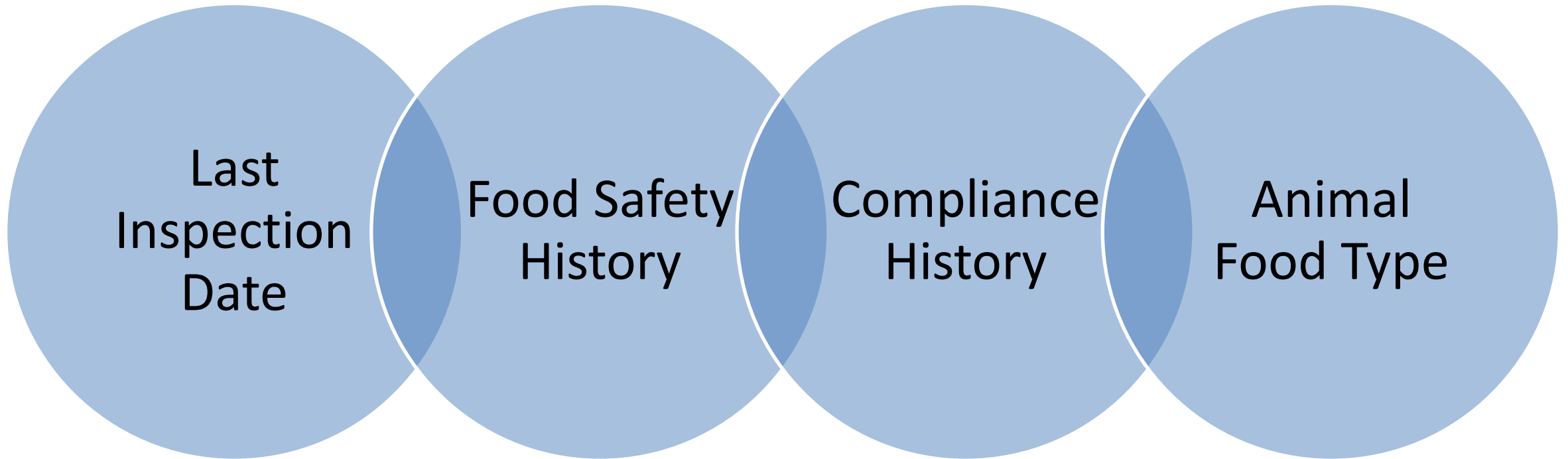
Comprehensive
Inspections &
Compliance



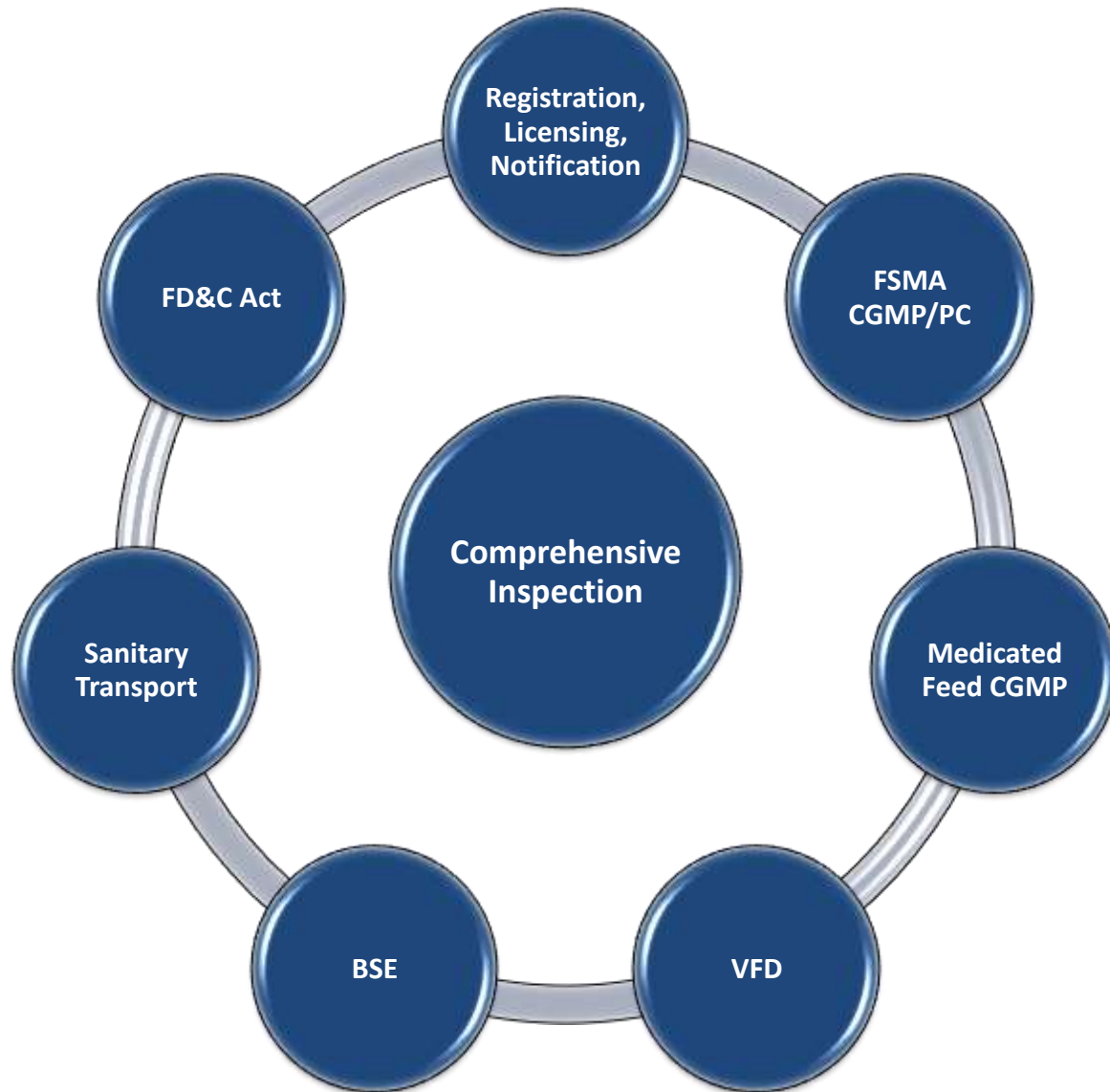
Risk-Based Inspection Inventory



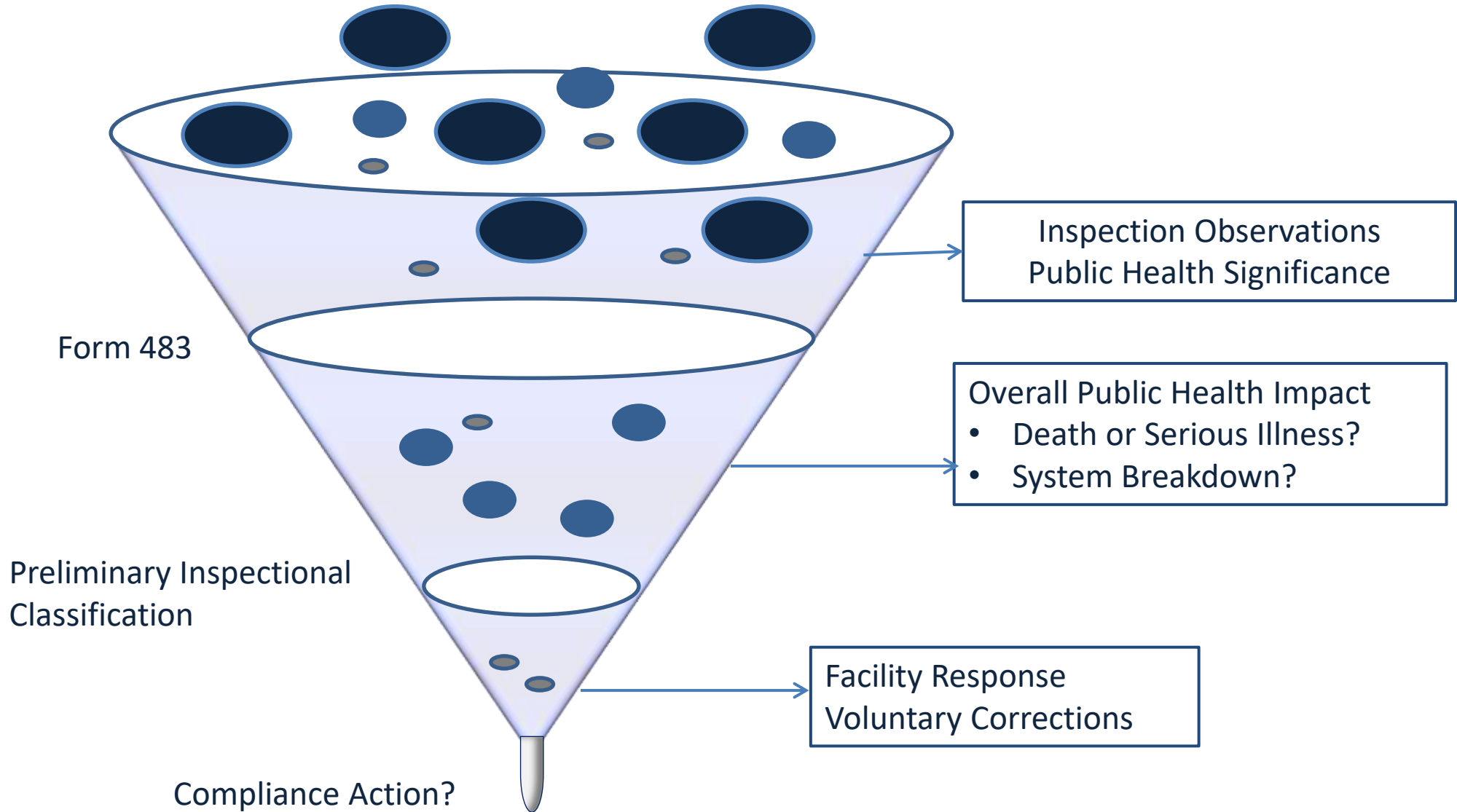
Risk-based factors for prioritizing animal food facility inspections



Comprehensive Inspection



Post-Inspection Compliance



Inspectional Updates



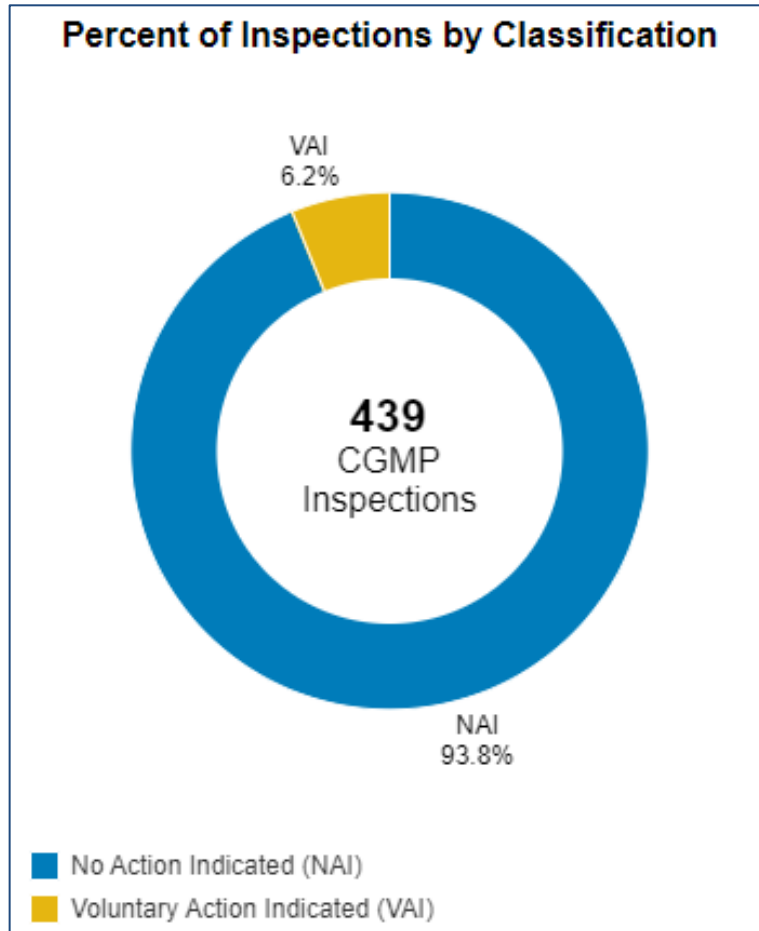
Inspectional Classifications

- No Action Indicated (NAI)
 - No objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further action).
- Voluntary Action Indicated (VAI)
 - Objectionable conditions were found and documented but the Agency is not prepared to take or recommend any of the regulatory actions since the objectionable conditions do not meet the threshold for regulatory action.
- Official Action Indicated (OAI)
 - Objectionable conditions were found, and regulatory action should be recommended.

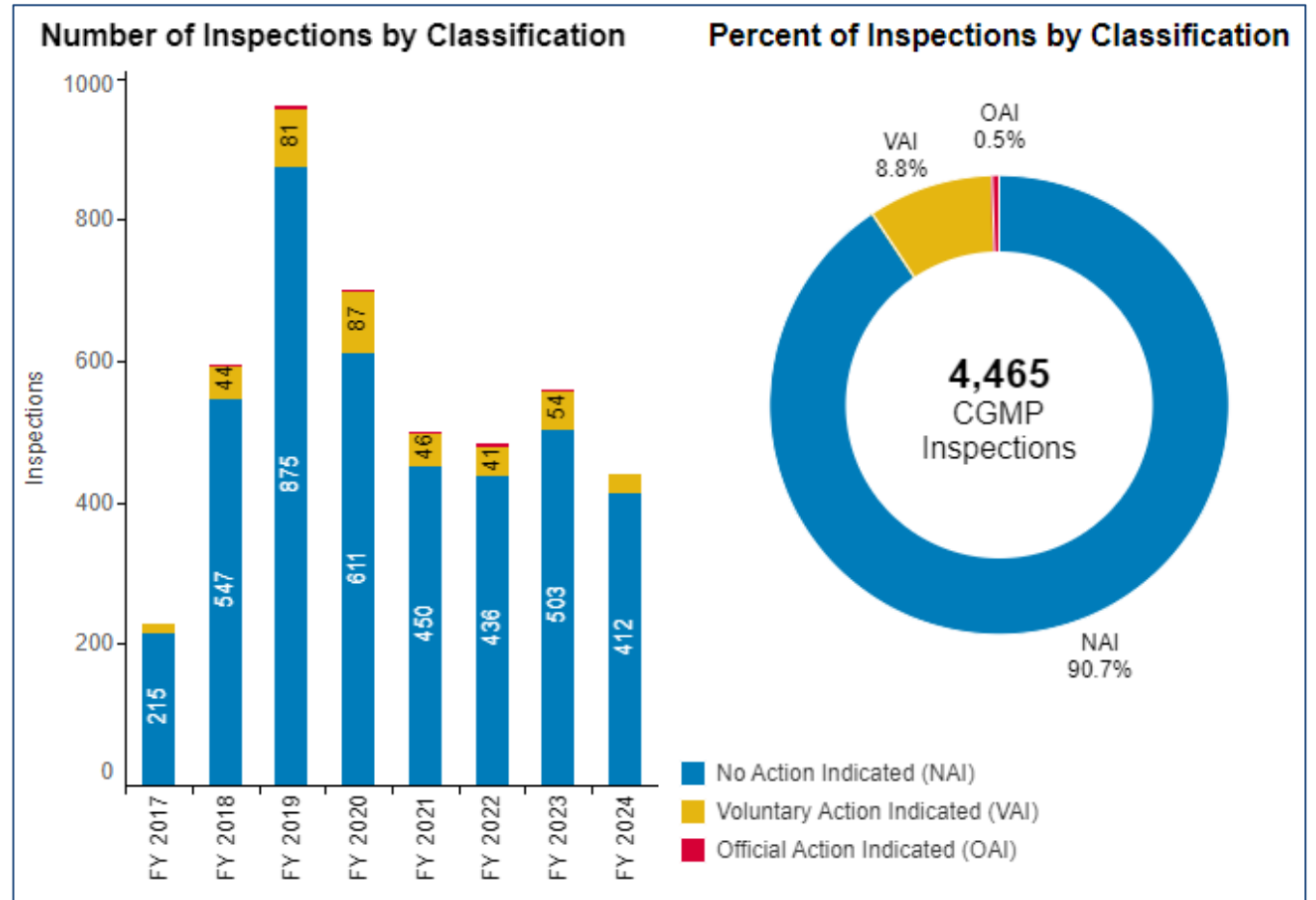
FSMA Metrics – CGMP Inspections



FY24 FDA and State CGMP Inspections



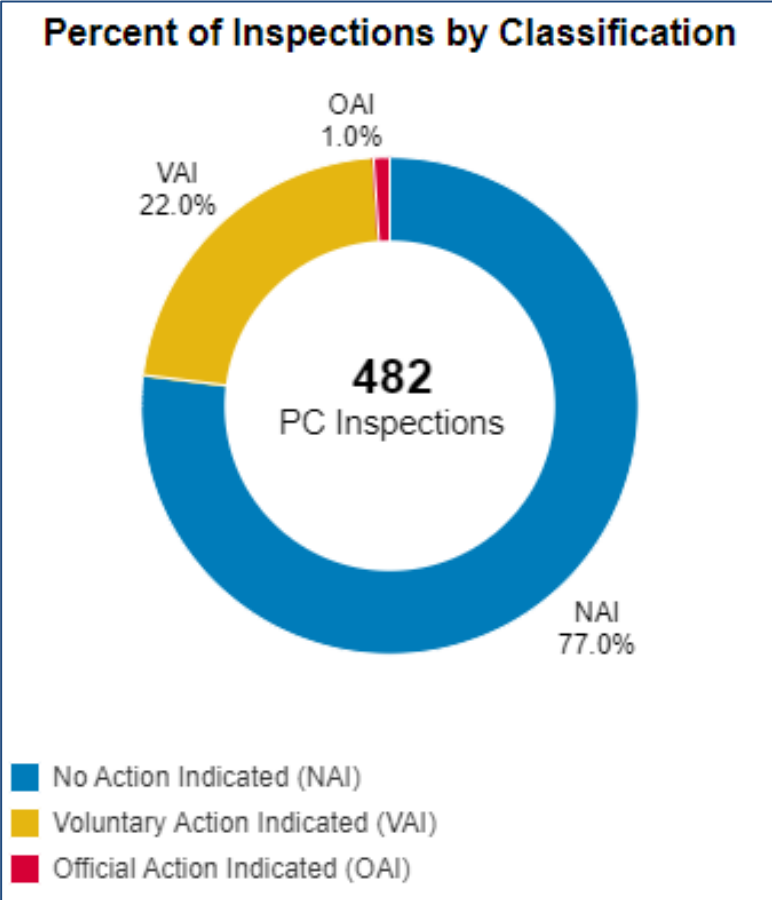
Historical FDA and State CGMP Inspections



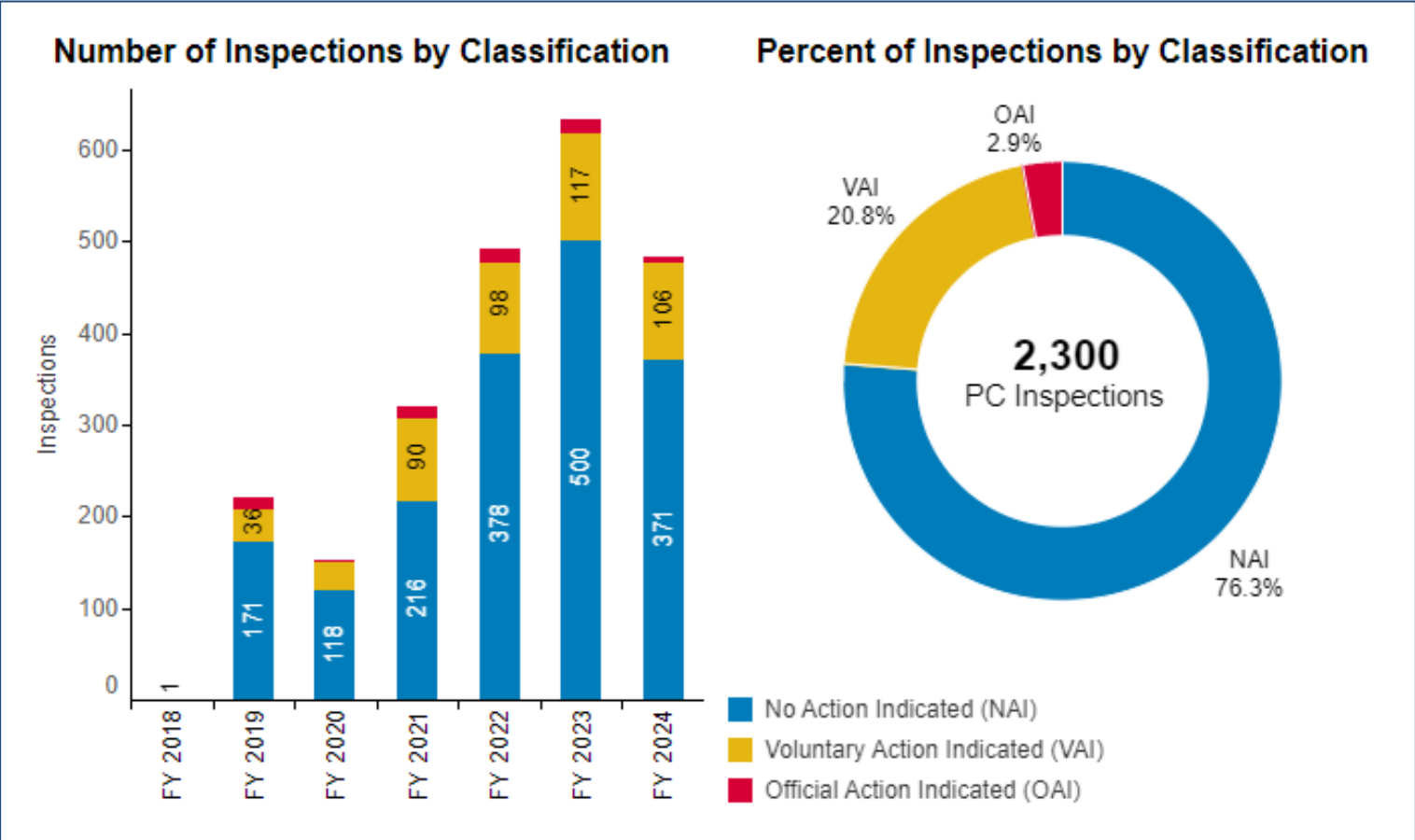
FSMA Metrics – PC Inspections



FY24 FDA and State PC Inspections



Historical FDA and State PC Inspections



Top 5 Animal Food Citations

CFR/FDCA Number	SHORT DESCRIPTION	FULL LONG DESCRIPTION
21 CFR 507.33(a)	Hazard Analysis	You did not [have a written hazard analysis] [identify and evaluate each known or reasonably foreseeable hazard] [include an evaluation of environmental pathogens] for each type of animal food you manufacture, process, pack or hold in your facility. Specifically, ***
21 CFR 507.34(a)(1)	Preventive Controls	You did not identify and implement preventive controls to ensure that any hazards requiring a preventive control are significantly minimized or prevented. Specifically, ***
21 CFR 507.31(a)	Food Safety Plan	You did not have a written food safety plan. Specifically, ***

Top 5 Animal Food Citations

CFR/FDCA Number	SHORT DESCRIPTION	FULL LONG DESCRIPTION
21 CFR 507.25(b)(2)	Contamination with Mycotoxins/Natural Toxins	You did not [evaluate] [use] the [raw materials] [ingredients] susceptible to contamination with mycotoxins or other natural toxins in a manner that does not result in animal food that can cause injury or illness to animals or humans. Specifically, ***
21 CFR 507.25(a)	Plant Operations	You did not [conduct operations in accordance with current good manufacturing practices] [ensure the safety and suitability of the food-packaging materials] [assign supervision of overall plant cleanliness] [take adequate precautions to prevent contamination of animal food] [use testing procedures to identify sanitation failures] [reject, treat or process to eliminate contaminated food] [conduct all animal food manufacturing under such conditions and controls to protect against contamination of animal food]. Specifically, ***

Animal Food Resources



Animal Food Resources

- [How do I Start an Animal Food Business? | FDA](#)
 - New resource for industry
 - Organizes all regulatory requirements that apply to animal food businesses by activities
 - Provides one place for businesses to go to determine what regulatory requirements apply and to easily access resources based on the regulations that they must comply with
- [FDA Resources for Animal Food Facilities](#)
 - One page printable resource with QR codes to animal food resources
- [Animal Food Facility Registration and Qualified Facility Attestation Frequently Asked Questions](#)



PCHF VERSION 2.0 - A NEW APPROACH TO HAZARD ANALYSIS

KATHY GOMBAS
FSMA SOLUTIONS

LILLIAN HSU
U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: CLAUDIA COLES



FDA's "Food Hazards and Controls" Guidance: Appendix 1

Contains Non-binding Recommendations
Draft-Not for Implementation

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>.

Appendix 1: Known or Reasonably Foreseeable Hazards ("Potential Hazards")

Table of Contents

- A1.1 Purpose of Appendix 1
- A1.2 Terms, Abbreviations, and Resources
- A1.3 Requirement for a Hazard Analysis
- A1.4 How We Developed Appendix 1
- A1.5 Organization of Appendix 1
 - A1.5.1 Food Groups Addressed by Appendix 1
 - A1.5.2 Tables of Known or Reasonably Foreseeable Hazards ("Potential Hazards")
 - A1.5.3 Organization of Each Table in Appendix 1
 - A1.5.4 The Food Subcategories in the Tables in Appendix 1 Address Raw Materials, Other Ingredients, and Multi-Component Foods
 - A1.5.5 Food Categories/Food Subcategories that Are LACF
 - A1.5.6 Infant Formula and Other Foods for Infants and Toddlers

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.
Appendix 1 (Known or Reasonably Foreseeable Hazards ("Potential Hazards")) - Page 1

- Issued Appendix 1 as revised draft on January 30, 2024
- Reorganized and revised Food Groups, Categories, Subcategories
- Updated *potential* hazards identified for certain ingredients/foods
- Removed potential process-related hazard tables
- Added explanatory text on how to use Appendix 1

Food Hazards and Controls Guide: Appendix 1

Food-related biological hazards tables

Table 1A: Known or reasonably foreseeable (“potential”) food-related biological hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>S. aureus</i>	Parasites	Viruses	Comments
Bread, Biscuits, Rolls, Brownies, Cookies, Pizza, Pie Crust	1	- Unbaked Bakery Items - Ready-To-Bake (RTB) Dough - RTB Crust - With or Without Inclusions ¹	Refrigerated or Frozen						X	X	X				Includes bagels, croissants, puff pastry, phyllo

Tables 1A through 1P do not identify any hazards requiring a preventive control in any Food Subcategory. It is the responsibility of the owner, operator, or agent in charge of each food facility to determine, through hazard analysis, whether a biological hazard identified in Tables 1A through 1P as a known or reasonably foreseeable (“potential”) biological hazard is a hazard requiring a preventive control in the facility’s food product.

Food Hazards and Controls Guide: Appendix 1

Food-related chemical hazards tables

- **Food Group 2A: Known or reasonably foreseeable (“potential”) food-related chemical hazards for Bakery Items**
- This Appendix does not include a Table of known or reasonably foreseeable (“potential”) food-related chemical hazards for Bakery Items. Instead, for known or reasonably foreseeable (“potential”) food-related chemical hazards for Bakery Items, you should see the Table(s) associated with the ingredients in your Bakery Item. For example:
- If your Bakery Item contains chocolate, you should consult Table 2D regarding known or reasonably foreseeable (“potential”) food-related chemical hazards for Chocolate and Candy.
- If your Bakery Item contains eggs, you should consult Table 2G regarding known or reasonably foreseeable (“potential”) food-related chemical hazards for Egg and Egg Products.
- If your Bakery Item contains wheat flour, you should consult Table 2J regarding known or reasonably foreseeable (“potential”) food-related chemical hazards for Grains, Pulses, Flours, and Starches.
- If your Bakery Item contains fruit, you should consult Table 2H regarding known or reasonably foreseeable (“potential”) food-related chemical hazards for Fruits and Vegetables.

Food Hazards and Controls Guide: Appendix 1

Food-related chemical hazards tables



Table 2J: Known or reasonably foreseeable (“potential”) food-related chemical hazards for Grains, Pulses, Flours, and Starches

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Grains, Non-Rice	1	Whole and milled grains (e.g., flour and bran)	Ambient					X ¹	X	Wheat, Rye, Sorghum, Oats, Barley, Triticale, Buckwheat, Corn, Amaranth, Millet, Quinoa (RACs and milled grain products)
Rice, Milled Rice Products	2b	Rice (whole and milled) and rice products	Ambient		X	X		X ²	X	White or Brown Rice, Rice protein, Sticky/sweet Rice, Basmati Rice, Jasmine Rice, Arborio rice, Rice-based noodles, Rice-based cereal

The Tables of Known or Reasonably Foreseeable (“Potential”) Food-Related Chemical Hazards do not identify any hazards requiring a preventive control in any Food Subcategory. It is the responsibility of the owner, operator, or agent in charge of each food facility to determine, through hazard analysis, whether a chemical hazard identified in these Tables as a known or reasonably foreseeable (“potential”) chemical hazard is a hazard requiring a preventive control for the facility’s food product.

Potential process- and facility-related hazards

A1.6 Tables of Known or Reasonably Foreseeable Hazards ("Potential Hazards") in Appendix 1

A1.6.1 Food-Related Biological Hazards

A1.6.1.1 The most relevant food-related biological hazards

A1.6.1.2 Note about viruses, parasites, and *Shigella* spp.

A1.6.1.2.1 Viruses and parasites

A1.6.1.2.2 *Shigella* spp.

A1.6.1.3 Note about biological hazards in food subcategories manufactured using exceptionally lethal processes

A1.6.1.4 Note about biological hazards in products produced in establishments that are under the jurisdiction of USDA

A1.6.1.5 Note about biological hazards in infant formula and other foods for infants and toddlers

A1.6.1.6 Note about biological hazards in food products produced using ingredients that are pasteurized or otherwise treated to control biological hazards

A1.6.1.7 Note about biological hazards in food products that consumers cook

A1.6.2 Food-Related Chemical Hazards

A1.6.2.1 The most relevant food-related chemical hazards

A1.6.2.2 Note about food allergen hazards and substances associated with a food intolerance or food-related disease

A1.6.2.3 Note about radiological hazards, dioxins, PCBs, and toxic elements

A1.6.2.4 Note about unapproved food and color additives

A1.6.2.5 Note about toxic element hazards in foods for infants and toddlers, including infant formula

A1.6.2.6 Note about mycotoxin hazards

A1.7 Process-related Hazards and Facility-related Hazards

A1.7.1 The Most Relevant Process-related and Facility-related Biological Hazards

A1.7.2 The Most Relevant Process-related Chemical Hazards

A1.7.3 The Most Relevant Process-related Physical Hazards

A1.8 How to Use the Tables in Appendix 1

- Instead of identifying potential process- and facility-related hazards, **Appendix 1 section A1.7** describes the most relevant of these hazards
- During the hazard analysis:
 - First, determine which of the hazards in section A1.7 are potential hazards for your product/process
 - For each potential hazard, evaluate whether it is a hazard requiring a preventive control

REMINDER

Definition: Hazard Analysis

The **process of identifying hazards and evaluating information on those hazards** (including the severity of the illness or injury if the hazard were to occur and the conditions that could lead to its presence), **to determine which hazards require a preventive control** and therefore should be addressed in a HACCP plan or a Food Safety Plan.

– *FSPCA, as cited in the FDA Hazard Guide*

New Hazard Analysis Approach

Potential Hazard Identification

INGREDIENTS:

- Ingredient inherent hazards
- **NEW:** identification of ingredient supplier's process- and facility-related hazards

PRODUCT PROCESS STEPS:

- identification of process- and facility-related hazards



**NEW TOOLS FOR POTENTIAL
HAZARD IDENTIFICATION**

New Hazard Analysis Approach



- *FSPCA new curriculum V2.0 Hazard Analysis chapter includes this NEW approach*
- *FDA has incorporated this approach into their regulator training*



FSPCA Curriculum V2.0

Chapter 6

HAZARD ANALYSIS FOR HUMAN FOOD

Hazard Analysis – Two Step Process

Step 1: Hazard Identification

- Brainstorm to generate a list of potential biological, chemical, and physical hazards
- List all potential hazards for:

1. raw materials and other ingredients

Ingredient-Related Hazards (Inherent Hazards)

AND
Supplier's Process-Related and Facility-Related Hazards

2. each manufacturing process step

Manufacturing Facility Process-Related and Facility-Related Hazards

Step 2: Hazard Evaluation

- Determine whether the potential hazard identified poses a significant risk to the consumer **in the absence of a preventive control** based on:
 - severity of the illness or injury
 - likelihood of occurrence
- Recognize that those hazards evaluated to be significant require a preventive control

Step 1: Potential Hazard Identification

When identifying potential hazards, the facility should consider:

SUPPLIER LEVEL

Raw materials & other ingredients

Ingredient-Related Hazards (Inherent Hazards)

AND
Supplier's Process-Related and Facility-Related Hazards

Salmonella in untreated Peppercorns (inherent hazard)



Allergen Cross-contact (supplier process-related hazard)



MANUFACTURING FACILITY

Manufacturing process steps

Process-Related and Facility-Related Hazards

that may be introduced or associated with the manufacturing process and the facility (e.g., mixing, packing in glass)

Packing in Glass



Ribbon Blender (metal on metal contact)





NEW TOOLS FOR HAZARD IDENTIFICATION

- There are many resources that can be used
- **NEW: January 2024 FDA's Draft Hazard Guide**

Appendix 1:

- Identify potential “inherent” ingredient hazards
- Identify common process- and facility-related hazards associated with processing steps

FDA Hazard Guide – Appendix 1 – 16 Food Groups

Each Food Group has Food Categories and Subcategories

Food Group A: Bakery Items

Food Group I: Game Meat Products

Food Group B: Beverage Items

Food Group J: Grains, Pulses, Flours, and Starches

Food Group C: Food Additives, Color Additives, and GRAS Substances

Food Group K: Nuts and Seeds

Food Group D: Chocolate and Candy

Food Group L: Oils and Oil Products

Food Group E: Dairy

Food Group M: Snack Foods

Food Group F: Dressings, Condiments, and Dips

Food Group N: Soups and Sauces

Food Group G: Egg and Egg Products

Food Group O: Spices and Herbs

Food Group H: Fruits and Vegetables

Food Group P: Food Sweeteners (Nutritive and Non-Nutritive)

Using the FDA Hazard Guide

Ingredient Hazard Identification

Let's identify potential ingredient-related biological and chemical hazards for

ROASTED ALMONDS

**Ingredient-Related Hazards
(Inherent Hazards)**

Identify Potential Ingredient-Related Hazards (Inherent Hazards):

- Biological Hazards (using FDA Appendix 1 Tables 1)
- Chemical Hazards (using FDA Appendix 1 Tables 2)

Using the FDA Hazard Guide

**Table 1K – Ingredient-Related Hazards (Biological Hazards):
ROASTED ALMONDS**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>S. aureus</i>	Parasites	Viruses	Comments
Nuts	1a	Peanuts, Raw	Ambient						X	X	X				Peanuts
Nuts	1b	Peanuts Roasted or Boiled	Ambient						X	X	X				Peanuts
Nuts	1c	Tree Nuts, Raw	Ambient						X	X	X				Includes all tree nuts
Nuts	1d	Tree Nuts, Roasted	Ambient						X	X	X				Includes all tree nuts
Nuts	1e	Nut Butters	Ambient						X	X	X				Includes product from peanuts and tree nuts
Edible Seeds	2a	Raw	Ambient						X	X	X				Includes edible seeds from flax, melon, pumpkin, sesame, sunflower
Edible Seeds	2b	Roasted	Ambient						X	X	X				Includes edible seeds from flax, melon, pumpkin, sesame, sunflower
Other Nut and Seed Products	3a	Nut and Seed Pastes	Ambient						X	X	X				Includes pastes from peanuts, tree nuts, and seeds, seeds
Other Nut and Seed Products	3b	Nut and Seed Flours	Ambient						X	X	X				Includes flour from peanuts, tree nuts, and seeds



Using the FDA Hazard Guide

**Table 2K – Ingredient-Related Hazards (Chemical Hazards):
ROASTED ALMONDS**



Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Nuts	1a	Peanuts, Raw and treated	Ambient					X ¹	X	Peanuts
Nuts	1c	Tree Nuts, Raw and treated	Ambient					X ¹		All tree nuts
Nuts	1c	Tree Nuts, Raw and treated	Ambient						X	Cashews and pecans
Edible Seeds	2a	Raw and treated	Ambient					X ¹	X	Melon, Pumpkin, Sunflower
Edible Seeds	2a	Raw and treated	Ambient			X				Sunflower

¹ The applicable mycotoxin is aflatoxin. (See CPG Sec. 570.200, CPG Sec. 570.375, and CPG Sec. 570.500 in Table 3 in section VI of the Introduction of this guidance.)

Hazard Identification
Columns 1 & 2

Ingredient Hazard Identification

Record Potential Biological and Chemical Ingredient-Related Hazards on the Hazard Analysis form

(1) Ingredient ROASTED ALMONDS	(2) Identify <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Ingredient-related hazards (inherent hazards)	B	Pathogenic <i>E. coli</i> , <i>Salmonella</i> , <i>L. mono</i>						
	C	Aflatoxin						
Supplier process-related and facility-related hazards	B	?						
	C	?						
	P	?						

FDA Hazard Guide – Appendix 1

Most Relevant Process-Related and Facility-Related Hazards:

- The Food Safety Team must consider those potential hazards originating from **processes** (process-related hazards), and the **food-production environment** (facility-related hazards)
- Each facility must identify potential process-related or facility-related hazards for its products based on its knowledge, experience, and history of hazards associated with its operations

FDA Hazard Guide – Examples of Common Process-Related and Facility-Related Hazards

Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards
BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging
	Bacterial pathogens – Presence due to ingredients added after process controls
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity
	Environmental pathogens – presence due to recontamination from the processing environment
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label
	Unintended food allergen presence – allergen cross-contact
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)
	Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils)
PHYSICAL HAZARDS A1.7.3	Metal
	Glass (when product packed in glass)
	Hard Plastic

FSPCA Form 0231 – Tool to use to rule out process- & facility-hazards that are not relevant (not “potential” hazards)

Do you know the almond supplier's process?

- The almond supplier sources raw, shelled almonds from a local grower/huller/sheller
- The roasted almond supplier dry roasts almonds per the California Almond Board (ABC) Pasteurization Program
- The dry roasting process used to treat almonds is validated by an ABC approved Process Authority and approved by ABC's Technical Expert Review Panel
- Sea salt is added on almonds after roasting
- Almonds are packaged in an oxygen permeable packaging after roasting
- No glass or hard plastic is used by the supplier
- The almond supplier also processes peanuts on shared equipment

Using the FDA Hazard Guide

Ingredient Hazard Identification

Let's identify potential biological, chemical, and physical supplier process- and facility-related hazards associated with making **SHELF STABLE ROASTED ALMONDS**



Supplier's Process-
Related and Facility-
Related Hazards

Identify Potential Supplier

Process-Related and Facility-Related Hazards

(using the FDA Hazard Guide, Appendix 1, and Chapters 2 and 3)

Using the FDA Hazard Guide



Common Supplier Process-Related and Facility-Related Hazards in SHELF STABLE ROASTED ALMONDS

FDA Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards	Potential? Yes/No
BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment	Yes - Potential
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control	No – Shelf stable
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control	No – Not formulated for safety
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP)	No – Not packaged in ROP
	Bacterial pathogens – Presence due to ingredients added after process controls	No – The ingredient added after roasting (sea salt) unlikely to have bacterial pathogens
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity	No – Not packaged in hermetically sealed container
	Environmental pathogens – presence due to recontamination from the processing environment	Yes – Roasted nuts are ready-to-eat, exposed to environment (after roasting) prior to packaging
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label	Yes – Almonds are a type of tree nut which is a major food allergen
	Unintended food allergen presence – allergen cross-contact	Yes – Supplier also handles peanuts
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)	No – Does not contain ingredients with a maximum use level for safety
	Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils)	Yes – Potential
PHYSICAL HAZARDS A1.7.3	Metal	Yes – May be present in field (lead shot)
	Glass (when product packed in glass)	No – Not packed in glass
	Hard Plastic	No – Hard plastic not used by supplier

Hazard Identification
Columns 1 & 2

Ingredient Hazard Identification

Record Potential Biological and Chemical Ingredient-Related Hazards on the Hazard Analysis form for Shelf Stable Roasted Almonds

(1) Ingredient Shelf Stable Roasted Almonds C	(2) Identify <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Ingredient-related hazards (inherent hazards)	B	Pathogenic <i>E. coli</i> , <i>Salmonella</i> , <i>L. mono</i>						
	C	Aflatoxin						
Supplier process-related and facility-related hazards	B	Recontamination with environmental pathogens <i>Salmonella</i>						
	C	Undeclared allergen – almond						
	C	Unintended allergen presence (cross-contact from peanuts)						
	C	Acrylamide						
	P	Metal (lead shot)						

Hazard Analysis – Two Step Process

Step 1: Hazard Identification

- Brainstorm to generate a list of potential biological, chemical, and physical hazards
- List all potential hazards for:

1. raw materials and other ingredients

Ingredient-Related Hazards (Inherent Hazards) ✓

AND
Supplier's Process-Related and Facility-Related Hazards ✓

2. each manufacturing process step

Manufacturing Facility Process-Related and Facility-Related Hazards

Step 2: Hazard Evaluation

- Determine whether the potential hazard identified poses a significant risk to the consumer **in the absence of a preventive control** based on:
 - severity of the illness or injury
 - likelihood of occurrence
- Recognize that those hazards evaluated to be significant require a preventive control

FDA's hazard analysis

- Similar to the process described in v. 2.0 of the FSPCA PCHF curriculum
- For the finished product, use section A1.7 Process- and Facility-Related Hazards in Appendix 1
 - Biological, chemical, or physical hazards related to the processing of the finished product at the facility
- For ingredients, use Appendix 1 to identify potential hazards for the ingredients
 - Use Tables 1 and 2 to identify ingredient-related biological and chemical hazards
 - Use section A1.7 to identify process- and facility-related hazards

FDA hazard analysis worksheets: Finished product

Finished Product: _____

Potential hazard for finished product (process-related; from section A1.7 Process and Facility Related Hazards of Appendix 1)	Does the hazard require a preventive control? (Y/N and why)	Controlled by facility? (Y/N) (If Yes – Process, Allergen, Sanitation, Other? If No – By downstream customer?)	At which step(s) will control(s) be applied at the facility?
Bacterial pathogens – presence/growth/toxin production due to survival of a lethal treatment			
Bacterial pathogens – growth and/or toxin production due to poor time/temperature control			
Bacterial pathogens – growth and/or toxin production due to poor formulation control			
Bacterial pathogens – growth and/or toxin production due to reduced oxygen packaging (ROP)			

- Screenshot of the first four rows (hazards are pre-populated)

FDA hazard analysis worksheets: Ingredients

Tables 1-2 of Appendix 1 – Potential Ingredient-related Biological and Chemical Hazards

Ingredient	Potential hazard (Table, Subcategory #, page #)	Does the hazard require a preventive control? (Y/N and why)	Controlled by supplier? (Y/N) (If Yes, Supply- chain at Receiving step)	Controlled by receiving facility [PC type/step] or downstream customer?

- Then, evaluate the hazards in section A1.7 for the supplier's manufacturing process

Summary:

Identifying potential hazards using Appendix 1

- Use Appendix 1 (and Chapter 3 as appropriate) to identify potential hazards for the finished product and ingredients

Hazard Analysis	Tables 1 & 2	Section A1.7 Process and Facility Related Hazards
Finished Product		x
Ingredient	x	x

- Then, **evaluate each potential hazard to determine whether they require a preventive control**



EVOLVING FOOD SAFETY PLANS: AN ADAPTIVE, RESPONSIVE PLANT CULTURE

SCOTT A. RANKIN
UNIVERSITY OF WISCONSIN-MADISON
MODERATOR: MATT BOTOS

Evolving Food Safety Plans: An Adaptive, Responsive Plant Culture

Scott A. Rankin, PhD

University of Wisconsin-Madison

Department of Food Science

November 19, 2024



Short Courses - Online

Milk Pasteurization and Process Control

The new online Milk Pasteurization Process Control School focuses on topics such as system design and operation, spoilage and pathogenic microflora, operation and maintenance of equipment and pumps, CIP systems, and cleaning and sanitation.

[Learn More >](#)

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Cleaning and Sanitation Workshop

The Cleaning and Sanitation Workshop online course covers the basics of cleaning and sanitation chemistry and practice. With speakers from industry and academia, it is designed to provide a strong overview of Cleaning and Sanitation practices.

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Now Available! Applied Dairy Chemistry

The Applied Dairy Chemistry course will provide a better understanding of the chemical and physical changes during processing and storage of dairy products and how these impact the overall quality.

[Learn More >](#)

[Register Online >](#)



Emergency Seal Applicator Training

This program is designed as a first step in gaining fundamental training to apply emergency seals to milk pasteurization systems as indicated in the PMO.

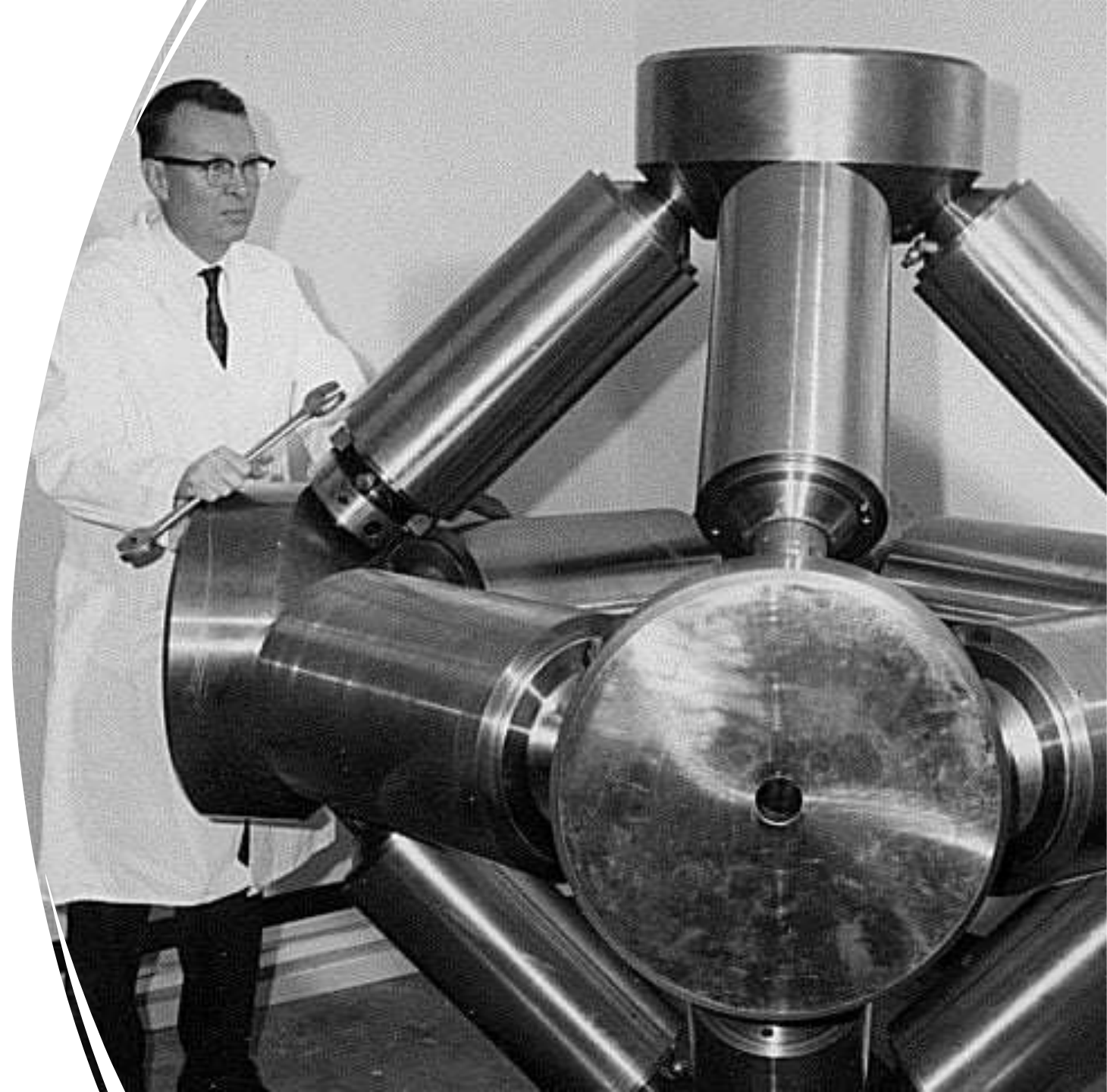
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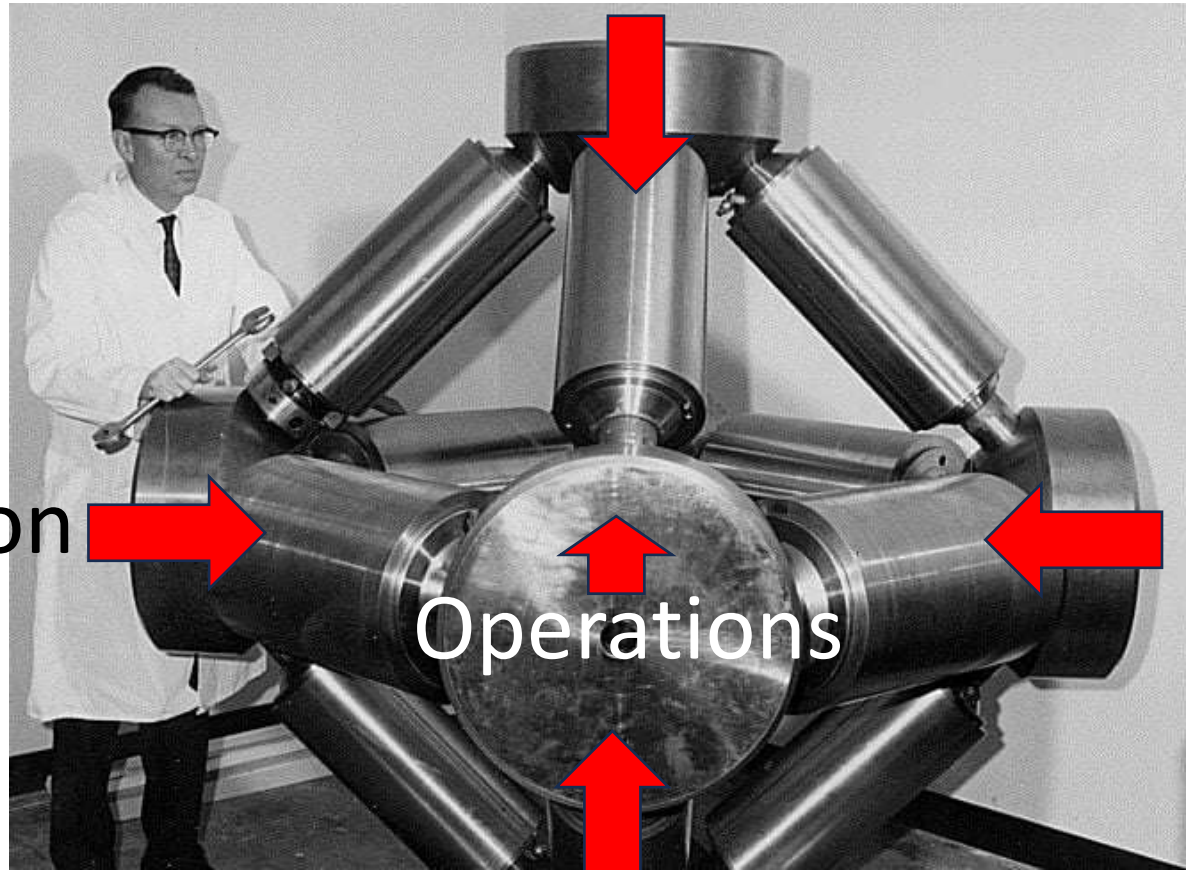
Background

Tetrahedral press



https://elkodaily.com/lifestyles/speaking-of-science-diamonds/article_ebf286a3-f6ca-5208-8fe0-b6d0f6a4b462.html

Literature



Litigation



Operations



Regulatory

Industry

After this talk you should

- Increased awareness of compliance challenges (**warm-up lap**)
- Consider some **best practices**: Leadership, Literacy, FSP, Valid/Verify
- Consider some **resources**
- Understand roles of **logic and experience**

Need for strong plant culture





The warm-up lap





Challenges: strong vs developing culture?

1. Your plant deals with multiple lines, multiple allergens. Your Food Safety Team is considering whether labeling is a critical control point or not.
2. Your internal micro testing results show that you have violative coliform counts in your finished product but sample testing from the state comes back clean.
3. Expenses for noted facility deficiencies (related to food safety) are double what you had budgeted.



FDA form 483 report

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: www.fda.gov/oc/industry	DATES OF INSPECTION 03/23/2015 - 04/23/2015* FIRM NUMBER 1000118167
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>	
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:	
OBSERVATION 1	
Failure to manufacture and package foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.	
Specifically, you manufactured ready-to-eat, frozen, dairy desserts which tested positive for <i>Listeria monocytogenes</i> . The following finished product manufactured by your firm tested positive for <i>Listeria monocytogenes</i> .	
A. Institutional Chocolate Ice Cream in a 3oz cup with a pull tab lid, Lot code 041516Q, produced 04/15/2014, tested positive for <i>Listeria monocytogenes</i> by the Kansas Department of Health Environment. Your firm distributed all (b) (4) 3oz cups of this lot between 04/15/2014 and 03/23/2015.	
B. (b) (4) produced on 03/23/2015, tested positive for <i>Listeria monocytogenes</i> by a third party laboratory selected by your firm. You reported you did not distribute the (b) (4) to your customers.	
C. Banana Pudding Ice Cream, Lot code 021217S, produced on 02/12/2015, tested positive for <i>Listeria monocytogenes</i> by the FDA. Your firm distributed (b) (4) pints of the Banana Pudding Ice Cream, Lot code 021217S, to your customers between 02/12/2015 and 03/26/2015.	
Subsequently, your firm initiated a voluntarily recall of all institutional ice cream products in a 3oz cup with a pull tab lid on 03/23/2015. On 04/07/2015, your firm expanded the voluntary recall to include all products manufactured on 04/07/2015 after 02/12/2015. Then on 04/20/2015, your firm expanded the voluntary recall to include all products manufactured by your firm.	

Challenges - regulatory

“Specifically, you failed to demonstrate your cleaning and sanitizing program is effective in controlling recurring microbiological contaminations.”

Interpretations?





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OBSERVATION 1

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Specifically, you manufactured ready-to-eat, frozen, dairy desserts which tested positive for *Listeria monocytogenes*. The following finished product manufactured by your firm tested positive for *Listeria monocytogenes*.

- A. Institutional Chocolate Ice Cream in a 3oz cup with a pull tab lid, Lot code 041516Q, produced 04/15/2014, tested positive for *Listeria monocytogenes* by the Kansas Department of Health Environment. Your firm distributed all (b) (4) 3oz cups of this lot between 04/15/2014 and 03/23/2015.
- B. (b) (4), produced on 03/23/2015, tested positive for *Listeria monocytogenes* by a third party laboratory selected by your firm. You reported you did not distribute the (b) (4) to your customers.
- C. Banana Pudding Ice Cream, Lot code 021217S, produced on 02/12/2015, tested positive for *Listeria monocytogenes* by the FDA. Your firm distributed (b) (4) pints of the Banana Pudding Ice Cream, Lot code 021217S, to your customers between 02/12/2015 and 03/26/2015.

Subsequently, your firm initiated a voluntarily recall of all institutional ice cream products in a 3oz cup with a pull tab lid on 03/23/2015. On 04/07/2015, your firm expanded the voluntary recall to include all products manufactured on 03/23/2015 after 02/12/2015. Then on 04/20/2015, your firm expanded the voluntary recall to include all products manufactured by your firm.

Challenges - regulatory

“Specifically, you failed to control recurring microbiological contaminations.”

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<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</p> <p>OBSERVATION 1</p> <p>Failure to manufacture and package foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.</p> <p>Specifically, you manufactured ready-to-eat, frozen, dairy desserts which tested positive for <i>Listeria monocytogenes</i>. The following finished product manufactured by your firm tested positive for <i>Listeria monocytogenes</i>.</p> <p>A. Institutional Chocolate Ice Cream in a 3oz cup with a pull tab lid, Lot code 041516Q, produced 04/15/2014, tested positive for <i>Listeria monocytogenes</i> by the Kansas Department of Health Environment. Your firm distributed all (b) (4) 3oz cups of this lot between 04/15/2014 and 03/23/2015.</p> <p>B. (b) (4) produced on 03/23/2015, tested positive for <i>Listeria monocytogenes</i> by a third party laboratory selected by your firm. You reported you did not distribute the (b) (4) to your customers.</p> <p>C. Banana Pudding Ice Cream, Lot code 021217S, produced on 02/12/2015, tested positive for <i>Listeria monocytogenes</i> by the FDA. Your firm distributed (b) (4) pints of the Banana Pudding Ice Cream, Lot code 021217S, to your customers between 02/12/2015 and 03/26/2015.</p> <p>Subsequently, your firm initiated a voluntarily recall of all institutional ice cream products in a 3oz cup with a pull tab lid on 03/23/2015. On 04/07/2015, your firm expanded the voluntary recall to include all products manufactured on 04/07/2015 after 02/12/2015. Then on 04/20/2015, your firm expanded the voluntary recall to include all products manufactured by your firm.</p>	

Who?

How?

“Specifically, you failed to demonstrate your cleaning and sanitizing program is effective in controlling recurring microbiological contaminations.”

Standard?



The warm-up lap



Best Practices:

- Leadership commitment
- Literacy investment
- Food Safety Plan
- Valid, verify





Best practices

Leadership commitment

BP: Leadership commitment – you?



Leadership Commitment For Growth and Driving Food Safety Culture

Sagar Mahmood Khan
Head of Global Quality Assurance - Product Governance

12 articles + Follow

February 1, 2020



TIP SHEET 4

MANAGEMENT COMMITMENT

Management commitment is when all employees are unified in their way of thinking about food safety. Simply meeting the Code requirements is not a commitment to food safety, because food safety is never truly implemented if there is no commitment. Senior site management supports the food safety system by their direct participation, actions, support and belief in food safety, incorporating this mindset in daily decisions.

Management commitment and food safety culture is a shared belief - with the key word being "shared." Values don't just live in the individual, but rather in groups and the organization. There is no one-size-fits-all solution; however, if management commitment to food safety is present, this shared belief will resonate throughout the organization.

This tip sheet will provide useful tips to drive management commitment while building the food safety culture at your site.

Building a Stronger Food Safety Culture



Management Commitment

What level of management commitment are your senior managers demonstrating?

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One of the common messages I hear from companies that have obtained certification to one of the GFSI-benchmarked schemes is that they have improved management systems. This can be a hard thing to measure and you may not know exactly what level of commitment is present. Here are some thoughts to help you determine the level of management commitment your senior managers are demonstrating.

Time seems to be the most valuable resource in today's busy world and work environment. Senior managers who are committed to food product integrity (food safety, quality, and legality) will dedicate a significant portion of their time to being directly involved in issues related to product integrity. This includes active involvement on the HACCP, self-inspection, internal audit, and food defense teams. In most instances, information received about the product and food safety programs is not secondhand. These leaders are on the:

- The senior site manager is a member of the HACCP team.
- The senior site manager is a member of the self-inspection team.
- The senior site manager is a member of the internal audit team.
- The senior site

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Former [redacted] Manager Pleads Guilty in Connection with Insanitary Plant Conditions Linked to 2018 Salmonella Poisoning Outbreak

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United States v. Park, 421 U.S. 658 (1975)

Argued: March 17, 1975

Argued: March 18, 1975

Decided: June 9, 1975

Annotation

PRIMARY HOLDING

Strict liability applies to a corporate officer charged with a public welfare offense under the federal Food, Drug, and Cosmetic Act, even if they did not engage in affirmative wrongdoing. An officer with an adequate degree of authority and responsibility must not only seek out and remedy violations but also implement policies to prevent violations.

United States v. Park, 421 U.S. 658 (1975)

Argued:

March 17, 1975

Argued:

March 18, 1975

Decided:

June 9, 1975

Annotation

Implications of this lawsuit?

PRIMARY HOLDING

Strict liability applies to a corporate officer charged with a public welfare offense under the federal Food, Drug, and Cosmetic Act, even if they did not engage in affirmative wrongdoing. An officer with an adequate degree of authority and responsibility must not only seek out and remedy violations but also implement policies to prevent violations.



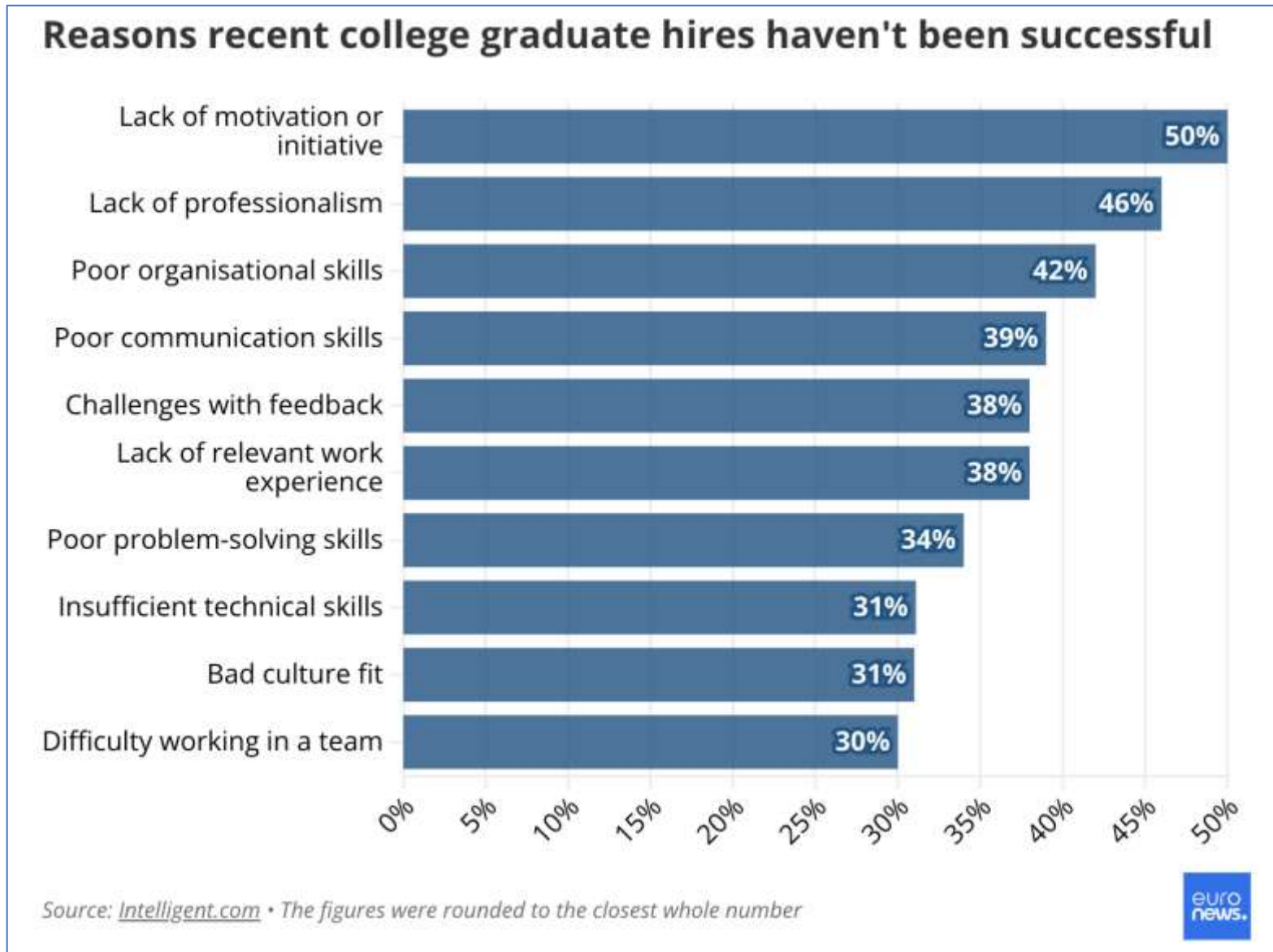
Best practices

Literacy investment

-Hamish McRae,
British economic
commentator

...the main asset of a large company is its human skills; the collection of individuals that work for it. It follows that companies likely to be most successful will be those who train their people best and nurture their skills.

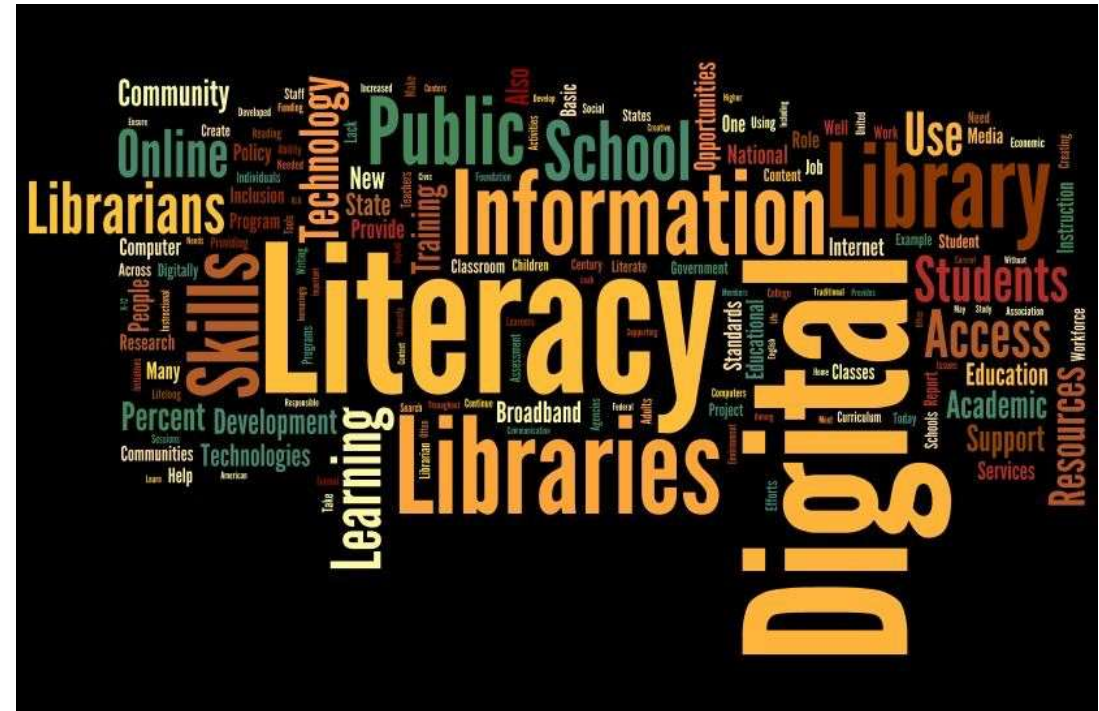
"As a result, it is up to the company to properly onboard the new employee and give ample training. In addition, the boss needs to act as a coach as well as a manager"



Best Practice

Literacy investment: Allergen example

- FSMA; Section 204, 2026?
- Key Data Elements (KDEs)?
- Critical Tracking Events (CTEs)?
- Food Traceability List?
- Exemption?





AMERICAN BAKERS
ASSOCIATION

Research

Events

Professional Development

2021 FASTER ACT: BAKERS' PRIORITY REMAINS CONSUMER SAFETY

Food Safety, Food Technical Regulatory Affairs Professionals



The dangerous practice of adding sesame to baked goods that have not previously contained the ingredient, often without notice, undermines the trust that people with food allergies place in the food industry.

WASHINGTON, DC - Today, the American Bakers Association (ABA) **sent a letter to Congress** regarding the commercial baking industry's implementation of and compliance with the 2021 Food Allergy Safety, Treatment, Education, and Research (FASTER) Act.

ARTICLES March 29, 2023

What all restaurant operators need to know about FDA's new Food Traceability Rule

New rules go into effect in 2026 and will require extensive changes.



FDA's Food Traceability Rule

Home | Education & Resources | Learning Center | Food & Nutrition | FDA's Food Traceability Rule



The Food Traceability List

Food Traceability List	Description
Cheeses, other than hard cheeses, specifically:	
<ul style="list-style-type: none"> Cheese (made from pasteurized milk), fresh soft or soft unripened 	Includes soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
<ul style="list-style-type: none"> Cheese (made from pasteurized milk), soft ripened or semi-soft 	Includes soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
<ul style="list-style-type: none"> Cheese (made from unpasteurized milk), other than hard cheese[1] 	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
Shell eggs	Shell egg means the egg of the domesticated chicken.
Nut butters	Includes all types of tree nut and peanut butters. Includes all forms of nut butters, including shelf stable, refrigerated, and frozen products. Examples include, but are not limited to, almond, cashew, chestnut, coconut, hazelnut, peanut, pistachio, and walnut butters. Does not include soy or seed butters.
Cucumbers (fresh)	Includes all varieties of fresh cucumbers.
Herbs (fresh)	Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 CFR 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 CFR 1.1305(e).
Leafy greens (fresh)	Includes all types of fresh leafy greens. Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi/bok choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Does not include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1), such as collards, are

	Iceberg lettuce, kale, red leaf, pak choi/bok choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Does not include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1), such as collards, are exempt from the requirements of the rule under § 1.1305(e).
Leafy greens (fresh-cut)	Includes all types of fresh-cut leafy greens, including single and mixed greens.
Melons (fresh)	Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon.
Peppers (fresh)	Includes all varieties of fresh peppers.
Sprouts (fresh)	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, allium sprouts, bean sprouts, broccoli sprouts, clover sprouts, radish sprouts, alfalfa & radish sprouts, and other fresh sprouted grains, nuts, and seeds.
Tomatoes (fresh)	Includes all varieties of fresh tomatoes.
Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, Loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomeio.
Fruits (fresh-cut)	Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Vegetables other than leafy greens (fresh-cut)	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Finfish (fresh and frozen), specifically:	
<ul style="list-style-type: none"> Finfish, histamine-producing species 	Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail.
<ul style="list-style-type: none"> Finfish, species potentially contaminated with ciguatoxin 	Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.
<ul style="list-style-type: none"> Finfish, species not associated with histamine or ciguatoxin 	Includes all species of finfish not associated with histamine or ciguatoxin. Examples include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout.[2] Siluriformes fish, such as catfish, are not included.[3]
Smoked finfish (refrigerated and frozen)	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish.[4]
Crustaceans (fresh and frozen)	Includes all crustacean species. Examples include but are not limited to shrimp, crab, lobster, and crayfish.

The "c" in cGMP

The "current" aspect of cGMP means that these practices should be updated to reflect technological advancements and new industry practices. Food processors are expected to stay informed and adapt to modern methods that could improve product safety and quality.





Best practices

FS Plan

BP: Food Safety Plan (A living document)

- PCQI credential
- FSMA
- **Valid, Verify**
- Recorded control measures
- cGMPs
- Training
- Required documents
- SOPs

Product: Clemson Ice Cream (variety of flavors) Page: 2 of 45
Plant Name: Clemson's '55 Exchange Creamery Issue Date: 12/9/2018
Address: Newman Hall, Clemson, SC 29634 Supersedes: N/A

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13 NOT IN USE Temperature Monitoring Log (See KE2 Software for records)	Nov 4, 2024 awilms
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	Oct 21, 2024 awilms
	Oct 28, 2024 awilms
	Oct 18, 2024 awilms
	Oct 28, 2024 awilms
	Oct 30, 2024 awilms
	Oct 18, 2024 awilms
	Oct 18, 2024 awilms
	8:44 AM awilms
	Oct 21, 2024 awilms

Valid method?
Verify efficacy?

SSOP: Cleaning and Sanitizing

SSOP – Cleaning and Sanitization?

- Easily understood, accurate?
- Edits?
- Valid method?
- **Verified effectiveness?**
- Record?





Verified
clean?

<https://www.dynamiconveyor.com/food-processing-packaging/>



Best Practices Resources



WISCONSIN FOOD PROCESSING AND FOOD SALES REQUIREMENTS FOOD SAFETY & LICENSING GUIDE



**Wisconsin Department of
Agriculture, Trade and
Consumer Protection**
*Division of Food and
Recreational Safety*



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Food Retail and Grocery

Elevate retail food safety with NSF. We offer audits, compliance, and training for a secure brand and satisfied customers.



Safeguard your customers and protect your brand by improving retail food safety — from store audits and supplier management to regulatory and labeling compliance. Look to NSF for best practices and sustainability in your retail and grocery operations with trusted auditing, certification, advisory services, and food safety training.



[HOME](#) > [STANDARDS](#) > Batch and Continuous Freezers for Ice Cream, Ices, and Similarly Froz

3-A 19-07

BATCH AND CONTINUOUS FREEZERS FOR ICE CREAM FROZEN FOODS

Description

Used for food processing of frozen dairy food. Does not apply to soft-serve frozen produc

THE FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

The Food Safety Preventive Controls Alliance (FSPCA) is the most trusted source of education and training programs for U.S. food manufacturers, importers, foreign suppliers, and food safety professionals around the world wanting to understand and use one or more of the prevention-oriented standards of the Food Safety Modernization Act (FSMA).

Upcoming FSPCA Events

- Oct 15 [FSPCA PCHE V2.0 Lead Instructor Refresher Training Opens for Enrollment](#)
Additional courses will be added in late November and beyond.
- Nov 21-22 [FSPCA Executive Advisory Board Meeting](#)
- Nov 21-22 [FSPCA Executive Advisory Board Meeting](#)

Current FSPCA News

The Food Safety Preventive Controls Alliance (FSPCA) at Illinois Tech's, Institute for Food Safety and Health (IFSH) was selected to receive the 2023 Food Safety Award from the International Association for Food Protection (IAFP)

[FSPCA June Newsletter](#)

[Registration Open: 2024 FSPCA Annual Conference](#)

[FSPCA Human Food Lead Instructor Application Open](#)

FDA FSMA Related News

[Update from the Deputy Commissioner for Human Food - Enhancing Traceability, Insights from Reagan-Udall Foundation Roundtables and Upcoming Public Engagement](#)

[FDA Releases FY 2022 Pesticide Residue Monitoring Report](#)



Advancing Food Safety Worldwide.[®]

A member-based association of more than 4,500 food safety professionals, IAFP is committed to advancing food safety worldwide by providing a forum for food safety professionals to exchange information on protecting the food supply.

Become a Member

AI

- Compliance
- Risk assessment
- Training
- SOP development
- Incident response
- Process optimization
- Etc.

1. Guidance on Compliance and Standards

ChatGPT can explain relevant food safety standards and regulatory requirements (e.g., HACCP, ISO 22000, and FDA guidelines) and help companies understand compliance. Manufacturers can use this information to improve processes, documentation, and ensure they meet or exceed regulatory requirements.

2. Risk Assessment and Hazard Identification

By asking ChatGPT about specific food production processes, manufacturers can identify potential hazards (biological, chemical, or physical) that could compromise food safety. ChatGPT can suggest preventive measures, such as sanitation procedures, to reduce these risks.

3. Training and Knowledge Sharing

ChatGPT can serve as a training aid for staff, offering customized training material on food safety, hygiene, and best practices. For example, it could create quizzes, role-play scenarios, or detailed explanations to reinforce employees' understanding of critical safety protocols.

4. SOP and Checklist Development

ChatGPT can assist in creating or improving Standard Operating Procedures (SOPs) and checklists that ensure consistency in safety practices across the production line. These SOPs might cover everything from raw material handling to equipment sanitization and final product testing.

5. Incident Response and Root Cause Analysis

In the event of a food safety incident, ChatGPT can offer guidance on steps to mitigate the issue and conduct root cause analysis. It can help manufacturers design a corrective action plan to address the problem and prevent recurrence.

6. Process Optimization and Efficiency

ChatGPT can suggest ways to streamline processes without compromising safety, potentially identifying areas where better organization or minor adjustments can improve food safety and production efficiency.

7. Vendor and Ingredient Risk Management

Manufacturers can use ChatGPT to establish criteria for assessing supplier quality and implementing traceability protocols, ensuring that all ingredients meet safety standards before entering the production facility.

8. Quality Control and Audits

ChatGPT can help manufacturers prepare for audits by guiding them through typical audit checklists, standards, and best practices for maintaining documentation. It can also assist in reviewing records to ensure that all safety processes are documented properly.

In summary, ChatGPT can act as a virtual consultant, trainer, and guide, offering valuable advice to help manufacturers improve food safety systematically and stay compliant with




AI

...with applications ranging from quality control to contamination detection and foodborne illness prediction.

...where algorithms can assess risks and detect early signs of contamination through pattern recognition

...A special issue ...is set for release in July 2025, addressing the innovations and challenges AI poses in fields like microbial risk assessment and quality assurance



Logic and Experience

Adaptive, Responsive Plant Culture





The life of the law has not been logic; it has been experience.

*The life of the
meal has not been logic;*



it has been experience.





From Logic

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Listeria bacteria found in milkshakes sold at [redacted] restaurant in Tacoma

For immediate release: August 18, 2023 (23-114)

Contact: [DOH Communications](#)

Listeria strain linked to six hospitalizations and three deaths

OLYMPIA – Listeria bacteria found in a [redacted] restaurant at [redacted] Ave. S., Tacoma, WA are associated with a [foodborne listeriosis outbreak linked to six hospitalizations and three deaths](#). Investigators found Listeria in the ice cream machines, which were not cleaned correctly. [redacted] the restaurant stopped using its ice cream machines Aug. 8, but Listeria can sicken people [redacted]

Most people who eat food contaminated with Listeria will not get seriously sick, but people who are pregnant, aged 65 or older, and those with weakened immune systems should call their health care provider if they eat a French Toastery milkshake between May 20 and Aug. 7, 2023 and have

To experience



The first lawsuit filed claims the company **is responsible for infecting** Thurston County resident _____, leading to **his hospitalization and death.**

Documents from the lawsuit say _____ had a milkshake from this _____ sometime between March and April 2023. In early May, he was hospitalized in Olympia due to **neck and arm numbness and pain and had surgery.** Ultimately, he was admitted to St. Joseph's in Tacoma where he died of Listeria complications.

"If _____, had cleaned that machinery properly, we wouldn't be talking about it," said Marler. **"People need to be held accountable for what they do to people."**

Legal profession?

Young Workers - You have rights!

Contact our *Listeria* Lawsuit Attorneys For a Free Consultation on Your Case

Safe workplace. OSHA wants you to have a safe and rewarding work experience. This site can help you prevent job-related injuries and illnesses.

Highlights

- [Keep Young Workers Safe: A Campaign for Young Worker Safety](#)
- [Self-Prevention Campaigns](#)
- [Most-Known Prevention Campaigns](#)



Discovery?

What Is the Discovery Phase In A Lawsuit?



Insurance companies?

subrogation: the assumption by a third party (such as an insurance company) of another's legal right to collect a debt or damages.

Manufacturer?

Cornell CALS College of Agriculture and Life Sciences **MQIP**

Listeria monocytogenes in the Dairy Environment

Background

Listeria monocytogenes is a bacterium common in the environment that can cause serious human diseases. Listeriosis, the general name for illnesses caused by *L. monocytogenes*, is almost always caused by consumption of food contaminated with the organism. Groups of people at risk for serious illness include fetuses of pregnant women, newborns, the elderly, and people with weakened immune systems. Severe forms of listeriosis result from the organism infecting the blood (septicemia) and ultimately the nervous tissue or brain. Illness can begin 2-8 weeks after consuming contaminated food, which makes it difficult to trace to the source.

***L. monocytogenes* and the Food/Dairy Industry**

L. Monocytogenes is widespread in the environment and has been isolated from:

- water
- soil and dust
- plants
- animal feed
- Feces and sewage

Listeria can be a common contaminant in the dairy environment, both on the farm and in the processing plant. On the farm, important sources include manure and improperly fermented silage. In the dairy plant, Listeria has been isolated from a variety of sites, although it is most frequently found in moist environments.

Logic & Experience

Equipment design?

Hygienic Shortcomings of Frozen Dessert Freezing Equipment and Fate of *Listeria monocytogenes* on Ice Cream-Soiled Stainless Steel

A. INUWA,¹ A. LUNT,² C. CZUPRYNSKI,¹ G. MILLER,³ AND S. A. RANKIN^{2*}

Language?

1 Gallon Bottle

Sanitizes countertops, upholstery and linens.

- Kills Norovirus, Salmonella, E. coli, Listeria and SARS-CoV-2 in 30 seconds.
- No rinsing required. No harsh fumes.
- Approved for use on food contact surfaces.



BOTTLES/CASE	PRICE PER BOTTLE	IN STOCK
1	\$17	4
4	\$17	\$16
12+	\$15	1

Shipping Lists Request a Catalog

Evolving Food Safety Plans: An Adaptive, Responsive Plant Culture

- Compliance challenges
- Best practices
- Resources
- Logic and experience





AWARDS PRESENTATION

JASON WAN, , PHD
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

BRIAN SCHANEBERG, PHD
INSTITUTE FOR FOOD SAFETY & HEALTH (IFSH)

KATHY GOMBAS
FSMA SOLUTIONS

LIFETIME ACHIEVEMENT AWARD

In recognition of contributions and support to FSPCA
and a lasting impact on Global Food Safety



**KATHERINE M.J.
SWANSON**

KATHERINE M.J. SWANSON, PH.D.

Katherine MJ Swanson is a successfully retired food safety expert, with extensive leadership experience spanning food safety management, training, regulatory affairs, and corporate policy development. In her last professional role, she served as Project Manager and Executive Editor for the first edition of the Food Safety Preventive Controls Alliance's Preventive Controls for Human Food curriculum. Prior to her FSPCA efforts, she held senior food safety management positions at Ecolab, The Pillsbury Company, and General Mills, and briefly as assistant professor of food microbiology at Cornell University and senior microbiologist for 3M ATP and Petrifilm™ applications. Katie has served on influential committees including the International Commission on Microbiological Specifications for Foods (ICMSF), National Advisory Committee on Microbiological Criteria for Foods (NACMSF), National Academies of Science committees, and the executive board of the International Association for Food Protection (IAFP). Katie has delivered food safety presentations on every continent except Antarctica, and in retirement, she has been catching up on interests ignored for many years including genealogical research, travel, and needlepoint.

Katie is an IAFP past president; wrote/edited numerous chapters, reports, and papers; and served on influential committees including the International Commission on Microbiological Specifications for Foods (past secretary), National Advisory Committee on Microbiological Criteria for Foods (seven years), and National Academies of Science committees. In retirement, Katie's interests include genealogy research, travel, and needlework ignored for many years.



VOLUNTEER OF THE YEAR AWARD

In recognition and appreciation for exceptional dedication and service to FSPCA.



**MARTIN
BUCKNAVAGE**

MARTIN BUCKNAVAGE

Martin Bucknavage is Penn State's Senior Food Safety and Quality Extension Program Specialist, providing training and technical support to food companies in the areas of food safety, food processing, and quality management. Prior to Penn State, he had 15 years of technical management experience in the food industry, managing commercial food testing laboratories and directing the quality and R&D functions for food manufacturing companies. He has lead instructor status for Food Safety Preventive Controls Alliance (FSPCA) for Human Foods, Animal Foods, and FSVP. Martin serves on the FSPCA Executive Advisory Board and co-chairs the FSPCA TAN and Human Food Curriculum Work Groups. He holds a BS degree in Microbiology and an MBA from Penn State, and an MS in Food Science from Virginia Tech.



VOLUNTEER OF THE YEAR AWARD

In recognition and appreciation for exceptional dedication and service to FSPCA.



**KATHERINE
SIMON**

KATHERINE SIMON

Katherine Simon is the Division Director of the Food and Feed Safety Division of the Minnesota Department of Agriculture, overseeing manufactured food, retail food, animal feed and produce safety inspection programs. Ms. Simon brings 15 years of regulatory experience including field inspection, supervisory, compliance and management roles. She received her Registered Environmental Health Specialist credential in 2008 and completed the International Food Protection Training Institute (IFPTI) Fellowship in Food Protection as a member of the 2010 Cohort. Ms. Simon served as a member of the FSPCA Steering Committee and assisted with curriculum review and development.



CERTIFICATE OF RECOGNITION

In grateful appreciation of the exceptional support and contributions to the development and review of the FSPCA Preventive Controls For Human Food V2.0 Curriculum.



**PCHF
CURRICULUM
UPDATE
WORK
GROUP**

PCHF CURRICULUM UPDATE WORK GROUP

- Kimberly Anderson
- Martin Bucknavage
- Claudia Coles
- Debra DeVlieger
- Elise Forward
- Kathy Gombas
- Connie Halvorsen
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- Lynette Johnston
- Donald Kautter
- Richard Kralj
- Tania Martinez
- Matthew Noonan
- Ruth Petran
- Jenny Scott
- Juan L. Silva
- Katherine Simon
- Warren Stone
- Wendy White
- Edith Wilkin
- Brian Yaun



1000 CLUB

IN RECOGNITION OF TRAINING 1000 OR MORE PARTICIPANTS, CUMULATIVELY IN THE FOUR FSPCA TRAINING CURRICULA, WITH FSPCA CERTIFICATES ISSUED.

2024 1000 Club Members

- Martin Bucknavage
- Bartosz Dobek
- Christopher Dunn
- Girish Ganjyal
- Nancy Johnson
- Christina Kelley-Astorga
- Juan Muniz
- Derrick Lee Payne PhD
- Christina Petrlik-Siegel



MARTIN BUCKNAVAGE

1000 CLUB



BARTOSZ DOBEK

1000 CLUB



DERRICK LEE PAYNE

1000 CLUB



TOP TEN FSPCA LEAD INSTRUCTORS

IN RECOGNITION OF THE NUMBER OF PARTICIPANTS TRAINED (INSTRUCTOR-LED) WITH FSPCA CERTIFICATES ISSUED BETWEEN AUGUST 15, 2023, AND AUGUST 15, 2024.

2024 Top Ten Lead Instructors – Animal Food

- David Fairfield
- Gary Huddleston
- Billie Johnson
- Chris Lincecum
- Rachel Montgomery
- Derrick Lee Payne
- Christina Petrlik-Siegel
- Jose Sabal
- Bitu Saidi
- Tielong Wang



DAVID FAIRFIELD

ANIMAL FOOD



GARY HUDDLESTON

ANIMAL FOOD



BILLIE JOHNSON

ANIMAL FOOD



CHRIS LINCECUM

ANIMAL FOOD



DERRICK LEE PAYNE

ANIMAL FOOD



JOSE SABAL

ANIMAL FOOD

2024 Top Ten Lead Instructors – FSVP

- Bob Bauer
- Bartosz Dobek
- Ricardo Islas
- Alexander Kashef
- Jin Kim
- Rachel Montgomery
- Nari Nayini
- Charles (Mike) Nolan
- Jose Sabal
- Christopher Snabes



BARTOSZ DOBEK

FSVP



NARI NAYINI

FSVP



JOSE SABAL

FSVP



CHRISTOPHER SNABES

FSVP

2024 Top Ten Lead Instructors – Human Food

- Earl Arnold
- Jeff Chilton
- Bartosz Dobek
- Matthew Docherty
- Cathy Martin
- Hipolito Nava Cruz
- Wonjun Oh
- Derrick Lee Payne
- Jose Sabal
- Jedsada Tipmontian



EARL ARNOLD

HUMAN FOOD



JEFF CHILTON

HUMAN FOOD



BARTOSZ DOBEK

HUMAN FOOD



HIPOLITO NAVA CRUZ

HUMAN FOOD



DERRICK LEE PAYNE

HUMAN FOOD



JOSE SABAL

HUMAN FOOD



JEDSADA TIPMONTIAN

HUMAN FOOD

2024 Top Ten Lead Instructors – Intentional Adulteration

- Maria Cecilia Cascabelo
- Jorge Descalzo
- Satoshi Imanari
- Kyota Murai
- Wonjun Oh
- Jirakorn Prasertcheeva
- Mario Sangiorgi
- Christopher Snabes
- Jedsada Tipmontian
- Jennifer van de Ligt



KYOTA MURAI

IA VA



MARIO SANGIORGI

IA VA



CHRISTOPHER SNABES

IA VA



JEDSADA TIPMONTIAN

IA VA



CLOSING REMARKS

JASON WAN, , PHD
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)



FSPCA 2024 ANNUAL CONFERENCE

A GLOBAL COMMUNITY NAVIGATING
A CHANGING LANDSCAPE



UPDATE ON THE IMPLEMENTATION OF THE IA RULE

CAPTAIN JON WOODY

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: HILARY THESMAR



**U.S. FOOD & DRUG
ADMINISTRATION**

FSMA Intentional Adulteration Rule

Regulatory Update 2024

What is Required?

- Food Defense Plan
 - Vulnerability assessment
 - Mitigation strategies
 - Food defense monitoring procedures
 - Food defense corrective action procedures
 - Food defense verification procedures
- Reanalysis
- Records
- Training



Training





- All people performing activities for this rule must be qualified individuals
- Individuals working at actionable process steps and their supervisors must also complete
 - Food defense awareness training
 - Training on the proper implementation of mitigation strategies at their actionable process steps

Training (cont)

- Individuals performing the following activities:
 - Food defense plan development
 - Performing vulnerability assessment
 - Identifying and explaining mitigation strategies
 - Performing reanalysis of the food defense plan
- Must also:
 - Complete training at least equivalent to standardized curriculum recognized as adequate by FDA
 - Or be otherwise qualified through job experience

FSPCA Training Offerings

FSPCA IA Rule Training Courses	Delivery Method	Intended Audience	Cost
Food Defense Awareness¹	Available now 	<ul style="list-style-type: none"> Workers at Actionable Process Steps (e.g., front line food workers) Supervisors of Workers at Actionable Process Steps Satisfies requirement in § 121.4(b)(2) 	Free
Overview of IA Rule	Available now 	<ul style="list-style-type: none"> Any stakeholder interested in learning more about the IA rule requirements This course is not associated with any IA rule training requirement 	Free

FSPCA IA Rule Standardized Curriculum Recognized by FDA ²	Delivery Method	Intended Audience	Cost
Conducting Vulnerability Assessments using Key Activity Types	Available now 	<ul style="list-style-type: none"> • Food professionals who conduct VAs using the KAT Method only • This course is strongly recommended before taking the Conducting Vulnerability Assessments course 	\$169.00 USD
Identification and Explanation of Mitigation Strategies	Available now 	<ul style="list-style-type: none"> • Food professionals who identify Mitigation Strategies to implement at Actionable Process Steps 	\$179.00 USD
Conducting Vulnerability Assessments	Available now 1-Day Course 	<ul style="list-style-type: none"> • Food professionals who conduct VAs using the 3 Fundamental Elements • This 1-day course must be taught by FSPCA VA Lead Instructors • The VA/KATs online course is strongly recommended before taking this course 	Varies – price set by independent IAVA Lead Instructors
Food Defense Plan Preparation and Reanalysis	Available now 	<ul style="list-style-type: none"> • Food professionals who prepare the Food Defense Plan and/or who conduct Reanalysis activities 	\$109.00 USD

Inspectional Framework for IA Rule

- Two-level inspectional approach
 1. Food Defense Plan Quick Check
 - Conducted on covered facilities during food safety inspections
 - High level review of Food Defense Plan (FDP)
 2. Food Defense Comprehensive Inspections
 - Conducted only at limited number of prioritized facilities during food safety inspection
 - Conducted by specially trained investigators
 - Critical evaluation of FDP, conclusions, rationale

Schedule of Inspections

- Food Defense Plan Quick Checks: Fall 2020
 - Started slow due to COVID
 - Add-on to other program inspections
 - Validating our inventory information and coverage
 - Will continue now that comprehensive inspections have begun
- Comprehensive Food Defense Inspections: August 2024

Food Defense Plan Quick Check Process

- Quick Check is conducted through short inspectional protocol that is relevant to the requirements of a food defense plan
 - 21 CFR 121.126 *Food Defense Plan*
- Visual, on-site inspection of the Plan
- No records collected
- Investigator can provide informational materials/additional resources
 - IA rule guidance fact sheets, FSPCA training

Food Defense Plan Quick Check Inspections

- What are we seeing?
 - Industry is developing food defense plans as required
 - Use of IA rule guidance is beneficial
 - KATs are showing significant utilization by industry
 - Key Activity Types and Hybrid are widespread for VA methodology

Comprehensive Food Defense Inspections

- Detailed review of food defense plan and inspection to determine status of plan implementation in the facility
 - Determine adequacy of plan components
 - Assess implementation status
- Conducted by Food Defense Inspection Team (FDIT) members
 - Specialized food defense training
 - Food Defense Team SMEs available for real-time consultation & technical support



Comprehensive Food Defense Inspections

- What are we seeing?
 - Firms are aware of IA rule and have FD plans
 - Interested in getting feedback and improving FD plans
 - Firms that use FDPB tend to be more organized and have addressed the requirements of the IA rule
 - Many questions firms have can be answered directly from guidance
 - Training is not a mitigation strategy
 - Cameras facilitate human observation



www.fda.gov/fooddefense

WINNING STRATEGIES: INDUSTRY EXPERIENCES IN ENHANCING FOOD SAFETY



PANELIST
DAVID CLIFFORD
NESTLE



PANELIST
JOE MEYER
KERRY



PANELIST
JOHN BUDIN
McCORMICK



MODERATOR
MATT BOTOS
CONNECT FOOD

REGIONAL FSMA CENTERS



PANELIST
ALEXIS HAMILTON
VIRGINIA TECH



PANELIST
ANNIE FITZGERALD
NORTHEAST CENTER TO
ADVANCE FOOD
SAFETY (NECAFS)



PANELIST
JOY WAITE-CUSIC
OREGON STATE
UNIVERSITY



PANELIST
JODI WILLIAMS
U.S. DEPARTMENT OF
AGRICULTURE



MODERATOR
JERRY WOJTALA
INTERNATIONAL FOOD
PROTECTION TRAINING
INSTITUTE (IFPTI)

FDA & FSPCA TECHNICAL ASSISTANCE NETWORKS



PANELIST/MODERATOR
KATHY GOMBAS
FSMA SOLUTIONS



PANELIST
LILLIAN HSU
U.S. FOOD AND DRUG
ADMINISTRATION
(FDA)



PANELIST
MARTIN BUCKNAVAGE
PENN STATE



PANELIST
DAWN JOHNSON
FOOD SAFETY
PREVENTIVE CONTROLS
ALLIANCE (FSPCA)

FSPCA Technical Assistance Networks - REFRESH



FSPCA Technical Assistance Network (TAN)

FDA FSMA RULE QUESTIONS

For questions related to the FSMA rules, FSMA programs, and FDA regulatory implementation strategies, please submit your questions to [FDA's FSMA Technical Assistance Network](#).

FSPCA SCIENTIFIC QUESTIONS

For scientific and/or technical food safety related questions, visit the [University Extension Specialist Directory](#).

FSPCA CURRICULA

For questions related to FSPCA training, curricula, Lead Instructor applications, or Lead Instructor administrative support, [please use the online form](#).

FSPCA PCHF V2.0 QUESTIONS

For questions specifically related to the Preventive Controls for Human Food Version 2.0 curriculum, [please use the online form](#).

For other questions, email fspca@iit.edu

FDA's FSMA Technical Assistance Network

Lillian Hsu
FDA | Office of Inspections and Investigations

FSMA Technical Assistance Network



- Launched on September 10, 2015
- Provide technical assistance to industry, regulators, academia, and consumers regarding FDA's Food Safety Modernization Act (FSMA)
- Address questions related to FSMA rule interpretation, applicability, programs, and implementation
- Does not address questions on FSPCA training or specific scientific/technical questions
 - [Link to FSPCA TAN](#)

FSMA Topic	Inquiries Received*
Accredited Third-Party Certification	377
Food Traceability	508
Foreign Supplier Verification Programs	3,403
Intentional Adulteration	356
Lab Accreditation	111
Preventive Controls – Animal Food	1,358
Preventive Controls – Human Food	5,130
Produce Safety	1,600
Sanitary Transportation	1,489
Voluntary Qualified Importer Program	58

**as of June 2024*

Approximately 80% are domestic, 20% international

How to contact the FSMA TAN

- Start with frequently asked questions
- If assistance is still needed, click “submit your question to the TAN”
- Mail option available

← Home / Food / Guidance & Regulation / Food and Dietary Supplements / Food Safety Modernization Act (FSMA) / FSMA Technical Assistance Network (TAN)

FSMA Technical Assistance Network (TAN)

Share X Post LinkedIn Email Print

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Frequently Asked Questions

The Technical Assistance Network staff has compiled answers to [frequently asked questions on FSMA](#). You may also use [FSMA Guidance Documents](#) to find answers to your questions.

Submit Your Question Electronically

Didn't find your question above?

For assistance with **human food** topics, [submit your question to the TAN](#).

For assistance with **animal food** topics, email the [CVM TAN Mailbox](#).

Mail Your Question

If you prefer to mail in your question, please send it to the address below:

Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Content current as of: 03/14/2024

Regulated Product(s)
Animal & Veterinary Food & Beverages

Food Safety Modernization Act (FSMA)

Frequently Asked Questions on FSMA

FSMA Rules & Guidance for Industry

What's New in FSMA

FSMA Training

FSMA Technical Assistance Network (TAN)

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>

Inquiry form

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

FDA Form: 3907
Expiration Date: Month XX, XXXX

I am a member of this category *

Email *

Confirm Email Address *

Country *

Zip Code *

Is your inquiry related to *

- General Inquiry
- Product Complaint
- Food Safety Modernization Act requirements (FSMA)

FSMA Topics *

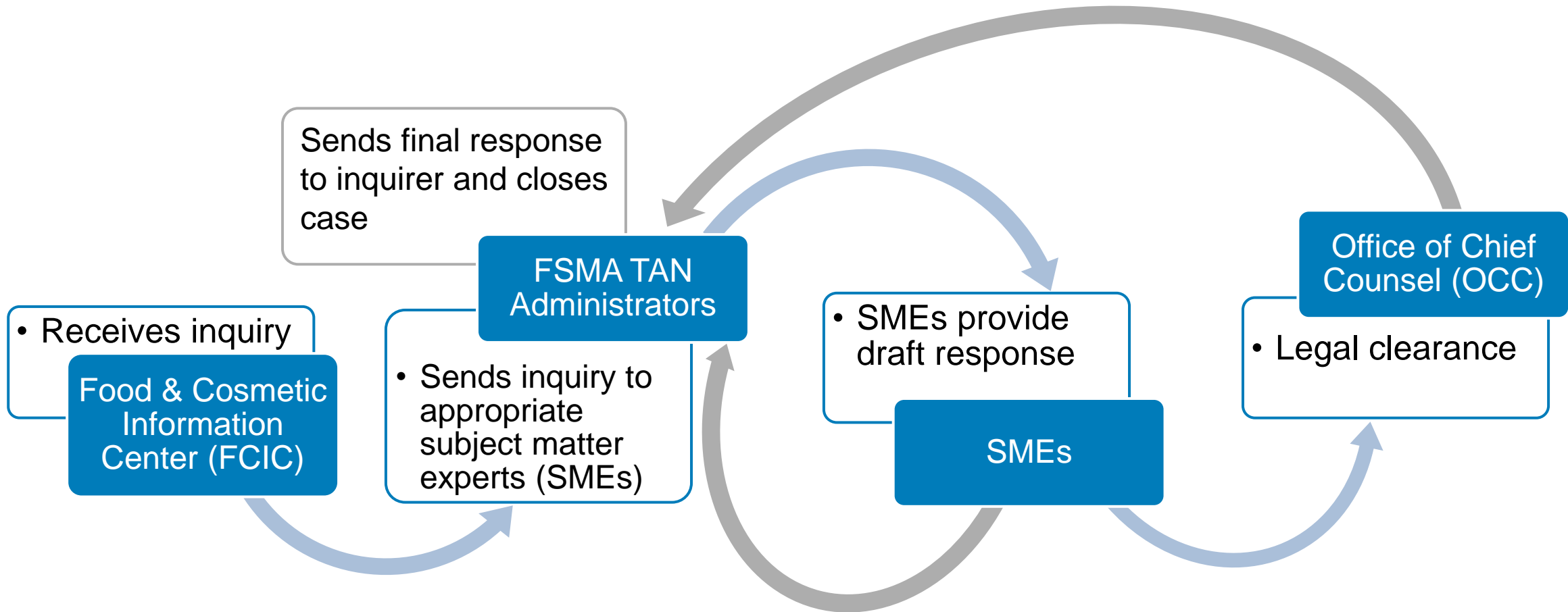
Inquiry (2500 character limit) *

-
- Accredited Third-Party Certification (3rd Party)
- Food Facility Registration
- Foreign Supplier Verification Program (FSVP)
- Intentional Adulteration
- Lab Accreditation
- Preventive Controls-Human Food
- Produce Safety
- Sanitary Transportation for Human and Animal Food
- Voluntary Qualified Importer Program (VQIP)
- Other
- Food Safety Dashboard Measure
- Food Traceability

The Food and Drug Administration's (FDA), Food Safety Modernization Act (FSMA) requires you to submit your web inquiry as soon as possible. However, response times may vary, due to public health priorities and the high volume of inquiries we receive. We strive to provide the public with accurate and current information, which at times requires extension requests. Please be assured that we will respond as soon as possible.

- Accredited Third-Party Certification (3rd party)
- Food Facility Registration
- Foreign Supplier Verification Program (FSVP)
- Intentional Adulteration
- Lab Accreditation
- Preventive Controls – Human Food
- Produce Safety
- Sanitary Transportation for Human and Animal Food
- Voluntary Qualified Importer Program (VQIP)
- Other
- Food Safety Dashboard Measure
- Food Traceability

TAN process – Human Foods Program



How to facilitate a timely and complete response

- Be as specific as possible
 - All activities conducted at the facility
 - Domestic or foreign establishment
 - Business size
 - Regulation(s) you are asking about
 - Explain abbreviations
- If you have follow-up questions and submit a new inquiry, include the initial case #

Example: Vague inquiry

- My client manufactures various cookies. Does FSMA apply? They have a HACCP plan. Do they need a PCQI? Also, do they need to have the FSVP?

Are the cookies for human consumption in the United States?

FSMA is 9 regulations... which one(s) are they asking about?

Does the business import human or animal food?

Is the business a qualified facility under part 117?

Is the business located in the United States or internationally?



Example: Detailed inquiry



- My client is a facility in NYC that manufactures various cookies for consumption in the United States. Average annual sales is approximately \$10 million. They import some of the ingredients such as chocolate chips directly from a manufacturer in France. They have a HACCP plan, and the plant manager is HACCP-certified. My questions are:
 - Do they need to have a PCQI under the FSMA Preventive Controls for Human Food regulation? If so, is HACCP training enough, or do they need PCQI training?
 - Do they need an FSVP?



FSPCA TAN – SCIENTIFIC QUESTIONS

MARTIN BUCKNAVAGE, PENN STATE

FSPCA SCIENTIFIC QUESTIONS

- University experts volunteering to provide support to participants regarding the development and implementation of the Food Safety Plan
- Purpose:
 - Answer scientific and technical questions
 - Provide direction and support documentation in areas such as validation, critical limits, environmental monitoring
- Participant inquirers choose from the list of volunteer experts and interact directly with that expert

FSPCA SCIENTIFIC QUESTIONS

Typical Queries

- Is there any research to support the use of UV light for bacterial reduction on the surface of a given food product?
- What type of chemical works best for use in a sanitizing rinse where the rinse temperature is low and there is a high organic load?
- Where do I go for getting my process validated?

FSPCA SCIENTIFIC QUESTIONS

Status

- Launched Oct 28, 2024
- There are currently 29 university staff who have agreed to serve on the TAN for Scientific Questions
- Each person is listed by state with their respective university and any areas of specialization
- Initial implementation focused on PCHF within the US, will next expand to other FSPCA program areas as well as to providing support for international inquiries
- If interested in participation, please contact fspca@iit.edu



FSPCA TAN – FSPCA CURRICULA

DAWN JOHNSON, FSPCA

FSPCA CURRICULA

- After you submit an inquiry to one of the **curriculum-related menu options**, experts are on hand to review your question and provide you with the resources you need

Submit a Question

*QUESTION REASON

Choose from the dropdown menu

Human Food V2.0 Curriculum

Animal Food

Foreign Supplier Verification Program

Intentional Adulteration

Food Traceability

FSPCA Administrative Support

Other

How do I apply to become an FSPCA FSVP Lead Instructor?

Which IA courses are appropriate for a Food Defense Qualified Individual?

FSPCA CURRICULA

- Use the **FSPCA Administrative Support** menu option for assistance with FSPCA products, resources, and processes. FSPCA staff will respond promptly.

Where do I find the most current Lead Instructor Resources?

Where can I get a copy of my FSPCA certificate?

I need to cancel my course

Submit a Question

*QUESTION REASON

Choose from the dropdown menu

Human Food V2.0 Curriculum

Animal Food

Foreign Supplier Verification Program

Intentional Adulteration

Food Traceability

FSPCA Administrative Support

Other



FSPCA TAN – PCHF V2.0 QUESTIONS

KATHY GOMBAS, FSMA SOLUTIONS

FSPCA PCHF V2.0 QUESTIONS

- Experts available to answer V2.0 curriculum queries
- Purpose:
 - assist V2.0 Lead Instructors with their future participant course deliveries
 - answer general questions about V1.2 and V2.0
 - FAQs will be posted based on queries asked

FSPCA PCHF V2.0 QUESTIONS

Query Examples

Q: How long are the FSPCA V1.2 participant course certificates valid?

A: The FSPCA participant course certificates including Human Food V1.2 and V2.0 do not have an expiration date.

PCQIs are not required to obtain a training certificate to comply with the FDA's regulation 21 CFR Part 117 training requirements; therefore, they are not required to "retake" the updated FSPCA participant course (V2.0).

One of the benefits of taking the updated curriculum is to be in line with FDA's current thinking since V2.0 curriculum has been updated to incorporate all of FDA's guidance information that was issued after V1.2 curriculum was published.

FSPCA PCHF V2.0 QUESTIONS

Query Examples

Q: When will Human Food V2.0 Curriculum blended course be available?

A: Now that the Human Food V2.0 curriculum has been finalized, FSPCA is vigorously developing the Blended Course, Lead Instructor Course, and V2.0 translations. FSPCA plans to have the Human Food V2.0 Blended Course available early in 2025.

MAIN
CONFERENCE
ROOM

BREAKOUT SESSION: RECALL IMPACTS



PRESENTER
MARTIN BUCKNAVAGE
PENN STATE



MODERATOR/SCRIBE
AMY PHILPOTT
PHILPOTT PR
SOLUTIONS, LLC

Analysis of Recalls 2024 – Jan to Sept



PennState Extension

Martin Bucknavage, Penn State Department of Food Science

Analysis of Recalls

- What do recent recalls indicate about the safety of our food supply?
- What are the most current issues faced by firms as indicated by recalls?
- How can we use this information to help firms improve?

FDA Data Dashboard

FDA Data Dashboard

Compliance Dashboards

[Inspections](#)

[Compliance Actions](#)

[Recalls](#)

[Imports Summary](#)

[Import Refusals](#)

[Imports Entry](#)

FSMA Data Search

Find firm compliance and enforcement information.

[Search Firm Information](#)

[Approved VQIP Importers](#)

[TFP Participants](#)

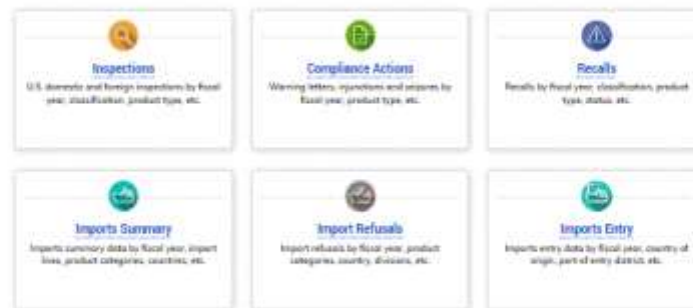


NOTE

- Sign up to receive notifications about FDA Data Dashboard updates and information.
- FDA Data Dashboard now has RESTful APIs for programmatic data retrieval. Visit our [API documentation page](#) for more information.

The FDA created the Data Dashboard to increase transparency and accountability by displaying and allowing the analysis of public FDA data through easy to use, visually accessible, customizable, and understandable graphics.

Compliance Dashboards

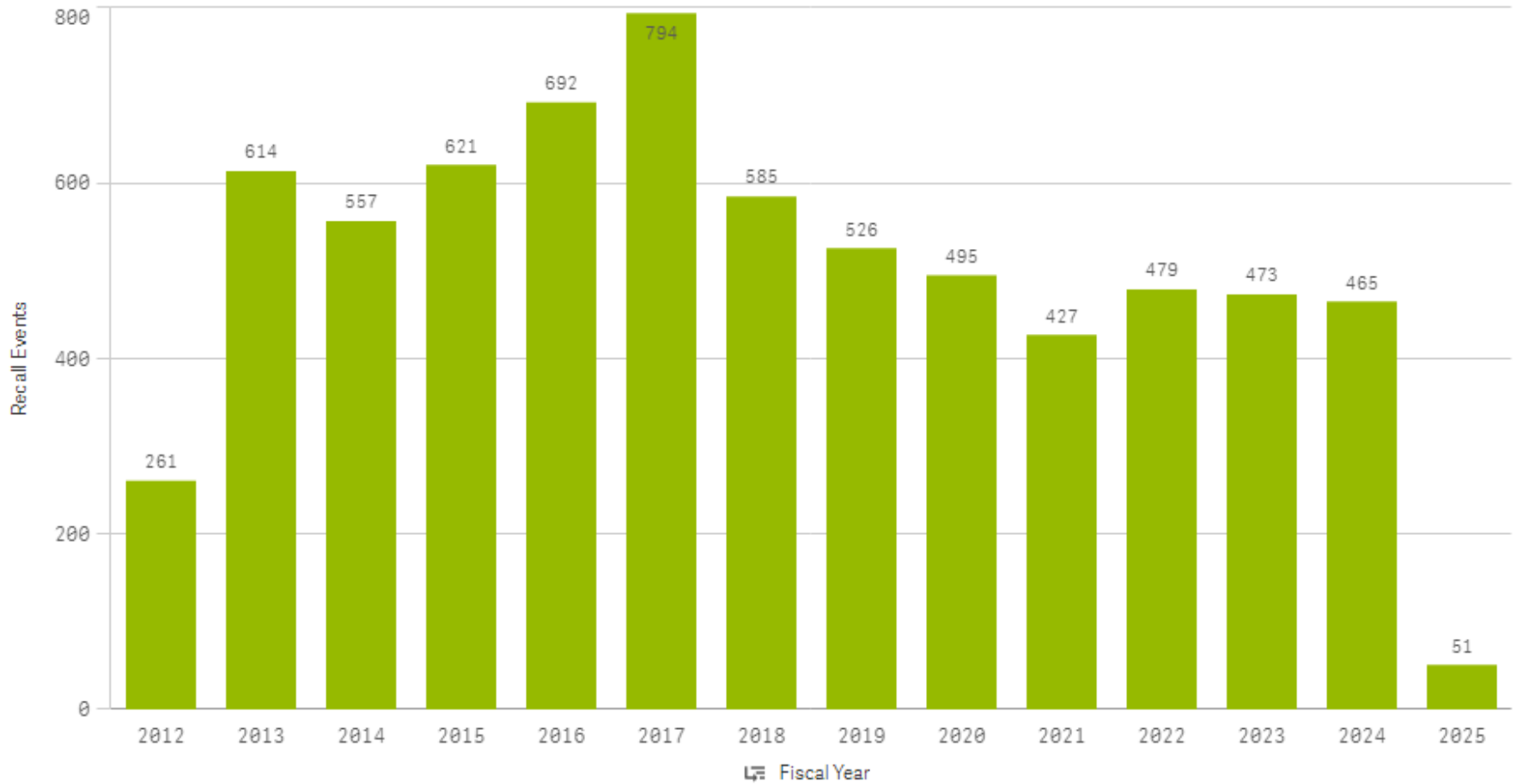


FSMA Data Search

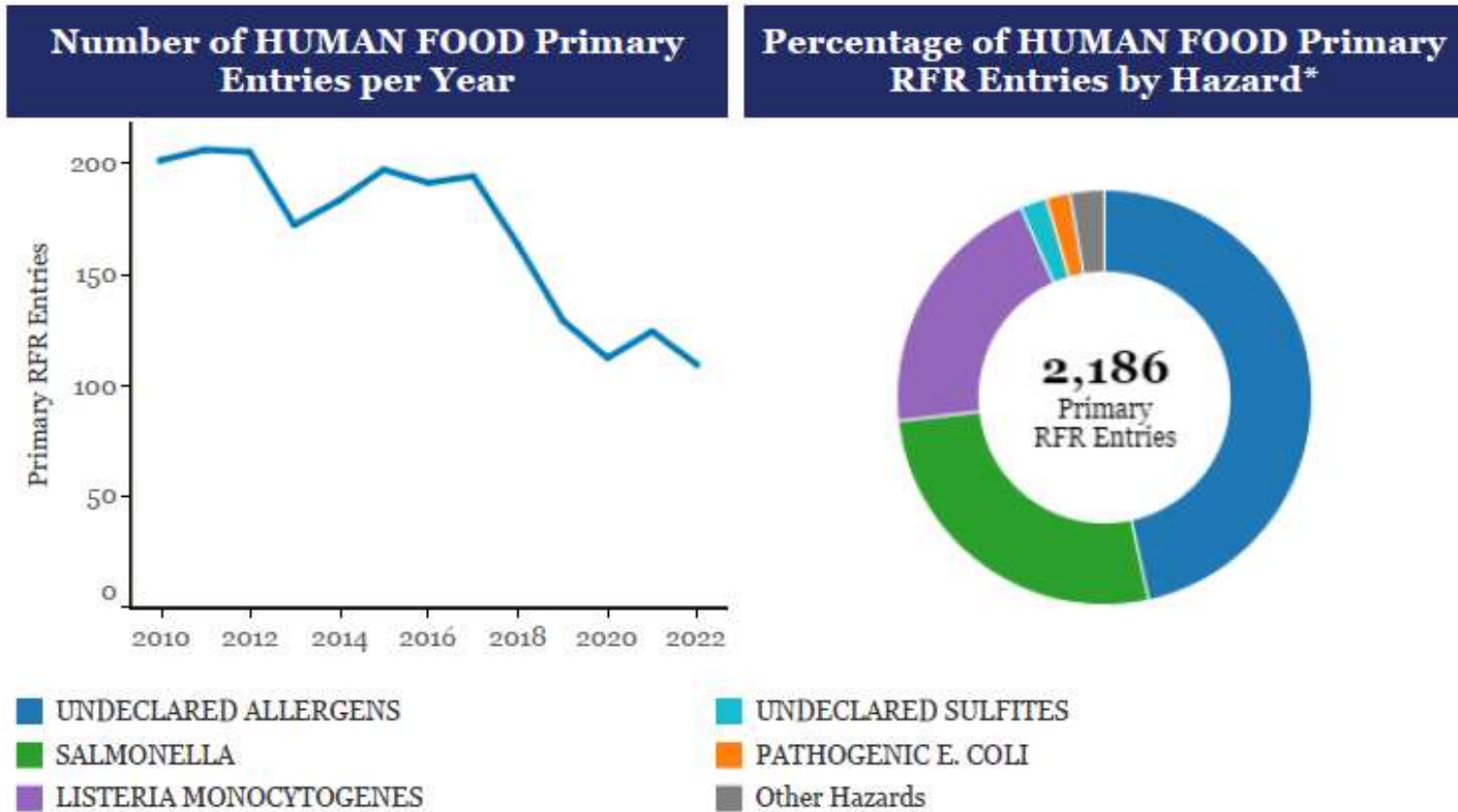
Recall Events FY 2012 to 2025 (Food and Cosmetics)

Recall Events by Fiscal Year

Fiscal Years: 2012 - 2025



Reportable Food Registry (thru FY 2022)



* "Other Hazards" includes primary entries with hazards less than 1.5% of total primary entries.

Is the US Food Supply Less Safe?

- There is no indication, based upon recall data or outbreaks, to indicate our food supply is getting worse.
- Potential impact by amplification in media due to highly visible outbreaks (E. coli O157:H7 in sliced onions, Listeria in deli meat), and recalls (waffles and RTE chicken, both Listeria) in an election year
- Social media creates an echo effect

Identifying Issues in Food Supply

- Investigate more recent recalls
 - Published retrospective studies lag too far in the past and/or take too much time into account
 - Allows one to identify issues where gaps still exist
 - Provides educators fodder to reinforce learning objectives

Methodology

- Evaluated about 148 posted recalls from January 1, 2024 to September 30, 2024
 - Type of Hazard
 - Source / Cause
 - How issue was identified
- Where possible, assessed size of company and any related factors
 - While FDA identifies 'small business' as less than 500, I will define it as less than \$25 million in sales.

Limitations

- Limited to posted recalls versus the all that are listed on Enforcement Report
 - May be the source of some bias
- Limited by the amount of information shared on the recall notice
- Did not include seafood or animal feed / pet food

FDA Recalls – January to September, 2024

Issue	Number
Allergens	58
<i>Listeria</i> (assoc with cheese outbreak)	35 (19)
<i>Salmonella</i>	20
Lead	12
Sulfites	6
Foreign Material	3
<i>E. Coli</i> (STEC)	2
<i>C. botulinum</i>	2
Mold growth	2

Undeclared Allergens

- Label Application – Mislabeling (22/58)
 - Often found by down-stream entity
 - Normally involves limited quantities of product
 - One common issue is misapplication of back ingredient label
- Label Design (19/58)
 - Small firms or imported product
- Formulation (9/58)
- Cross-contact (6/58)
 - Often found through customer complaint

The majority of recalls are associated with small firms

Listeria monocytogenes

Queso fresco and cotija cheeses manufactured by Rizo Lopez Foods, Inc., of Modesto, California

- Total Illnesses: 26
- Hospitalizations: 23
- Deaths: 2
- In January 2024, the Hawaii DOH tested product made by Rizo-López Foods and found the outbreak strain in the product.
- FDA conducted inspections at the Rizo-López Foods facility and found the outbreak strain from two environmental samples that were collected at the facility.
- Product was used by other firms resulting in multiple secondary recalls – demonstrates the need for Supplier Preventive Controls.

Listeria monocytogenes

Outside of the cheese recall, *Listeria* related recalls are primary due to sample testing.

- State or Federal agencies
- Internal testing
- Customer testing
- Supplier-related testing

Salmonella

Imported basil from Columbia recalled after being involved in outbreak.

- Total Illnesses: 12 and Hospitalizations: 1

Confectionary product - liquid coating supplier notified customers that there was a potential for contamination with *Salmonella* from an ingredient that was potentially contaminated from one of their suppliers

Sample testing primary reason for recalls

- Seven imported products – recalls issued after testing

***E. coli* (STEC)**

E. coli outbreak linked to raw milk cheese from Raw Farm Brand.

- Illnesses: 11
- Hospitalizations: 5 (2 HUS)

Recalled organic walnut halves and pieces were sold in bulk bins at natural food and co-op stores

- Total Illnesses: 13
- Hospitalizations: 7
- Deaths: 0

Lead in Cinnamon Apple Sauce

- Foreign supplier of apple sauce used a cinnamon source that had lead chromate added to it as part economic adulteration
- FDA reported 90 confirmed cases of lead poisoning in children
- Put additional attention on supplier's supplier relationship

Following this issue, FDA conducted a sampling of cinnamon in the US and found additional cases of elevated lead in cinnamon which resulted in recalls. These cases were not as high as those found in the applesauce.

Other Types of Recalls

- Sulfites – dried fruit, especially if imported
- Foreign material – there has been improvement over the past several years
- Issues related to process – mold growth, *C. botulinum*, and under-processing

Identification of How Issues are Discovered – Trigger Elements

- Customer feedback systems
- Increased testing by various entities (Gov agencies, customers, etc)
- Improved microbiological analysis

Need for Improvement

Reinforces the need to utilize Preventive Controls approach.

Allergens PCs

- Cannot take allergen control for granted.
- PCs at label design and application, but also formulation and areas where cross-contact is a risk

Sanitation PC for environmental hazards including Listeria

- Product may be subject to sample testing of the product

Supply chain preventive controls

- Allergen labeling (although may be more FSVP)
- Biological and chemical hazards

Outreach to small and very small firms

Utilizing Published Recall Data

- Instructors should keep abreast of food safety issues and utilize worthy examples to reinforce learning objectives
- Drill down to gain the best understanding of root cause
- Refrain from guessing at potential causes or sources, or clearly indicate that it is a just speculation

Thank you!

Questions?

Martin Bucknavage

Penn State Department of Food Science

mwb124@psu.edu

**SALON
4**

BREAKOUT SESSION: ANIMAL FOOD CASE STUDY



EXPERT
JENNIFER ABRAHAMZON
U.S. FOOD AND DRUG
ADMINISTRATION (FDA)



EXPERT
DAVID FAIRFIELD
NATIONAL GRAIN AND
FEED ASSOCIATION (NGFA)



MODERATOR/SCRIBE
CHRIS LINCECUM
COOPERATIVE FARMERS
ELEVATOR (CFE)

ANIMAL FOOD BREAKOUT SESSION

Case Study: *Mitigating Hazards Under a Flexible Regulation*

EXPERTS:

Jennifer Abrahamzon, FDA CVM

David Fairfield, National Grain and Feed Association

MODERATOR/SCRIBE:

Chris Lincecum, Cooperative Farmers Elevator



Breakout Objective

Discuss options for how to effectively mitigate animal food hazards under Part 507 regulations – *Pre-requisite Programs* versus *Preventive Controls*

Background Information

1. Review hazard analysis requirements
2. Review preventive control management components

Case Studies

1. Aflatoxin
2. Nutrient toxicity, e.g., elevated copper, elevated vitamin D

Hazard Analysis Process

Does the agent have the potential to cause illness or injury in humans or animals?

Hazard

Is the hazard associated with the:

- Facility or
- Type of animal food?

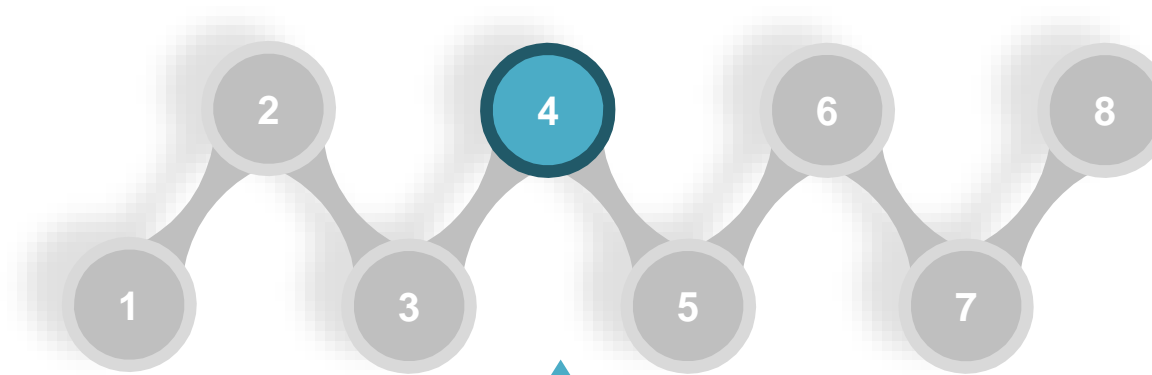
Known or Reasonably Foreseeable Hazard

Is the hazard:

- Severe and
- Probable?

Hazard Requiring a Preventive Control

Step 4



Assess Probability that the Hazard Will Occur in Absence of Preventive Controls

Example: Use a Probability Score Rubric

*Can consider prerequisite programs, such as CGMPs

Step 4 – FSPCA AF Curriculum

Manual Note: A facility should consider whether an effective prerequisite program (such as CGMP) reduces the probability that a known or reasonably foreseeable hazard may occur. This consideration may result in the facility determining that, based on the overall hazard analysis:

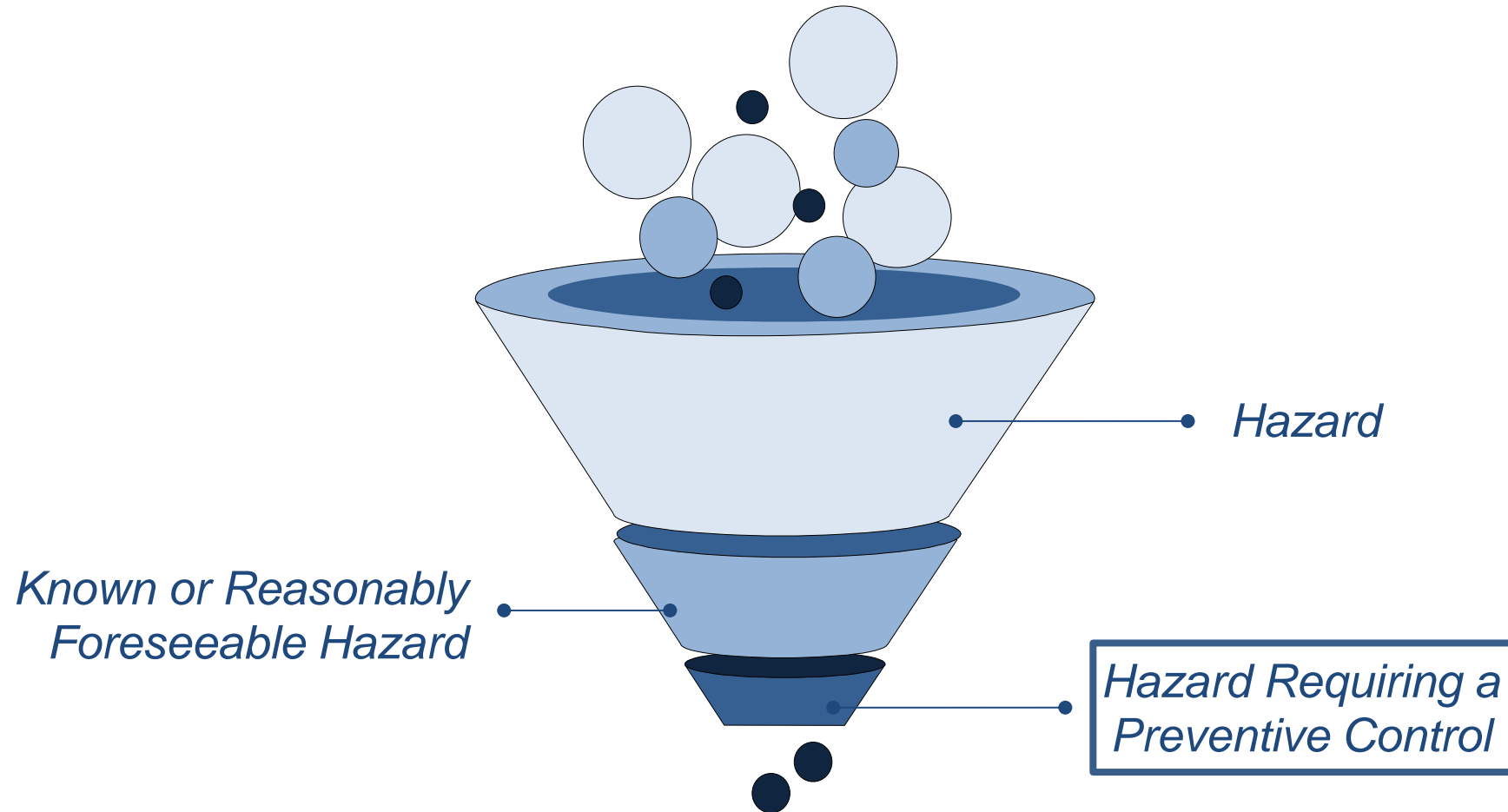
- the hazard does not require a preventive control;
- the hazard requires a preventive control and the prerequisite program is the preventive control; or
- the hazard requires a preventive control beyond the prerequisite program.

This prerequisite program must be effectively implemented to reduce the probability, thus having procedures and routine recordkeeping in place are a good industry practice.

Additional FDA Perspectives on Use of Pre-Requisite Programs

- Used to reduce probability a hazard will occur in the absence of a preventive control. Frequently used for hazards such as:
 - Aflatoxin and other mycotoxins
 - Drug carryover and nutrient deficiency/toxicities
- Must be robust and consistently implemented to support hazard analysis determinations
- Pre-requisite program design and implementation failures have been a frequent root cause of recall and compliance situations

Hazard Analysis Process



Preventive Control Management Components

- Monitoring
- Corrective actions and corrections
- Verification
 - Validation
 - Verification of monitoring and corrective actions
 - Verification of calibration of equipment and instrumentation
 - Verification by product testing and/or environmental monitoring
 - Reanalysis of the food safety plan

Use of Pre-Requisite Programs

Must be robust and consistently implemented to support hazard analysis determinations ... having procedures and routine recordkeeping in place are a good industry practice

To be robust and consistently implemented, what kind of design and management components should a pre-requisite program have?

Aflatoxin

	Prerequisite Program	Preventive Control
Mitigation Process/Procedure		
Are we sure it works? (Validation)		
Are we doing it consistently? (Monitoring)		
What do we do when something goes wrong? (Correction/Corrective Action)		
Are we really sure we're doing it consistently? (Verification of Monitoring/Corrective Action)		
Does the equipment work right? (Verification – Calibration)		
Is the animal food safe? (Verification – Product Testing/Environmental Monitoring)		
Is the entire system working? (Reanalysis)		

Vitamin D Nutrient Toxicity

	Prerequisite Program	Preventive Control
Mitigation Process/Procedure		
Are we sure it works? (Validation)		
Are we doing it consistently? (Monitoring)		
What do we do when something goes wrong? (Correction/Corrective Action)		
Are we really sure we're doing it consistently? (Verification of Monitoring/Corrective Action)		
Does the equipment work right? (Verification – Calibration)		
Is the animal food safe? (Verification – Product Testing/Environmental Monitoring)		
Is the entire system working? (Reanalysis)		



SUPPLY CHAIN DISRUPTIONS: SOLUTIONS FOR THE FOOD INDUSTRY

JOHN SPINK
FOOD FRAUD PREVENTION ACADEMY
MODERATOR: JERRY WOJTALA

Supply Chain Disruptions: Solutions for the Food Industry



John W Spink, Ph.D.

Food Fraud Prevention Academy
John.Spink@YorkPartnersLLC.com
517-381-4491

Also: Assistant Professor (Fixed-Term),
Department of Supply Chain Management,
Business College, Michigan State
University (USA) (14-yr, #1 SCM)

Courses: Intro to SCM, Procurement Contracting, Customs
& Security, Lean Systems, & Negotiation (2+k/yr)

 The logo for the Food Safety Preventive Controls Alliance (FSPCA). It features the letters "FSPCA" in a blue, sans-serif font. The letter "P" is stylized with a green and blue circular graphic element behind it. A registered trademark symbol (®) is located to the upper right of the "A".

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

**2024 FSPCA ANNUAL
CONFERENCE**

Chicago
November 19, 2024 (Day 2)
1:45 to 2:45 pm
Moderator: Jerry Wojtala

Food Fraud Prevention Resources

Textbook: Food Fraud Prevention (Spink, 2019)

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

- With a **'certificate of completion'** based on **assessments**
- On-demand, ten professional training hours

CORE

1. Food Fraud Prevention Overview MOOC
2. Food Fraud Vulnerability Assessment & Prevention Strategy (VACCP) MOOC
3. Food Fraud Supply Chain Management & Procurement MOOC
4. Food Fraud Prevention Audit Guide MOOC

Specialty

1. Food Defense Threat Audit Guide MOOC
2. Food Fraud & Enterprise Risk Management (ERM)
3. Food Fraud Advanced Criminology – Intelligence & Investigations
4. Developing an Organic Fraud Prevention Plan (with OTA)

Also:

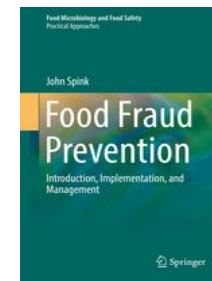
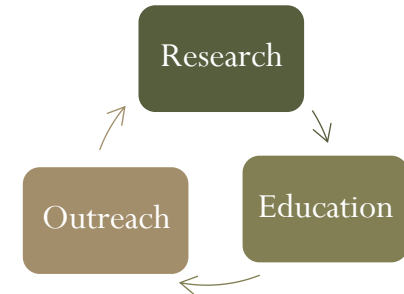
1. **USDA NOP** – Organic Fraud and the Criminal Mind (See USDA.gov)
2. **USDA NOP** – Preventing Organic Product Fraud (See USDA.gov)

Master Certificate in FF Prevention: Complete Core and Specialty

Professional Education: Workshops and Events

- **MooLive: Seven MOOCs in four webinars: January, March, April, June**

Professional Services: Workshops and Consulting including Retainer



Link to Textbook:

<http://www.anrdoezrs.net/links/9101220/type/dlg/https://www.springer.com/us/book/9781493996193>



Why Spink? Food Fraud to Food Safety to Supply Chain Management... and back...

- My core research area is *Food Fraud Prevention*.
- *Food Fraud Prevention* syncs into the *Food Safety Management Systems*.
- *Food Safety Management Systems* contribute to high performance *Supply Chain Management*.
- *Supply Chain Management* includes an interconnect set of systems that can provide efficiency for *Food Fraud Prevention* and *Food Safety Management Systems*.
- Food Safety is often thought of as a ‘food’ problem.
- This chapter reverses the focus and considers food safety in the context of a supply chain disruption.

“The nature of the world marketplace is a shift to constant supply chain disruptions and emerging risks which leads to a need to build systems to not only ‘fix’ current problems but to become resilient to ‘everything’ and ‘anything’ and ‘all the time.’”

*Supply Chain Disruptions are now a top-down matter...
defined by the impact on the enterprise in enterprise risk
management terms.*

*The resource allocation decision-making is based on a
defined, quantitative, analytical 'risk tolerance.'
This is including for agencies (see the GAO Green Book).
But isn't this what we've always been doing with Food
Safety and HACCP?*

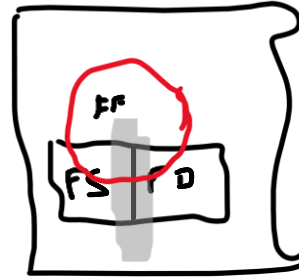
*Yes, but with a positioning nuance as a supply chain
disruption we have a system to compare it with 'everything.'*



Preliminary Comment

Preamble: Food Fraud Prevention: Original MDARD Meeting and the Evolving

- Evolution of the Food Fraud concept:
 - A separate thing (to three circles) MDARD:
 - Presented nationally) AFDO, 2007, Invited by Wojtala
 - Presented between Acheson presentations and he had to put down his Blackberry, then invited to FDA, oh it's testimony? The FDA EMA Public Meeting.
 - Added Food Quality: FDA EMA meeting May 1, 2009
 - To the matrix: MDARD, quarterly meeting, May 10, 2009
 - Journal publication in 'Defining the Public Health Threat of Food Fraud,' 2011
 - Note: FDA presented in April 2017
 - Note: presented by China CFSA in 2015



State of Michigan Ag & Food Protection Strategy Team, ~2006



Economically Motivated Adulteration (EMA), Quantitative Risk Assessment (QRA) MDA APS Case Study, May 1+, 2009



Note: ChatGPT4.0 – Review

- Artificial Intelligence provides tremendous opportunities...
- within reason.
- What is 'reason'? (Create, with cites from spink & HBR)
 - Supply Chain Disruptions: Solutions for the Food Industry (Pretty good... too non-food, over-applied)
 - Action Items and Next Steps (Not helpful, generic)
- Citations: (FANTASTIC!!!)
 - Spink, J. "Supply Chain Vulnerability and Resilience: A Framework for Food Industry Adaptation," *Journal of Supply Chain Management*, 2020.
 - Harvard Business Review, "Building a Resilient Supply Chain," 2021.
 - Spink, J. "Mapping Risks: Tools for Strategic Supply Chain Decisions," *Journal of Food Protection*, 2022.
 - Harvard Business Review, "The Agility Imperative in Supply Chain Management," 2022.

Q: Confidence in recommending this for your company???

Manuscript for Dr. John Spink's Presentation:

Title: *Supply Chain Disruptions: Solutions for the Food Industry*

Introduction
Good morning, ladies and gentlemen,

Today, I'd like to address a critical topic that resonates deeply across the food industry: supply chain disruptions. These challenges have become the new norm, reshaping how we think about the global food supply. The question we must ask ourselves isn't just how to "fix" current problems but how to design resilient systems capable of adapting to "everything" and "anything."

The global food supply chain is no stranger to volatility. However, recent events—from the pandemic to geopolitical conflicts, climate change, and labor shortages—have highlighted a shift: we are moving into an era where disruptions are not just likely; they are inevitable. This requires us to rethink supply chain management not as a reactive process but as a proactive, dynamic strategy.

Today, I'll draw upon foundational supply chain management principles I've published and

Action Items and Next Steps for Food Companies to Reduce Supply Chain Disruptions

1. Conduct Comprehensive Risk Assessments

- Action Item: Identify and prioritize potential risks in your supply chain, including supplier vulnerabilities, transportation delays, and external threats like climate change or geopolitical issues.
- Next Steps:
 - Map your entire supply chain to identify critical nodes and dependencies.
 - Perform regular risk assessments, leveraging tools like Failure Modes and Effects Analysis (FMEA) or Supply Chain Risk Management (SCRM) frameworks.
 - Develop a risk prioritization matrix to allocate resources to the most significant vulnerabilities (Spink, 2019).

2. Implement Enhanced Traceability Systems

Citations:

1. Spink, J. "Supply Chain Vulnerability and Resilience: A Framework for Food Industry Adaptation," *Journal of Supply Chain Management*, 2020.
2. Harvard Business Review, "Building a Resilient Supply Chain," 2021.
3. Spink, J. "Mapping Risks: Tools for Strategic Supply Chain Decisions," *Journal of Food Protection*, 2022.
4. Harvard Business Review, "The Agility Imperative in Supply Chain Management," 2022.

Doesn't exist

Blog post, 2007

Doesn't exist

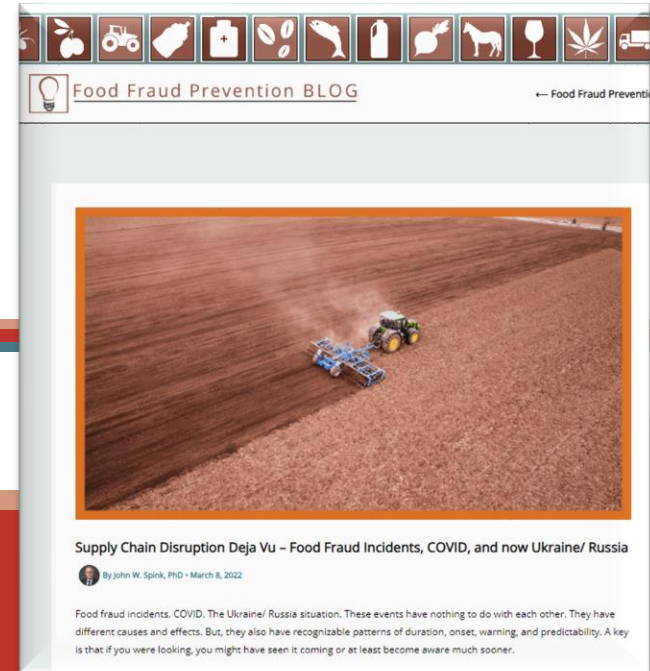
Doesn't exist

Supply Chain Disruptions

The new normal – get ahead or keep chasing fires

There are very few ‘black swan events’ – mostly ‘gray swans’

Scenario to scan to higher level disruptions



The Bottom Line

- Board of Directors focus on business uncertainty (reducing or at least understanding it)
- Enterprise Risk Management (ERM/ COSO) is being applied deeper into the business (to frontline resource allocation decisions).
- Government/ Industry testing increasing and, in more detail,
- AI/ Machine learning applied deeper into the business (finding anomalies more quickly)
- IOT/ 5G/ Internet is sharing information more quickly
- Supply chain stresses are high and increasing (consistent)
- Supply chain disruptions are high and increasing (consistent)
- Supply chain OMNICHANNEL adds massive complexity, novel disruptions, and tremendous traceability and transparency
- Other entities are trying to find their place (e.g., CODEX, WTO)
- ...so, now what?

Food Safety in Supply Chain Management, or Vice Versa? Yes.

Quality Management & Supply Chain Disruption Systems





Integrated Supply Chain Management (ISCM)

What is Supply Chain Management

- ...it's not just purchasing manager's who don't listen to you.
- It's managing the movement of everything from everywhere to everywhere...
- At anytime, anything can go wrong that shuts down your entire company:
 - Suez Canal
 - Texas ice storm
 - Computer chips shortage for cars
 - COVID for... everything...
 - India shut down again... what about new future disruptions...
 - *...or quality issues such as food safety incidents.*

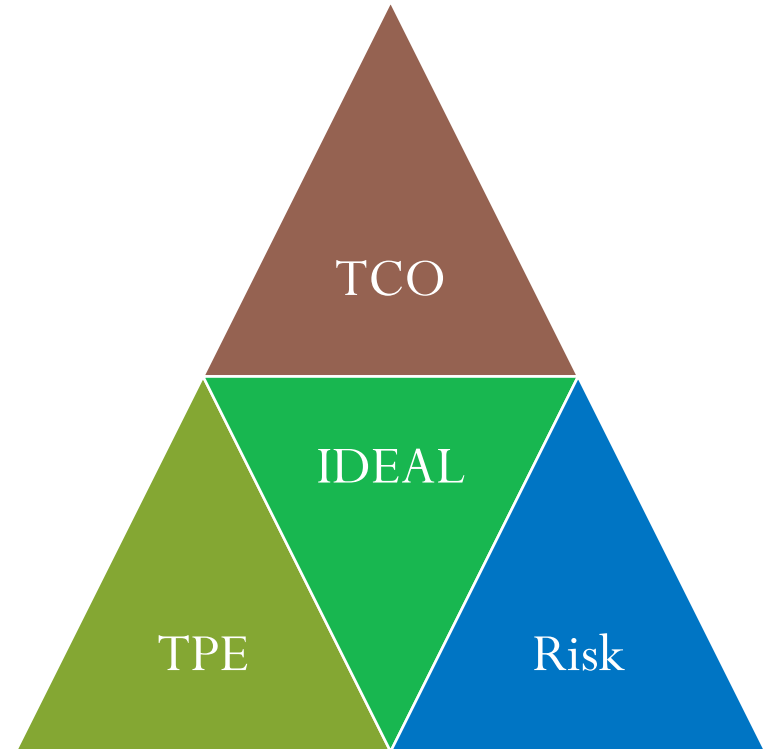
Michigan State University
Department of Supply Chain
Management
Business College

- Bachelors, MS and PhD Programs
 - #1 Undergraduate Program
 - #1 Research Productivity
- Integrated Supply Chain: sourcing, operations, logistics and the engagement
- Introduction to Supply Chain Management: required for all business students, 2500 students per year, integrated concepts applied to all business areas: finance, accounting, human resources, marketing, management, etc.

Fundamental Supply Chain Processes

BALANCE: TCO-TPE-Variability

- TCO: total cost of ownership
- TPE: total product experience
- RISK: variability, what could go wrong?
- IDEAL: optimal state



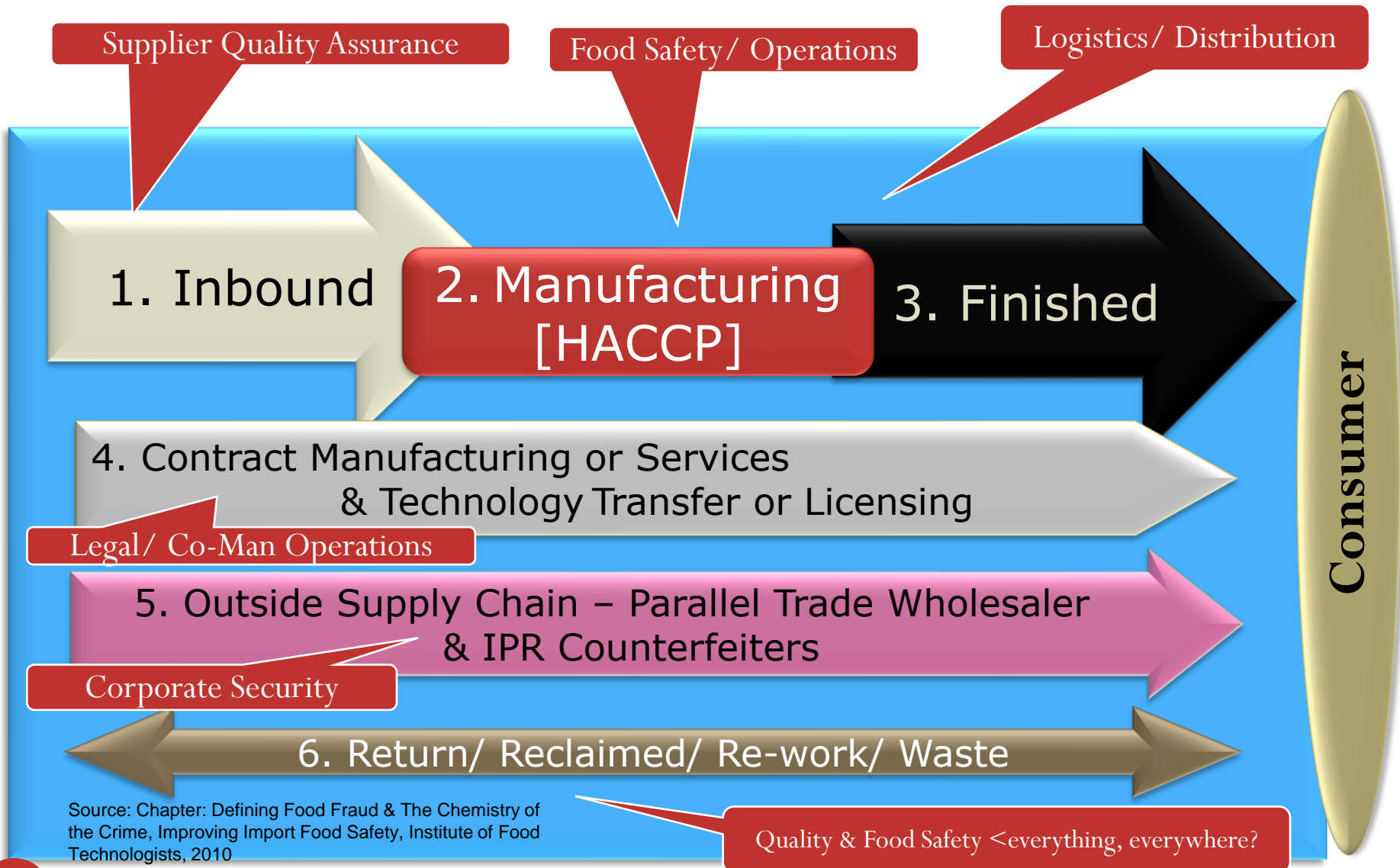
Balance of Activities

The Enterprise

- Operations
- Sourcing & Procurement
- Logistics
- Customer Service
- Functions: Risk Management, Quality, Sustainability, CSR, etc.



Food Supply Chain Management Accountability



Source: Chapter: Defining Food Fraud & The Chemistry of the Crime, Improving Import Food Safety, Institute of Food Technologists, 2010

Supply Chain Management Basics

Efficient communication starts with understanding THEIR system and using THEIR terminology...

From the supply chain management literature:

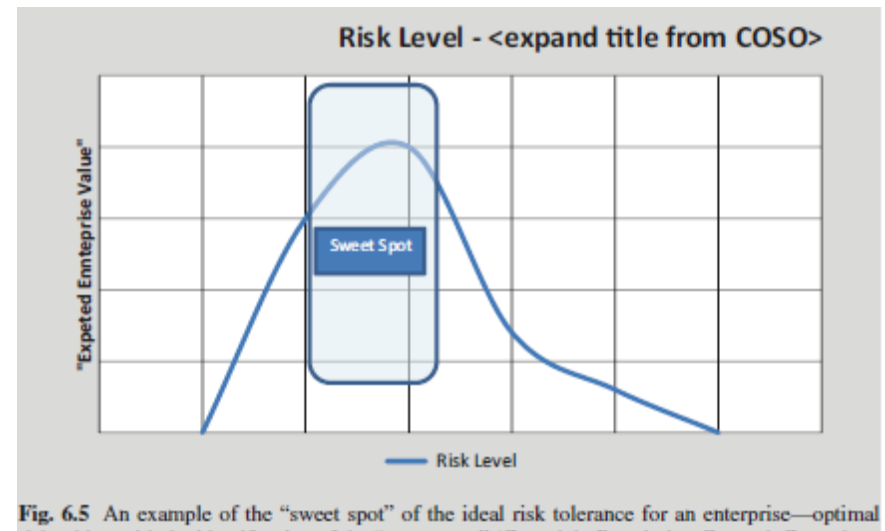
- ***Supply Chain Risk Management (SCRM)***: “is the process of identifying, assessing, and mitigating the risks to the integrity, trustworthiness, and authenticity of products and services within the supply chain.” (RefX)
- ***Supply Chain Risk***: “the likelihood and impact of unexpected macro and/or micro-level events or conditions that adversely influence any part of a supply chain leading to operational, tactical, or strategic level failures or irregularities.” (RefC)
- ***Supply Chain Disruption***: ‘unplanned and unanticipated (event) that disrupts the normal flow of goods and materials within a supply chain.’ (RefD)

Food Safety in terms of Enterprise Risk Management (ERM/ COSO)

- Chapter 08 – FUNCTIONS:
- Reference: Spink, John, Overview of Integrated Supply Chain Management: Sourcing, Operations & Logistics, ISBN 978-x-xx-xxxxxx-x. IN PRESS, (Version 9/1/2020)

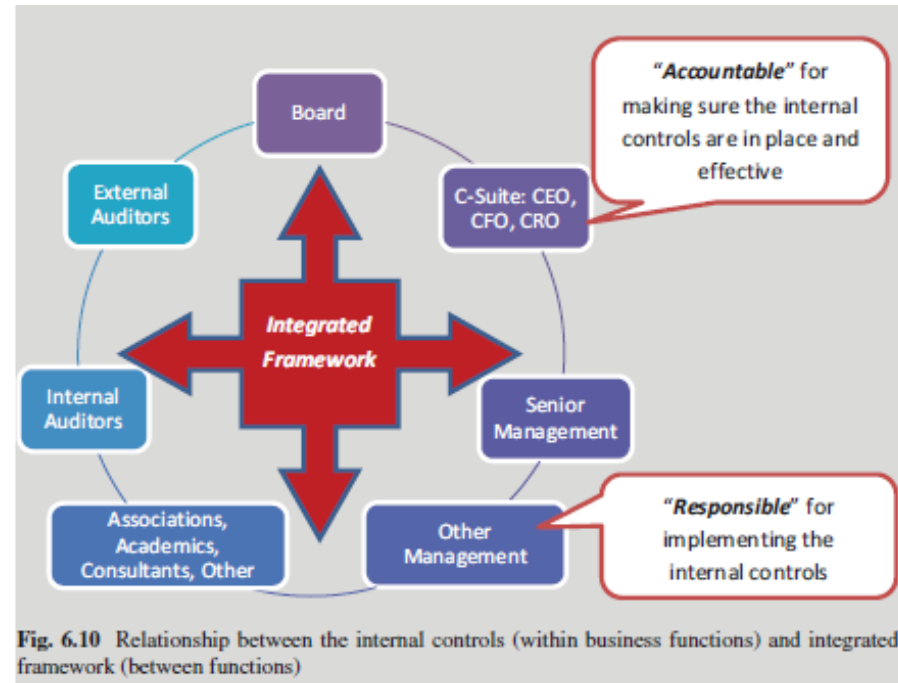
Risk Tolerance – a Sweet Spot

- No activity is without risk – there is no “zero risk”
- There is a ‘risk tolerance’ level that is unique for each company that is...
- Constantly changing.
- Yes, illegal is an ‘intolerable risk.’
- Yes, an ongoing incident is an ‘intolerable risk.’
- Vulnerabilities and prevention are to be determined.
- There is a ‘sweet spot.’



How to Manage *Everything*???

- Need a way to coordinate:
 - Internal Controls
 - Integrated Framework
- Events that defined the need for ERM:
 - Enron
 - Parmalat
 - WorldComm
 - Later, sub-prime lending crisis



Sarbanes-Oxley (SOX, SARBOX)

- Corporations have control systems called “internal control” and “integrate framework”
- Sarbanes-Oxley (SOX, SARBOX) is a US law from 2002 that requires “a” process.
- One type of process is Enterprise Risk Management developed by COSO (more on this later...)
- Whether public or private company... there are oversight requirements.

*Not having a robust ERM system in place is criminal...
literally...*

Serious for CEO/ CFO (and you)?

- An annual submission is referred to as a “**10-K form**” and a quarterly submission which is a “10-Q form” (see Fig. 6.7) (MSU-FFI 2017) citing (Kellogg Company 2017).
- The submission includes personal signed statements by the CEO and CFO for both the **10-Q form** and Sarbanes-Oxley compliance (see Figs. 6.7 and 6.8).

Exhibit Page 1 of 1

EX-32.1 4 k-2017q2ex321.htm EXHIBIT 32.1 Exhibit 32.1

SECTION 1350 CERTIFICATION

I, John A. Bryant, hereby certify, on the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that

(1) the Quarterly Report on Form 10-Q of Kellogg Company for the quarter ended July 1, 2017 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Kellogg Company.

/s/ John A. Bryant
Name: John A. Bryant
Title: Chairman and Chief Executive Officer

A signed copy of this original statement required by Section 906 has been provided to Kellogg Company and will be retained by Kellogg Company and furnished to the Securities and Exchange Commission or its staff on request.

Date: August 4, 2017



Publically posted
statement and signature of
the CEO & CFO

ERM and CRO

How the decision-makers decide on projects

- A focus on Strategic Risks
 - Sarbanes-Oxley
 - Securities and Exchange Commission (SEC)
 - Financial Reports and Analysts
- Enterprise Risk Management (ERM) and a Chief Risk Officer (CRO) are becoming more common.
 - Understand and speak the language of risk
 - Use a Risk Matrix and Risk Summing
 - CFO/CRO expanding focus to all-hazards within their structure

Enterprise Risk Management ERM (Financial and Managerial Accounting)

Committee of Sponsoring Organizations of the Treadway Commission

- A US regulatory requirement for the all the public companies.
- Becoming standard financial reporting practice
 - Reducing operational surprises and losses
 - Identifying and managing multiple and cross-enterprise risks
 - Improving deployment of capital
- Reference: www.COSO.org

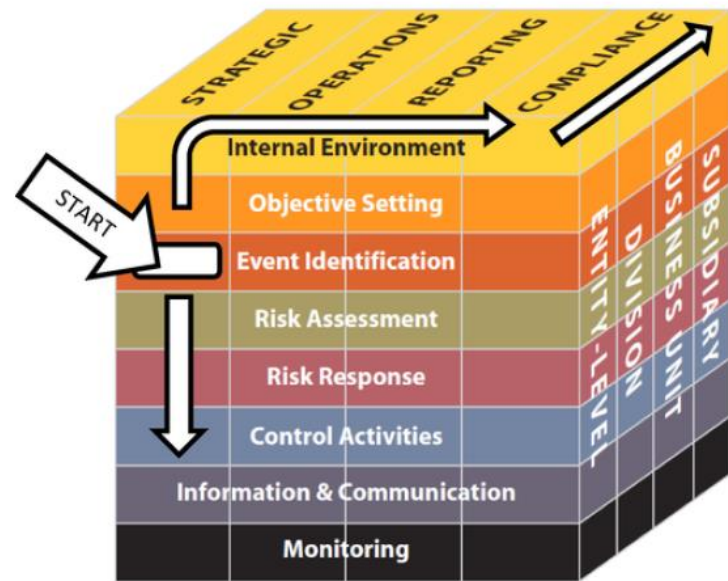


Fig. 5. The “COSO Cube” which presents the Enterprise Risk Management concepts (COSO 2014a,b).

Corporate Risk Map

- All risks or vulnerabilities need to be assessed within the Corporate Risk Appetite on the Corporate Risk Map

Board / C-suite cannot allow red

Control or Disclose

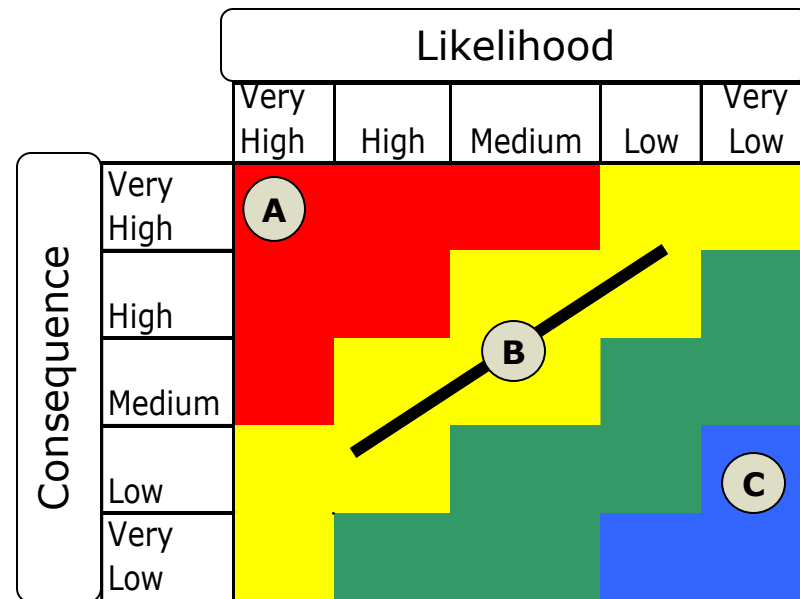
LAB RESULTS
1. Salmonella

		Likelihood				
		VH	H	M	L	VL
Impact	VH	A1		B3		
	H			C4		A3
	M		A2	D5		
	L					D2
	VL					

Figure 3. Corporate Risk Map Plotting Food Fraud Initial Screening Risk Assessments

Enterprise Risk Map: Risk-Informed Decision-Making

- Risk Analysis
 - Hazard Identification
- Risk Decision-Making
- “Risk Tolerance”
- “Risk Appetite”
- Reference: www.COSO.org, ISO 31000

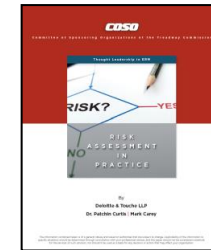


* ISO 31000 Risk Management

*So, is Supply Chain risk a problem? Supply
Chain disruption*

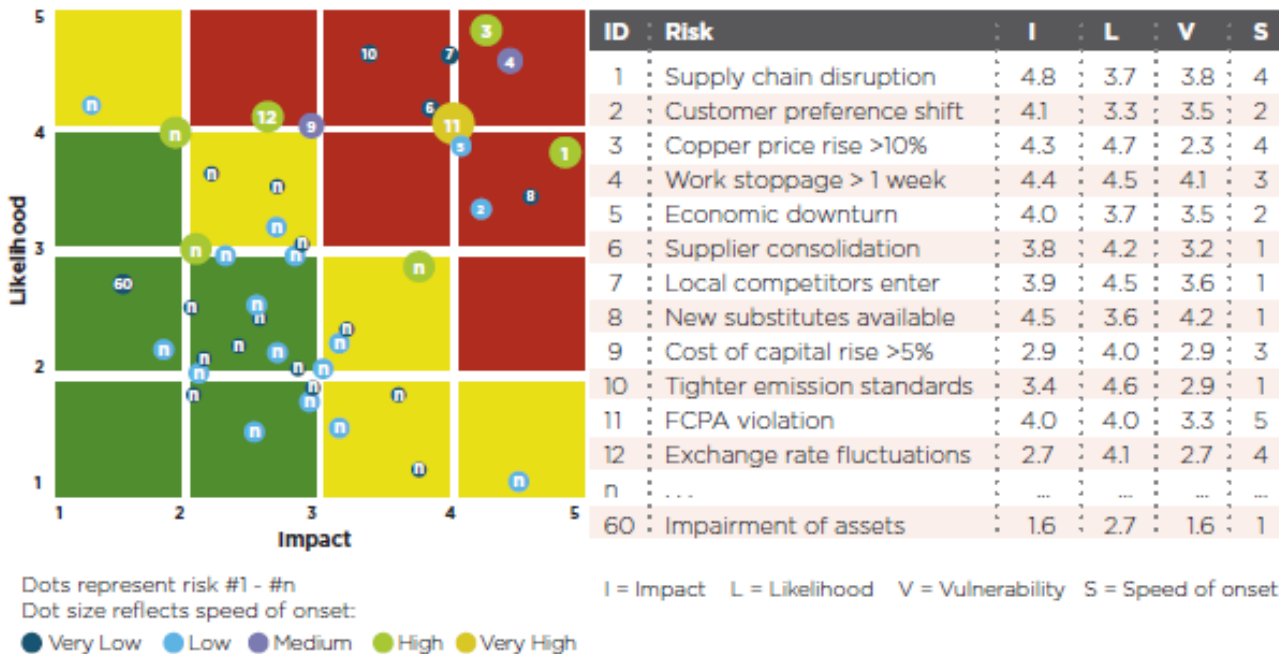
So, is a Supply Chain Disruption a problem? What about Food Safety?

- Illustrative Heat Map
- #1 – Supply Chain Disruption



Ref: COSO (2020), Risk Management in Practice

Exhibit 7: Illustrative Heat Map



Explain Food Safety under this entry



So, Now What?

Takeaway Points

- Explain food safety (and related food risks) in terms of Supply Chain Disruptions.
- Explain the problem and resource allocation decision-making proposals in terms of the risk tolerance using Enterprise Risk Management (ERM/ COSO).
- Talk in terms of ‘managing the inherent vulnerability or risk’ rather than of ‘fixing problems.’

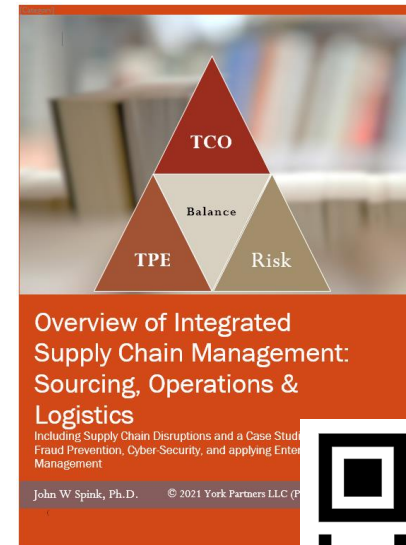
Resources: Supply Chain Management Book

NEW BOOK, pre-order, July release

Integrated Supply Chain Management – Source, Operation & Logistics

- Including Supply Chain Disruptions and a
- Case Study of Food Fraud Prevention, and
- Applying Enterprise Risk Management
- Required reading in MSU SCM undergraduate courses (all MSU business school students)
- Supply Chain Management teaching Supply Chain Managers about best practices in Supply Chain Management.

For an update: <https://scmintr.com/>



Discussion

John Spink, PhD

Twitter: [Food Fraud](#) and [#FoodFraud](#)

www.FoodFraudPrevention.com





BREAKOUT SESSIONS REPORT OUT

CLAUDIA COLES

SEAFOOD PRODUCTS ASSOCIATION (SPA)

MODERATOR: RON TANNER

Breakout Session Summary: Human Food

Glenn's presentation included information on:

- What's new in FSMA
- The FDA food-related reorganization and impact on Human Foods Program and Office of Inspections and Investigations
 - New OI boundaries, recall coordinators
- Inspection accomplishments: generally increasing our inspection numbers
 - MOST inspections are NAI (no action indicated) or VAI (voluntary action indicated)
→ we want the industry to work on making comprehensive corrective actions to prevent a VAI from becoming an OAI (official action indicated)
 - Top observation in GMPs pertains to sanitary operations; in PC, pertains to missing a hazard that requires a preventive control
- Smart Hub: where people can report a problem to FDA

Breakout Session Summary: Human Food

- FY 25 priorities: focusing on hiring the best and the brightest to the field, 2 Tier Program, revised rTAN process for real-time inspection assistance to FDA investigators and state inspectors
- Encouraged use of the industry portal: private secure portal for the firm and FDA (unique passcode) through which firms can submit their corrective action plans and track the status of the review process in FDA

Open Q/A Session:

- covered topics ranging from foreign entities that do/not have to register with FDA, data on inspection findings for international markets, dietary supplements and dietary ingredients, 2 Tier program, impact of reorg on whether a firm may get a human food inspection and an animal food inspection by different investigators

Breakout Session Summary: Animal Food

Jennifer Abrahamzon provided updates to FDA Perspectives

- FDA Reorganization
 - Now Inspectors will only be performing either Animal or Human food inspections
 - Office of Animal Food Inspectorate is now split into East/West Divisions
- Risk-Based Inspection Inventory
 - There is an algorithm used to prioritize who will be inspected
 - Factors involved include:
 - Last Inspection Date
 - Food Safety History
 - Compliance History
 - Animal Food Type
- Comprehensive Inspections
 - All applicable regulatory requirements included in one inspection visit
- Post Inspection Compliance
 - Slide 11 displays the known funnel represented to what happens with a post-inspection
 - Inspection Observations
 - Form 483 (issued or not)
 - Overall public health impact
 - Violation Classification (NAI, VAI, OAI)
 - NAI – No Action Indicated – Nothing found
 - VAI – Voluntary Action Indicated – Objectionable conditions were found, agency not prepared to take any regulatory action
 - OAI – Official Action Indicated - Objectionable conditions were found and regulatory action should be recommended
 - Facility Response Voluntary Action
 - Compliance Action

Breakout Session Summary: Animal Food

- FSMA inspection metrics were discussed
 - Historical FDA and State CGMP and PC Inspections
- Top 5 Animal Food Citations
 - PC - Hazard Analysis
 - PC - Preventative Controls
 - PC - Food Safety Plan
 - CGMP - Contamination with Mycotoxins/Natural Toxins
 - CGMP - Plant Operations
- Animal Food Resources
 - FDA website has specific information to help companies
 - How do I start an Animal Food Business
 - FDA Resources for Animal Food Facilities
 - Animal Food Facility Registration and Qualified Facility Attestation with Frequently Asked Questions

Breakout Session Summary: Animal Food

Q&A

- Does ASF and HPAI need to be identified as a known or reasonably foreseeable hazard?
 - No, right now, there is not clear science that animal food is a likely route of transmission for ASF and HPAI
- Is there any Guidance for any mycotoxins other than Aflatoxin?
 - Yes, Fumonisin and DON also have levels established in guidance for animal food
 - Zearalenone does not right now but we are currently reviewing the science to consider whether establishing limits would be appropriate in the future
- What is the timeline to have all Animal Food Inspectors performing all animal food inspections after the reorganization?
 - As of Oct 1, going forward all animal food inspections will be conducted by the investigators aligned to animal food in the reorganization
- Are the states also inspecting using only animal food inspectors?
 - Yes, they have traditionally had separate animal food inspectors
- Is there percentage emphasis on inspecting Pet Food vs Animal Food?
 - All inspections are based on the algorithm the FDA utilizes to prioritize facility's risk for inspections, there is not a specific number of inspections dedicated to any particular sector

Breakout Session Summary: Recall Impacts

Martin Bucknavage analyzed 2024 recall data from resources such as the [FDA Data Dashboard](#) and found that:

- Yearly number of food (not including seafood or animal food) and cosmetic recalls are not increasing over time.
- There is no indication, based upon recall data or outbreaks, to indicate our food supply is getting worse.
- The media amplifies recall news and often treats recalls the same, whether or not they are associated with outbreaks.
- Social media creates an echo effect; recall headlines used as clickbait.
- There are definitely better detection systems in the U.S. than there were 20 years ago, but in many more cases, finding a problem that results in a recall is a matter of preventive measures not being followed.

Breakout Session Summary: Recall Impacts

- **Allergens:** When it comes to recalls due to allergens, mislabeling is often the cause, and while any firm can have a recall due to allergens, we see it more commonly with small firms (less than \$25 million in sales).
- **Listeria monocytogenes:** Recalls typically result from testing by any number of entities (govt, customers, suppliers, companies).
- **Salmonella:** Recalls typically result from sample testing. Think about using
- **E. coli:** Several recalls were involved in outbreaks.
- **Other:**
 - Lead – a supplier's supplier issue
 - Sulfites – use Preventive Controls
 - Foreign materials: seen improvement, fewer recalls than a decade ago

Breakout Session Summary: Recall Impacts

What have we learned?

- Almost all of the recent recalls are attributed to a breakdown in Preventive Controls.
- Especially with small companies, the less common areas (e.g. mixing room) not the big areas (floors) are often missed
- Design systems with sanitation in mind, especially in Zones 2-4, and facilitate the identification of permanent and transient Listeria.
- The Sanitation chapter in the Preventive Controls has been bolstered
- Recall data can be used to stress the importance of the Preventive Controls approach, but we, as trainers and educators, must drill down, not guess and use good data when we talk to the media, students and even our employees.

Breakout Session Summary: Recall Impacts

Discussion and Q&A

- Do you have information on the types of allergens that most often result in recalls?
 - Dairy, wheat, soy, and even anchovies in Worcestershire sauce are among the most common, but more detailed data is available on the dashboard
- What should you do about regulatory exceptions for qualified facilities or small suppliers?
 - They may not need a preventive controls plan, but they still need to have controls in place
- Establishing a protocol to check rolls of labels every day is especially helpful in high-speed, high-output facilities because it is very easy to load the incorrect labels or receive the incorrect labels from the provider. If you have old rolls, verify them as if they were new. In general, have a robust packaging program.

Breakout Session Summary: Recall Impacts

Discussion and Q&A cont'd

- FARRP from the University of Nebraska, is a world leader in allergen research and an excellent resource. WHO also has an interactive allergen resource.
- Allergens of concern differ for every country, so if you export, know the allergen regulations in the receiving country.
- www.safeicecream.org is a good educational tool, especially for small ice cream producers.
- Can also work with retailers, such as Whole Foods, who buy from small producers, to provide training.
- It can be tough getting small companies to attend training, but it is so important.

Breakout Session Summary: Animal Food Case Studies

Reiterated the Hazard Analysis Funnel

- How are we looking and evaluating our hazards?
- Also looked at Step 4 from the PCQI Animal Food course
 - Looking at hazards when conducting a Hazard Analysis
 - Use this to mitigate how hazards occur
 - Also refer to Step 4 instructor notes for this, helps to clarify if you only need a GCMP to reduce the probability or need a PC to control the hazard
- How are we identifying a PC?
- Do you have the right Pre-requisite programs?

Breakout Session Summary: Animal Food Case Studies

Aflatoxin Discussion

- Does this need a PC or a pre-requisite?
- Discussed the PC Management Components
 - Monitoring
 - Corrective Actions
 - Verification and Validation
- There was lots of open discussion on this subject matter
 - There were different opinions on when this should be a PC and not a PC
 - Lots depended on what type of livestock you're feeding
- How does Sampling and Testing help mitigate the risk?
 - Sampling and Testing procedures varied vastly. Participants stated this depends what they fill works for the volume they have
 - Testing in house and validating that against other 3rd party labs works for validation if needed
- How do you take a sample?
 - Refer to FDA Guidance on proper sampling procedures
- How much should you monitor?
 - What works for your company to mitigate risk when utilizing a pre-requisite or PC
 - Proper Corrective Action procedures were discussed
 - How can we mitigate hazards from re-occurring
- If nothing else works effectively, a Re-Evaluation of your food safety plan may be necessary



CLOSING REMARKS

JASON WAN, , PHD

INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

2025 FSPCA Annual Conference - Save the Date!



November 18-19, 2025
Chicagoland Area