FSPCA 2023 ANNUAL CONFERENCE

BUILDING GLOBAL FOOD SAFETY CAPACITY
THROUGH EDUCATION, TRAINING AND OUTREACH

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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

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WELCOME

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

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OPENING REMARKS

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

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State of the Institute

Agenda

- 35 Years and Counting
- Year-in-Review
- The Future - Vision and Plan

35 Years and Counting

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Founding Members

Letters of Support

Kraft Foods
Quaker Oats
FMC Corporation
Wm. Wrigley Jr. Company
CPC
Dean Foods

Financial

Kraft Foods
$250,000

FMC Corporation
$100,000

Wm. Wrigley Jr. Company
$100,000

NCFST Year 1 = $700,000

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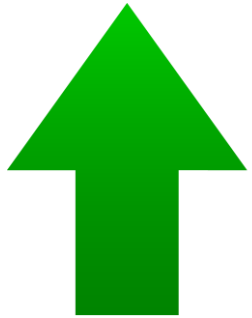
Year-in-Review

by the numbers

$7.5 M

2021 - 2022



$8.6 M

2022 - 2023

Membership 

FSPCA 

Grants / Projects 

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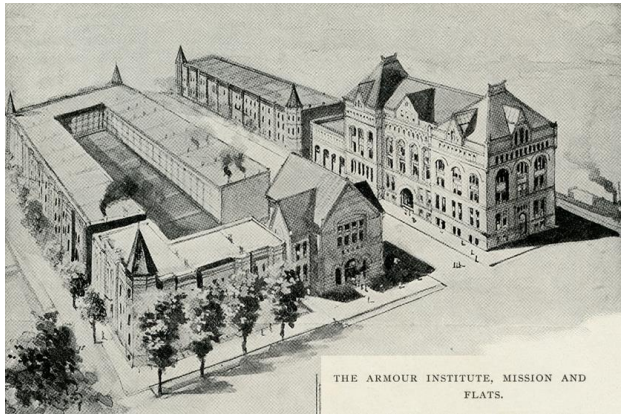
The Future

a vision and a plan

Illinois Tech

"million dollar sermon"

*In 1890, Chicago minister Frank Wakeley Gunsaulus said that with **$1 million**, he could build a school where **students of all backgrounds** could prepare for meaningful roles in a changing industrial society.*



"billion dollar sermon"

*On Sept 15, 2022, President Raj Echambadi and Board of Trustees Chair Mike Galvin launched "Power the Difference" to **grow** its student body; **invest** in faculty, facilities, and educational programs; **develop** and **deliver** new world-leading research programs; and **serve** as the premier technology-focused university in Chicago.*

The 2024 WSJ Best Colleges in America

#23
nationally

#1
in Illinois

The Wall Street Journal/College Pulse ranking emphasizes how much a college improves its students' chances of graduating on time, and how much it boosts the salaries they earn after graduation.

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IFSH Strategy

a vision and a plan

IFSH Strategic Planning Research

+100

Stakeholder Groups Interviewed

- **IFSH**
- **Academia**
- **FDA**
- **Industry**

- ✓ IFSH was recognized as a leader with a long history of success and expertise.
- ✓ Beyond the accolades IFSH has enormous opportunity towards the future.
- ✓ Many themes were born out of the stakeholder group interviews.

The IFSH Difference

- ✓ Located near and in Chicago; a global food hub of well-connected brands and experts.
- ✓ An FDA Center of Excellence with the FDA Division of Food Processing Science and Technology co-located.
- ✓ Exceptional member network of individuals and organizations from industry and academia.
- ✓ GMP and BSL-2/3 level pilot plants and high bay processing facility.
- ✓ A reputation for conducting high-quality research.
- ✓ **Providing food safety training and educational excellence.**
- ✓ **Facilitator of conversations between FDA, industry, and academia.**
- ✓ Diverse set of stakeholder services.

Challenges → Opportunities

- **Age of facilities and equipment are insufficient and will struggle to support future expansion and operations.**
- Distance between Moffett and Mies.
- Improve internal communications within IFSH, and between IFSH and IIT.
- Enhance support for students to promote their success and development.
- Unclear way-of-working between FDA and IFSH.
- Re-think funding strategies to sustain and expand research and operational activities.
- Member network resources are not fully utilized by IFSH.
- Current research capabilities are not well known or understood by members in the network.
- Operational inefficiencies preventing expansion of research topics.

Our IFSH Promise...

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Convene

Convene conversations between academia, industry and government

Curate

Curate relevant research, applications, trends and ideas for partners

Clarify

Clarify what food safety means, and what is required to achieve it

Community

Community engagement and education developing the next generation of food science experts

Strategic Goals… We Will…

Clarify

- Strengthen collaboration among IFSH, FDA, and FSPCA to streamline education functions and build a strong education and training brand.
- Leverage its vast network to expand its educational training resources and offer cutting-edge programs that drive innovation in food safety learning.

Campus Opportunity

a vision towards the future

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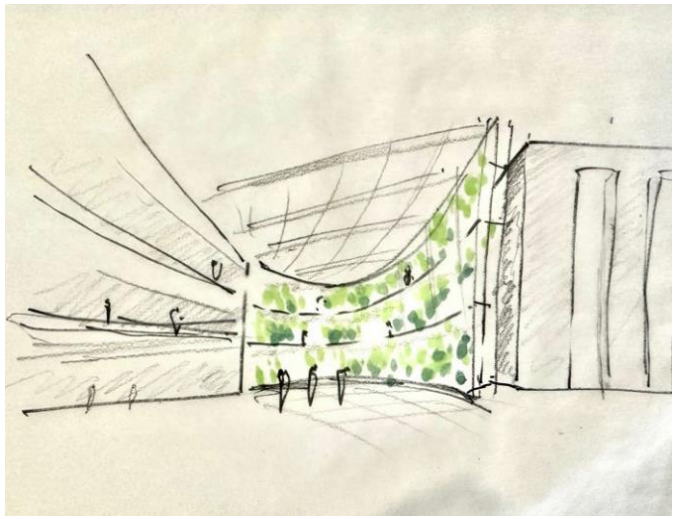
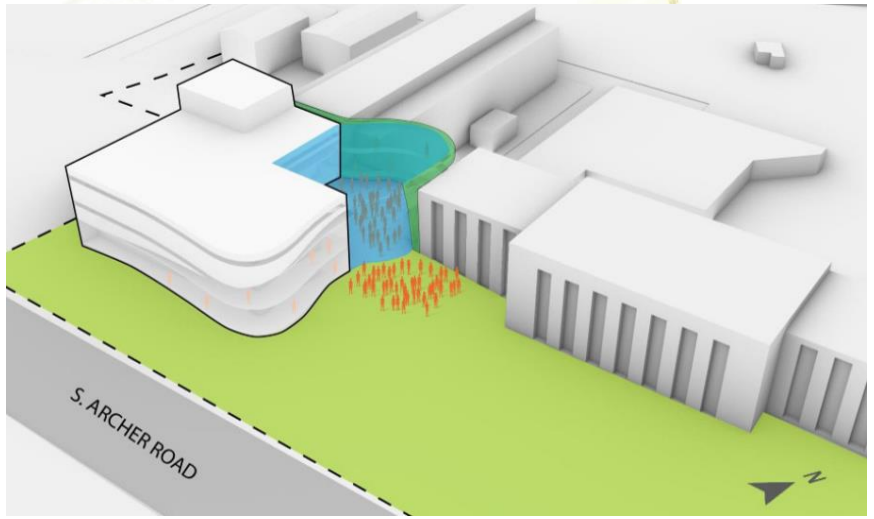
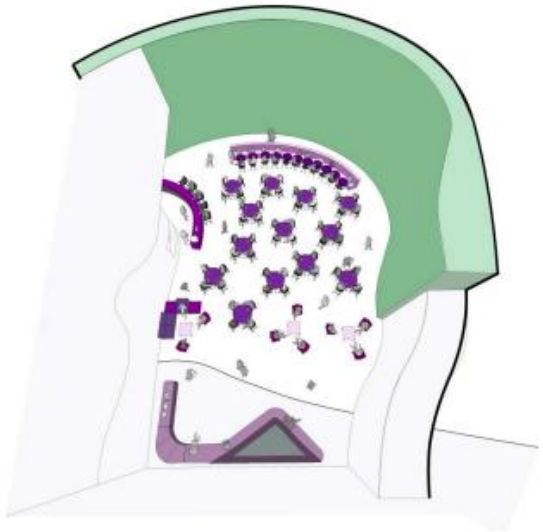
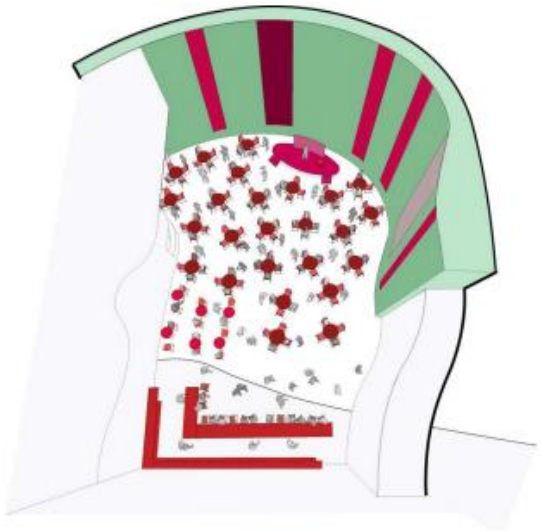
Phase 1
LEVEL 02
RB LEVEL 01




S. ARCHER ROAD
N

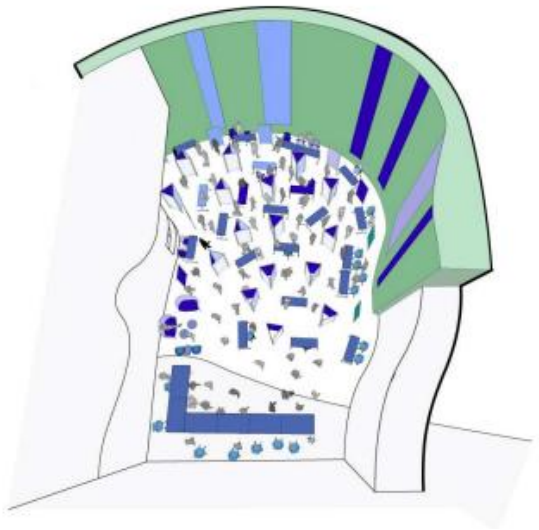
Everyday Life
Meeting Space

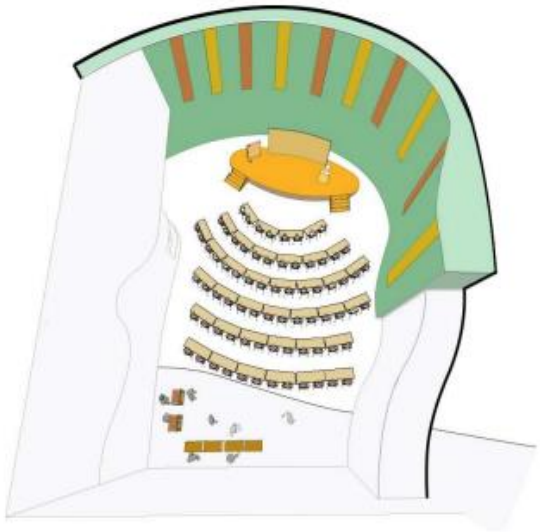




Fundraiser Event
The Ballroom

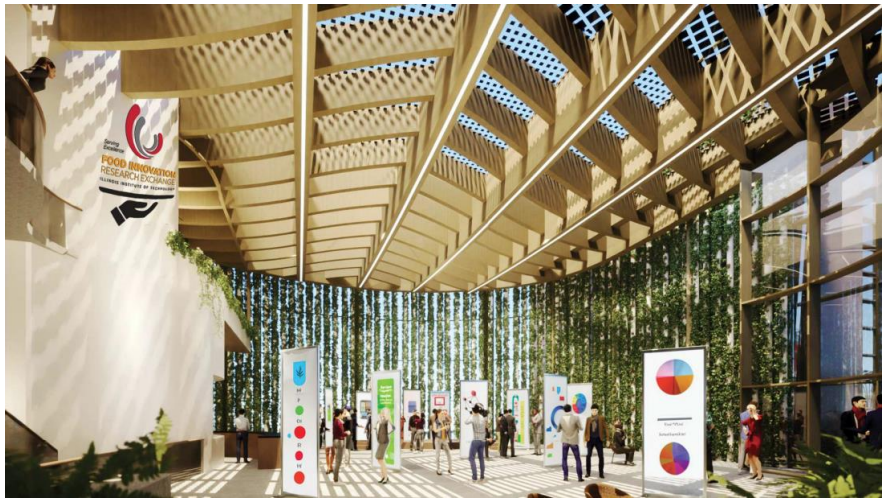
Science Fair
Scientific Industry

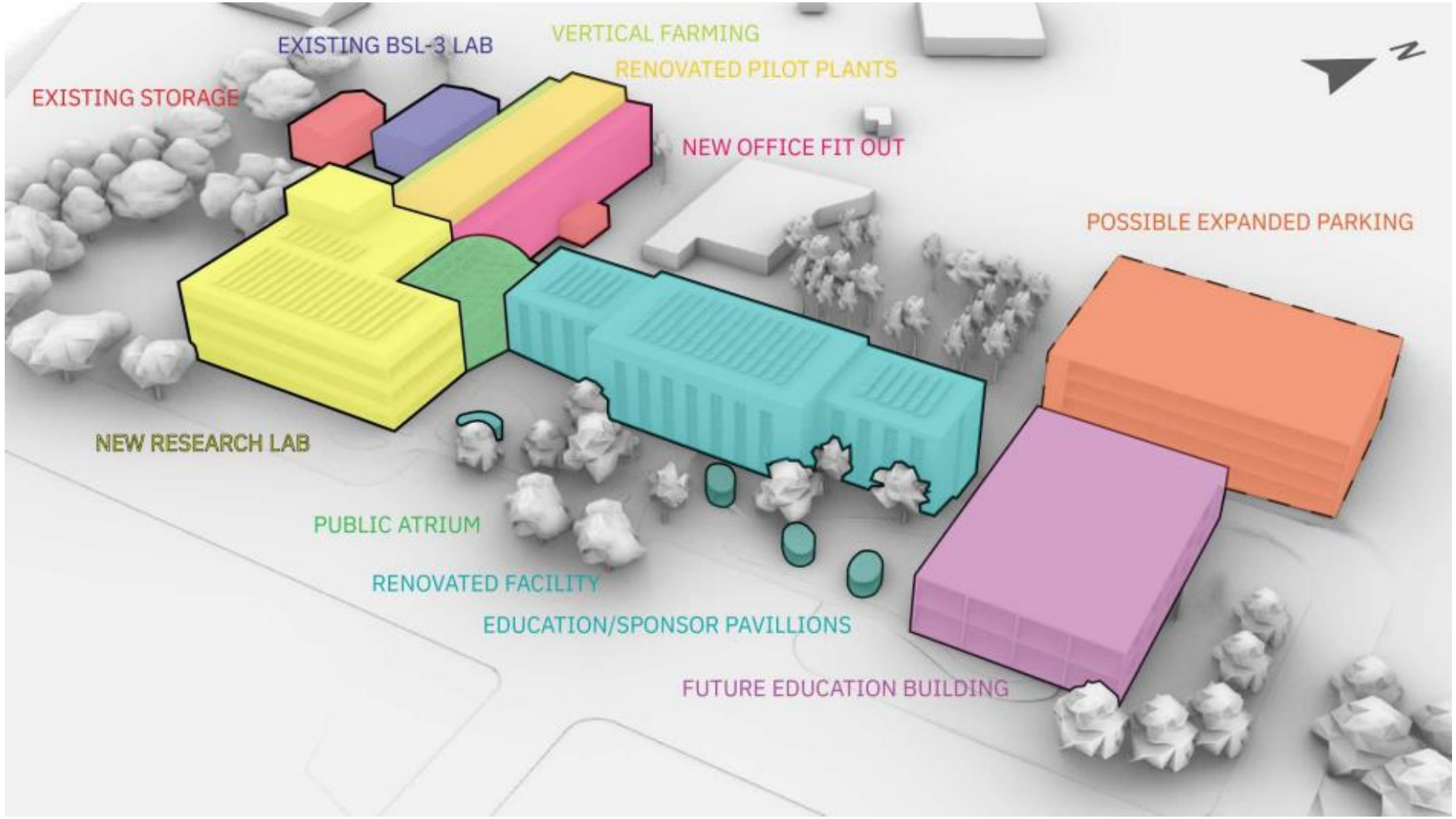




Seminar Space
Industry Partners


ILLINOIS TECH


FOOD INNOVATION
RESEARCH EXCHANGE


EXISTING BSL-3 LAB
VERTICAL FARMING
RENOVATED PILOT PLANTS
EXISTING STORAGE
NEW OFFICE FIT OUT
POSSIBLE EXPANDED PARKING
NEW RESEARCH LAB
PUBLIC ATRIUM
RENOVATED FACILITY
EDUCATION/SPONSOR PAVILLIONS
FUTURE EDUCATION BUILDING
N


Sustainability Goals
- IIT University Standards
- GSA Standards
- Guiding Principles for Federal Buildings
- Federal Sustainability Plan (EO 14057)
- LEED Gold
- Bedford Park Mobility Plan
Legend
On-Site Solar Power
Building Integrated Shading
Indoor Thermal Comfort + Outdoor Heat Mitigation
Permaculture + Community Garden
Increased Biodiversity
Native Species Research Garden
Increased Bike / Ped Mobility + Safety
Localized Bus Transit

Thank You

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FEATURED SPEAKER VIDEO

SEAN CASTEN
U.S. CONGRESSMAN

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FSPCA OPERATIONAL HIGHLIGHTS

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

FSPCA Annual Conference | October 17-18, 2023

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FSPCA

- **Established in Dec. 2011 with FDA FSMA funding, now self-sustaining**

- **VISION:** Be an 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

FSMA Rules Published

Regulation	Final Publication
Preventive Controls (Human Food)	Sept 17, 2015
Preventive Controls (Animal Food)	Sept 17, 2015
Produce Safety	Nov 27, 2015
Foreign Supplier Verification Program	Nov 27, 2015
Accredited Third Party Certification	Nov 27, 2015
Sanitary Transport	April 5, 2016
Intentional Adulteration	May 27, 2016
Food Traceability	Nov 15, 2022

FSPCA Standardized/Core Curricula

All FSPCA Participants Manuals are publicly available on the FSPCA website

In development – Food Traceability core curriculum

FSPCA Update 2023

- IAFP Food Safety Award 2023
- Preventive Controls for Human Food (PCHF) Curriculum V2.0
  - Version 2.0 Pilot (Aug 22-24, 2023)
  - Lead Instructor Refresher courses – Early 2024
- Food Traceability Course Development
- FSPCA Training Highlights (as of October 3, 2023)
- FSPCA Webinars and Newsletters
- FSPCA Website Update October 2023
- FSPCA Annual Conference

FSPCA Receives IAFP Food Safety Award 2023

2023 FSPCA Lead Instructor Courses

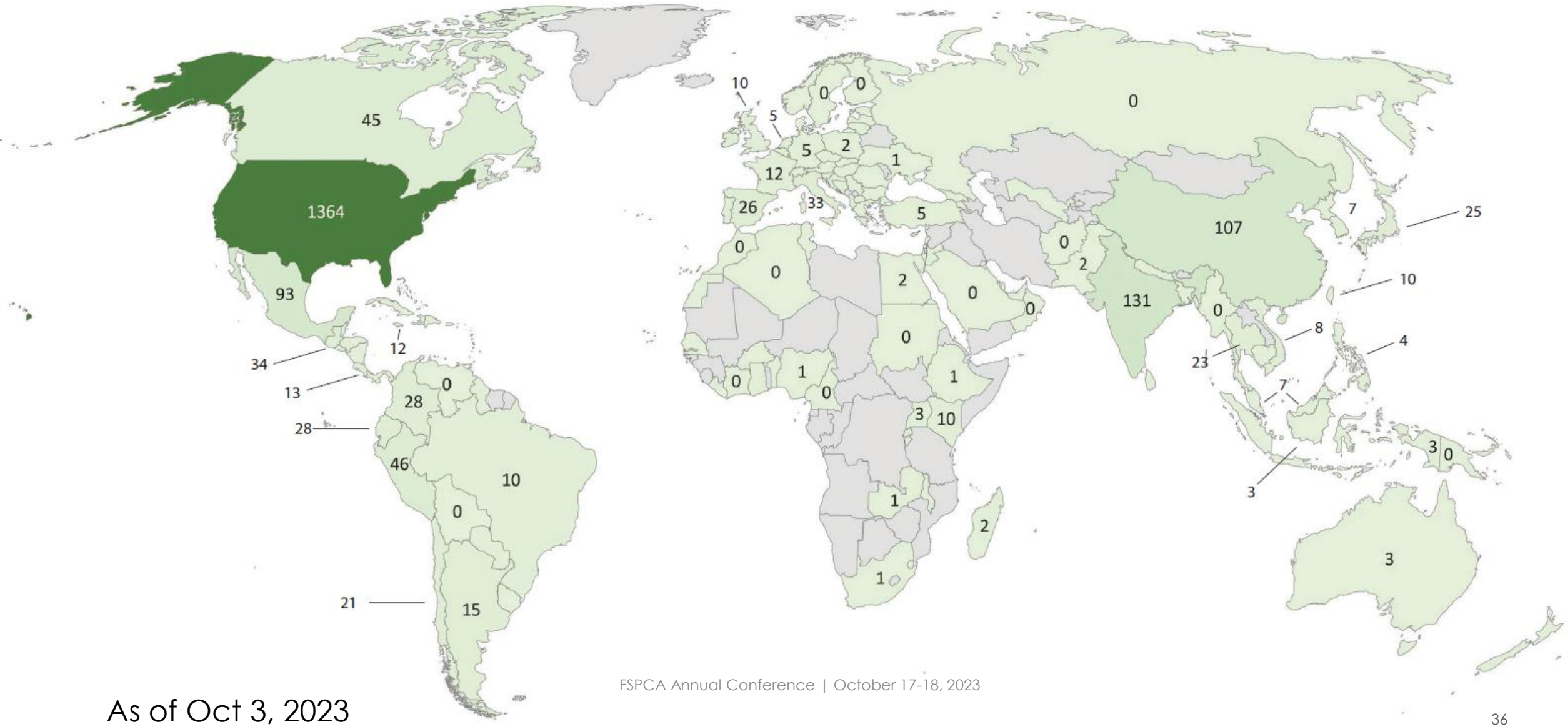
- **Virtual Human Food Lead Instructor Course**
  - April 10-14, 2023
  - June 19-23, 2023
  - August 14-18, 2023
- **In-Person Animal Food Lead Instructor Course**
  - November 28- 30, 2023, IFSH
- **Virtual FSVP Combination Course**
  - December 11-15, 2023
- **Virtual IAVA Combination Course**
  -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

Updated FSPCA Website, October 2023

- The new FSPCA website launched in October better serves our stakeholders: lead instructors, course participants, and food industry professionals.
- The redesigned website provides a more user-friendly experience, intuitive and streamlined navigation, and sports a fresh new look.

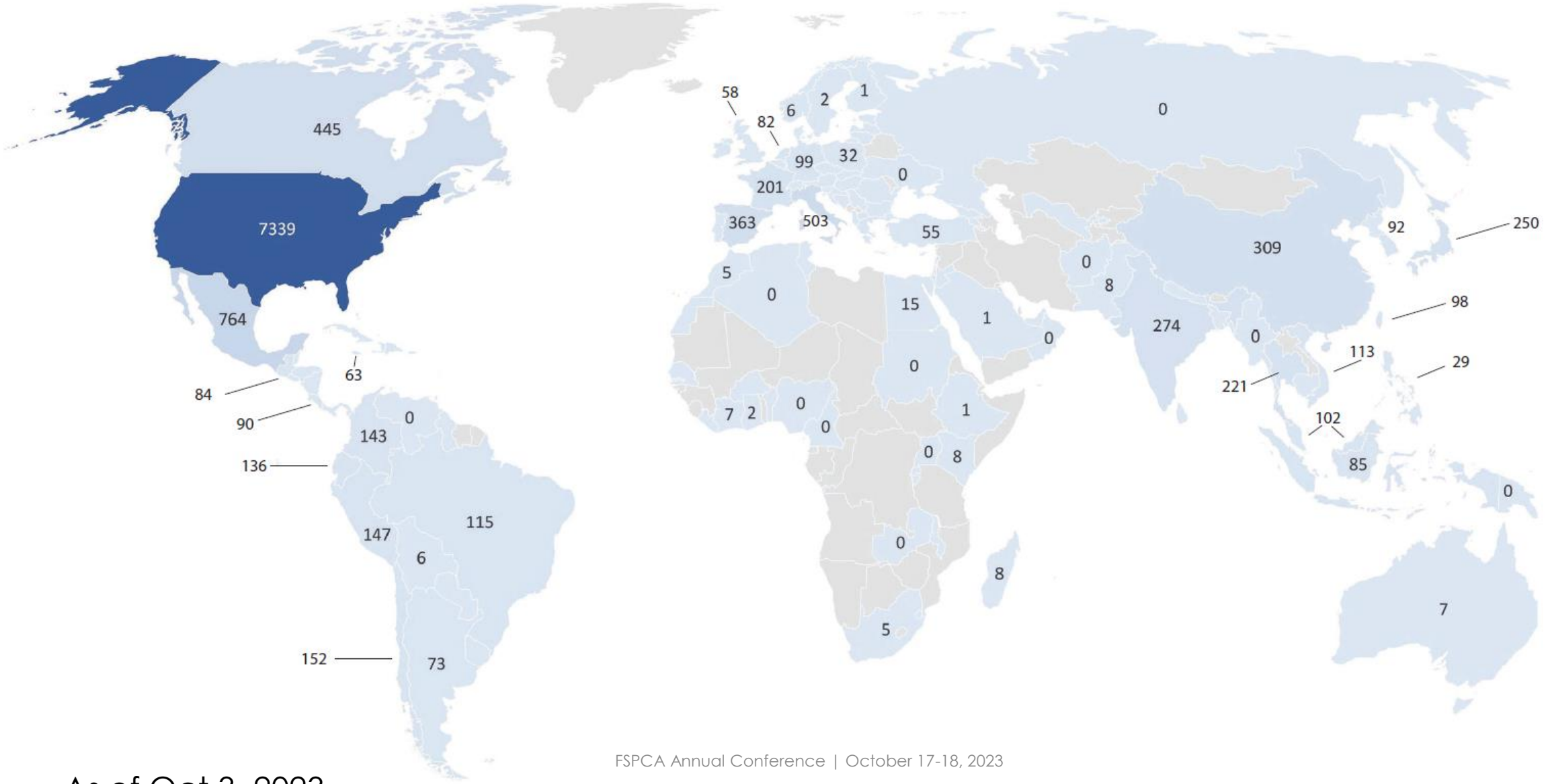
www.fspca.net

Number of PCHF Lead Instructors by Country: Total 2,288



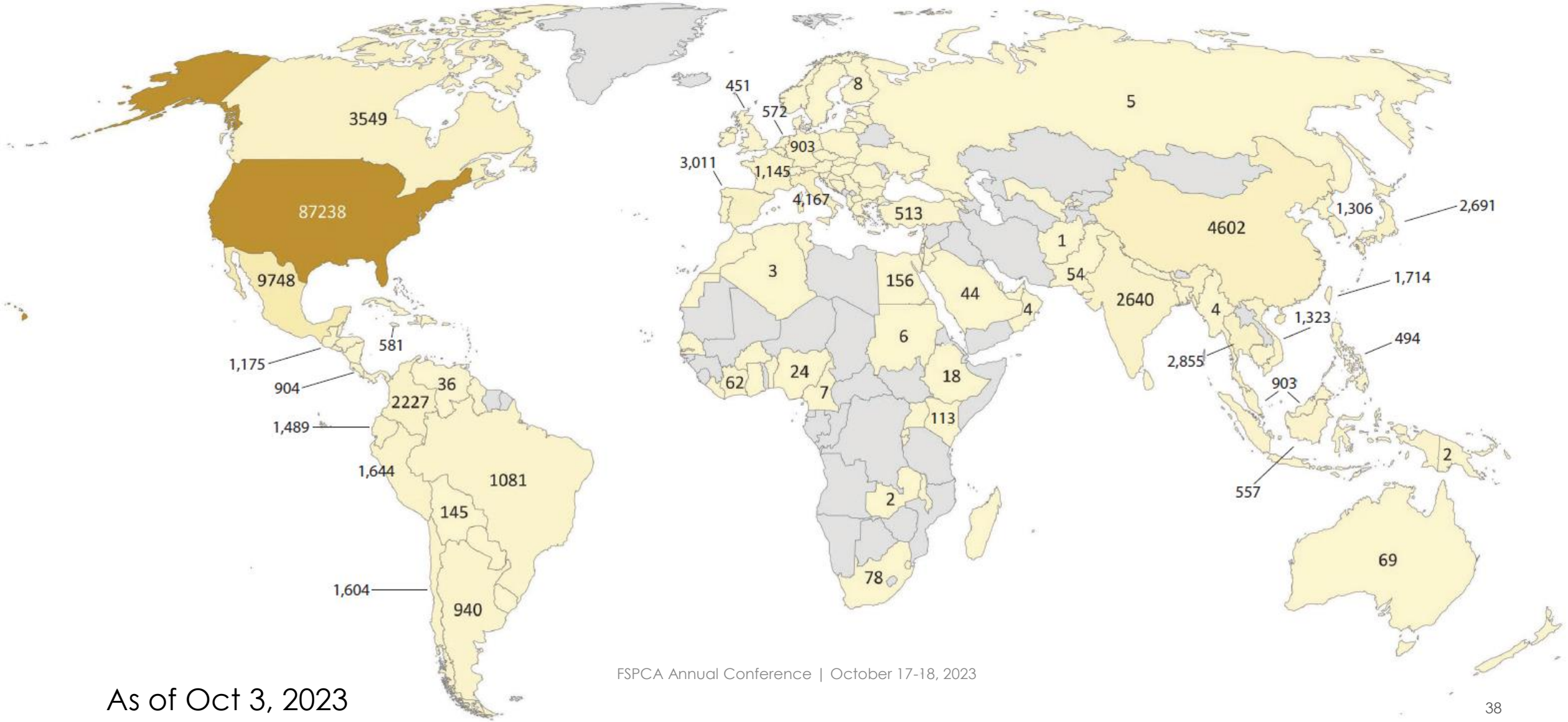
As of Oct 3, 2023

Number of PCHF Participants Courses Completed: Total 13,200



As of Oct 3, 2023

PCHF PCQI Certificates Issued by Country: Total 149,634



As of Oct 3, 2023

FSPCA Training Metrics

As of October 3, 2023

FSPCA has trained

3,065 Lead Instructors
from 80 countries

who are now using the FSPCA curricula to train industry personnel
on food safety preventive controls principles and practices.

181,718 food safety personnel
from 138 countries

have been trained using the FSPCA standardized and core curricula
who are now assisting the industry in producing safe food all over the world.

ALL METRICS

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FSPCA Annual Conferences

FSPCA AC 2023 (Oct 17-18)
In-person at Marriott Chicago Southwest, Burr Ridge, IL

2023 Annual Conference Program

- Highlights from FDA senior officials on FSMA inspections.
- Insights from industry leaders in food safety practices and FSMA implementation.
- Latest updates on FSMA training curricula and case studies.
- Networking with food safety leaders from government, academia and industry.
- FSPCA award and recognition program.

THANK YOU!

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

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FDA UPDATE: THE PAST, PRESENT AND FUTURE OF FSMA IMPLEMENTATION

GLENN BASS
U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: MATTHEW BOTOS

FSPCA Annual Conference | October 17-18, 2023

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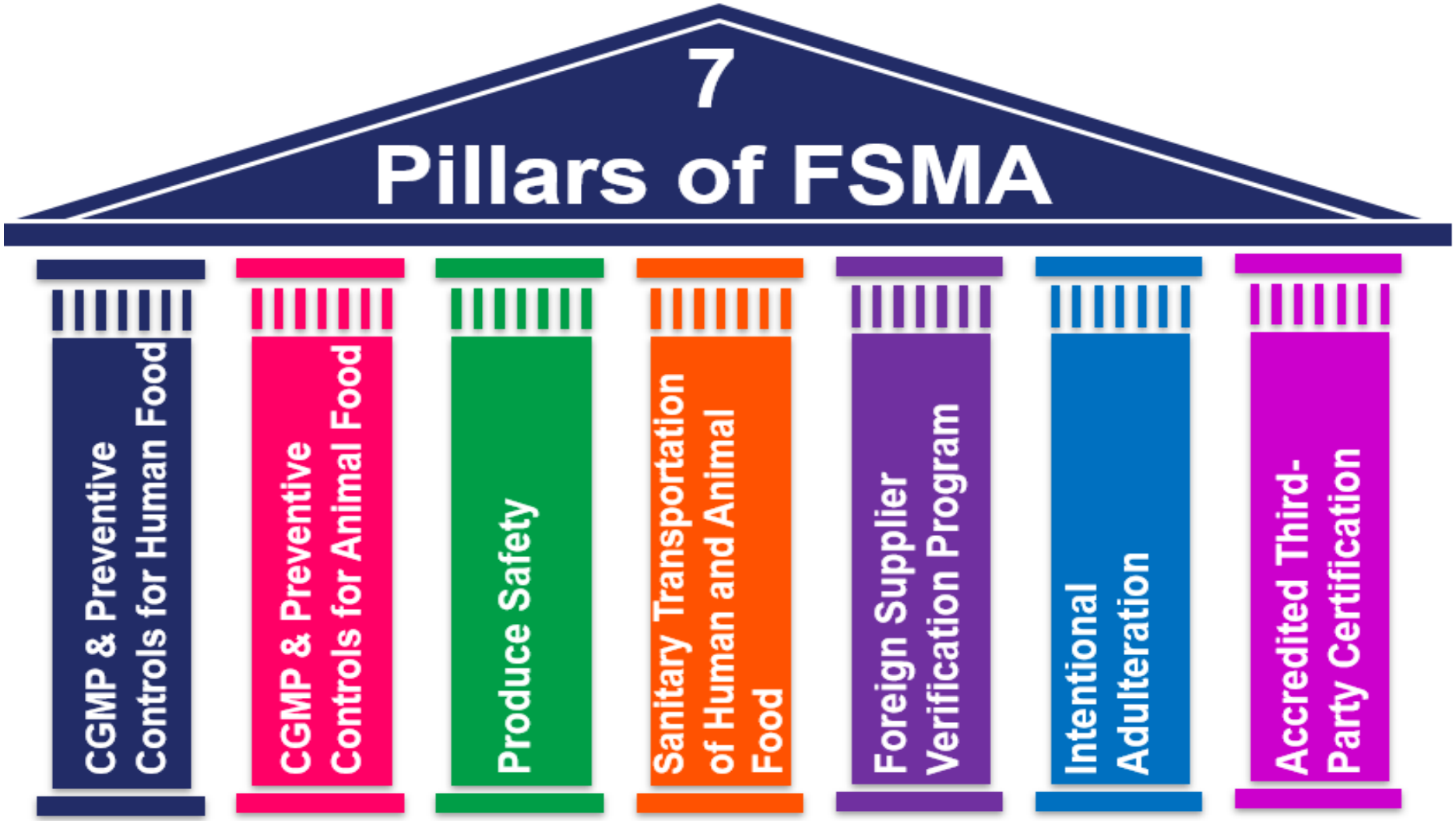
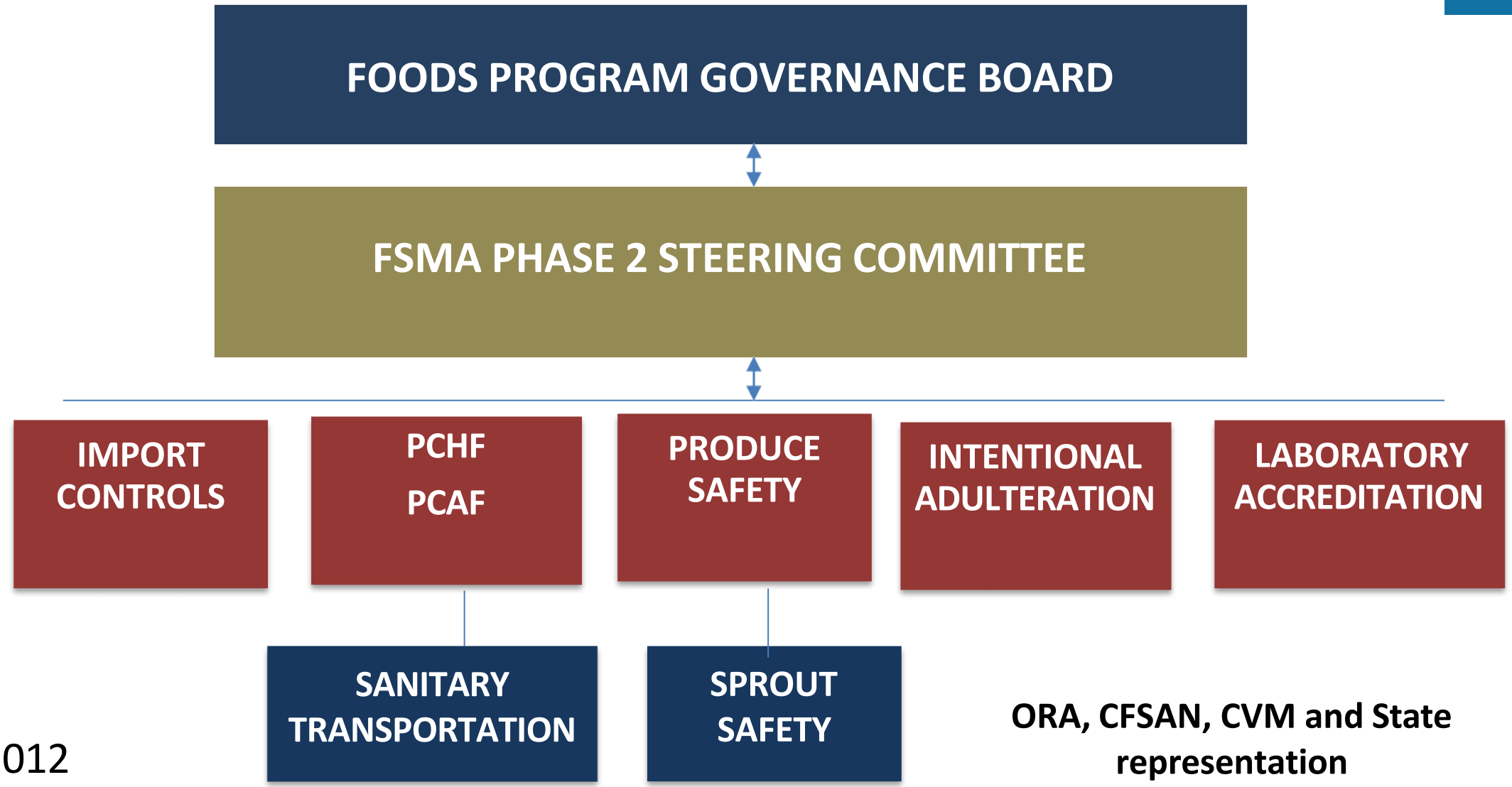
The Past, Present and Future of FSMA Implementation

Glenn Bass
Deputy Program Director
Co-Chair: FSMA Steering Committee
Office of Human and Animal Food – West
Office of Regulatory Affairs
U.S. Food & Drug Administration

2023 FSPCA Annual Conference| Oct 17, 2023

Food Safety Modernization Act (FSMA)





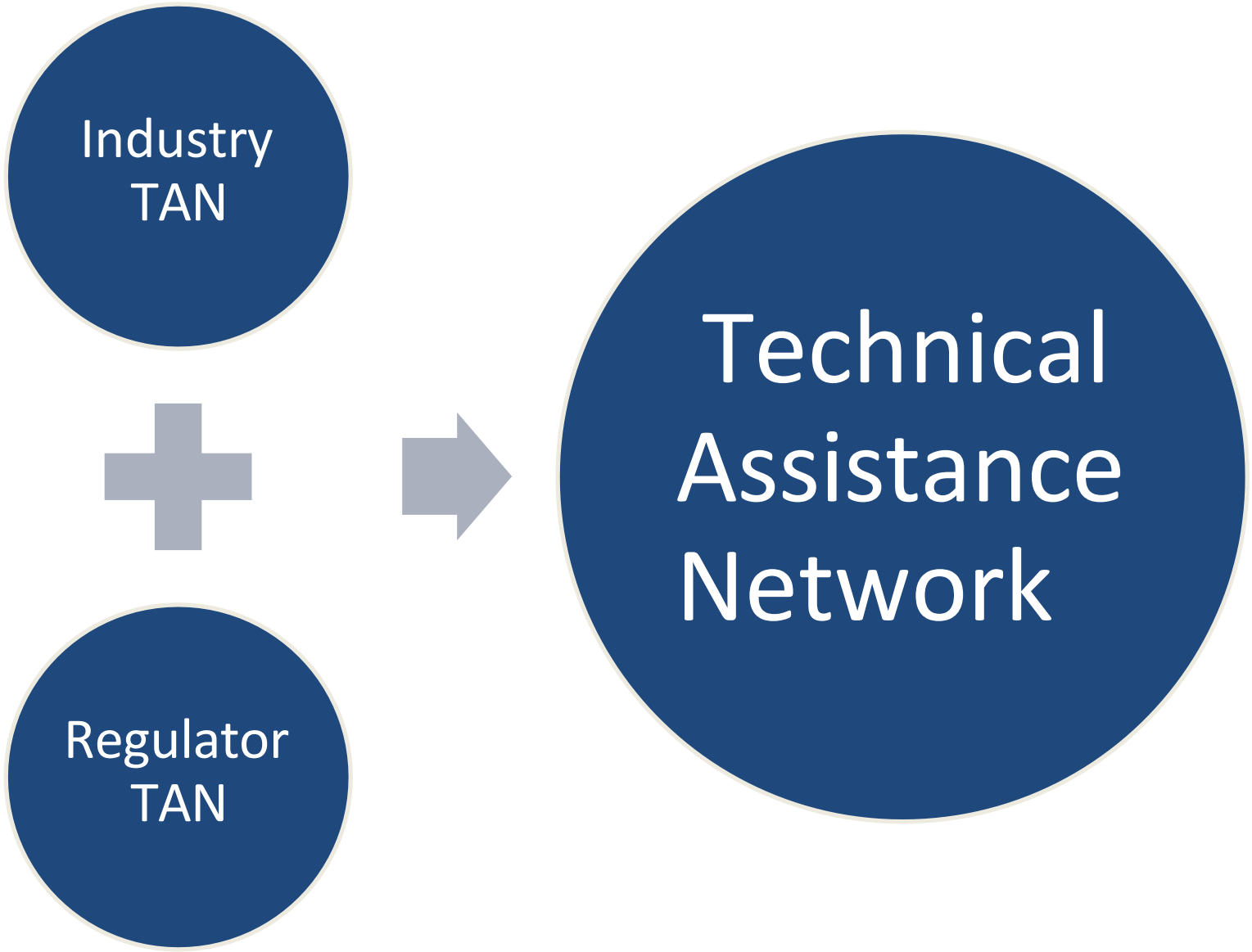
2012

ORA, CFSAN, CVM and State representation

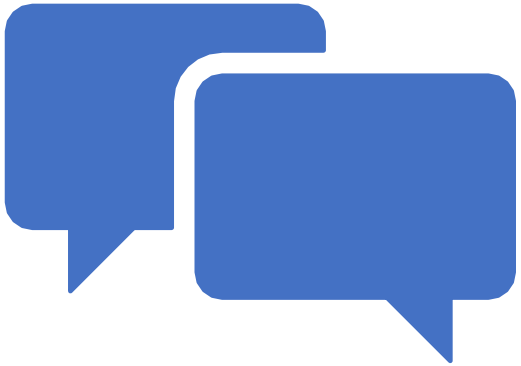
FDA Training Courses – FY 2018 – FY 2023

FD254 PC for HF Regulators (47)	VM102 CGMP AF Regulators (23)	VM220 PC for AF Regulators (21)
<u>Participants</u> FDA = 550+ State = 490+	<u>Participants</u> FDA = 267+ State = 210+	<u>Participants</u> FDA = 208+ State = 179+

Dynamic Workforce


Industry TAN
Regulator TAN
Technical Assistance Network

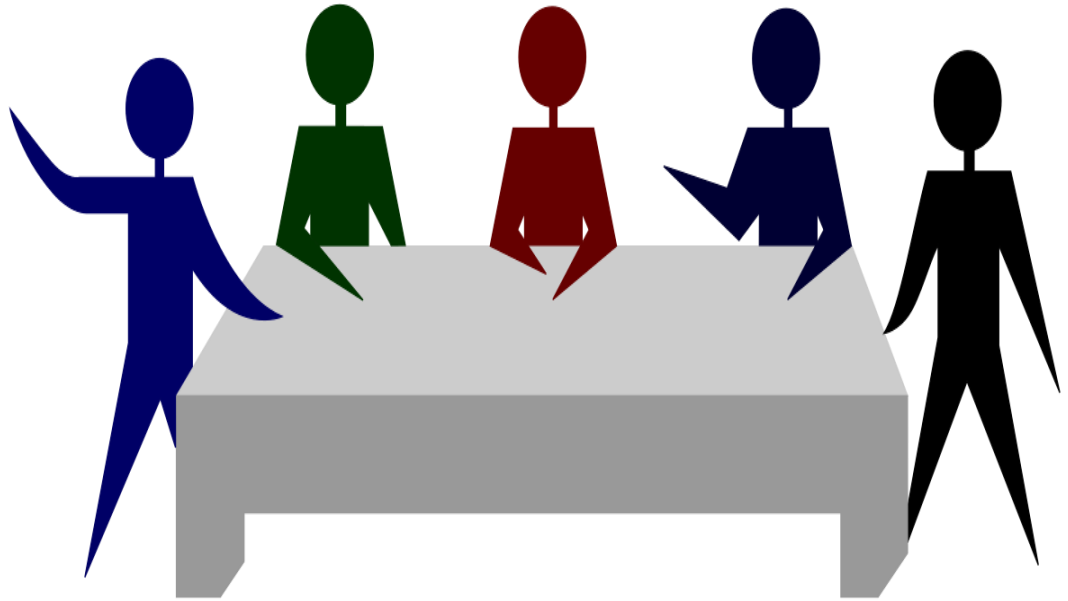
FSMA Chats



- Initiated in 2013
- 50+ plus
- Topics: from Intentional Adulteration (IA) to Food Traceability Rule (FTR)
- Web page: http://inside.fda.gov:9003/ora/fsma/ucm366919.htm

Collaborations

- State partners
- Alliances
- Associations
- Federal partners
- International partners



1. Produce Safety Rule (PSR)
2. Preventive Controls (PC)
   - Inspection Protocols and Tabular Establishment Inspection Report (EIR)
3. FDA Releases Two New Chapters of Draft Guidance for the Preventive Controls for Human Food Rule | FDA

1. Observation Corrective Action Report: OCAR

- Corrective Action Report

- Industry Portal*

FDA Voluntary Observation Corrective Action Report (OCAR) Industry Portal

For Human and Animal Food Processing Facilities

FDA U.S. FOOD & DRUG ADMINISTRATION

HIGHLIGHTS

- ★ Secure electronic portal for firms to provide corrective actions (CA) and documentation in response to inspectional observations
- ★ Communication with FDA on observations, corrective actions and observation status(es)
- ★ Phased roll-out to human and animal food facilities

BENEFITS

- ✓ Elite groundbreaking project with direct beneficial public health impacts
- ✓ Real-time management of CA activities and documents
- ✓ Increased efficiency/improved CA workflow
- ✓ Intelligent CA activity and document organization/security/control
- ✓ Facilitated/enhanced CA communication with FDA
- ✓ Refined turnaround times intended to improve the CA experience
- ✓ Higher productivity
- ✓ Green business practice
- ✓ Industry Portal Representative (IPR) access as well additional sub-accounts as necessary

SELECTION CONSIDERATIONS

- Documented observations
- Geographic location
- Active registration
- Total number of facilities applying
- Categories/types of products
- Inspection and compliance history
- FDA Division management input
- FDA work plan obligations
- Firm size
- IT capabilities
- IPR involvement

PARTICIPATION CRITERIA

- ❑ Portal participation is VOLUNTARY!
- ❑ Domestic human or animal food firm
- ❑ Maintain current FDA registration
- ❑ Inspection with observations presenting opportunities for CAs
  - ❑ FDA inspection with FDA 483 observations, or
  - ❑ Documented Discussion observations
- ❑ IT capabilities
  - ❑ Secure, stable broadband internet services
  - ❑ Familiarity with web-based document upload
- ❑ Must adhere to required User Agreement
- ❑ IPR is identified along with up-to-date contact information

Not all interested firms will be selected for Phase I!

HOW TO PARTICIPATE

- ❑ Send email expressing interest and addressing inclusion criteria applicability to the FDA post-inspection firm response email address provided by the investigator
- ❑ Emails should include
  - ❑ Firm name and address
  - ❑ Date of qualifying inspection
  - ❑ IPR name, title and email address
- ❑ FDA will notify applicants if they have been selected using the contact information provided
- ❑ Communicate interest within 5 business days after the current

For additional information or related questions, please email: OCARFAQs@fda.hhs.gov

Have you seen our Blog? FDA Voice

4. Foreign Supplier Verification Program (FSVP)

https://www.fda.gov/media/153288/download?attachment

5. Intentional Adulteration (IA)

- FY24 IA Rule FDPQC Inspections Assignment

6. Food Traceability Rule (FTR)

Frequently Asked Questions: FSMA Food Traceability Rule | FDA

Two (2) Tier Inspection Program:

- Tier 1: (RRA or onsite): Supply Chain and Recall Programs
  - Adequacy
- Tier 2: Implementation + other PC components

Staff Development:

Quarterly PC Meeting with FDA & State Partners

Formalized Program: PCHF & PCAF OJE

- Coach-OJE (Division)
- OHAFO/NEs: 1 day Webinar/Workshop
- On-site Coach-OJE with CSO along with OHAFO/NE

PC Coach OJE Agenda (sample)

Topic

- PC OJE Background
- OJE Coach Roles and Responsibilities
- Systems thinking During OJE inspection
- Components of a PC inspection
- Review PC Job Aide

Topic

- Tips: Good Practices
- Tips: Do's and Don'ts
- Completing PC OJE Feedback form
- Provide OJE Feedback to CSO
- Provide OJE Feedback to Supervisor
- Next step for PC OJE Coach

PC Coach OJE Job Aide:

- Initial Interview
- Gathering Information For Hazard Analysis
- Hazard Analysis
- Evaluating The Food Safety Plan
- Food Safety Plan Implementation
- Documenting Observations

PCHF Coach Webinar

- Cohort # 1: FY 22
- Cohort # 2: FY23
- Cohort # 3: FY 24

PCAF Coach Webinar

- Cohort # 1: FY23
- Division Specific : FY 23

Current OJE
VM220 and FD254

PCHF

OJE Complete	HAFE	HAFW	Total
No	37	15	52

Division	# of OJE PCHF Coaches
HAFE1	2
HAFE2	3
HAFE3	2
HAFE4	2
HAFE5	3
HAFE6	1
HAFW1	3
HAFW2	4
HAFW3	2
HAFW4	1
HAFW5	2
HAFW6	1
Total	26

PCAF

OJE Complete	HAFE	HAFW	Total
No	7	5	12

Division	# of PCAF OJE Coaches
HAFE1	1
HAFE4	1
HAFE6	1
HAFW1	2
HAFW2	2
HAFW3	1
HAFW4	1
Total	9

Opportunities For Consideration

- Appendix 1: Host a symposium to discuss the standards of the hazard analysis for specific commodities and risk management practices (i.e., mycotoxins).
- Develop industry wide courses that are commodity specific: What to Expect During an FDA Inspection.
- Develop a regulator course specific to industry regulatory personnel.

Thank You

BREAKOUT SESSIONS: ASK AN EXPERT

Have a burning FSMA question? This is your chance to get answers to your questions, and learn from questions that others ask.

HUMAN FOOD

ANIMAL FOOD

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BREAKOUT SESSION: ASK AN EXPERT
FDA PERSPECTIVES ON HUMAN FOOD

EXPERT:
GLENN BASS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR:
JASON WAN

INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

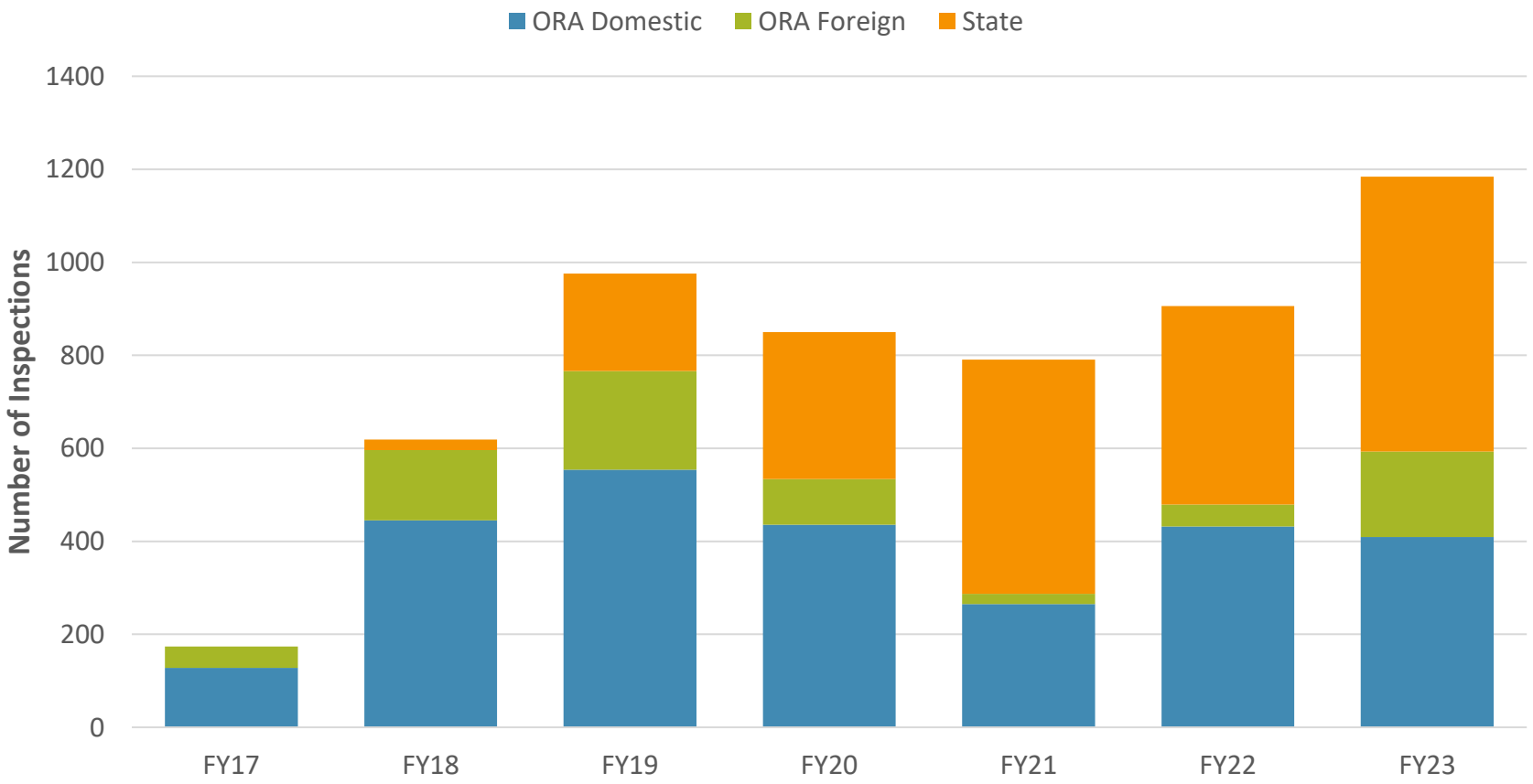
SCRIBE:
LILLIAN HSU

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

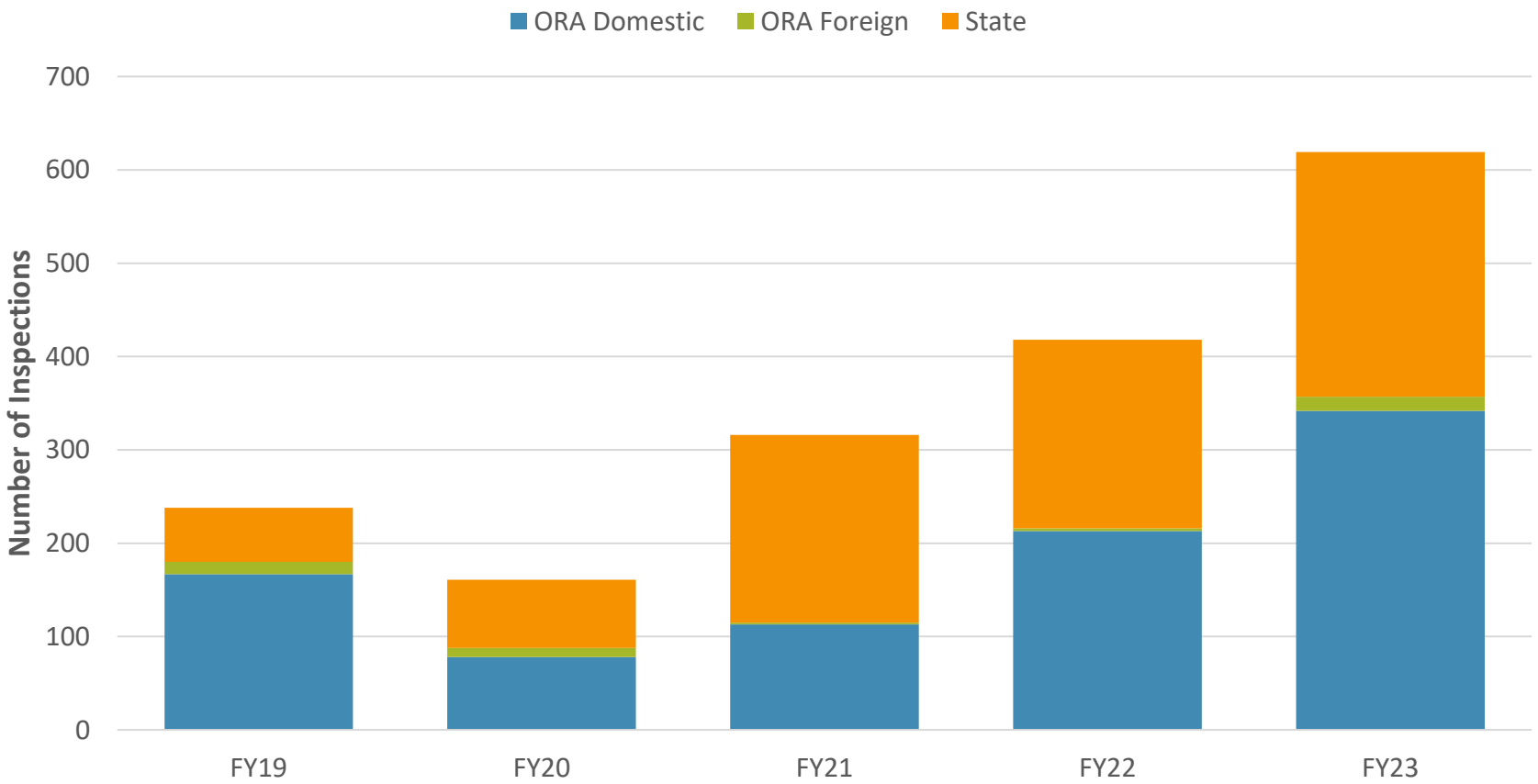
U.S. FOOD & DRUG ADMINISTRATION

FSMA Inspection Numbers

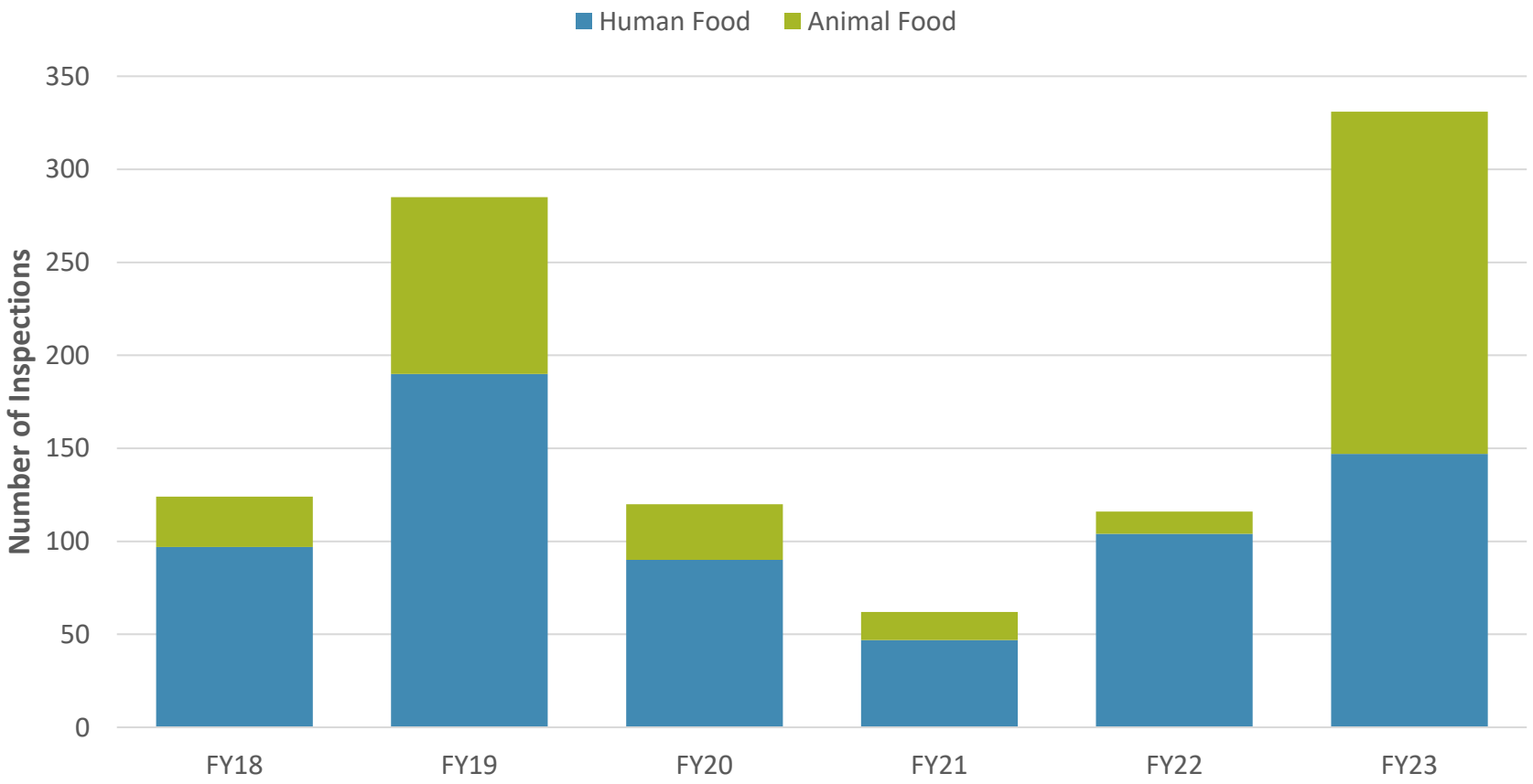
Preventive Controls – Human Food



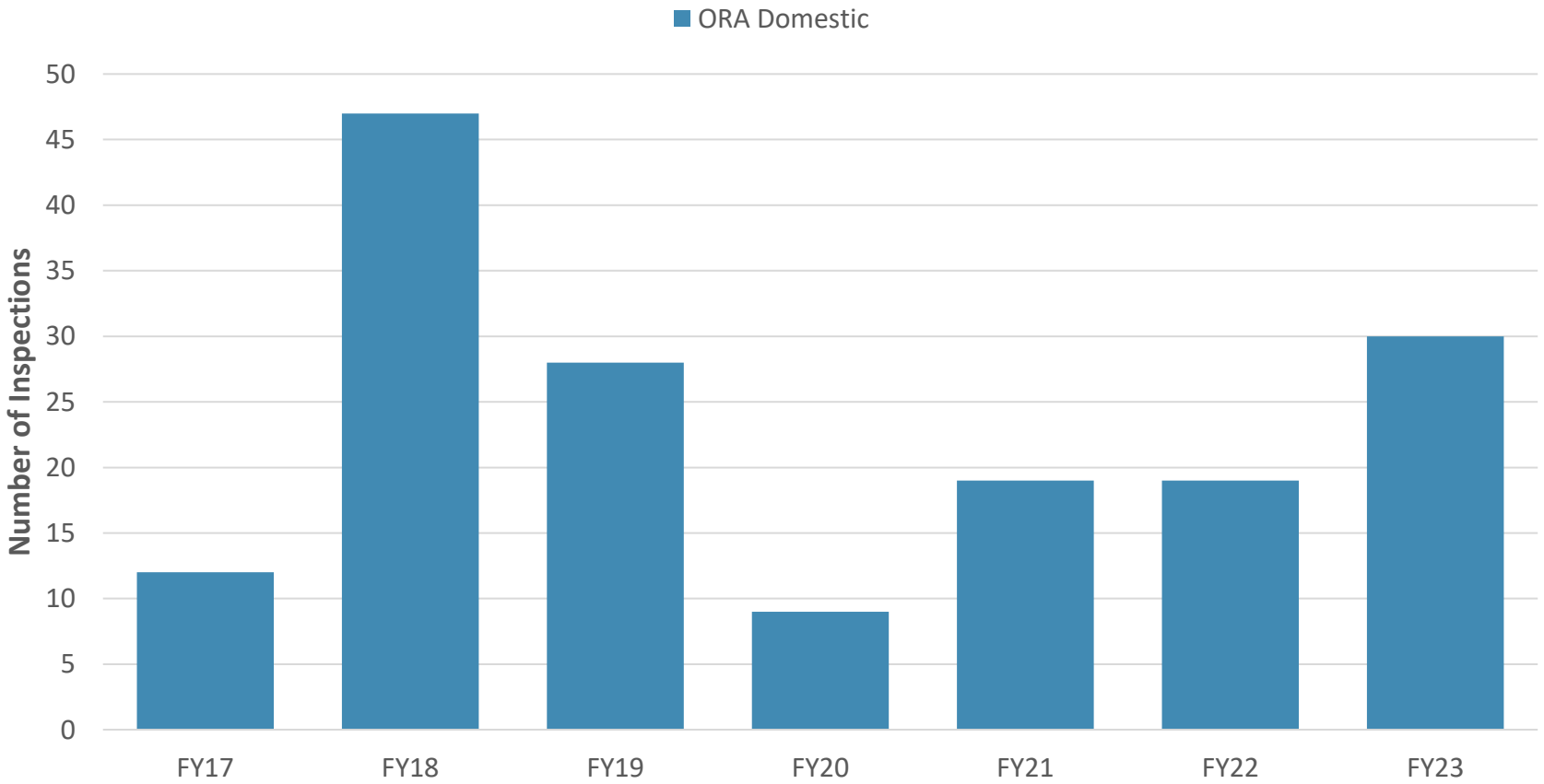
Preventive Controls – Animal Food



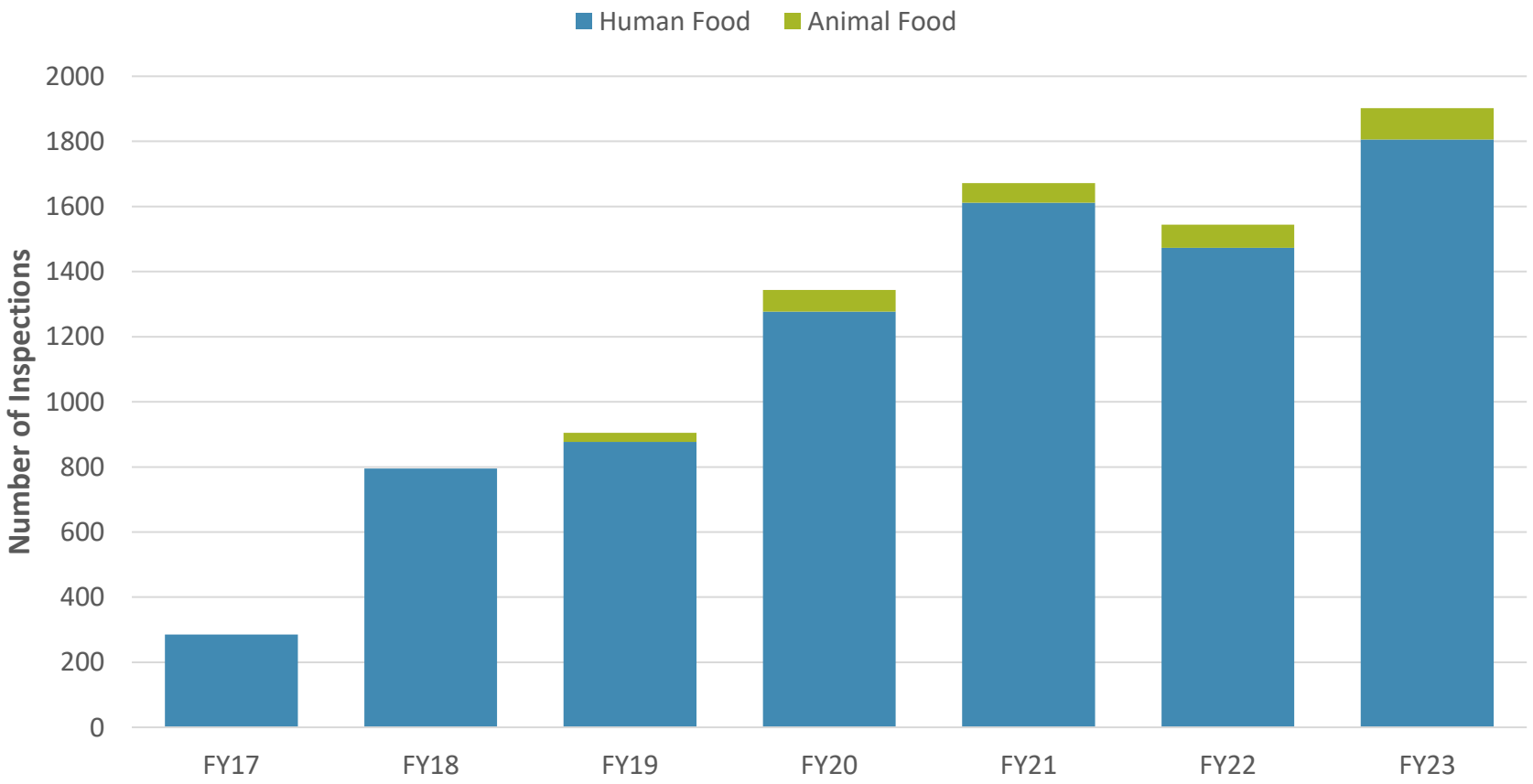
Sanitary Transportation Inspections



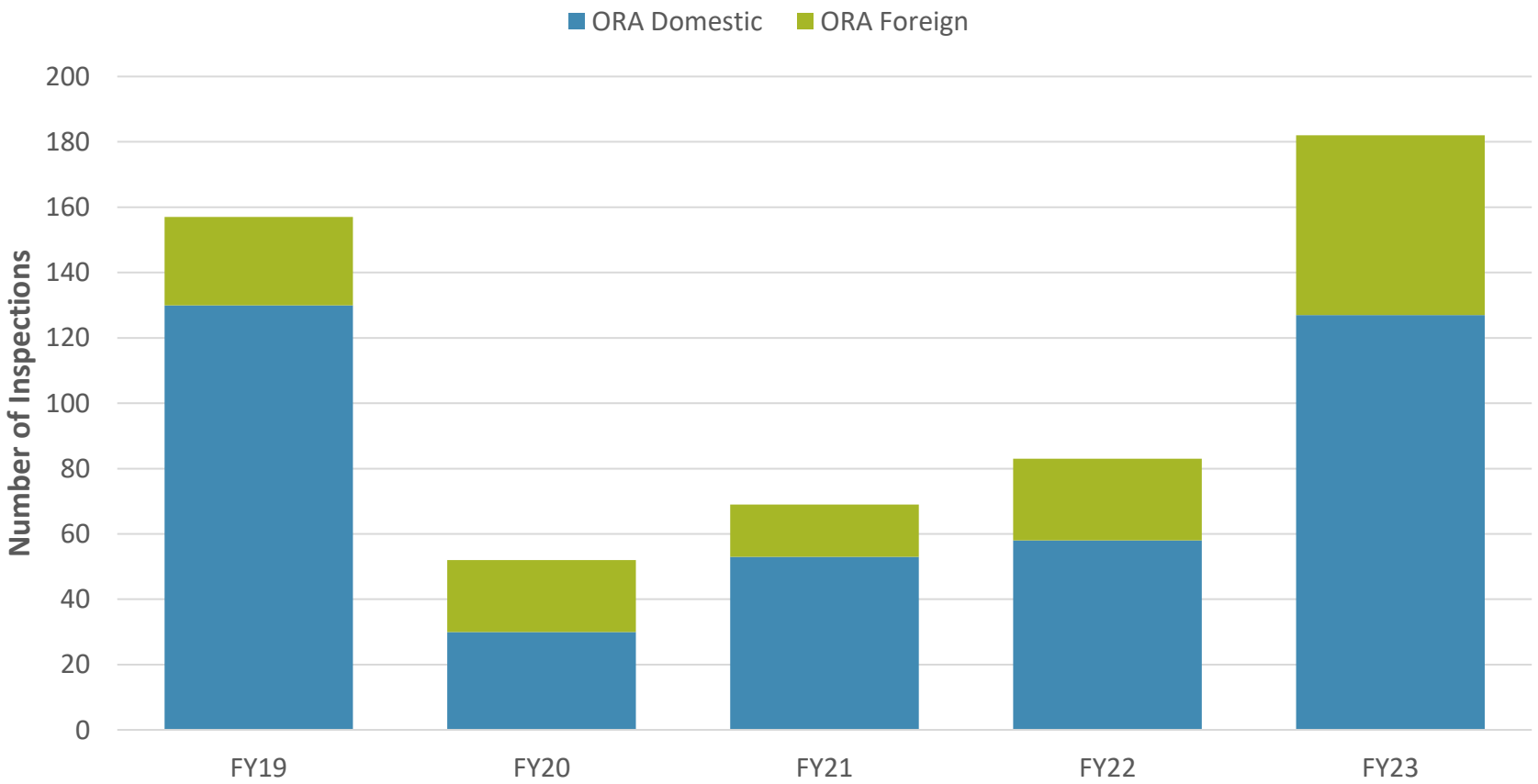
Sprout Safety



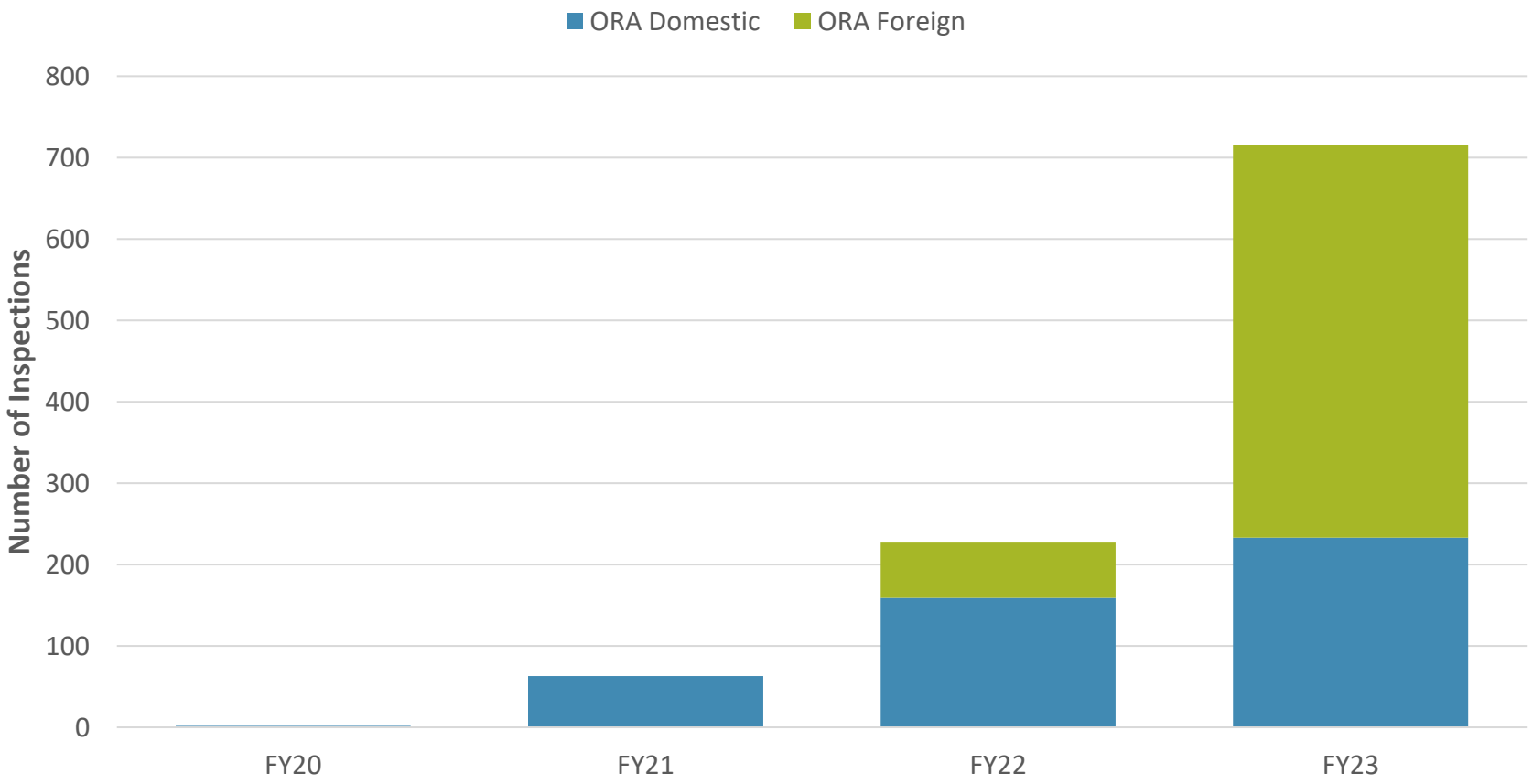
Foreign Supplier Verification Program



Produce Safety



Intentional Adulteration

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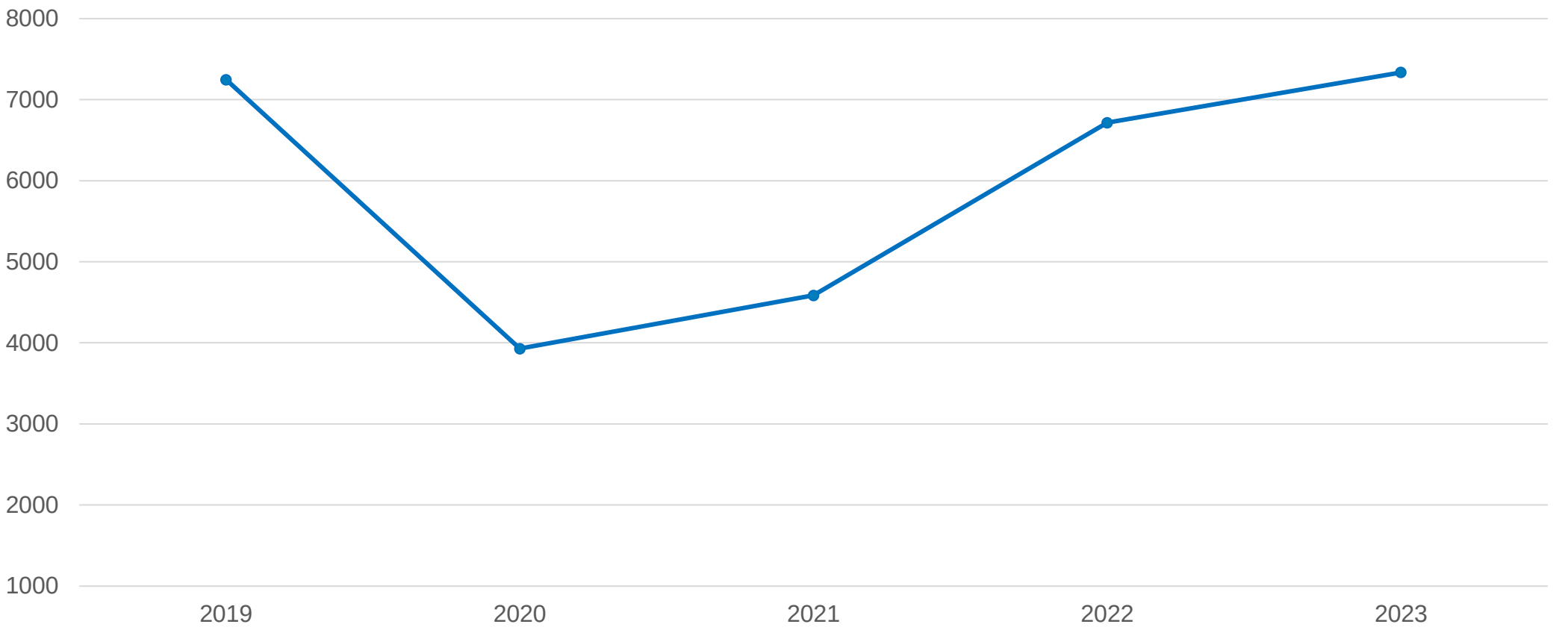
FDA Domestic Inspections, FY 2019 – FY 2022



FY 2023 FSMA Inspections (unofficial)

- Modernized cGMPs Human Food Domestic: 4415
- Modernized cGMPs Human Food Foreign: 999
- Modernized cGMPs Human Food State: 5060
- Preventive Control Human Food Domestic: 409
- Preventive Control Human Food Foreign: 184
- Preventive Control Human Food State: 591

FY 2023 FSMA Inspections (unofficial)

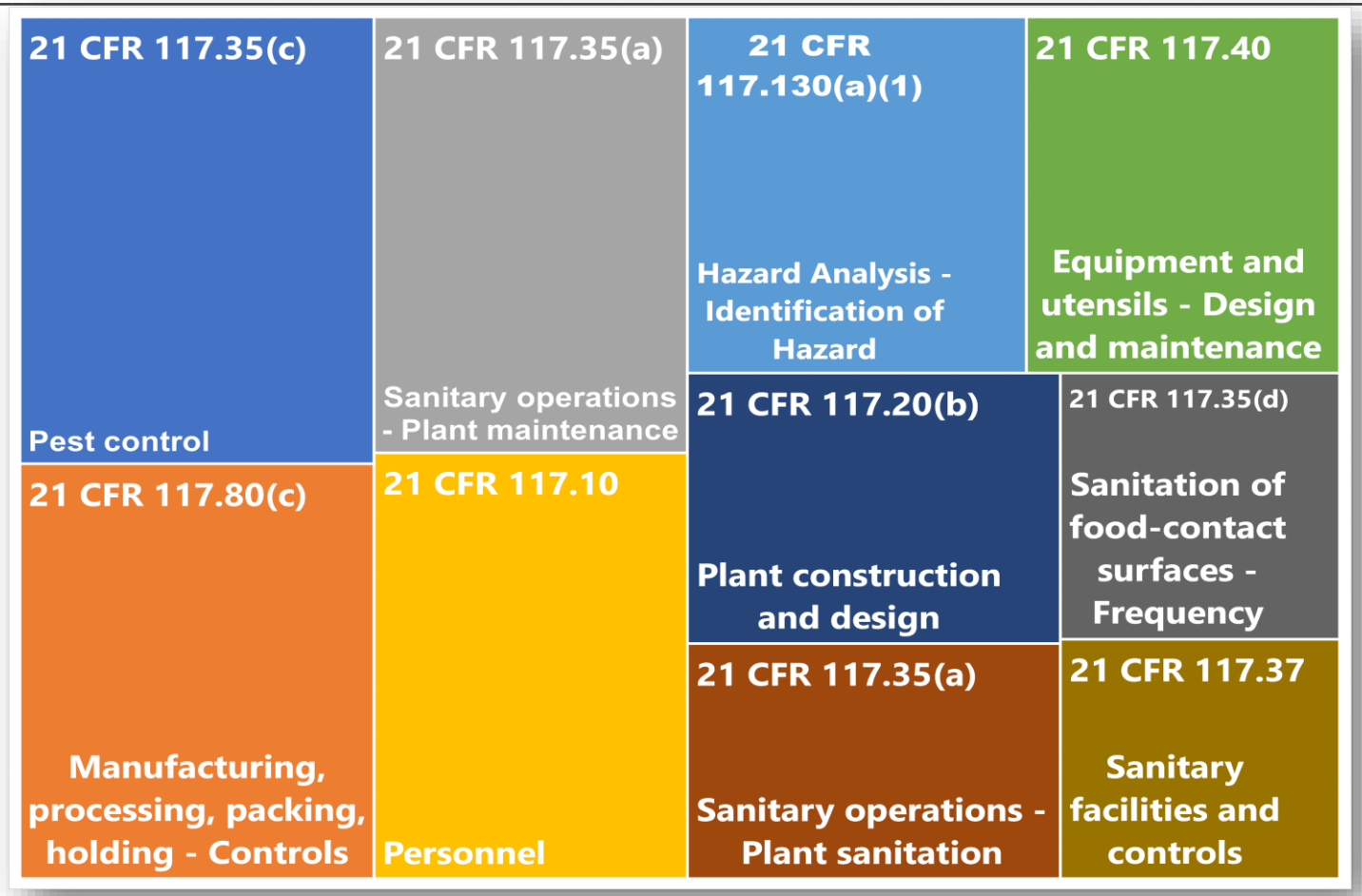
- Foreign Supplier Verification Human Food Domestic: 1806
- Intentional Adulteration Domestic: 233
- Intentional Adulteration Foreign: 482
- Produce Domestic: 127
- Produce Foreign: 55

FDA DATA DASHBOARD

https://datadashboard.fda.gov/ora/cd/inspections.htm

Top 10 Domestic Inspection Observations, FY19 – FY23

Preventive Controls Human Food, 21 CFR 117



Thank you

BREAKOUT SESSION: ASK AN EXPERT
FDA PERSPECTIVES ON ANIMAL FOOD

EXPERT:
DIANNE MILAZZO
U.S. FOOD AND DRUG ADMINISTRATION (FDA)

EXPERT:
DAVID FAIRFIELD
NATIONAL GRAIN AND FEED ASSOCIATION (NGFA)

MODERATOR:
MATTHEW BOTOS
CONNECT FOOD

SCRIBE:
CHRIS LINCECUM
COOPERATIVE FARMERS ELEVATOR (CFE)

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

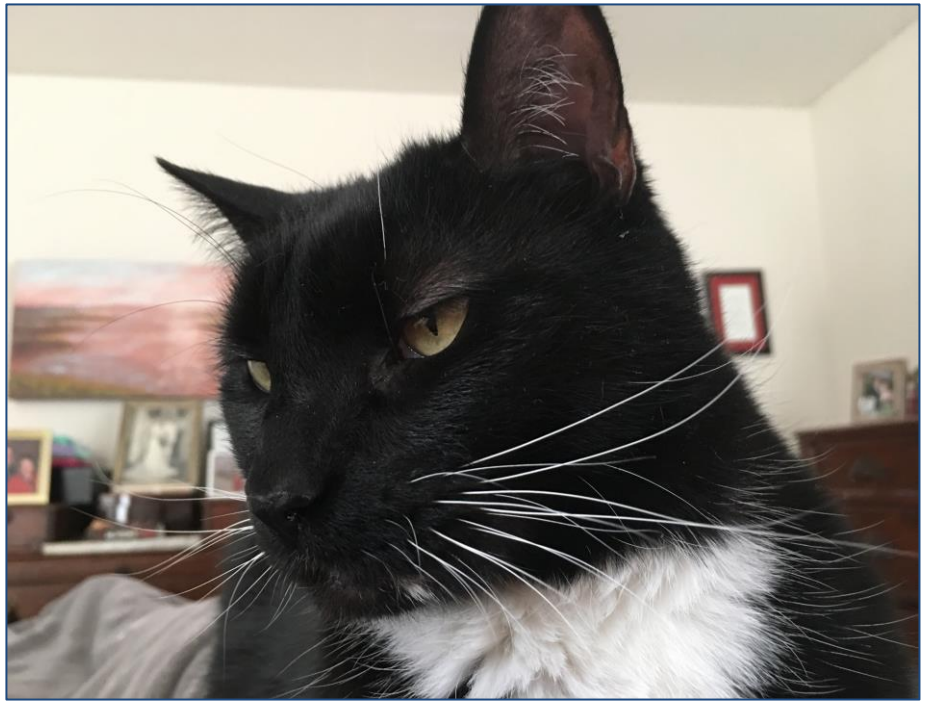
Ask an Expert: FDA Perspectives on Animal Food
FSCPA Annual Lead Instructor Conference

Dianne Milazzo, Consumer Safety Officer
Food Policy Team
Office of Surveillance & Compliance
Center for Veterinary Medicine

October 17, 2023

Session Topics

- Top 3 Citations for Animal Food
- Animal Food & Feed Resources
- FSCPA Animal Food Curriculum



Top 3 Citations for Animal Food

Top 3 Food Safety Observations for Animal Food Facilities in FY23

- 21 CFR 507.33 - Hazard Analysis
- 21 CFR 507.34(a)(1)- Preventive Controls
- 21 CFR 507.31(a) – Food Safety Plan

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 & 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

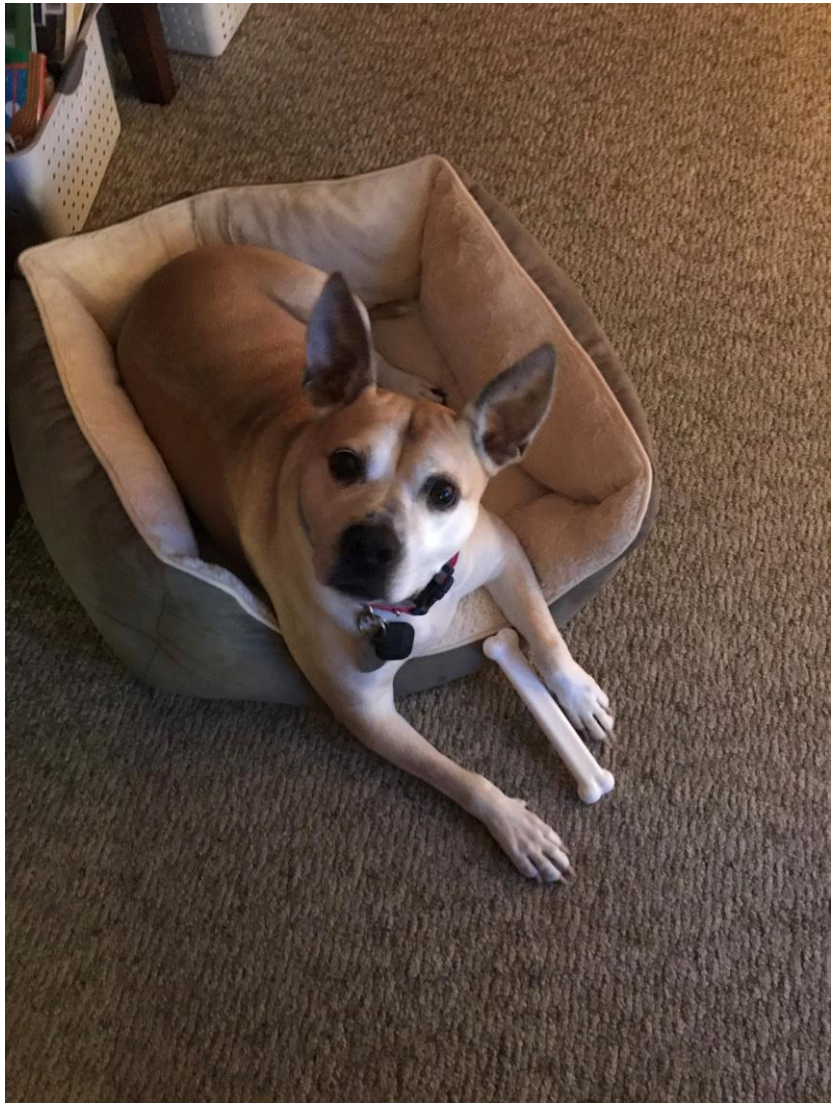
Animal Food and Feed

FDA Resources for Animal Food Businesses

- LINK: https://www.fda.gov/media/172062/download?attachment

FSPCA Animal Food Curriculum

QUESTIONS?

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FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FDA FSVP UPDATE

LORIE S. HANNAPPEL
U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: HILARY THESMAR

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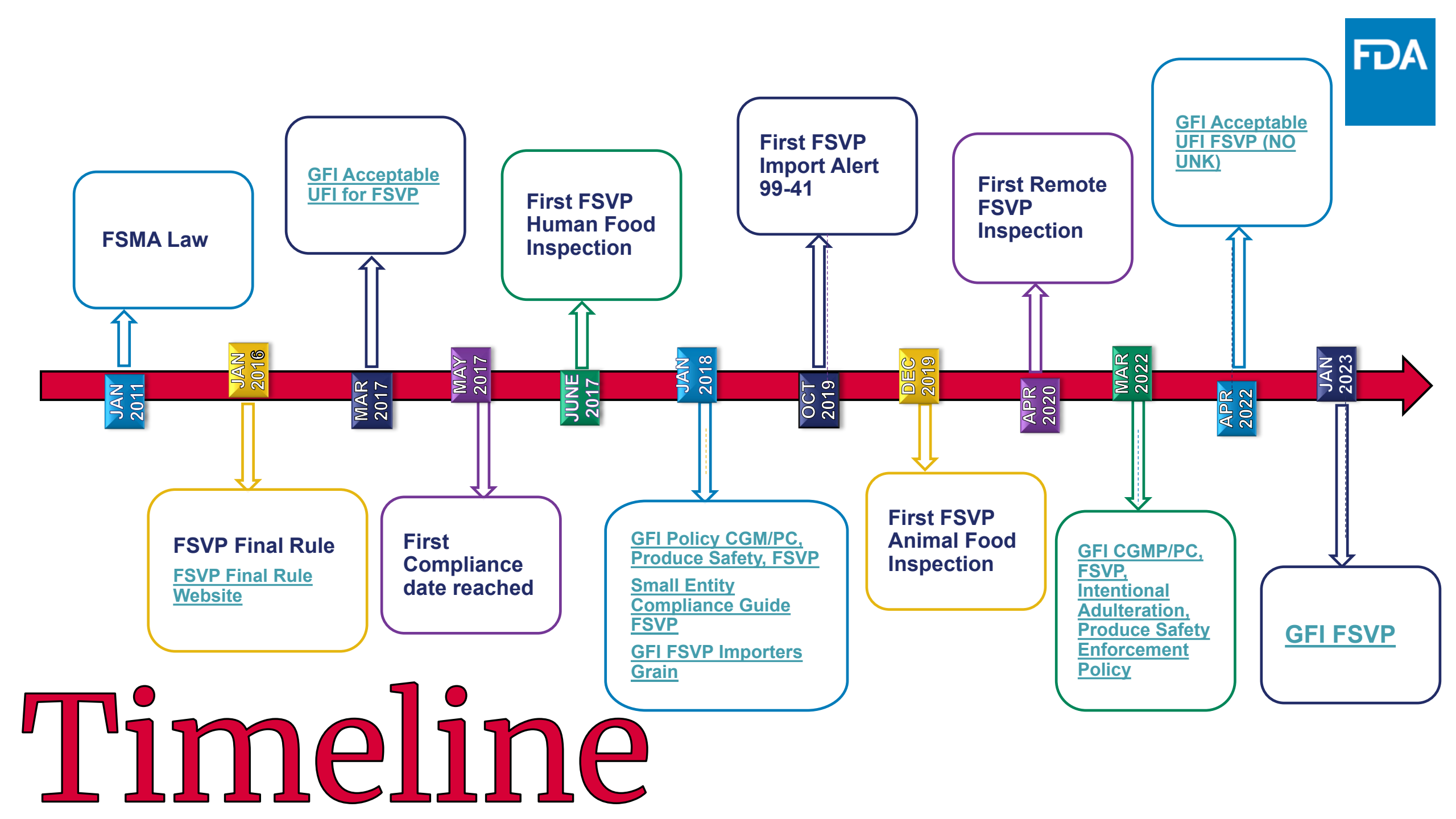
U.S. FOOD & DRUG ADMINISTRATION

FSVP, Where are We?

(Foreign Supplier Verification Programs)

Consumer Safety Officer Lorie Hannappel
October 2023


FDA
FSMA Law
JAN 2011
GFI Acceptable UFI for FSVP
JAN 2016
FSVP Final Rule
FSVP Final Rule Website
MAR 2017
First Compliance date reached
MAY 2017
First FSVP Human Food Inspection
JUNE 2017
GFI Policy CGM/PC, Produce Safety, FSVP
Small Entity Compliance Guide FSVP
GFI FSVP Importers Grain
JAN 2018
First FSVP Import Alert 99-41
OCT 2019
First FSVP Animal Food Inspection
DEC 2019
First Remote FSVP Inspection
APR 2020
GFI CGMP/PC, FSVP, Intentional Adulteration, Produce Safety Enforcement Policy
MAR 2022
GFI Acceptable UFI FSVP (NO UNK)
APR 2022
GFI FSVP
JAN 2023
Timeline

Overview

Inspections:

FY21-FY24 FSVP Inspection Statistics, Remote vs Onsite, Industry Portal

Enforcement:

FY21-FY23 FSVP Inspection Classifications, FY23 Top Citations, Enforcement Actions: Warning Letters & Import Alerts

FSVP Data:

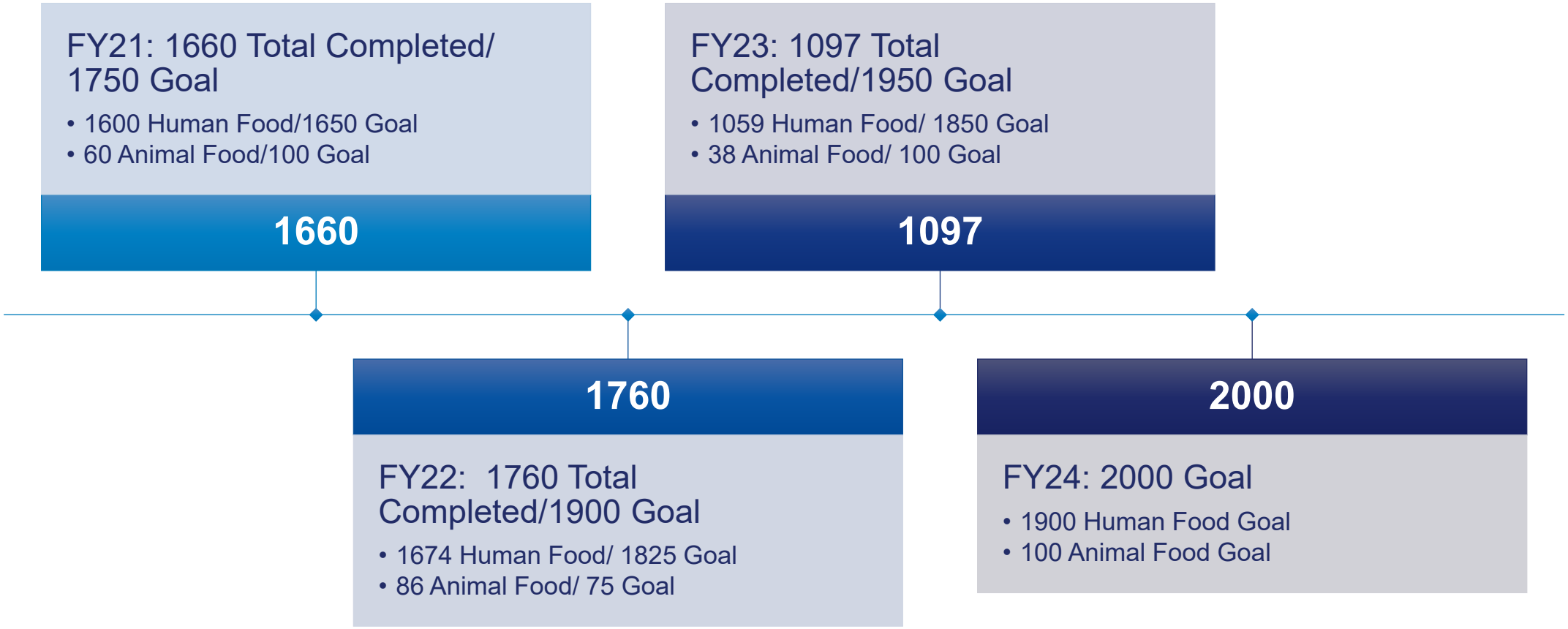
FDA Data Dashboard & FDA TRACK

FSVP GFI:

Guidance for Industry (GFI) Highlight's

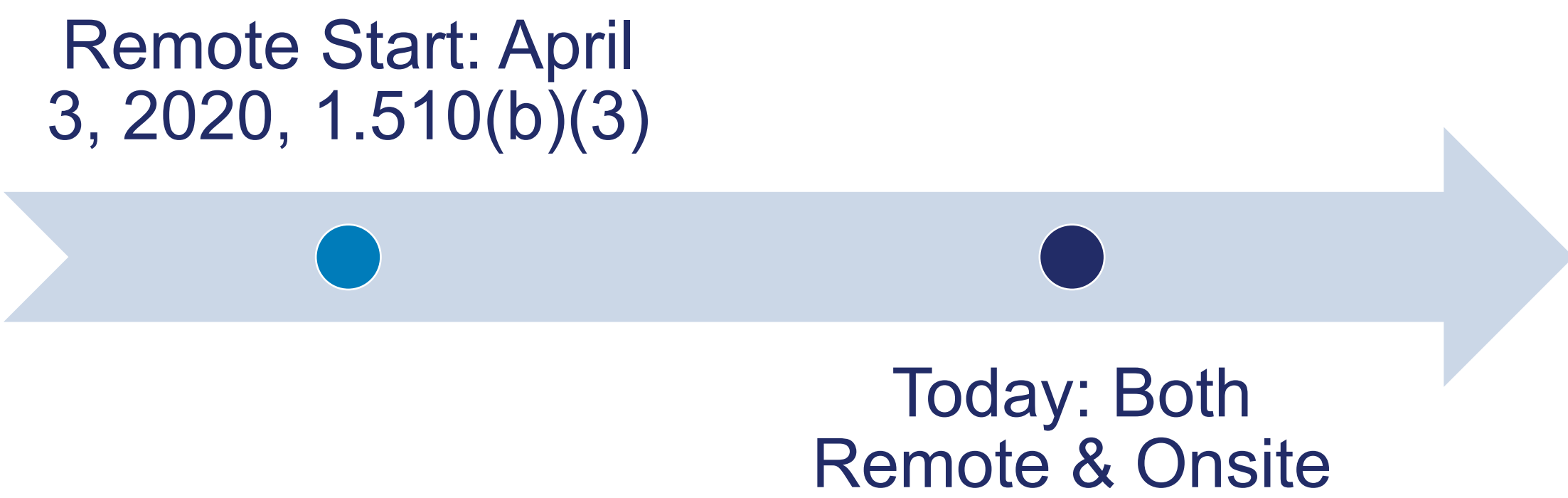
Inspections

FY21–FY23 FSVP Inspection



❖Numbers from FDA TRACK

Remote vs Onsite



FSVP Importer Portal for FSVP Records Submission

- PROGRAM EFFICIENCY
- CENTRALIZED LOCATION TO COMMUNICATE
- ALLOW USERS TO SUBMIT LARGE SIZE DOCUMENTS
- CONTROL TYPES OF RECORDS FDA RECEIVED
- COMMUNICATE INVESTIGATION STATUS
- CONTROL AND PREVENT UPLOADS AFTER INSPECTION CLOSE-OUT

Enforcement

Inspection Classifications

OAI: Official Action Indicated

- Serious objectionable conditions or practices were found
- Regulatory and/or administrative actions are **recommended**

VAI: Voluntary Action Indicated (VAI)

- Objectionable conditions or practices were found
- The agency is not prepared to take or recommend any administrative or regulatory action

NAI: No action indicated (NAI)

- **No** objectionable conditions or practices were found during the inspection

FY21–FY23 FSVP Inspection Classifications*

FY21	FY22	FY23*

• Human Food
  • OAI: 94 (5.9%)
  • VAI: 940 (58.8%)
  • NAI: 566 (35.4%)
• Animal Food
  • OAI: 0
  • VAI: 34 (56.7%)
  • NAI: 26 (43.3%)
	• Human Food
	  • OAI: 100 (6.0%)
	  • VAI: 855 (51.1%)
	  • NAI: 719 (43.0%)
	• Animal Food
	  • OAI: 0
	  • VAI: 41 (47.7%)
	  • NAI: 45 (52.3%)
		• Human Food
		  • OAI: 20
		  • VAI: 548
		  • NAI: 491
		• Animal Food
		  • OAI: 0
		  • VAI: 10
		  • NAI: 28

❖Numbers from FDA TRACK, some inspections pending final classification*

Top 10 FY23 FSVP Citations

	CFR	SHORT DESCRIPTION
1	21 CFR 1.502(a)	Develop FSVP
2	21 CFR 1.505(a)(2)	Evaluation - performance, risk
3	21 CFR 1.506(e)(1)	Verification activity before import, periodically
4	21 CFR 1.506(a)(1)	Approved supplier procedures - importer established
5	21 CFR 1.504(b)(1)	Hazard analysis biological, chemical, physical
6	21 CFR 1.504(a)	Hazard analysis written
7	21 CFR 1.506(b)	Supplier verification - establish written procedures
8	21 CFR 1.506(d)(1)(i)	Verification activity assurance
9	21 CFR 1.505(b)	Supplier approval - document
10	21 CFR 1.506(d)(1)(i)	Verification activity frequency

Enforcement Actions: Warning Letters (W/L)

FY19: 2 W/L

- 1st Warning Letter (W/L)

FY20: 46 W/L

FY21: 58 W/L

FY22: 87 W/L

FY23: ~65 WL

Enforcement Action: Import Alert 99-41

FSVP Import Alert 99-41:
July 2019

Specific to:

FSVP Importer,
Foreign Supplier,
and **Food(s)**

First FSVP Importer placed on Import Alert 99-41:

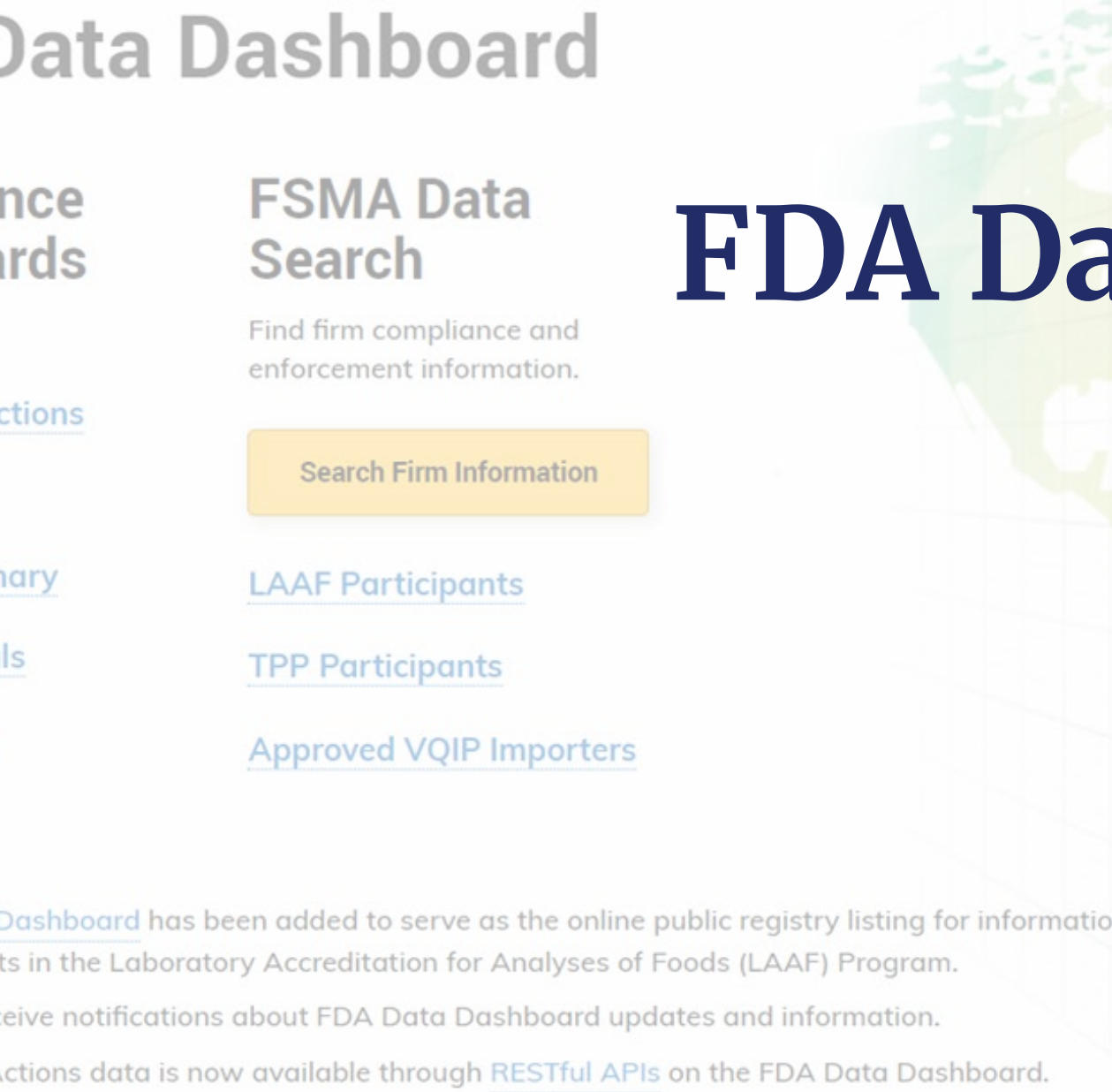
October 2019

Removal IA 99-41:

-Petition must include document submission of completed CA's

-If FDA decides Petition has met criteria for removal, FSVP Importer will receive letter indicating removal from DWPE

FDA Data Dashboard & TRACK

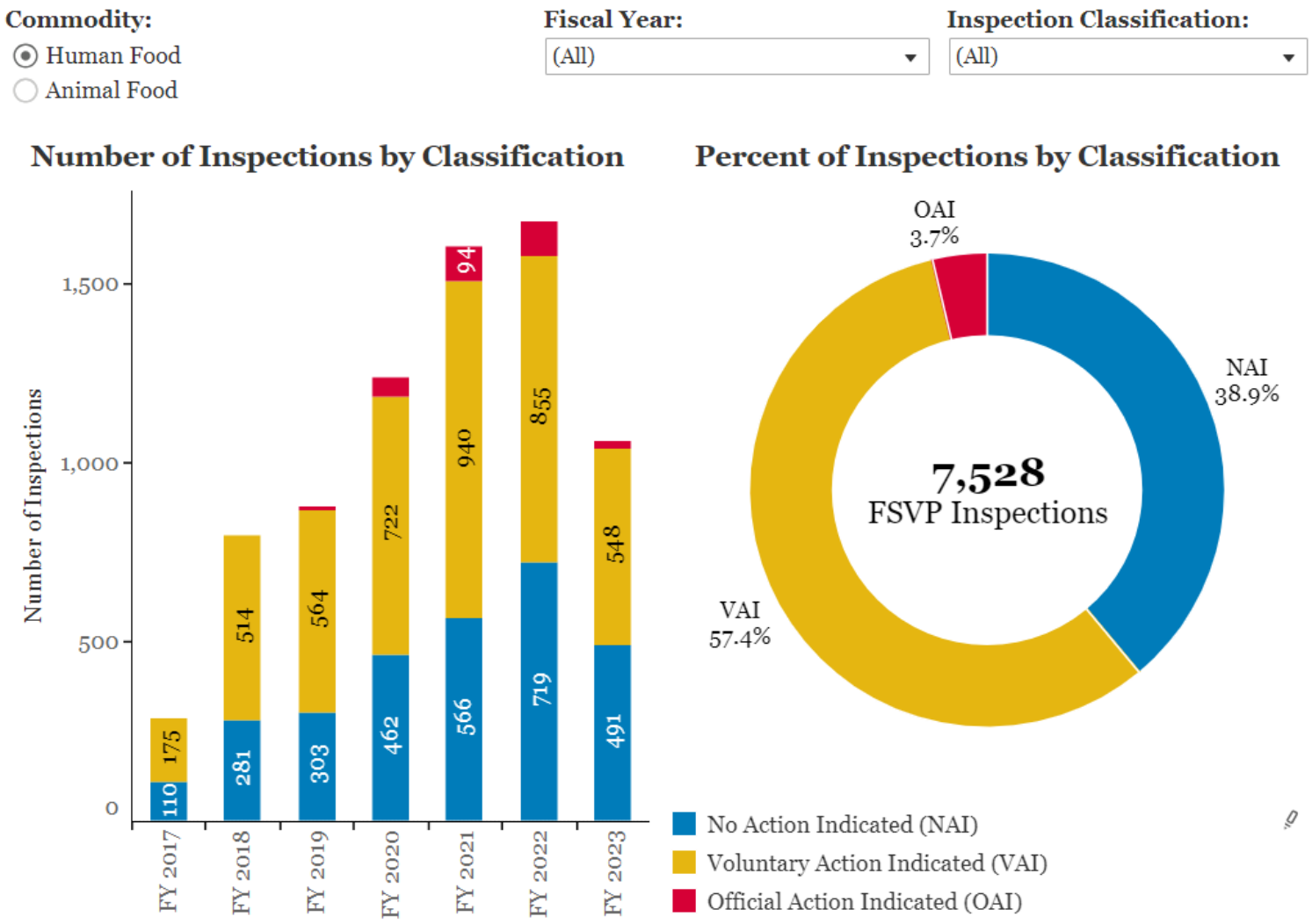


FDA Data Dashboard

FDA Data Dashboard

- External resource portal
- Industry & stakeholder
- Compliance history of Foreign Supplier's (FS)
- Information for FS approval
- Identify potential hazards

FDA-TRACK: Imported Food



FSVP Inspections Classifications

FSVP Guidance for Industry (GFI) Highlight's

Guidance for Industry (GFI): Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

FSVP GFI Issued January 2023

Guidance for industry on FSVP requirements

Agency's current thinking

Recommendations
(unless specific regulatory or statutory requirements cited)

Questions and Answers for understanding of FSVP requirements

Similar terms used by U.S. Customs and Border Protection (CBP) differences clarified

Accurate DUNS

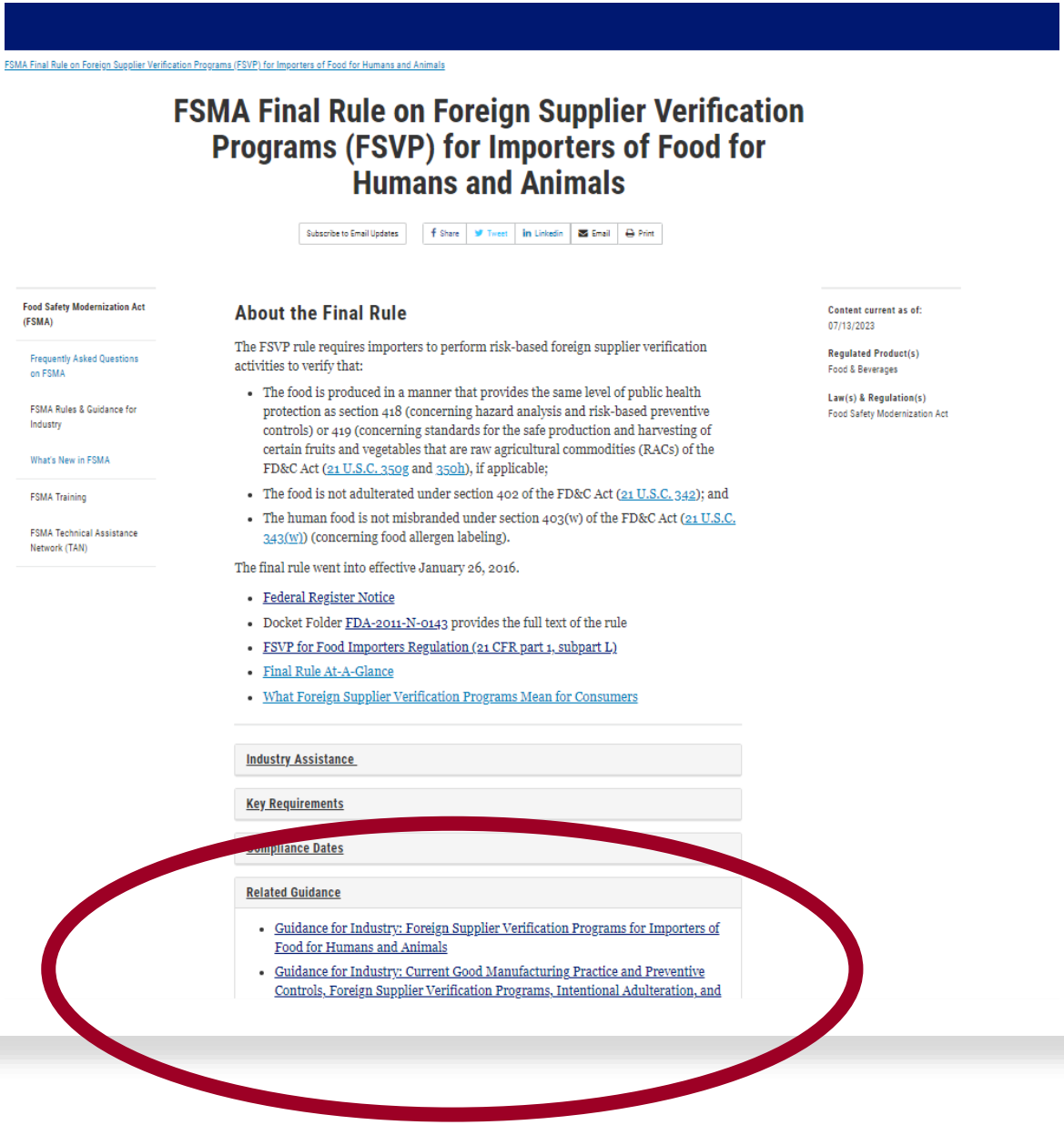
GFI Compliance Providing Acceptable UFI for FSVP Regulation

Policy allowing temporary use of UNK	Developed to provide importers time to obtain DUNS	Avoid delays during entry process

Updated April 2022

Importers must comply with section 1.509

Legal Name, Email Address, and DUNS



FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

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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)

About the Final Rule

The FSVP rule requires importers to perform risk-based foreign supplier verification activities to verify that:

- The food is produced in a manner that provides the same level of public health protection as section 418 (concerning hazard analysis and risk-based preventive controls) or 419 (concerning standards for the safe production and harvesting of certain fruits and vegetables that are raw agricultural commodities (RACs) of the FD&C Act (21 U.S.C. 350g and 350h), if applicable;
- The food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and
- The human food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning food allergen labeling).

The final rule went into effective January 26, 2016.

- Federal Register Notice
- Docket Folder FDA-2011-N-0143 provides the full text of the rule
- FSVP for Food Importers Regulation (21 CFR part 1, subpart L)
- Final Rule At-A-Glance
- What Foreign Supplier Verification Programs Mean for Consumers

Industry Assistance

Key Requirements

Compliance Dates

Related Guidance

- Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
- Guidance for Industry: Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and

Content current as of: 07/13/2023

Regulated Product(s): Food & Beverages

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

[FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals]


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HACCP AND PREVENTIVE CONTROLS

MARTIN BUCKNAVAGE
PENN STATE

TANIA MARTINEZ
DEMOS GLOBAL GROUP, INC.

MODERATOR: CLAUDIA COLES

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Preventive Controls and HACCP for US Firms

- US firms have different requirements depending upon the applicable regulation
- The concept is the same, HACCP-based, but there are differences in definitions and specific requirements
  - FDA FSMA – Preventive Controls for Human Foods 21CFR part117
  - FDA Seafood – 21 CFR part 123
  - FDA Juice - 21 CFR part 120
  - FDA-LACF/AF- 21 CFR part 113 & 114
  - USDA - 9 CFR Part 304

- Third-party audit requirements under international standards, generally follow HACCP with its 12 step and 7 principles

Challenges For Facilities Operating Two or More Plans

- The need to maintain different plans to account for regulatory requirements and present during inspection
- Addressing the needs of different groups of inspectors / auditors
- Meeting the training requirements

What the Food Safety Plan Adds to HACCP

Element	HACCP Plan	Added in Food Safety Plan
Hazard analysis	Biological, chemical, physical	Chemical hazards to include radiological; consider economically motivated hazards
Preventive controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs
Parameters and values	Critical limits	Parameters and minimum/maximum values (= critical limits for process controls)
Monitoring	Required for CCPs	Required as appropriate for other preventive controls
Corrective actions or corrections	Corrective actions	Corrective actions or corrections, as appropriate
Verification	For process controls	As appropriate for all preventive controls; supplier verification required when supplier controls a hazard
Records	For process controls	As appropriate for all preventive controls
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified

Preventive Controls and HACCP for US Firms

- Common practice negates some of the differences in regulatory definitions and basic regulatory requirements, for example, whether the flow diagram is required
- The differences that standout are the added preventive controls, specifically for allergens, sanitation, and supply chain controls (when called for by the hazard analysis)
- Some concepts are further defined with the Preventive Controls – for example, the terms correction and exception records
- Training requirements are for all employees

Facilities that utilize HACCP and Preventive Controls

- FDA beverage facilities that manufacture 100% juice products
- FDA facilities that manufacture some products with seafood
- Dual jurisdiction facilities that operate under both FDA and USDA

Juice HACCP and the FDA Food Safety Modernization Act: Guidance for Industry

- Juice processors are exempt from Subpart C for Preventive Controls and will follow 21 CFR part 120, the Juice HACCP regulation, which is based on the Hazard Analysis and Critical Control Point (HACCP) concept.
- Juice processors still must meet the applicable requirements of 21 CFR 117 subparts A, B, and F (for the records required by subpart A).
- When a facility manufactures, processes, packs, or holds both exempt (juice produced under 21 CFR part 120) and non-exempt products (for example, juice beverages or juice cocktails that are not covered by 21 CFR part 120), the activities that apply to non-exempt products and their raw materials or ingredients must meet the requirements of 21 CFR part 117 (including subparts C and G), unless an exemption applies.

Juice HACCP and the FDA Food Safety Modernization Act: Guidance for Industry

- CGMP requirements in 21 CFR part 117 (mostly in subpart B) generally align with the requirements of 21 CFR part 110, with the non-binding provisions in 21 CFR part 110 removed or made binding.
- In addition, 21 CFR 117 subpart B addresses allergen cross- contact explicitly in the regulatory text. In addition, Contains Nonbinding Recommendations 7 training, which was recommended in 21 CFR part 110, is now mandated in 21 CFR 117 subpart A (refer to question 4).

Seafood HACCP and the FDA Food Safety Modernization Act: Guidance for Industry

- Seafood processors must meet the requirements of specific subparts of the CGMP & PC Regulation.
- Specifically exempts the processing activities of seafood processors from the requirements of subpart C, and subpart G (if the seafood processor is in compliance with the seafood HACCP regulation with respect to the activities that are subject to part 123).
- Seafood processors still must meet the requirements of subparts A, B, and F (for the records required by subpart A) of part 117.

FDA Seafood and Juice HACCP and the FDA Food Safety Modernization Act

Training

- Appropriate training of workers training in the principles of food hygiene and food safety, including health and personal hygiene, as appropriate to the food, the facility, and the individual's assigned duties (21 CFR 117.4(d))
- Supervisory personnel
- Records of training

Facilities Operating Under USDA Inspection

- USDA facilities are exempt from FSMA and Preventive Controls
- Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems (9 CFR Part 304)

Meeting the Challenge

- Take same conceptual approach when conducting the hazard analysis and addressing hazards as appropriate
- Address all optional components for the plan by using best practice
- Utilizing a preventive control approach across all products will be beneficial for addressing allergens, sanitation in the post-process environment, and supplier control
- It is always best to use the appropriate standardized forms
- Important to keep up with regulatory developments

Challenges in the Implementation of Preventive Controls for Foreign Food Manufacturers companies

- **Assuming that because they comply with their regulation,** they comply with the USA different requirements depending upon the food product and its process.
- **Deciding what type of audit for compliance they will have to choose,** e.g. An audit to their own private standard, audits to several GFSI benchmarked schemes or an "FDA accredited" audit ? Many time this is decided not even by their company, but by their clients….
- **The implementation of a supplier program.** FDA's requirements are much more explicit than most of the other benchmarked schemes. FDA approach is more an fairly structured approach and clearly adapted to USA regulatory standards.

Challenges in the Implementation of Preventive Controls for Foreign Food Manufacturers companies

- **The actual understanding between the identification and management of preventive controls** because they will need to escalate its monitoring and validation of non-CCP controls and have clear that there are other Preventive Controls different than the Process Preventive Controls…
- **A big challenge now is the IAVA (IA rule).** Entities are accustomed to implement the general strict measures of a food facility and they think they are covered with this, as supposed to do a very detailed specific VA where the significant vulnerability is identified in an specific step of the process

CHALLENGES OF THEIR OWN MIND SETTING….

- Very important cultural issues: e.g.:

  " I had done this for 100 years and this is the way it is…..",

  " FDA inspected me already and they did not find anything….
  So I am "certified" to export to the USA"

  " Why do I have to do this… when nobody had asked me to do it"?

  "I am not planning to invest in an audit or adapt my system because I don't know yet if I will be able to have a substantial gain in the USA market…"

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AWARDS PRESENTATION

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

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LIFETIME ACHIEVEMENT AWARD

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

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JENNY SCOTT

Jenny Scott is retired from the Office of Food Safety at the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition, where was a Senior Advisor. She was the technical lead for the Preventive Controls for Human Food rule and guidance. Prior to joining FDA in August 2009, Jenny was Vice President of Science Policy, Food Protection, at the Grocery Manufacturers Association (which merged with the National Food Processors Association/Food Products Association) in Washington, DC, where she held various positions over a 29-year tenure. She received a B.A. degree in biology from Wellesley College, an M.S. in bacteriology from the University of Wisconsin, and an M.S. in food science from the University of Maryland. She served several terms on the U.S. National Advisory Committee on Microbiological Criteria for Foods. She is a past president of the International Association for Food Protection and a fellow of both IAFP and the Institute of Food Technologists. Until her retirement she served as the U.S. Delegate to the Codex Committee on Food Hygiene.

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WELCOME BACK

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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
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FSPCA EXECUTIVE ADVISORY BOARD UPDATE

KATHY GOMBAS
FSMA SOLUTIONS

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Innovation Through Collaboration

FSPCA Executive Advisory Board

- **Launched:** April 2020
- **Purpose:** Advisory Board to the FSPCA Director
- **Charter:** Identify opportunities for improving the performance, image, and reputation of FSPCA
  - provide professional & strategic advice regarding FSPCA offerings & services
- **Members:** volunteers representing industry, academia, and regulatory

Let's Meet the Board!

FSPCA EAB Members

First Name	Last Name	Organization
Martin	Bucknavage	Penn State Department of Food Science
Claudia	Coles	Seafood Products Association
David	Fairfield	National Grain and Feed Association
Kathy	**Gombas (Chair)**	**FSMA Solutions**
Chris	Lincecum	Cooperative Farmers Elevator
Modestar	Liyokho	Kerry, Inc
Tania	Martinez	Demos Global Group, Inc.
Amy	Philpott	Philpott PR Solutions LLC
Juan	Silva	Mississippi State University
Katherine	Simon	Minnesota Department of Agriculture
Douglas	Stearn	CFSAN - FDA EX Officio Member
Jennifer	Thomas	CFSAN - FDA EX Officio Member

FSPCA Management

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Brian Schaneberg – IFSH Executive Director
Jason Wan – FSPCA Director
Jerry Wojtala – IFPTI Executive Director
Steve Mandernach – AFDO Executive Director
Dawn Johnson – FSPCA Program Manager

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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FSPCA Strategic Plan

Vision: Be the 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.

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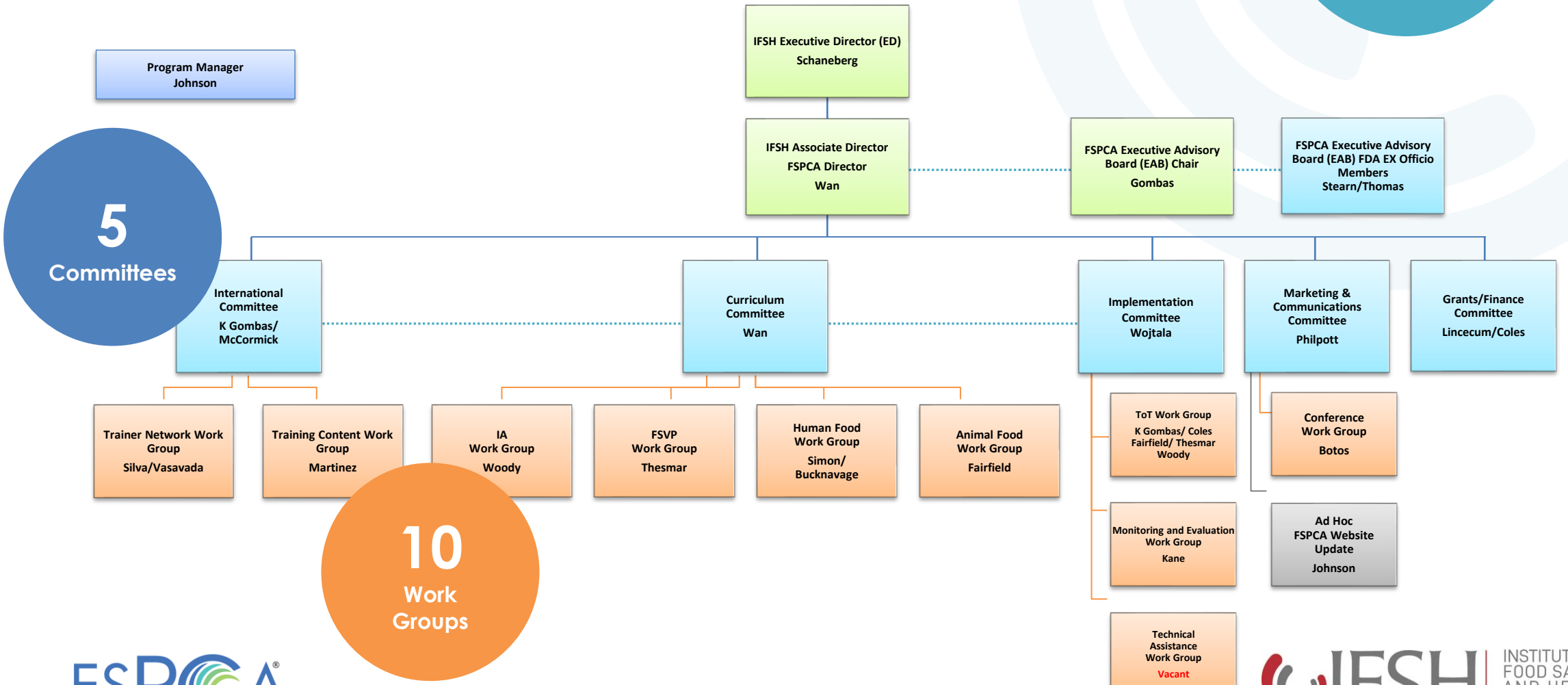
FSPCA Structure

3,065
Lead Instructors



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FSPCA Strategic Framework

GOAL 1	Attract, develop, recognize, and support volunteers and lead instructors	
OUTCOME	**Sustain and support volunteer base** • Create greater **awareness of volunteer activities** • Create **recognition and appreciation process** for significant volunteer contributions	• Quarterly Newsletter; Improved Website; E-blasts • NEW: FSPCA Annual Awards and Recognition Program
	Sustain and support lead instructors • 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
	Maintain and expand diversity of volunteers and lead instructors	Online FSPCA Volunteer Interest Form

FREE FSPCA Webinars

2023	Topic	Presenter(s)	Invitees
March 14	FDA FSVP Final Guidance	Kevin Kwon, FDA	FSVP LIs
March 27	Food Traceability Rule	Chris Waldrop, FDA	All LIs
April 25	FSPCA Food Safety Plan Teaching Examples – Teaching Tips	Kathy Gombas Claudia Coles	PCHF LIs
May 25	FSPCA FSVP Foreign Supplier Awareness Module	Hilary Thesmar	Open to Public
June 30	Update on PCHF Curriculum V2.0	Martin Bucknavage Katherine Simon	PCHF LIs
August 10	The FSPCA PCHF and FSVP LI Resource Portals	Claudia Coles	PCHF and FSVP LIs
Sept 19	FSPCA Annual Conference Pre-view	Matt Botos Ron Tanner	Open to Public
Oct 26	FSPCA Website Update	Dawn Johnson Amy Philpott	Open to Public
Nov 14	FDA FSVP Update	Lorie Hannappel, FDA	FSVP LIs
Dec TBD	IAVA Inspectional Strategy	FDA Invited	IAVA LIs

FREE FSPCA Webinars

Public webinar presentations and recording links are posted to FSPCA's website

Lead Instructor webinar presentations and recording links are posted to the LI Portals

FSPCA Strategic Framework

GOAL 2	Build and maintain strategic relationships	
OUTCOME	**Evaluate existing FSPCA relationships** to leverage past investments and explore new opportunities	FAS, IICA, FDA
	Evaluate potential relationships that may provide new and additional value to the FSPCA	International Engagement

Strategic Relationships

- 20% of Egypt food exports go to US – expected to grow substantially
- FSPCA collaboration between Land O'Lakes Venture 37 and USAID
- Deliver Preventive Controls for Human Food Participant and Lead Instructor courses
  - Industry QA Managers
  - Build capacity of trainers in Egypt to assist industry to increase exports to the US

FSPCA Strategic Framework

GOAL 3	Create responsible marketing and outreach strategies to promote products and services	
OUTCOME	Develop and implement an outreach and encouragement plan to **attract new Lead Instructors and engage current Lead Instructors**	
	Develop and execute a **marketing plan for promoting FSPCA products and services,** including product updates and revisions	
	Develop a 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	Small processors International engagement
	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.	

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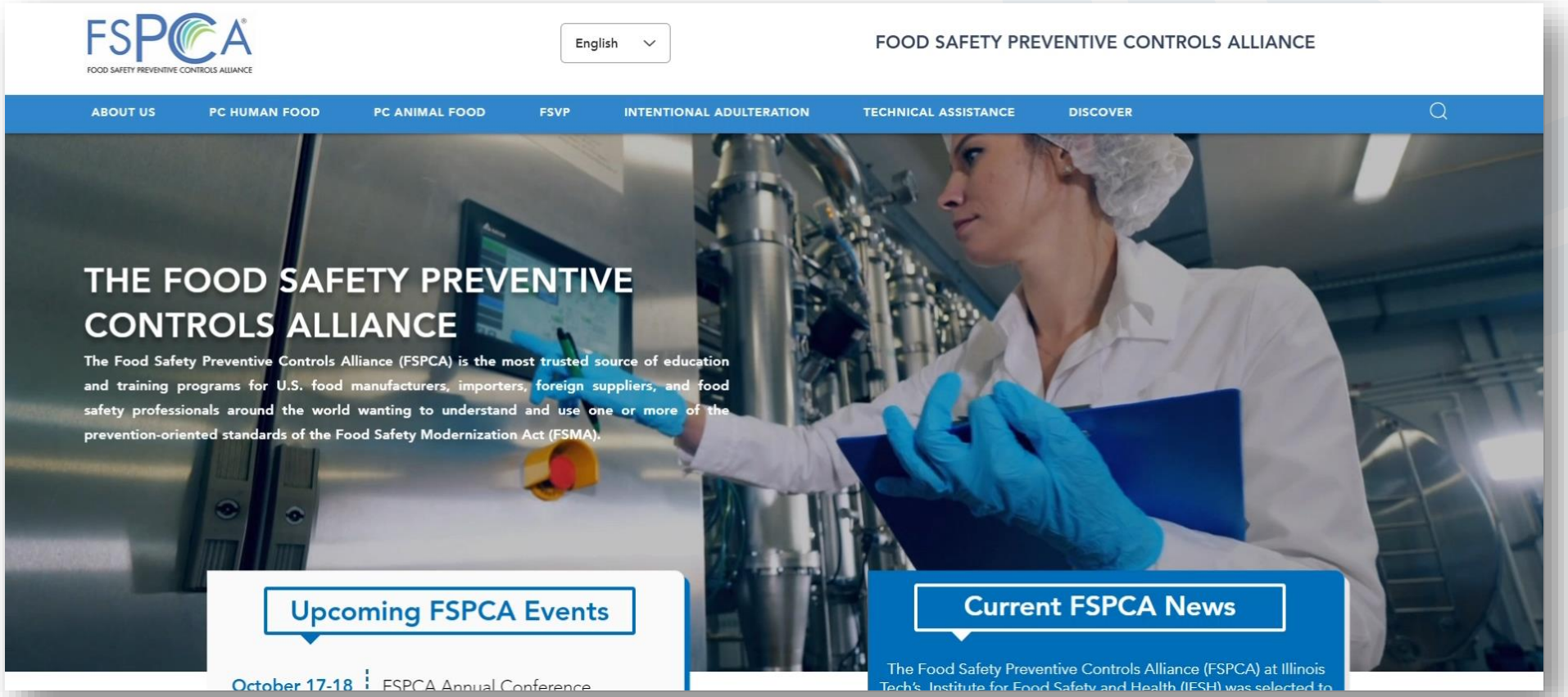
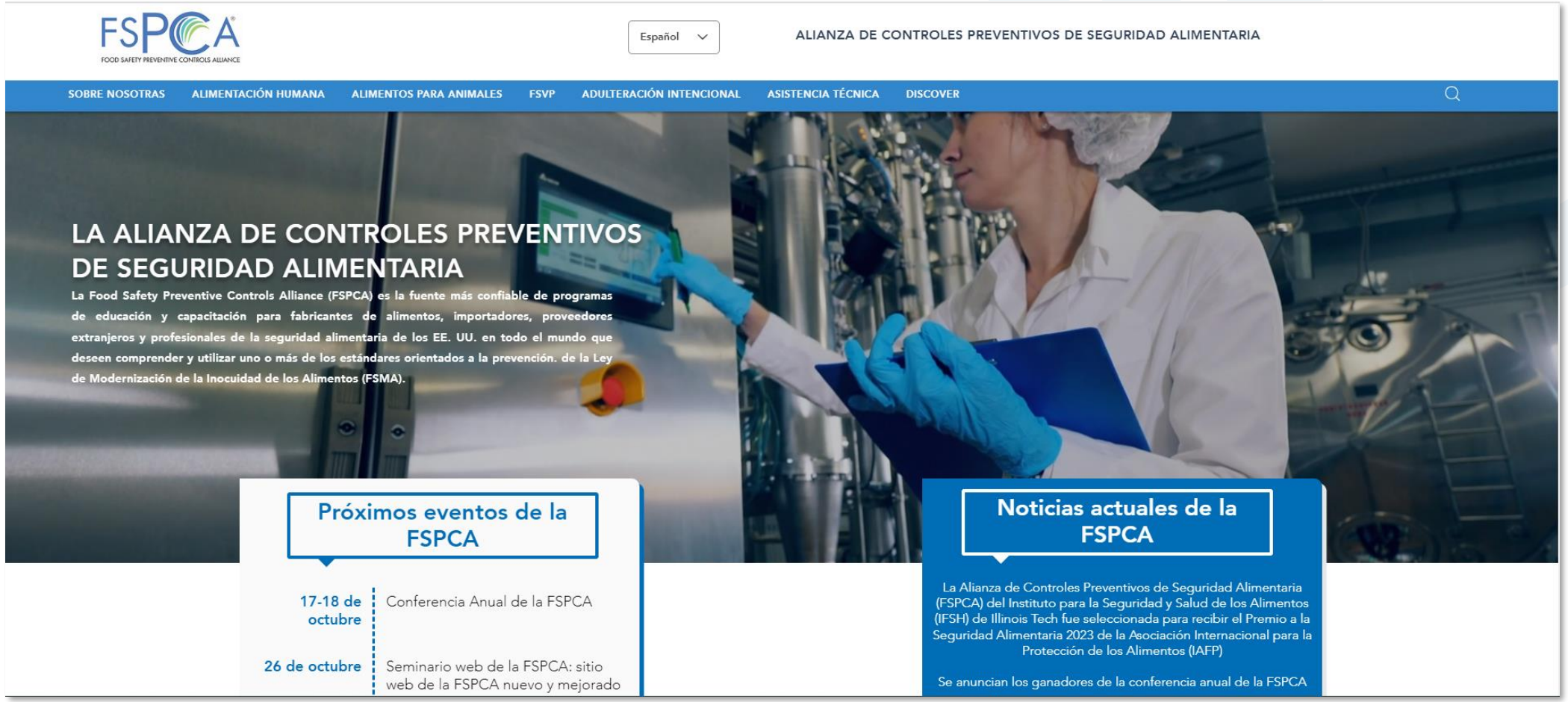
FSPCA Website Remodel



FSPCA Website Remodel (Español)



FSPCA Strategic Framework

GOAL 4	**Develop and maintain the organizational infrastructure to promote uniformity, harmonization in maintenance of curricula and delivery to ensure accuracy, quality, and relevancy**	
OUTCOME	Ensure the FSPCA **organizational infrastructure is updated** and operational	FSPCA Operational Plans
	Develop procedures for **reviewing and revising existing products** to ensure accuracy and current information	
	Implement **curriculum management principles and operational procedures** to ensure quality development and maintenance best practices are utilized	
	Eliminate barriers pertaining to distance, cost, and language to ensure the **quality of international course delivery**	
	Maintain **quality control systems** for consistent and **high-quality** **course delivery by Lead Instructors**	

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	Preventive Controls for Human Food Participant Course V2.0
	Establish a process to **explore and evaluate additional value-added products and services**	
	Implement a system to **identify and address stakeholder needs**	
	Plan and prioritize the **development of new products**	Food Traceability Core Curriculum

NEW - FSPCA Food Traceability Curriculum

- FDA final rule on "Requirements for Additional Traceability Records for Certain Foods"
  - Published on Nov 21, 2022
  - Single compliance date for the industry is January 20, 2026

- FSPCA established Food Traceability Rule Core Curriculum Editorial Team to develop:
  - Learning objectives of the Food Traceability Rule core curriculum
  - Content for the curriculum to meet the learning objectives
  - Exercises and teaching examples for training

Next Steps

- FSPCA EAB Meeting Oct 19-20 following conference
- Finalize Strategic Plan
- Review 2024 Operational Plans with FSPCA Director & Committee Chairs


Mahalo
Grazi
THANK
YOU
Danke
Shukran

FSPCA
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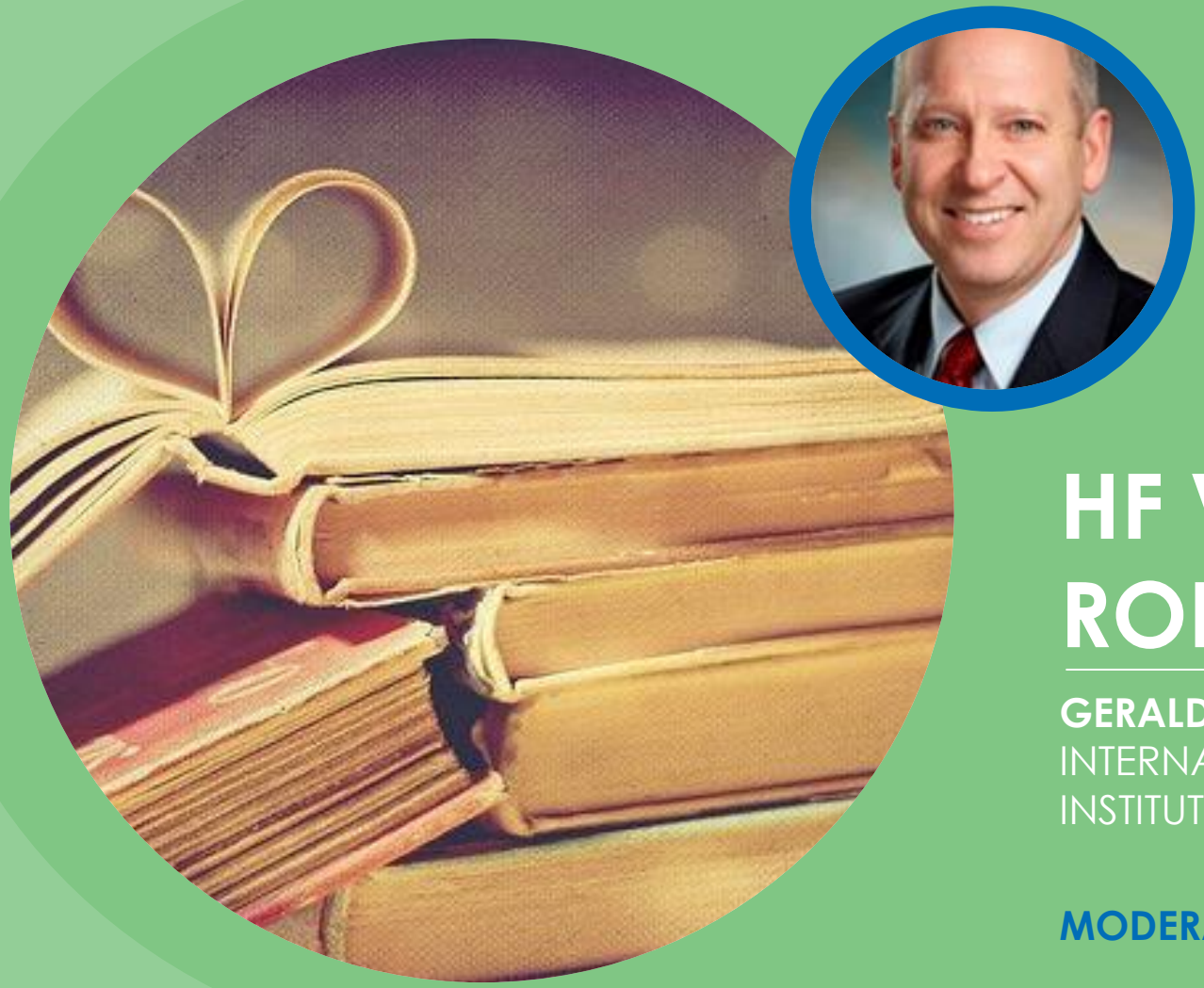

HF V2.0 CURRICULUM ROLLOUT

GERALD WOJTALA
INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE (IFPTI)

MODERATOR: KATHERINE SIMON

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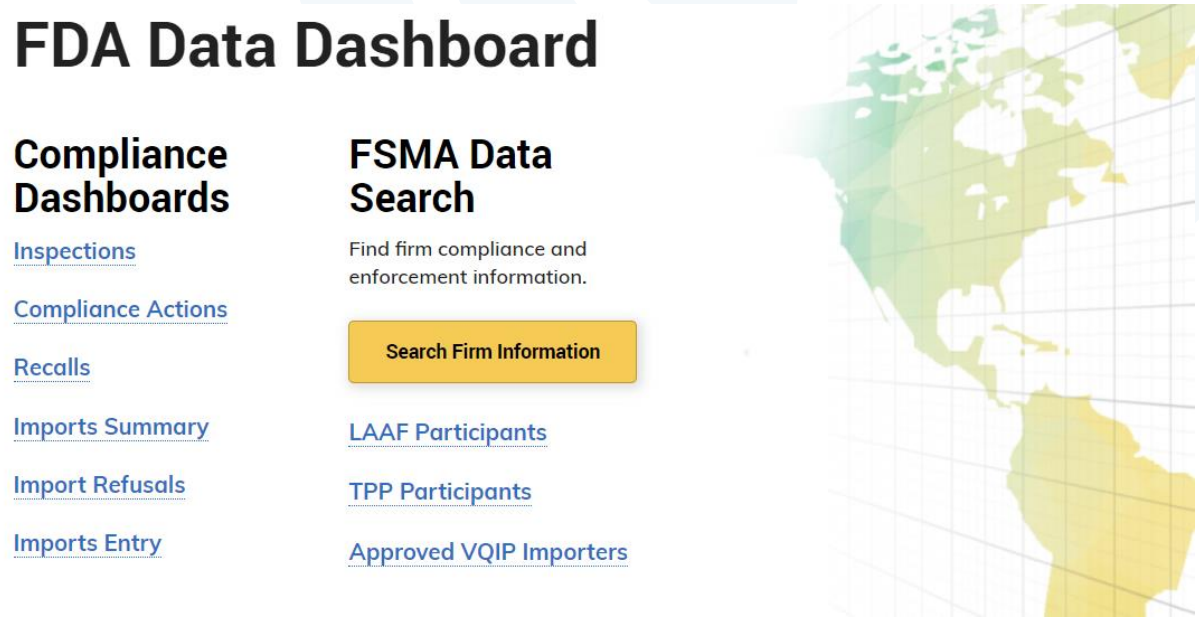
What Were the Update Objectives?

- Update references, e.g., RFR, CDC
- Streamline sections, reduce redundancy
- Support development of key concepts
- Increase small and mid-sized applications
  - Examples in the course are tied to Teaching Examples



What Were the Update Objectives?

- Gain recognition as an approved HACCP-based curriculum
- Align with FDA current thinking
  - Draft Guidance and other regulatory updates
  - Appendix 1: Hazards Guide

Curriculum Team

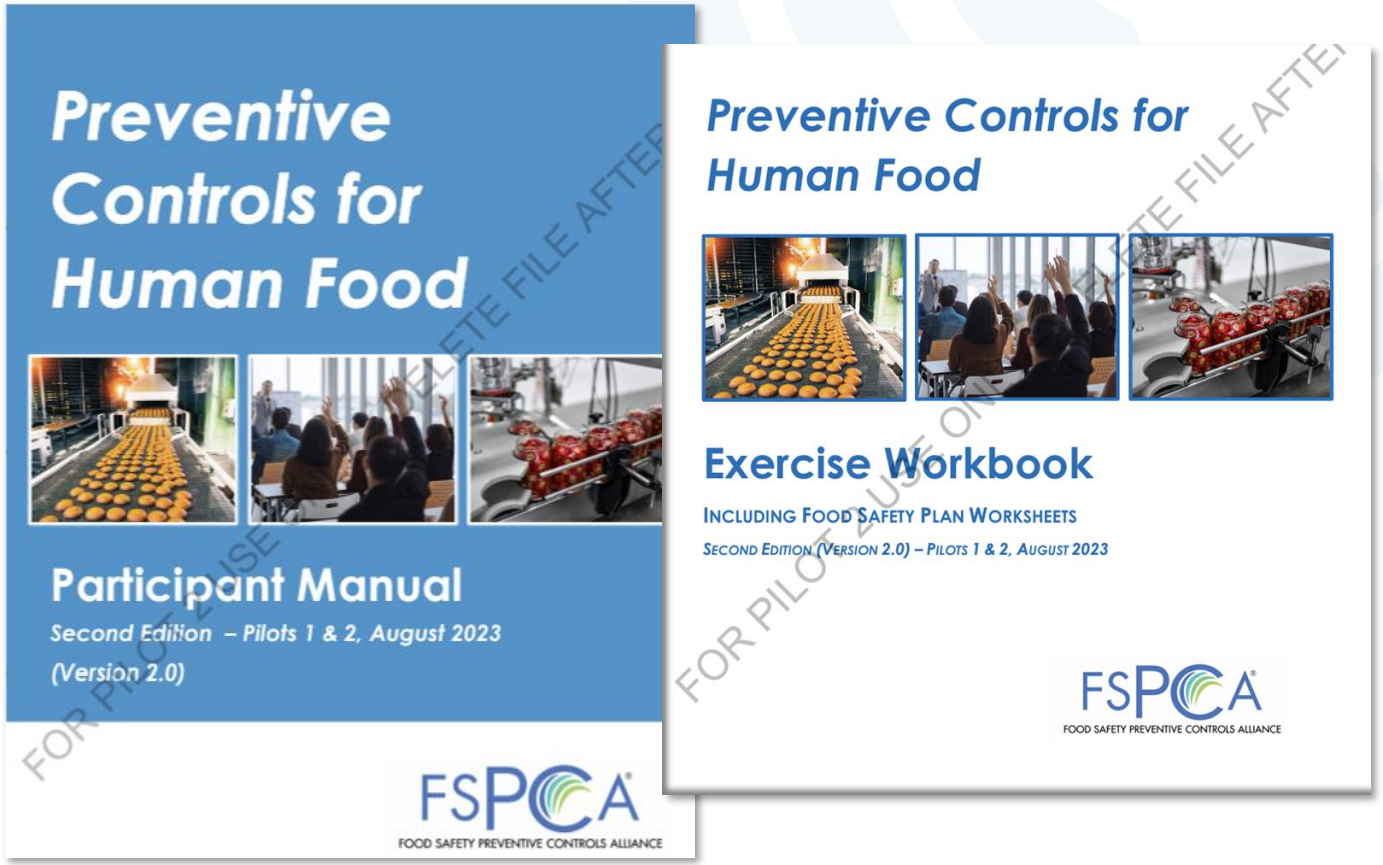
- **Kimberly L. Anderson**, California Department of Public Health
- **Martin Bucknavage** (Co-chair), Pennsylvania State University
- **Claudia Coles**, Seafood Products Association
- **Deb DeVlieger**, U.S. FDA (retired)
- **Elise Forward**, Forward Food Solutions
- **Kathy Gombas**, FSMA Solutions
- **Connie Halvorsen**, International Food Protection Training Institute
- **Lillian Hsu**, U.S. FDA
- **Lynette Johnston**, North Carolina State University
- **Richard Kralj**, Pennsylvania State University
- **Tania Martinez**, Demos Global Group, Inc.
- **Matthew Noonan**, U.S. FDA
- **Ruth Petran** (Editor), Ruth Petran Consulting, LLC.
- **Jenny Scott**, U.S. FDA (retired)
- **Juan L. Silva**, Mississippi State University
- **Katherine Simon** (Co-chair), Minnesota Department of Agriculture
- **Warren Stone**, Zone One Consulting, LLC.
- **Jason Wan**, Institute for Food Safety and Health
- **Wendy White**, Georgia Institute of Technology
- **Brian Yaun**, U.S. FDA

Version 2.0

Participant Manual

- Slides = 638
- Exercises = 11
- Pages = 628

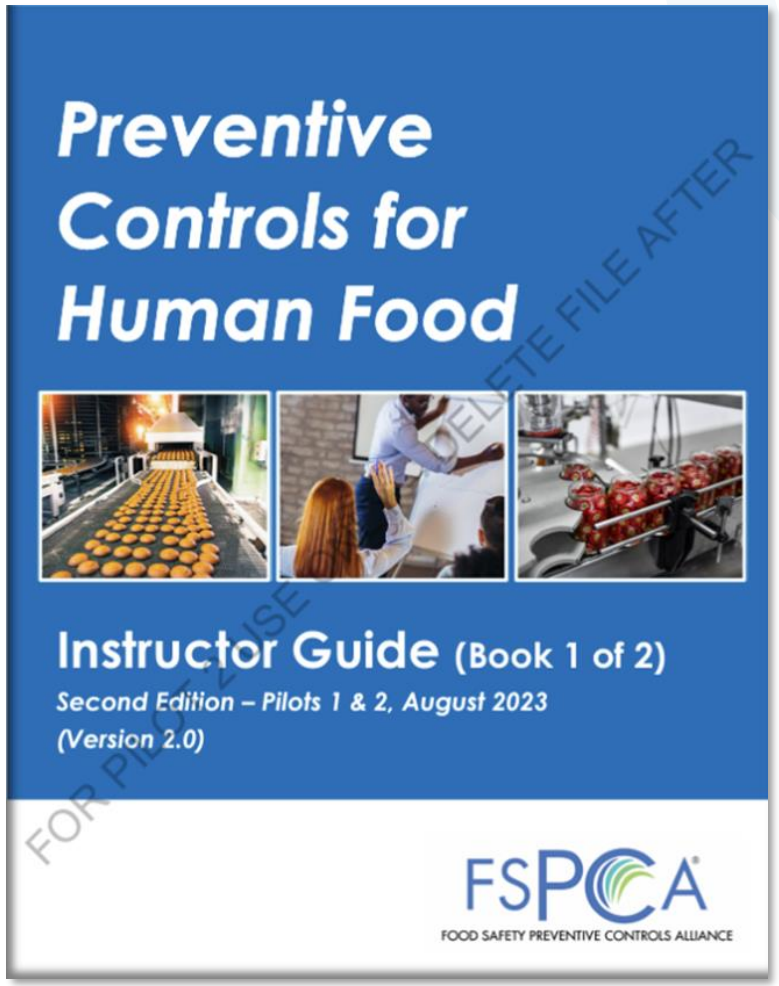
- 20 hours minimum (23 recommended)



Version 2.0

Instructor Guide

- Chapter Administration
- Instructor Notes
- Assessment Strategies
- Engagement Strategies
- Resource Links
- More



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PCHF Chapter Overview

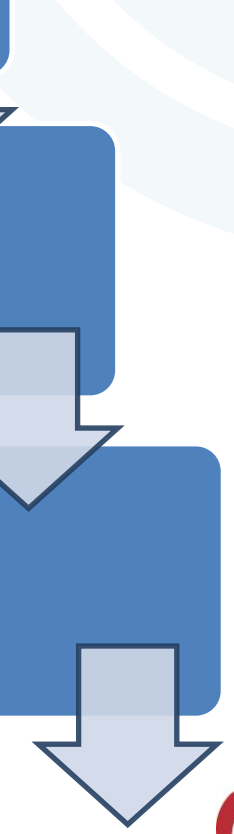
- **Preface –** The Preventive Controls for Human Foods Course
- **Chapter 1 –** Introduction to Preventive Controls and the Food Safety Plan
- **Chapter 2 –** Good Manufacturing Practices and Other Prerequisite Programs
- **Chapter 3 –** Biological Food Safety Hazards
- **Chapter 4 –** Chemical, Physical and Economically Motivated Food Safety Hazards
- **Chapter 5 -** Preliminary Steps for Plan Development and Resources
- **Chapter 6 –** Hazard Analysis
- **Chapter 7 –** Preventive Controls Overview

PCHF Chapter Overview

- **Chapter 8 –** Process Preventive Controls / Critical Control Points
- **Chapter 9 –** Process Preventive Controls – Critical Limits, Monitoring and Corrective Action
- **Chapter 10 –** Process Preventive Controls – Verification and Monitoring
- **Chapter 11 –** Food Allergen Preventive Controls
- **Chapter 12 –** Sanitation Preventive Controls
- **Chapter 13 –** Supply Chain Preventive Controls
- **Chapter 14 –** Food Safety Plan Management, Verification and Training
- **Chapter 15 –** Recall Plan
- **Chapter 16 –** Regulation Overview / FDA Regulatory Oversight

Progression

1. Curriculum Workgroup
2. DEC 2022 Walkthrough
3. JUN 2023 Walkthrough



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Progression

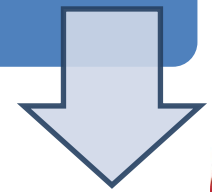
4. AUG 2023 Pilot

5. Fall 2023 Text Finalization & Proofing

6. 2024 Submit to FDA

Progression

7. FDA Review
8. Final Edits & Publishing
9. Lead Instructor Refresher



Progression

10. Blended Course
11. Translations
12. LI Course

What About the LI Refresher?

Format (not the full course):

- Teaching Materials
- Chapter by Chapter overview of content and strategies
- Administrative Updates
- Q&A

Post-Refresher Resources

- Additional Q&A sessions
- Videos of chapters demonstrating model deliveries
- LI Webinars
- Instructor Portal resources
- LI Community Portal
- Two Bookstores

What About the LI Refresher?

- Mandatory attendance to retain LI status
- 2,288 Lead Instructors
  - 57 sessions x 40 per session
  - Two sessions per week = 7 months
  - Therefore, mostly virtual offerings
- Cadre of Refresher Instructors (RFIs)
- Anticipated to be ~5 hrs. in length

What About the LI Refresher?

- All Lead Instructors will be notified via email, newsletter, website, and Chatter Group, and be given ample time to complete the refresher
- Once enrolled, access to the public teaching materials
- After completion, V2.0 Portal access will be granted
- May register and teach a V2.0 course immediately after completion
- System will not allow a V1.2 LI to register a V2.0 course
- May continue using V1.2 until the retirement date (TBD)

LI Marketing of V2.0

- Do PCQIs need to take V2.0?
- Benefits of attending 2.0
- Marketing materials
- Advertising policy

Translations

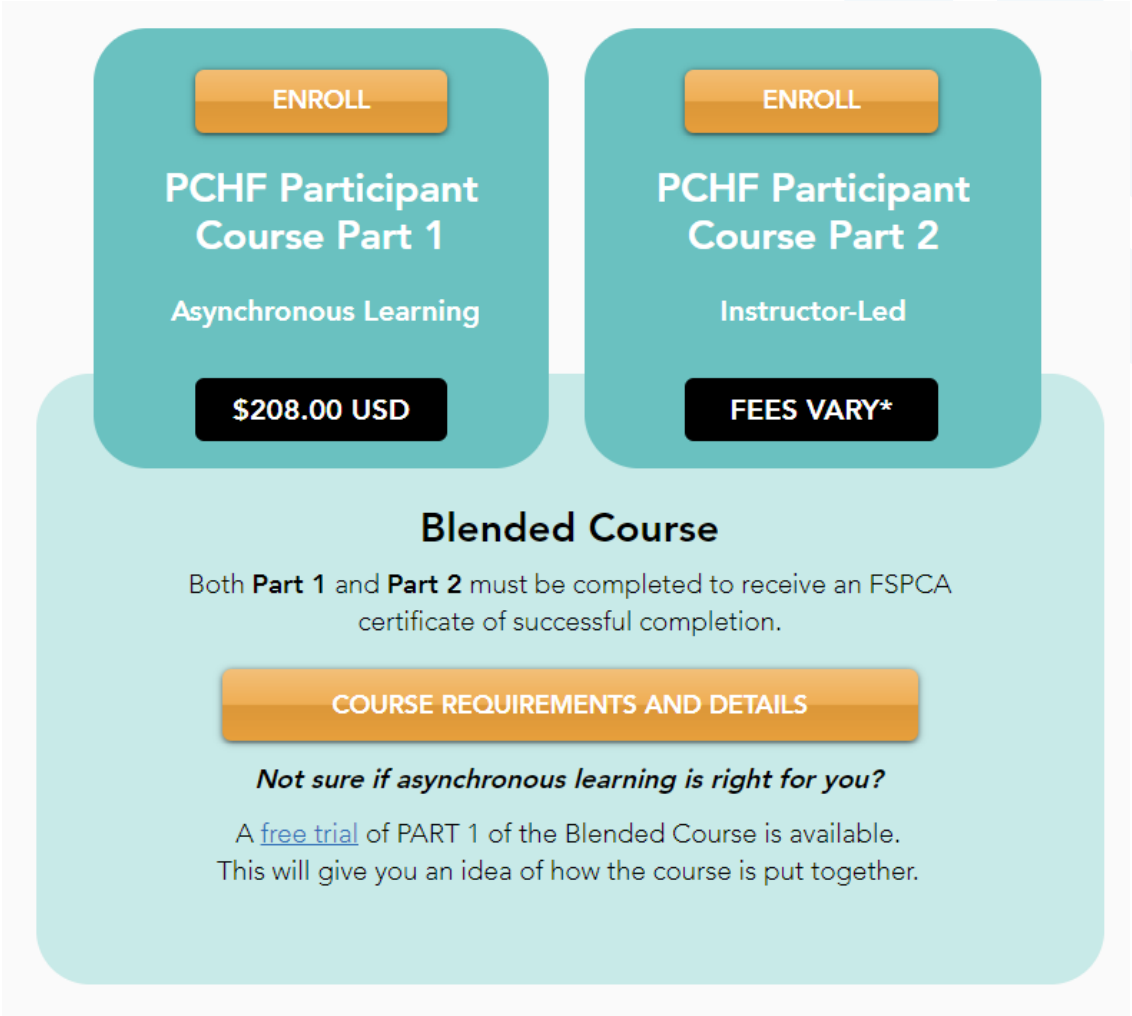
- Spanish

FSPCA Controles Preventivos de Alimentos para Humanos

- Chinese

针对人类食品预防控制措施的在线培训课程

Blended Course



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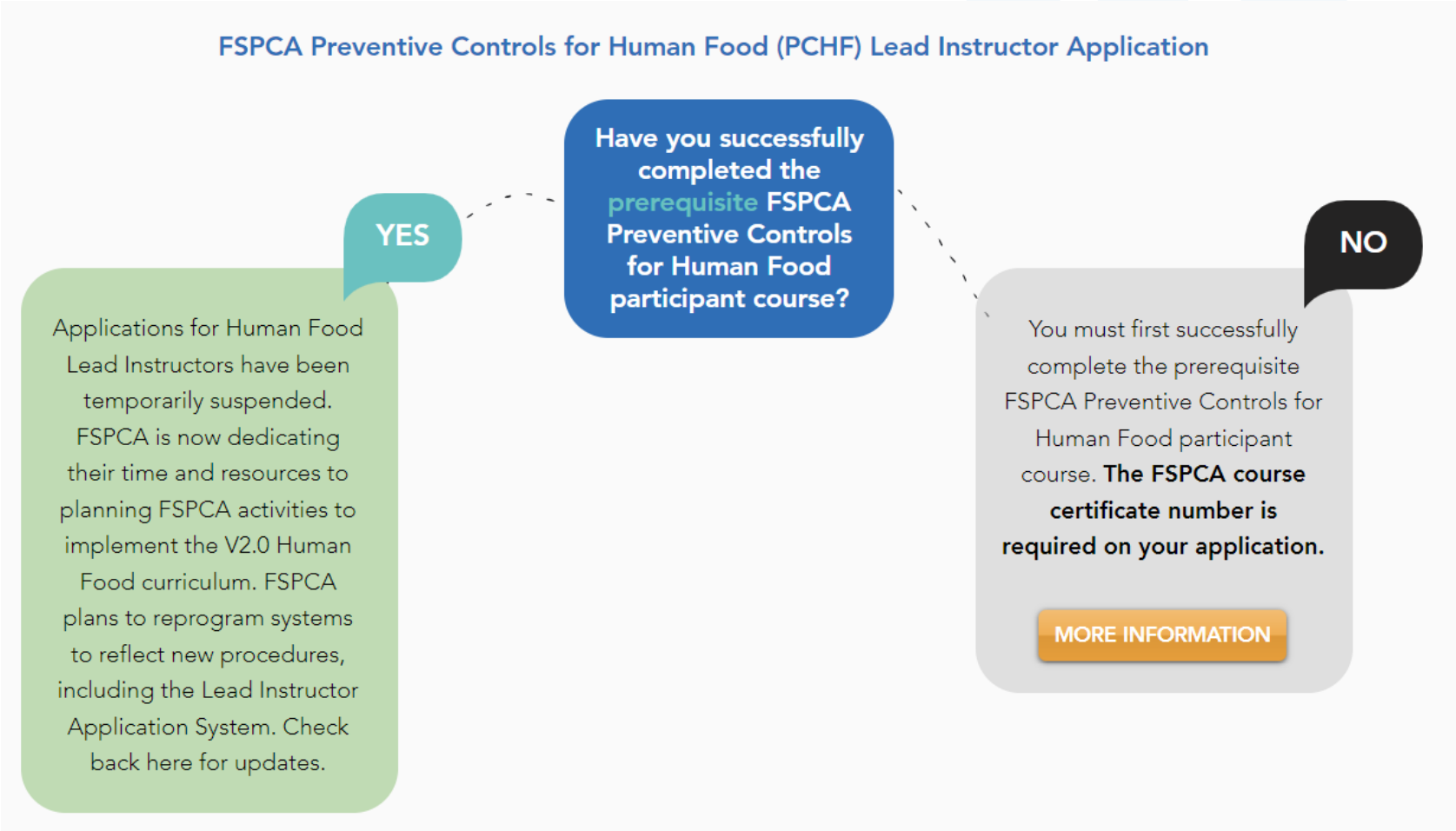
Lead Instructor Course



Lead Instructor Course

- System was shut off June 2023
- Application process revamped
- Exam will be required
- All previously approved candidates will need to reapply
- New Trainers of Trainers will be selected for V2.0

Other FSPCA Curricula

- Preventive Controls for Animal Food
- Foreign Supplier Verification Programs
- Intentional Adulteration
  - IA Rule
  - Food Defense Awareness
  - Conducting Vulnerability Assessments
  - Key Activity Types
  - Mitigation Strategies
  - Plan Preparation and Reanalysis
- Traceability

FDA Foreign Supplier Verification Programs (FSVP) Guidance Overview

Kevin Kwon, JD
Regulatory Counsel

CFSAN Office of Compliance
Compliance Policy Staff

Updates in the FSVP Final Guidance

Various sections:

- New questions added (focus of today's presentation)
  - Applicability of FSVP regulation and who can conduct FSVP
  - Territories and others
  - FSVP customer provisions and import admissibility
  - Other new ones that are frequently encountered by FDA
- Revised certain questions to provide clarity
- Removed duplicative information
- Combined certain questions for clarity
- Editorial changes and updates

Question Topics with Changes Based on the Guidance:

- A. To what foods does the FSVP regulation apply? (21 CFR 1.501)
- B. What FSVP must I have? (21 CFR 1.502)
- C. Who Must Develop my FSVP and perform FSVP activities? (21 CFR 1.503)
- D. What hazard analysis must I conduct? (21 CFR 1.504)
- E. What evaluation for foreign supplier approval and verification must I conduct? (21 CFR 1.505)
- F. What foreign supplier verification and related activities must I conduct? (21 CFR 1.506)

Question Topics with changes cont…

- G. What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation? (21 CFR 1.507)

- I. How must the FSVP importer be identified at entry? (21 CFR 1.509)

- J. How must I maintain records of my FSVP? (21 CFR 1.510)

- K What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation? (21 CFR 1.511)

- L. What FSVP may I have if I am a very small importer, of I am importing certain food from certain small foreign suppliers? (21 CFR 1.512)

A. To What Foods Does the FSVP Regulation Apply?

A6: Can an entity who is not the FSVP importer assume the responsibilities for developing, maintaining, and following the FSVP.

No. The FSVP importer can identify the qualified individuals to perform certain FSVP activities on the importer's behalf-in some circumstances, provided that the importer conducts a required review and assessment of the individual's activities. But the FSVP importer is the entity with the responsibility for developing, maintaining, and following the FSVP regulation.

A21: Does FSVP apply when food is imported into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories?

FDA does not interpret the FSVP regulation to apply when food is imported into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other Territories that are outside the Customs territory of the United States. Therefore, FDA does not expect entities to have conducted FSVP activities or submit FSVP importer identification information when they import food into the U.S. Territories that are outside of the Customs territory of the United States. CBP defines "Customs territory of the United States" to include the 50 states, Puerto Rico, and the District of Columbia. (See 19 CFR 101.1)

Although FDA does not interpret the FSVP regulation as applying when food is imported into the Territories that are outside the Customs territory of the United States, we note that such food is still subject to other FDA food safety requirements because the FD&C Act applies to Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories.

We also note that the FSVP regulation requires the importer to ensure that their importer identification is provided "when filing entry with United States Customs and Border Protection." (See 21 CFR 1.509(a)) This mechanism is generally not available when food is imported into Territories that are not part of the Customs territory of the United States.

- **A22: Does FSVP apply when food is imported into Puerto Rico and the District of Columbia?**

- A: Yes. Puerto Rico and the District of Columbia are not States, but they are part of the Customs territory of the United States. (See 19 CFR 101.1) FSVP requirements apply when food from foreign suppliers is imported into any part of the Customs territory of the United States, including Puerto Rico and the District of Columbia.

- **A23: Does FSVP apply when food is produced by a foreign supplier in a foreign country and then transhipped through Guam, the U.S. Virgin Islands, the Northern Mariana Islands, or other U.S. Territories into the Customs territory of the United States?**

- A: Yes. If a food is produced in a foreign country by a foreign supplier and it is only transshipped through the Territory, then it is subject to FSVP when it is offered for import. FDA will apply FSVP when it is imported into the Customs territory of the United States, even if it was transshipped through a Territory such as Guam. Transshipment of a food in this scenario involves shipment into and out of the Territory without the food undergoing any processing or use in the manufacture of another food. CBP entry is made for articles from the Territories when they arrive in the Customs territory of the United States, and FSVP importer identification required under 21 CFR 1.509(a) can be provided when filing entry with CBP at that time.

- **A24: Does FSVP apply when it is produced in the Territories and then shipped into the Customs territory?**

- No. If the establishment that manufactures/processes the food, raises the animal, or grows the food is located in the Territories of the United States, that entity is not a foreign supplier (see 21 CFR 1.500, defining foreign supplier as the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature). Because such food is not produced by a foreign supplier and then exported to the United States, it is not subject to FSVP requirements. (However, if the manufacturing/processing that takes place in the Territories is of only a de minimis nature, there may still be a foreign supplier and the food could be subject to FSVP.)

Summary of FSVP in the Territories

- FSVP applies only when food is produced in foreign countries.
- FSVP does not apply when food is produced in foreign countries and shipped directly to a Territory that is outside the Customs Territory of the United States.
- FSVP does apply when food produced in a foreign country is transshipped via a Territory.
- This approach aligns with the purpose of FSVP as well as the practicality in that there is not easy way to administer FSVP when food enters the U.S. via Territories outside the Customs Territory.

B. What FSVP must I have?

- **B6: If I hire a contractor or consultant to perform an FSVP activity on my behalf (such as conducting the hazard analysis or performing supplier verification activities), would the contractor or consultant be considered "another entity"?**

- No. A qualified individual who is retained as the importer's contractor or consultant to perform FSVP activities is not considered to be "another entity".

C. Who Must Develop My FSVP and Perform FSVP Activities?

- **C8: Can a qualified individual be located outside of the U.S.?**

- Yes, the FSVP regulation does not require a qualified individual to be located in the U.S.

D. What Hazard Analysis Must I conduct?

- D22: Am I required to have a copy of the hazard analysis available during an FDA FSVP inspection?

- A: The FSVP regulation requires the hazard analysis to be written. (21 CFR 1.504(a)). You must keep records of the hazard analysis as an original record, true copy (e.g., scanned copy or other accurate reproduction of the original), or electronic record (21 CFR 1.510(a)). You must provide the records of your hazard analysis promptly to an authorized FDA representative, upon request, for inspection and copying (21 CFR 1.510(b)). We recommend that your records include enough detail to allow us to determine that the requirements of 21 CFR 1.504 have been met (e.g., that you identified all hazards requiring control).

E. What Evaluation for Foreign Supplier Approval and Verification Must I Conduct?

- **E13. How may I obtain information about the FDA compliance history of my foreign supplier?**

- There are a number of ways you can obtain information about the FDA compliance history of your foreign supplier. You can obtain information directly from your foreign supplier. In addition, you may use the FDA Data Dashboard to access and search publicly available information on FDA's website. The Data Dashboard is designed to support the understanding, accountability, and analysis of public FDA data through easy to use, visually accessible, customizable, and understandable graphics. The datasets and data include the Inspections Database, Recalls, Import Alerts, and other selected data elements from the compliance and enforcement related information on FDA.gov.

G. What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation? (21 CFR 1.507)

G.8 Q: If I import a food for which an identified hazard will be controlled after importation and I disclose within documents accompanying the food that the food is not processed to control the identified hazard, could the food be subject to refusal of admission if FDA determines that the food is adulterated with the identified hazard?

A: As discussed in the previous questions, the FSVP regulation includes provisions that apply when an importer identifies hazards requiring a control ("identified hazard") but does not conduct supplier evaluation or verification activities for those hazards because the importer is relying on another entity in the distribution chain to provide the necessary control (see 21 CFR 1.507(a)(2)(i), 1.507(a)(3)(i), 1.507(a)(4)(i)). Under these provisions, the importer must provide a disclosure to inform entities in the distribution chain that the food has not been processed to control the identified hazard (see *id.*). The disclosure requirement does not replace or alter FDA's authority under section 801(a) of the FD&C Act, relating to refusal of admission of a food offered for entry that appears to be adulterated or misbranded. Rather, the disclosure requirement provides an alternative to the importer conducting supplier evaluation and verification steps by informing entities in the distribution chain that the food has not been processed to control the identified hazard. Therefore, when FDA determines that a food offered for import is adulterated or misbranded, FDA will not generally consider the importer's compliance with the disclosure requirement as sufficient evidence to overcome the appearance of the violation.

Continued…

- In addition, FDA does not view compliance with the disclosure requirement as a substitute for the information required under section 801(b) of the FD&C Act and 21 CFR 1.95 for reconditioning proposals to bring a product into compliance (e.g., by applying a "kill step" to a contaminated food). Under 21 CFR 1.95(a) - (b), applications for authorization to relabel or perform other action to bring the product into compliance shall contain detailed proposals for bringing the product into compliance and shall specify the time and place where such operations will be carried out and the approximate time for their completion. FDA has the authority to grant or deny an application to recondition. A disclosure provided in accordance with 21 CFR 1.507(a), by contrast, would only state that the accompanying food is not processed to control the identified hazard. Thus, a disclosure provided in accordance with 21 CFR 1.507(a) generally would not provide all of the information that FDA expects for reconditioning proposals. Therefore, when FDA determines that a food offered for import is adulterated or misbranded, FDA will generally not view a disclosure statement, in and of itself, as sufficient evidence to demonstrate adequate reconditioning. For importers that would like to recondition the food, FDA will continue to expect the submission of a reconditioning proposal to assure compliance. Reconditioning proposals are typically submitted using Form FDA 766 to the compliance officer listed on the Notice of FDA Action.

Customer Provisions and Import Admissibility

- Question on if disclosure statement could be used to import a product that is known to be adulterated.
- Issue is addressed for the first time in the final guidance.
- Final guidance makes it clear that compliance with the "customer provisions" has no bearing on whether a product appears adulterated for purposes of admissibility.

K. What FSVP Must I have if I am Importing a Food Subject to Certain Requirements in the Dietary Supplement Current Good Manufacturing Regulation (21 CFR 1.511)

K31. What if I import dietary supplements and I meet the eligibility criteria to be a very small importer?

A. If you import dietary supplements and you meet the eligibility criteria to be a very small importer (see the definition of "very small importer" in 21 CFR 1.500 and the eligibility documentation requirements in 21 CFR 1.512(b)(1)(i)), you may choose to comply with the modified requirements for very small importers in 21 CFR 1.512 (see Section III.L of this document) rather than the requirements for importers of dietary supplements in 21 CFR 1.511.

L. What FSVP May I Have if I am a Very Small Importer or I am Importing Certain Food from Certain Small Foreign Suppliers? (21 CFR 1.512)

- **L.6: Which foods should I include in (and exclude from) the calculation of annual sales plus market value to determine my status as a very small importer?**

- To determine your status as a very small importer of human food, you should include all human food, including food imported, manufactured, processed, packed, or held by all subsidiaries and affiliates, regardless of what U.S. food safety regulations the food is subject to. For example, you would include food manufactured under the preventive controls for human food regulation as well as food not subject to the preventive controls requirements (e.g., seafood, juice, LACF, and dietary supplements). Likewise, you would include RACs (such as produce (including produce subject to the produce safety regulation), grains, milk, and eggs) and products subject to the jurisdiction of the USDA (e.g., meat products for human consumption).

- To determine your status as a very small importer of animal food, you should include all animal food, including food imported, manufactured, processed, packed, or held by all subsidiaries and affiliates. This would include all animal food subject to the preventive controls for animal food regulation, as well as animal food that is not subject to those requirements. You would not include food intended for consumption by humans or other items that are not animal food.

- **L7: Can an importer that is an affiliate or subsidiary meet the definition of "very small importer" even if the parent company's annual sales exceed the very small importer threshold?**

- The sales of the importer, including all affiliates and subsidiaries, are included in the calculation for determining whether the very small importer threshold is satisfied (21 CFR 1.500). If the parent company owns or controls the importer, then the importer would be a subsidiary of the parent company. The importer would not consider the parent company a subsidiary, because the importer is not the entity that owns or controls the parent company. A subsidiary importer only includes the operations of the parent company in the calculation if the parent company is an affiliate of the subsidiary importer. If the parent company is related to the importer by ownership or other means of control, the importer should consider the parent company an affiliate and include the parent company's annual sales in determining whether the importer meets the "very small importer" definition.

M. What FSVP May I Have if I Am Importing Certain Food from a Country with an Officially Recognized or Equivalent Food Safety System? (21 CFR 1.513)

M4: Do the modified FSVP requirements apply to all foods from a country with an officially recognized or equivalent food safety system?

No. The modified FSVP requirements apply only to food that is not intended for further manufacturing or processing. This includes packaged food and RACs that will not be commercially processed further before consumption. For example, the modified FSVP requirements may apply if you are importing fresh apples that are intended to be sold to consumers in a raw, unprocessed state. However, the modified requirements would not apply if you import frozen apple pieces that are to be used as an ingredient in the commercial production of apple pies. In addition, a systems recognition arrangement or equivalence agreement with a foreign country may cover only certain types of foods. The modified FSVP requirements apply only to foods not intended for further processing that are within the scope of such arrangement or agreement (see Question M.3).

Resources to Instructors

- FSVP Final Guidance
- FSMA FSVP Final Rule and Resources
- Frequently Asked Questions on FSMA | FDA
- FSVP Records Requirements for Standard and Modified Requirements
- FSVP Compliance Program
- Conducting Remote Regulatory Assessments

Thank you!

Questions?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GUIDANCE OVERVIEW: PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF)

Chapter 11 – Food Allergen Program & Chapter 16 – Acidified Foods

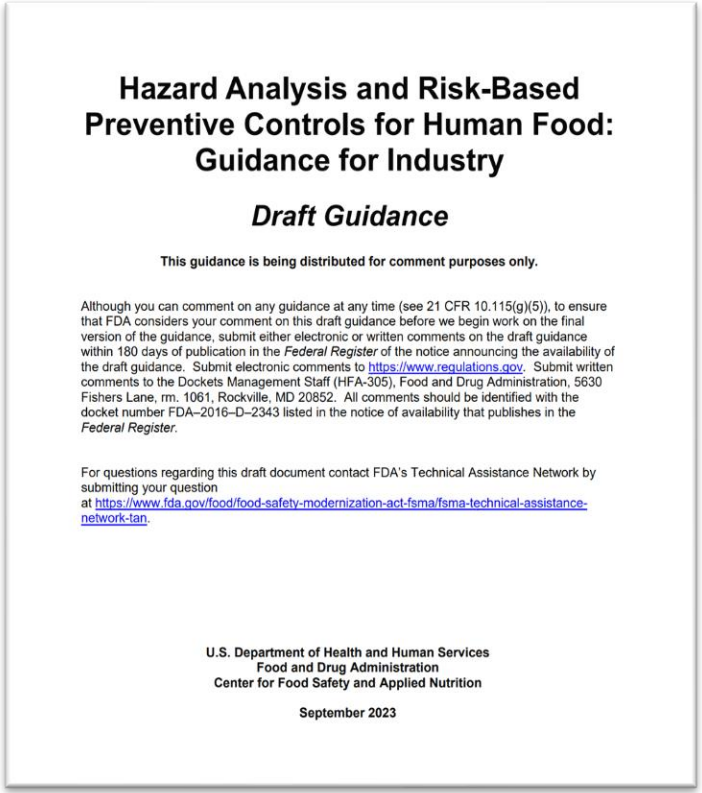
FSPCA Annual Conference

October 17, 2023

Lillian Hsu
FDA | Office of Food Policy & Response

Draft Guidance for Industry: Hazard Analysis & Risk-Based Preventive Controls for Human Food

- Purpose: help industry develop a food safety plan in accordance with the PCHF requirements
- Draft guidance consists of 17 chapters and 3 appendices
- Chapter 11 and Chapter 16 issued on September 26, 2023



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

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA–2016–D–2343 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document 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.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

September 2023

Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food

Draft Guidance chapters published to-date*

Chapter	Title	Chapter	Title
	Introduction and Purpose	11	Food Allergen Program
1	The Food Safety Plan	14	Recall Plan
2	Conducting a Hazard Analysis	15	Supply-chain Program for Human Food Products
3	Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food	16	Acidified Foods
4	Preventive Controls	Appendix 1	Potential Hazards for Foods and Processes
5	Application of Preventive Controls and PC Management Components	Appendix 2	Food Safety Plan Forms
6	Use of Heat Treatments as a Process Control	Appendix 3	Bacterial Pathogen Growth and Inactivation

**FDA will consider comments received on these chapters before finalizing*

CHAPTER 11
FOOD ALLERGEN PROGRAM
DRAFT GUIDANCE

https://www.fda.gov/media/172318/download?attachment

Understand the hazards

- Unintended allergen presence due to allergen cross-contact
  - Allergen cross-contact: unintentional incorporation of a food allergen into a food

- Undeclared allergens due to incorrect label:
  - when a food is formulated to contain a major food allergen but it is not declared on the label

Preventive controls

- Must be written
- Must include, as appropriate:
  - Monitoring
  - Corrective actions
  - Verification activities
- Guidance provides recommendations and illustrative examples on how to develop control procedures, and monitoring, verification, and corrective action procedures for food allergen hazards

Allergen cross-contact controls

- If **allergen cross-contact** is a significant hazard, facility must establish and implement preventive controls
  - Enhance the CGMP measures for prevention of allergen cross-contact with written control procedures, including PC management components
  - Example:
    - CGMPs require that work-in-process (WIP) and rework be handled in a manner that protects against allergen cross-contact
    - Preventive control: Establish and implement written procedures to manage re-entry of WIP and rework, including monitoring, verification, and corrective actions
- Typical PCs to address allergen cross-contact:
  - Sanitation PC for cleaning shared equipment/utensils
  - Process PC for ingredient addition
  - Supply-chain PC for allergen cross-contact that may occur at the supplier

Allergen cross-contact controls: cleaning shared equipment/utensils

- Written allergen cleaning procedures to include:
  - Purpose of the cleaning procedure
  - Frequency of cleaning
  - Who is responsible for performing the cleaning
  - Instructions for performing the specific cleaning procedures
  - Written procedures for monitoring and/or verification activities
  - Corrective actions to take when cleaning is not properly implemented
  - Forms that will be used to document activities performed

Allergen cross-contact controls: cleaning (cont'd)

Monitoring and verification activities

- Specific activity to be monitored or verified depends on the type of cleaning procedure
- Examples
  - Observing each step in a cleaning process as it is being conducted
  - Calibrating an automated cleaning system to ensure appropriate temperatures and cleaning agent concentrations are used during CIP
  - Observing that production equipment is visibly clean
  - Using ATP swabs, protein swabs, or allergen-specific test kits to detect food residues that remain after cleaning

Allergen cross-contact controls: ingredient procedures

- Prevent addition of the wrong ingredient into a food
- May be useful if it is not readily apparent that an ingredient is or contains a major food allergen
  - For example, a seasoning mix contains a soy flavoring agent
- Control procedures depend on factors such as:
  - Where and when facility transfers ingredients from original packaging to containers used in production
  - How ingredients are identified after transferring them from original packaging

Allergen cross-contact controls: supplier controls

- May be necessary if **allergen cross-contact at the supplier** is a significant hazard
- In general, annual onsite audit is the expected supplier verification activity
- Onsite audit could cover:
  - Storage and handling practices for ingredients, WIP, rework, and finished products
  - Methods used for product containment and identification
  - Production practices, including for use of rework and WIP
  - Production scheduling
  - Movement of raw materials and other ingredients that are/contain a major food allergen
  - Use of specific utensils, implements, and tools
  - Sanitation procedures, including monitoring and post-cleaning verification activities
- If supplier voluntarily uses allergen advisory labeling to disclose potential for unintended allergen presence for an ingredient:
  - Periodic ingredient testing by the receiving facility may be prudent
  - PCQI should provide rationale in the food safety plan on whether there is a need to carry forward the advisory labeling to the finished food
- Corrective actions, including reanalysis to address supplier non-conformance
- Guidance chapter includes many illustrative scenarios

Allergen cross-contact and advisory labeling

- May be appropriate if facility cannot provide adequate assurance that food has been protected from **allergen cross-contact**, even with appropriate CGMPs and allergen cross-contact controls in place
  - Advisory labeling does *not* remove obligation to adhere to requirements for CGMPs and allergen cross-contact controls
- If the PCQI determines advisory labeling is appropriate:
  - PCQI should provide written justification in the food safety plan as to why allergen cross-contact controls cannot ensure protection of food from allergen cross-contact, including if an ingredient is received with allergen advisory labeling
  - Labeling for the food could include information that calls attention to the possible unintended allergen presence in the food
- Advisory labeling must be truthful and not misleading
- Strategically design/place advisory statement so it is easily noticed by the allergic consumer

Undeclared allergen controls

- Ensure that a finished food is not misbranded under section 403(w) of the FD&C Act by making sure:
  - Product label includes all ingredients that are or contain a major food allergen, and
  - Correct label is applied to the correct product (product label matches recipe/formulation of the product being manufactured)
- Recommend label controls and PC management components for:
  - Content of product label during development, ordering, production, and receipt
  - Managing printed labels, including storage, use, and disposition of product labels before, during (including staging and packaging/labeling steps), and post-production
- Guidance provides many recommendations on how to ensure proper label content and management of labels, including:
  - What and how to monitor/verify that procedures are properly implemented
  - Corrective actions/corrections for label controls

Illustrative examples: How to establish and implement a food allergen program

- Dessert Manufacturer A who makes:
  - Raspberry sorbet (no allergens),
  - Vanilla ice cream (milk allergen),
  - Vanilla frozen custard (milk and egg), and
  - Vanilla frozen custard with almonds (milk, egg, tree nuts)

- Bakery B who makes:
  - Oatmeal cookies (wheat, egg, soy),
  - Caramel chip cookies (wheat, egg, soy, and potential for unintended milk presence in vegan caramel chips), and
  - Peanut butter cookies (wheat, egg, peanut, soy)

CHAPTER 16
ACIDIFIED FOODS
DRAFT GUIDANCE

https://www.fda.gov/media/172317/download

Emergency Permit, Acidified Foods, and PCHF

- Purpose of chapter
  - How to leverage the procedures, practices, and processes that a facility establishes, and records they keep, to satisfy applicable requirements in:
    - 21 CFR 108.25 Acidified Foods (Emergency Permit Control)
    - 21 CFR Part 114 Acidified Foods
    - 21 CFR Part 117 CGMP & PCHF

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Requirements in Part 117	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114

- Helpful tables:
  - Table 16-2 Quick Reference Guide: listing of specific acidified food requirements and corresponding PCHF requirements
  - Appendix 16-1: listing of key requirements specific to acidified foods that do not have corresponding requirements in part 117 & additional resources available to help achieve compliance

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AWARDS PRESENTATION AND LEAD INSTRUCTOR RECOGNITION

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IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
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VOLUNTEER OF THE YEAR AWARD

In recognition of dedication, time, expertise, leadership
and services to FSPCA.

KATHY GOMBAS

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KATHY GOMBAS

Kathy Gombas is the founder of FSMA Solutions, a consulting group, which provides food safety solutions to the food industry. She works with large food companies in conducting corporate food safety system gap assessments to identify vulnerabilities and assists small to medium size businesses in developing food safety plans and supporting programs.

Kathy is currently the chair of the Food Safety Preventive Controls Alliance (FSPCA) Executive Advisory Board; co-chair of the FSPCA International Committee working on industry training, outreach, and technical assistance programs for food companies worldwide; and co-chair of the FSPCA Trainer of Trainers Work Group responsible for training and monitoring of FSPCA Lead Instructors. Kathy is an FSPCA Trainer-of-Trainers and Lead Instructor for Foreign Supplier Verification Programs and Preventive Controls for Human Food.

Kathy was an FDA Senior Advisor supporting the Agency's FSMA implementation efforts including regulator training and the FDA FSMA Technical Assistance Network. Prior to FDA, Kathy held corporate food safety positions at Dean Foods and Kraft Foods.

Kathy graduated from Northern Arizona University with a B.S. in Microbiology.

SPECIAL APPRECIATION AWARD

In recognition of unwavering support and services to FSPCA.

DIANNE MILAZZO

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DIANNE MILAZZO

Dianne Milazzo works at the FDA as a Consumer Safety Officer on the Food Policy Team in the Office of Surveillance and Compliance at the Center for Veterinary Medicine (CVM). She has been with FDA for almost 23 years joining in November 2000. Prior to joining CVM in June 2014, Dianne was a field investigator in the Richmond, Virginia Resident Post of the Baltimore District Office (now Division 2 East) where she conducted a variety of inspections of FDA regulated products. She was the District's Center for Veterinary Medicine Specialist and program monitor.

From June 2014 to present, she has worked at the Center for Veterinary Medicine spearheading projects related to animal food including the writing of regulations, development of trainings, development of information technologies for use by food safety staff and during work planning, development of compliance programs, development of guidance documents, development of the FSPCA Preventive Controls Animal Food curriculum and gathering data for food safety performance measures. She is involved in many workgroups at CVM working with CFSAN and ORA involving New Era for Smarter Food Safety and Data Modernization. She is the co-lead for Phase II implementation of the Preventive Controls Animal Food and FSVP regulations as well as involved with activities related to the Sanitary Transportation regulation.

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LEAD INSTRUCTOR RECOGNITION

FSPCA Annual Conference | October 17-18, 2023

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Top Ten Lead Instructors

- Top Ten FSPCA Lead Instructor recognition is based on the number of course participants trained, with FSPCA certificates issued, in **each** of the Alliance's curricula, between August 15, 2022 and August 15, 2023.

FSPCA 1000 Club

- The "FSPCA 1,000 Club" recognizes FSPCA Lead Instructors who have **cumulatively** trained a minimum of 1,000 course participants, with FSPCA certificates issued, in total of the four FSPCA training curricula.
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Food
  - Foreign Supplier Verification Programs
  - Intentional Adulteration Vulnerability Assessments

BREAKOUT SESSION: FSVP CASE STUDIES

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Scenario 1

Sally's Surplus

- Imported 2.9 million in food sales annually for the last 5 years.
- Imports a wide variety of surplus items from RTE to dog biscuits to household goods
- Received and stored in a over 100,000 sqft warehouse until sold to customers
- Owns food company in Sallborg, Slovania
- Imports 5% alcohol products
- Importing since 2016

What FSVP Requirements?

- Standard FSVP Requirement?
- What amount is Human Food and what Amount is Animal Food?
  - 20% is Animal Food or 580,000 and 80% is Human Food or 2.32 million
  - Human Food = **Standard FSVP Requirements**
  - Animal Food = possible Modified FSVP Requirements
- Does the Company have any subsidiaries and does this increase the gross sales?
  - Total subsidiaries over 3 million for Animal Food
    - Animal Food = **Standard FSVP Requirements**

FSVP VSI
Adjusted for Inflation

Human Food Years	Human Food Avg*
2018-2020	1.14 million
2019-2021	1.17 million
2020-2022	1.22 million

Animal Food Years	Animal Food Avg*
2018-2020	2.86 million
2019-2021	2.92 million
2020-2022	3.05 million

Human Food Year	Human Food $*
2018	1.12 million
2019	1.14 million
2020	1.16 million
2021	1.21 million
2022	1.30 million

Animal Food Year	Animal Food $
2018	2.81 million
2019	2.86 million
2020	2.90 million
2021	3.02 million
2022	3.24 million

*Rounded up- for most accurate calculations refer to FSMA Inflation Adjusted Cut Offs | FDA

Scenario 2

Olive's Olive Bar

- Imports several varieties of olives, olive oils, and figs
- Imports from several small olive growers in Albania
- Gross Annual Sales:
  - 1.8 million 2022
  - 1 million 2021
  - 1 million 2020
  - 0.8 million 2019
- 2 of the 38 olive growers have avg annual sales greater than $500,000
- Fig growers avg annual sales are less then $500,000

What FSVP Requirement?

- Standard FSVP Requirements?
  - 2022, 2021, 2020 = 1.26 mil
  - Correct calculation:
    - 2021, 2020, 2019 = 0.9 mil
  - May choose to comply with **modified FSVP requirements**
- Does grower/Produce Safety Regulations apply?
  - Since oils are cured prior to importing they would not fall under Produce Safety
  - If imported fresh, considered not covered produce due to inedible
  - Figs are considered covered produce
  - Qualified Exemption due to less then $500,000 so may choose to comply with **modified FSVP requirements**

FSVP VSI
Adjusted for Inflation

Produce Safety Years	Produce Safety Avg*
2018-2020	1.14 million
2019-2021	1.17 million
2020-2022	1.22 million

Produce Safety Year	Produce Safety $*
2018	562,119
2019	572,499
2020	579,022
2021	603,202
2022	648,321

*Rounded up- for most accurate calculations refer to FSMA Inflation Adjusted Cut Offs | FDA

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FAQS, ETC.

BOB BAUER
ASSOCIATION OF FOOD INDUSTRIES (AFI)

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Trade Show Samples

- I bring this up in Chapter 3 after we cover entries for research or evaluation.
- I ask the group: What do people think about whether trade show samples would fall into this category?
- Most times, the discussion leads the majority to say trade show samples would not be considered an entry for research or evaluation.
- I outline why and mention the trade show organizers have partners who will handle FSVP requirements.
- Good time to mention FSVP guidance document. This is covered there (question A.32).

Serving the U.S.
Food Import Sector

Difficulty in Obtaining Required Documentation

- I cover this in chapter 2, page 12 – definition of foreign supplier.
- It flows well with the bold text under the slide that says the supplier may not be the entity from which the importer gets the product.
- It's a great place first to cover the role of foreign distributors and then go into difficulties FSVP importers might have in getting the required information.
- The short answer is that if there's a refusal or inability to supply the documents, the relationship ends.

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Food Import Sector

Accepting Documents in Another Language

- This is a surprise to some.
- Some ask whether if they accept some records in one or more languages other than English do they have to accept all records in another language.
- Stress that the FSVP qualified individual(s) must be able to understand the language.
- No need for "certified" translation but they should have confidence in the translation.
- What if FDA inspector doesn't speak that language?

Serving the U.S.
Food Import Sector

Definition of a Qualified Facility

- Great spot to remind folks of the size of FDA and FSMA.
- I find – based on the question in the group exercise at the end of the chapter – that a lot of people don't understand this definition the first time out.
- I use the exercise as a way to reinforce things and make sure they know what a qualified facility is.

Serving the U.S.
Food Import Sector

One FSVP Importer for All of a Supplier's Entries?

- Many suppliers sell to multiple importers.
- I'm often asked why one importer couldn't serve as the FSVP importer for all entries by a supplier.
- This is a great time to reinforce the responsibility being put on the FSVP importer.
- It also presents an opportunity to remind them of what an FSVP inspection looks like.
- Though we go into detail about inspections in chapter 10, I find it useful to give a brief outline a couple of times earlier in the course.

Serving the U.S.
Food Import Sector

BREAKOUT SESSION: HUMAN FOOD CASE STUDIES

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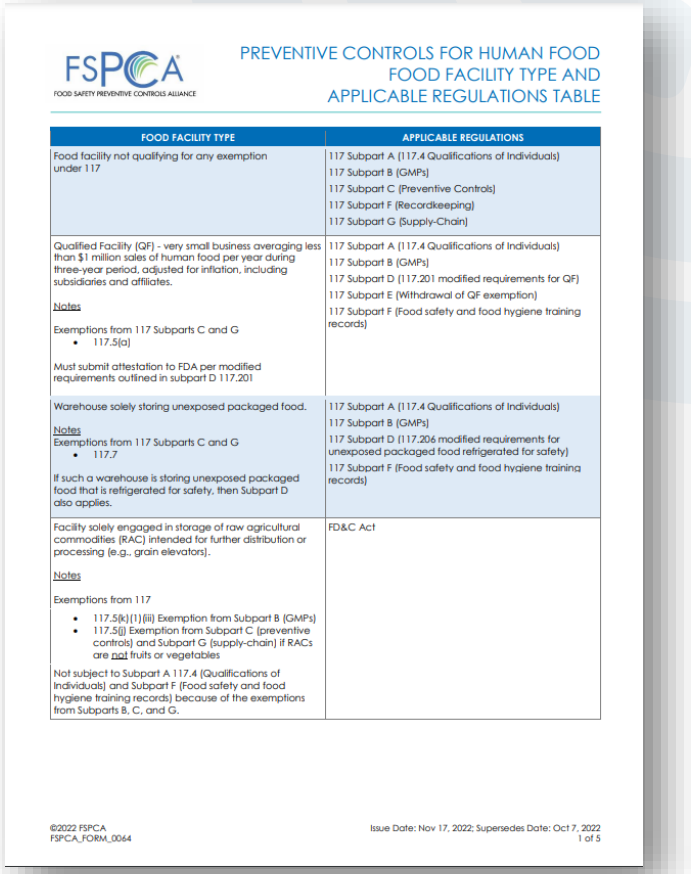
PCHF Food Facility Type and Applicable Regulations Table (FORM_0064)

- Updated Nov 17, 2022
- Available on FSPCA website and PCHF Lead Instructor Portal
- Scan the QR Code to see FORM_0064 on your handheld device



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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

PREVENTIVE CONTROLS FOR HUMAN FOOD
FOOD FACILITY TYPE AND
APPLICABLE REGULATIONS TABLE

FOOD FACILITY TYPE	APPLICABLE REGULATIONS
Food facility not qualifying for any exemption under 117	117 Subpart A (117.4 Qualifications of Individuals) 117 Subpart B (GMPs) 117 Subpart C (Preventive Controls) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain)
Qualified Facility (QF) - very small business averaging less than $1 million sales of human food per year during three-year period, adjusted for inflation, including subsidiaries and affiliates. Notes Exemptions from 117 Subparts C and G • 117.5(a) Must submit attestation to FDA per modified requirements outlined in subpart D 117.201	117 Subpart A (117.4 Qualifications of Individuals) 117 Subpart B (GMPs) 117 Subpart D (117.201 modified requirements for QF) 117 Subpart E (Withdrawal of QF exemption) 117 Subpart F (Food safety and food hygiene training records)
Warehouse solely storing unexposed packaged food. Notes Exemptions from 117 Subparts C and G • 117.7 If such a warehouse is storing unexposed packaged food that is refrigerated for safety, then Subpart D also applies.	117 Subpart A (117.4 Qualifications of Individuals) 117 Subpart B (GMPs) 117 Subpart D (117.206 modified requirements for unexposed packaged food refrigerated for safety) 117 Subpart F (Food safety and food hygiene training records)
Facility solely engaged in storage of raw agricultural commodities (RAC) intended for further distribution or processing (e.g., grain elevators). Notes Exemptions from 117 • 117.5(k)(1)(iii) Exemption from Subpart B (GMPs) • 117.5(j) Exemption from Subpart C (preventive controls) and Subpart G (supply-chain) if RACs are not fruits or vegetables Not subject to Subpart A 117.4 (Qualifications of Individuals) and Subpart F (Food safety and food hygiene training records) because of the exemptions from Subparts B, C, and G.	FD&C Act

FSPCA_FORM_0064
Issue Date: Nov 17, 2022; Supersedes Date: Oct 7, 2022
1 of 5

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To Whom do 21 CFR 117 Subparts Apply?

Subpart A	117.4 Qualifications of Individuals
Subpart B	Current Good Manufacturing Practice
Subpart C	Hazard Analysis and Risk-based Preventive Controls
Subpart D	Modified Requirements (117.201 for Qualified Facility) (117.206 for Unexposed Packaged Food Refrigerated for Safety)
Subpart E	Withdrawal of a Qualified Facility Exemption
Subpart F	Requirements Applying to Records That Must be Established and Maintained
Subpart G	Supply-chain Program

See PCHF Food Facility Type and Applicable Regulations Table (FSPCA FORM 0064)

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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SCENARIO 1

Fruit Delicious, LLC

- Food Processor located in Yakima, WA
- Receives apple fruit raw agricultural commodities (RACs) from various farms and packers in the region. Does not grow own fruit
- Presses apples into juice for secondary processing & produces dehydrated apple slice products
- Bulk juice is refrigerated and shipped to secondary processor in California
- Dehydrated apple slices are plain or cinnamon flavored, packaged and distributed across the U.S.
- Average annual sales is over $4,000,000
- Apple fruit waste (cores, pomace, culls, etc.) held and distributed to an animal food manufacturer for use as animal food

21 CFR Part 117	Subject	Exempt
Subpart A	X	
Subpart B	X	
Subpart C	X	*X
Subpart D	N/A	N/A
Subpart F	X	
Subpart G	X	*X

Dehydrated Fruit Slices

- 21 CFR 117: Subparts A, B, C, F and G

***Pressed Fruit Juice**

- 21 CFR Part 120 Juice HACCP
- 21 CFR Part 117: Subparts A, B, and F

Fruit Waste for Use as Animal Food

- Fruit Delicious, LLC only holds human food byproducts for use as animal food, must follow provisions in 117.95 or 507.28

SCENARIO 2

Betty Stone's Markets

- Betty Stone's Markets operates grocery stores in San Francisco, CA
- Betty Stone's owns and manages a warehouse at a separate location called Betty's Distribution Center (BDC)
- BDC holds finished food products that are in unexposed packaging
- Products stored in the warehouse are Betty Stone's Markets branded products produced by approved suppliers
- Warehouse has refrigerated units for food products including vacuum packed bean curd requiring temperature control for food safety
- Total sales > $5,000,000 annually

21 CFR Part 117	Subject	Exempt
Subpart A (QI)	X	
Subpart B	X	
Subpart C		X
Subpart D	*X	
Subpart F	**X	
Subpart G		X

Facility solely engaged in the storage of unexposed packaged food

- Subparts A & B apply
- Exemption from 117 Subparts C & G per 117.7
- *Subject to Subpart D – Modified Requirements, specifically 117.206 modified requirements for unexposed packaged food refrigerated for food safety
- **Only food safety & food hygiene training records in 117.4(d) and time/temperature control records for Subpart D

SCENARIO 3

Unbeetable Lettuce

- Packinghouse (not on a growing field) located in Salinas, CA
- Receives vegetable raw agricultural commodities (RACs) from various farms in the region
- Packs vegetable RACs into cardboard boxes with vent holes
- Distribution of packed produce RACs to restaurants and wholesalers in Washington, Oregon, and Nevada
- Average annual sales is $3,000,000

21 CFR Part 117	Subject	Exempt
Subpart A (QI)	X	
Subpart B	*X	
Subpart C		X
Subpart D	N/A	N/A
Subpart F	X	
Subpart G		X

Off-farm produce packinghouse

- Not a primary production farm (not a grower)
- Not a secondary activities farm (does not meet ownership requirements)
- Only performs farm-related activities on produce RACs → qualifies for enforcement discretion from subparts C and G
- *Subject to subpart B CGMPs, or could choose to comply with applicable requirements in 21 CFR Part 112 Produce Safety rule

SCENARIO 4

Mighty Might

- Mighty Might is a manufacturer of dietary ingredients and dietary supplements located in Salt Lake City, UT
- Specializes in powdered, nutritional consumer goods marketed as dietary supplements
- Use ingredients identified as allergens by the FDA; does not have dedicated production lines
- Total sales > $4,000,000 annually
- Mighty Might complies with 21 CFR 111 - Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

21 CFR Part 117	Subject	Exempt
Subpart A (QI)	DI/DS	
Subpart B	DI/*DS	
Subpart C	DI	DS
Subpart D	N/A	N/A
Subpart F	DI/**DS	
Subpart G	DI	DS

Dietary Ingredients (DI)

- No exemptions from any subparts of 117

Dietary Supplements (DS)

- Subpart A 117.4 Qualifications of Individuals beyond what is in Part 111 regarding personnel qualifications requirements
- *When a 117 subpart B CGMP requirement is not specified in 21 CFR Part 111, then 117 subpart B will apply
- Exemption from 117 subparts C & G per 117.5(e) for facilities in compliance with 21 CFR Part 111 and Serious Adverse Event Reporting for Dietary Supplements
- **Only food safety & food hygiene training records

SCENARIO 5

Sweet Magnolias Bakery

- Manufacturer of brownies, blondies, and Samoa bars located in Charleston, SC
- Owned by Sweet Magnolias Inc., which is comprised of a retail store and another manufacturing facility that only makes chocolate chip cookies, located in NC
- Incoming raw materials including flour, sugar, chocolate chips, and coconut for the various baked goods are received through interstate commerce
- Distribution of baked goods to Sweet Magnolias Inc.'s retail location
- Total sales by Sweet Magnolias Bakery is $700,000 annually
- Total sales by Sweet Magnolias Inc. is:
  - $4 Million by the retail store
  - $400,000 by the cookie facility

21 CFR 117	Subject	Exempt
Subpart A (QI)	X	
Subpart B	X	
Subpart C		X
Subpart D	X	
Subpart F	X	
Subpart G		X

Qualified Facility

- Sweet Magnolias Bakery would count its own sales and the sales by the cookie manufacturing facility that is part of the parent company ($700,000 + 400,000) which is < $1,220,364 (adjusted for inflation)
  - Would not count sales by the retail store component of the parent company as it is not an affiliate
- Exempt from subparts C and G (21 CFR 117.5(a))
- Subject to modified PC requirements outlined in 21 CFR 117.201 (Subpart D) (submitting attestations to FDA)

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

INTENTIONAL ADULTERATION UPDATE

CAITLIN MARTIN
U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: JOHN COLLIER

FSPCA Annual Conference | October 17-18, 2023

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Mitigation Strategies to Protect Food Against Intentional Adulteration (IA Rule)

Regulatory Update

FSPCA Annual Conference 2023

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 Continued

- Individuals performing the following activities: (1) Writing or overseeing the writing of the food defense plan, (2) Performing a vulnerability assessment (3) Identifying and explaining the mitigation strategies, (4) Performing a reanalysis of the food defense plan must also:
  - Complete training for these activities at least equivalent to that received from a standardized curriculum recognized as adequate by the FDA
  - Or be otherwise qualified through job experience

FSPCA IA Training Offerings

FSPCA IA Rule Training Courses	Delivery Method	Intended Audience	Cost
Food Defense Awareness[1]	Available now 	• 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 	• 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 ONLINE TRAINING	• 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 ONLINE TRAINING	• Food professionals who identify Mitigation Strategies to implement at Actionable Process Steps	$179.00 USD
Conducting Vulnerability Assessments	Available now 1-Day Course 	• 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 ONLINE TRAINING	• Food professionals who prepare the Food Defense Plan and/or who conduct Reanalysis activities	$109.00 USD

Inspection Framework

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

FDPQC Process

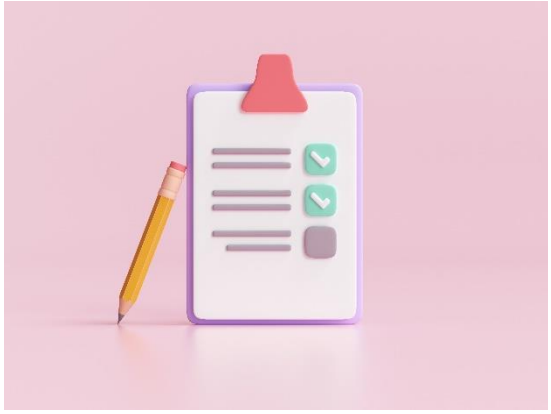
- The Quick Check is conducted through a short inspectional protocol that is relevant to the requirements of a food defense plan
  - 21 CFR 121.126 *Food Defense Plan*
- Visual, on-site inspection of the plan
- No records collected
- Investigator can provide informational materials and where to find additional resources
  - e.g., IA rule guidance, factsheets, training

Schedule of Inspections

- Food Defense Plan Quick Checks: March 2020
  - Started slow due to Covid pandemic, but now being routinely conducted
  - Add-on to other program inspections
  - Validating our inventory information and coverage
- Begin Comprehensive Food Defense Inspections: Mid-2020s (upcoming)
  - Build baseline data, develop prioritization process, develop regulator advanced training

FDPQC Inspections

- What are we seeing?
  - Industry is developing Food Defense Plans as required
  - Use of IA Rule Guidance is beneficial
    - Key Activity Types and Hybrid approach are widespread
  - KATs are showing a significant utilization by industry



Food Defense Inspections (FDIs)

- 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 CSOs with specialized food defense training
  - CFSAN Food Defense SMEs available for real-time consultation & technical support

FDI Program Requirements

- Information Security
- Consistent Application of Intentional Adulteration Rule Requirements
- Focus inspections on prioritized facilities

Thank you!

- FDA's website has additional information that is available for review at your convenience
- www.fda.gov/food/food-defense
  - Factsheets
  - Q/A documents
  - Full text of the IA rule
  - Guidance
  - FSMA TAN (Technical Assistance Network)
- Fooddefense@fda.hhs.gov

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FOOD TRACEABILITY TRAINING AND TOOLS

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

JUAN L. SILVA
MISSISSIPPI STATE UNIVERSITY

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Outline

- FDA Food Traceability Rule
- FSPCA Optional Module on Food Traceability (for PCHF Lead Instructors)
- Development of FSPCA Food Traceability Core Curriculum
- Tools and Resources

FSMA Food Traceability Rule (21 CFR Part 1 Subpart S)

- Final Rule published: November 21, 2022
- Effective date: January 20, 2023
- Compliance date: January 20, 2026
- These slides summarize selected points that may be important to manufacturers of food subject to Preventive Controls for Human Food (PCHF) rule.

Who Must Comply With the Food Traceability Rule?

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

Exemptions

- Certain small producers, e.g., farms exempted from FSMA regulations.
- Foods that receive certain types of processing.
- Foods subject to a kill step, provided certain records are kept.
- A complete list of exemptions is in: § 1.1305 What foods and persons are exempt from this subpart?
- A tool to identify exemptions is at https://collaboration.fda.gov/tefcv13/

Rule Components/Key Concepts

Food Traceability List

- FDA used a risk-ranking model to help identify foods subject to enhanced recordkeeping requirements.

Critical Tracking Events (CTE)

- Key points/steps along the supply chain where it is most important to collect traceability information.

Key Data Elements

- Data/information required for each CTE.

Traceability Plan

- Description of how and where you maintain records, how you identify foods on the FTL, how you assign traceability lot codes, and POC for questions on your plan (and farm map for most growers).

Additional Requirements

- Records must be provided to FDA within 24-hours (or a reasonable time to which FDA agrees) upon request.
- During an outbreak, FDA can request records be provided in a sortable electronic spreadsheet.

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Select Definitions in the Food Traceability Rule § 1.1310

- Food Traceability List
- Critical Tracking Event
- Key Data Element
- Traceability Lot Code
- Food Traceability Plan
- Kill Step
- Manufacturing/ Processing
- Receiving
- Transformation
- Shipping
- Initial packing

Food Traceability List (FTL)

- **Food Traceability List (FTL)** means the list of foods for which additional traceability records are required to be maintained (foods subject to the rule).
- The term "Food Traceability List" includes both the foods specifically listed and foods that contain listed foods as **ingredients**, provided that the listed food that is used as an ingredient remains in the **same form** (e.g., fresh) in which it appears on the list.

Food Traceability List (FTL)

- Cheeses (other than hard)
- Shell eggs
- Nut butters
- Cucumbers (fresh)
- Herbs (fresh)
- Leafy greens (fresh)
- Leafy greens (fresh-cut)
- Melons (fresh)
- Peppers (fresh)
- Sprouts (fresh)
- Tomatoes (fresh)
- Tropical tree fruits (fresh)
- Fruits (fresh-cut)
- Vegetables (fresh-cut)
- Finfish (fresh & frozen)
- Smoked finfish (refrigerated & frozen)
- Crustaceans (fresh & frozen)
- Molluscan shellfish, bivalves (fresh & frozen)
- Ready-to-eat-deli salads (refrigerated)

Food Traceability List (FTL)

- Foods specified as "fresh" on the FTL.
- FTL foods not specified as "fresh" (such as Nut butters).
- Multi-ingredient foods made using either "fresh" FTL foods, or FTL foods not specified as "fresh" (such as nut butters).
  - No change of the form of the FTL food.
  - No kill step to the FTL food.

More information on FTL at:
https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list

Traceability Plan*

- **Traceability Plan** is a description of internal procedures used to maintain records under the Food Traceability Rule, intended to help FDA more quickly review and understand the traceability information provided by a firm involving a food on the Food Traceability List.

**excerpt from FDA webinar 12/7/2022*

Traceability Plan - Components

Businesses that are subject to the Food Traceability Rule, including farms, must establish and maintain a traceability plan containing the following information:

1) A description of the procedures you use to maintain the records you are required to keep, including the format and location of these records.
2) A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold.
3) A description of how you assign traceability lot codes to foods on the Food Traceability List, if applicable.
4) A statement identifying a point of contact for questions regarding your traceability plan and records.
5) If you grow or raise a food on the FTL (other than eggs), a farm map showing the areas in which you grow or raise such foods.

Traceability Plan - Maintenance

- You must update your traceability plan as needed to ensure that the information reflects your current practices and to ensure you are in compliance with the rule.
- You must retain your previous traceability plan for 2 years after you update the plan.

Record Maintenance and Availability

- Legible original paper, electronic, or true copies, stored to prevent deterioration or loss, may include electronic links.
- Available within 24 hours of an FDA request (or other reasonable timeframe to which FDA agrees), may be stored offsite or by another entity.
- Record retention: 2 years unless otherwise stated
- During an outbreak, records must be provided in an electronic sortable spreadsheet within 24 hours of request (including by phone).

In Development - FSPCA Food Traceability Core Curriculum

- FSPCA Food Traceability Core Curriculum Editorial Team
- Scope, content and target audient of the core curriculum
- Proposed completion date – end of 2024 - early 2025
- Food Traceability training rollout - 2025

Resources/Tools

Sources

FDA U.S. FOOD & DRUG ADMINISTRATION

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IFT GFTC Global Food Traceability Center

GS1 US

Type

- General background
- Webinar- general
- Videos- supply chain examples
- Tools
- Traceability plan/records development/workbooks
- Training
- FAQs

General

- FDA Webinar on the Food Traceability Final Rule (12/07/2022, 3h length) https://www.youtube.com/live/flUW3cE0dAw?feature=share

- Overview of the final rule, including:
  - foods and entities covered by the rule,
  - explain the exemptions from the rule, and
  - discuss the recordkeeping and disclosure requirements of the rule
  - Q&A

Terminology & Exemptions

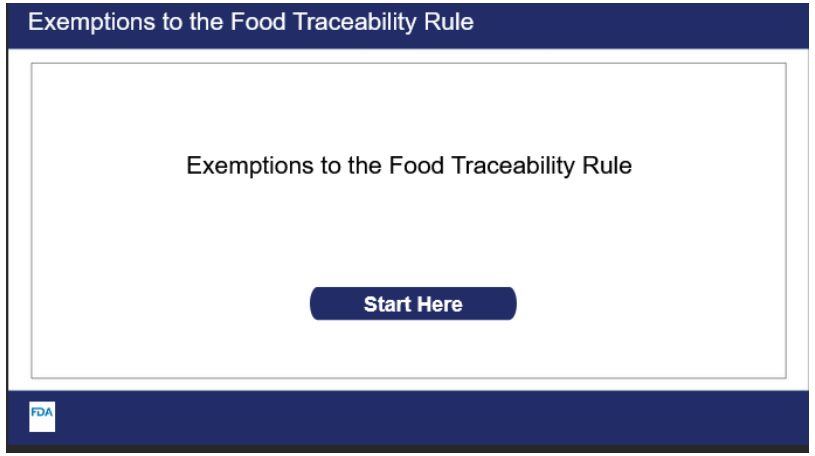
- Glossary of terms (IFT's Global Food Traceability Center (GFTC)):

https://www.ift.org/gftc/tools-and-training/glossary-of-terms

- **Barcode**
- **Electronic Data Interchange (EDI)**
- **Global Data Synchronization Network (GDSN)**
- **Radio Frequency Identification (RFID)**

- Exemptions to the Food Traceability Rule (FDA)

https://collaboration.fda.gov/tefcv13/



Supply chain examples - FDA

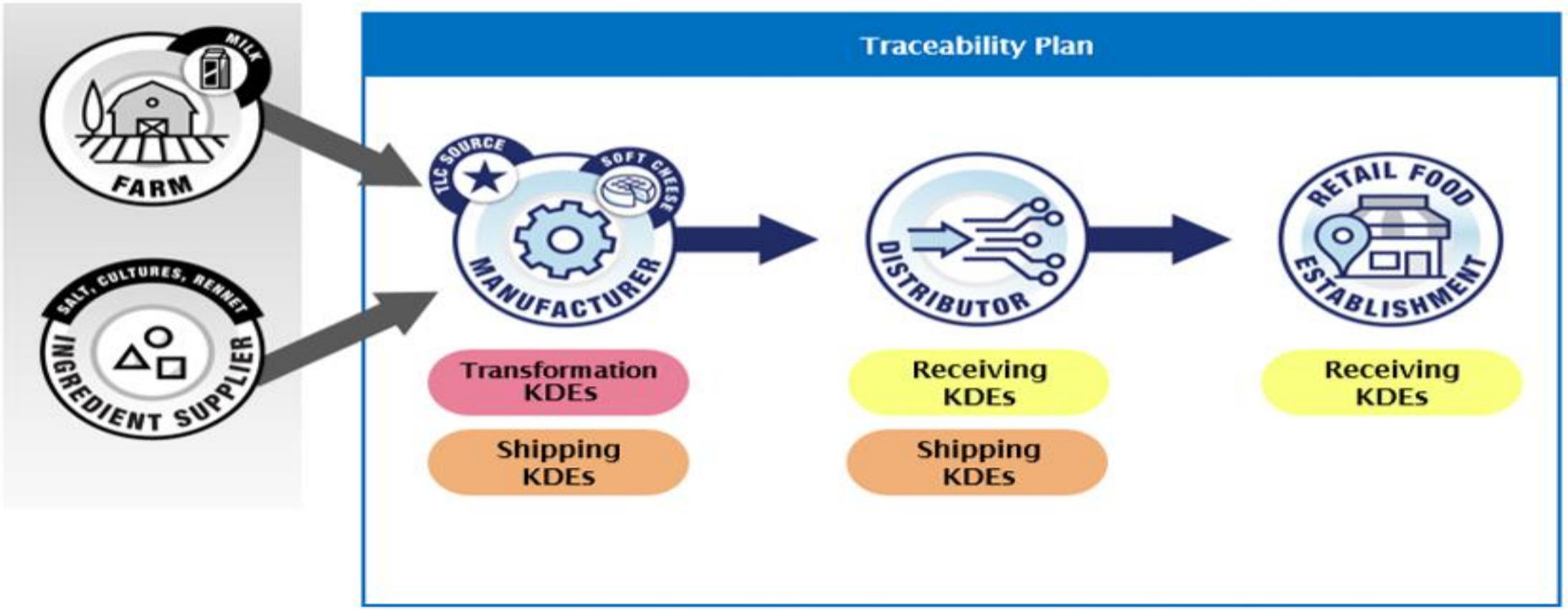
- Show Key Data Elements required for the Critical Tracking Events for certain examples
  - Produce Supply Chain Example
  - Seafood Supply Chain Example
  - Cheese Supply Chain Example

    - Aquacultured tilapia
    - Canned tomatoes
    - Canned salmon
    - Imported mangos
    - Shell eggs
    - Fresh produce meant for meal kits

- Video Presentation
- Transcript (| Español (Spanish) | Bahasa Indonesia | 中文 (Chinese, Simplified) | แบบไทย (Thai) | Tiếng Việt (Vietnamese))
- Slides (| Español (Spanish) | Bahasa Indonesia | 中文 (Chinese, Simplified) | แบบไทย (Thai) | Tiếng Việt (Vietnamese))

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods#64aed2b4bcbd4

Example* – Supply Chain, Cheese



Example Credit - Slides: https://www.fda.gov/media/163056/download
Example Credit - Transcript: https://www.fda.gov/media/163060/download

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Commodity-specific Food Traceability Videos - IFT

- Cucumbers, Tomatoes, Peppers, & Melons
- Fresh Leafy Greens
- Seafood
- Tropical Tree Fruits
- Sprouts
- Cheese
- RTE Deli Salads
- Fresh Cut Produce from Listed Foods & from Unlisted Foods
- Nut Butters
- Shell Eggs

https://info.ift.org/global-food-traceability-center-fsma-resources

Traceability Best Practice Guides - IFT

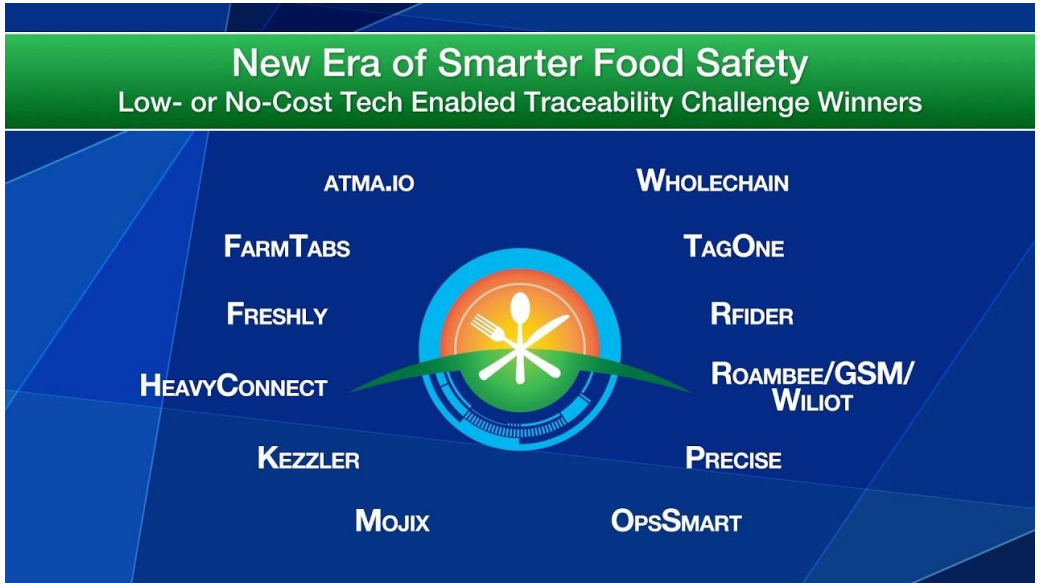
Traceability Best Practice Guides (PDFs)

- Complete Guidance Document on the Best Practices in Food Traceability
- Bakery Traceability Best Practices
- Meat & Poultry Traceability Best Practices
- Processed Food Traceability Best Practices
- Produce Supply Chain Traceability Best Practices
- Seafood Traceability Best Practices
- Dairy Traceability Best Practices

- https://www.ift.org/gftc/research-and-resources/traceability-library

Technologies/Software

- Low- or No-Cost Food Traceability Challenge - FDA https://www.fda.gov/food/new-era-smarter-food-safety/meet-winners-fdas-low-or-no-cost-food-traceability-challenge
- Low or no-cost technologies - IFT
- https://www.ift.org/gftc/research-and-resources/tech-enabled-traceability-report



GS1 Standards & FAQ (to comply with) FSMA 204

- How the GS1 System of Standards can help meet the requirements of the Food Traceability Rule.
- Key components FSMA 204 regulation, & GS1 Standards that could apply.
- Audience: familiar with GS1 Standards but would like to understand how they can be applied to comply with the new regulation. http://ow.ly/YRu050OEeov

https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/food/guideline-toolkit/GS1-FSMA-204-FAQs.pdf

00:00 - Introduction

02:35 - FSMA 204 – History & Background

03:38 - FSMA 204 CTE & KDE Requirements Explained

04:31 - How GS1 Identification Keys Can Help

05:28 - GS1 Barcodes and Other Data Carriers

06:35 - GS1 Data Sharing

07:16 - Achieving End-to-End Supply Chain Visibility

08:21 - GS1 US Resources

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FDA FAQs

- The Food Traceability List (FTL)
- Risk-Ranking Model for Food Tracing (RRM-FT)
- Initial Packer
- First Land-Based Receiver
- Transformation
- Intracompany Shipments and Cross-Docking
- Farms
- Retail Food Establishments (RFEs) and Restaurants

- Comingled Raw Agricultural Commodities (RACs)
- Traceability Lot Code (TLC)
- Implementation
- Kill Step
- General
- Importers
- Food Traceability Plan
- Records Maintenance and Availability
- Enforcement
- Product Tracing System

https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule

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BREAKOUT SESSIONS REPORT OUT

CLAUDIA COLES

SEAFOOD PRODUCTS ASSOCIATION (SPA)

MODERATOR: RON TANNER

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Ask an Expert: Human Food

Expert: Glenn Bass | Moderator: Jason Wan | Scribe: Lillian Hsu

- Glenn presented inspection data pertaining to FSMA inspections, including:
  - # of limited scope and full scope PCHF inspections
  - # of FSVP inspections
  - # of intentional adulteration inspections
  - # of produce inspections and sprouts inspections
- Generally, trend over time since the dip in 2020 is increasing the # of all inspection types
- Referenced the FDA Data Dashboard as a resource for the public to look up inspectional data and metrics under FSMA
- Top 10 domestic inspection observations from FY 19-FY23
  - 9 GMP observations: Pest control (117.35(c)), plaint maintenance (117.35(a)), design and maintenance of equipment and utensils (117.40), process controls (117.80(c)), personnel (117.10), plant construction and design (117.20(b)), sanitation of food-contact surfaces (117.35(d)), sanitary facilities and controls (117.37)
  - 1 PC observation: identification of hazard (117.130(a)(1))

Ask an Expert: Human Food

Expert: Glenn Bass | Moderator: Jason Wan | Scribe: Lillian Hsu

- Q/A themes
  - Intentional adulteration
    - When comprehensive inspections will start? 2025
    - Do FSVP importers need to verify compliance with IA? No.
    - Will FDA share publicly the common misses we're seeing from the IA quick checks? Caitlin mentioned she will discuss more during her session tomorrow
    - Are IA comprehensive inspections going to be standalone? No, tack-on to another food safety inspection, done by the same investigator
  - PCHF
    - What do manufacturers of alcoholic beverages have to do? Exempt from subparts C and G of part 117; subject to GMPs unless there's some other exemption from the GMPs
    - Can FDA/FSPCA work on a checklist for what to expect during a PCHF inspection? Refer to PCHF CPGM, and the FSVP CPGM as starting point
    - How do we ensure states are calibrated and how can we continue to build synergy/leverage states? We can offer states On-the-job experience (OJE) opportunities; PC CSO quarterly calls for FDA and state staff who have completed the PCHF regulators course to share hot topics, newest policies/current thinking, recurring questions from the rTAN
    - Is GMP training required/what training is required? 2 requirements pertaining to training: qualified individuals trained to do their jobs, and training in food safety and food hygiene; then there's PCQI training – not required, as someone can be qualified by experience; FDA focuses on the adequacy of the FSP and implemented controls
  - Food Traceability
    - Implementing FTR is not a small task; we are still struggling with basics (9/10 observations are GMP issues) – how do we reconcile that? We have heard from the industry regarding the challenges; we are still working on the details of FTR implementation; Claudia and Glenn mentioned the importance of food safety culture; Claudia encouraged LIs to get the message out there

Ask an Expert: Animal Food

Experts: Dianne Milazzo, David Fairfield
Scribe: Chris Lincecum

- Questions focused on PCAF – inspections, modified requirements for qualified facilities, AF curriculum and course resources, application of requirements to certain products
- Top 3 most frequent citations for animal food PC program
  - 21 CFR 507.33 - Hazard Analysis, inadequate hazard identification, hazard evaluation
  - 21 CFR 507.34(a)(1)- Preventive Controls, failure to identify necessary PC and/or inadequate implementation
  - 21 CFR 507.31(a) – Food Safety Plan, no food safety plan, and/or missing components
- Use of Prerequisite Programs – If relied upon to reduce probability of hazard occurrence, must be robust and consistently implemented to support hazard analysis determinations

Ask an Expert: Animal Food

Experts: Dianne Milazzo, David Fairfield
Scribe: Chris Lincecum

- NEW RESOURCE - FDA Resources for Animal Food Businesses, includes info on registration, ingredients, regulations and more - https://fda.gov/media/172062/download?attachment
- AF Curriculum – Several suggestions that AF curriculum should be updated. In the meantime, FSPCA is developing lead instructor content to provide updated time-specific information and updated example animal food safety plan

Case Studies: FSVP

Experts: Bob Bauer, Lorie S. Hannappel
Moderator: Hilary Thesmar | Scribe: Dianne Milazzo

- 2 Scenarios
  - Sally's Surplus - FSVP importer of both human and animal food
    - Standard vs Modified requirements?
      - Separate sales of human and animal food to determine value for each
      - Include any subsidiaries/affiliates associated with FSVP importer into value for each
      - Standard requirements apply
  - Olive's Olive Bar – FSVP importer of olive oil, olives, and figs
    - Standard vs Modified requirements
      - Grower and qualified facilities
      - Olives are not imported fresh and are inedible if fresh – won't be considered covered produce
      - Modified requirements apply

Case Studies: FSVP

Experts: Bob Bauer, Lorie S. Hannappel
Moderator: Hilary Thesmar | Scribe: Dianne Milazzo

- Trade show samples?
  - require an FSVP and must meet the requirements
  - Trade shows to document food safety requirements but there is a perception of
- Foreign supplier may or may not be the manufacturer
  - May have to go through a distributor to get the documents needed from the manufacturer
- Accepting documents in another language
  - Need to understand the language
  - Get them to translation documents in anticipation for an inspection

Case Studies: FSVP

Experts: Bob Bauer, Lorie S. Hannappel
Moderator: Hilary Thesmar | Scribe: Dianne Milazzo

- Explained the definition of a Qualified Facility as per the FSVP regulation
- Why doesn't a foreign supplier use just one FSVP Importer for all your products?
  - Sell to many FSVP Importers so not and therefore each FSVP Importer must develop their own FSVP for each product they receive based on size of their business (i.e., very small importer vs not a very small importer)
- Customs Broker – never want them to be FSVP Importer so it's passed along to next receipant of the product aka the 'FSVP Importer

Case Studies: Human Food

Experts: Kathy Gombas, Claudia Coles, Lillian Hsu
Moderator: Gerald Wojtala | Scribe: Debra DeVlieger

- Introduced PCHF Food Facility Type & Applicable Regulations Table (FORM_0064)
  - Updated October 7,2022
  - Form can be used to determine which regulations and subparts of 21 CFR 117 apply to a specific food facility

- Presented 5 food facility scenarios of various sizes that process a variety of products
  1. Juice processor with animal food byproducts
  2. Warehouse (with retail)
  3. RAC off farm packing house
  4. Dietary ingredients and supplements
  5. Bakery – qualified facility

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CLOSING REMARKS

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

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THANK YOU!

SEE YOU NEXT YEAR

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