



FSPCA 2023 ANNUAL CONFERENCE

BUILDING GLOBAL FOOD SAFETY CAPACITY
THROUGH EDUCATION, TRAINING AND OUTREACH



WELCOME

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



OPENING REMARKS

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

State of the Institute

Agenda

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

35 Years and Counting



Founding Members

Letters of Support

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

Financial

Kraft Foods
\$250,000

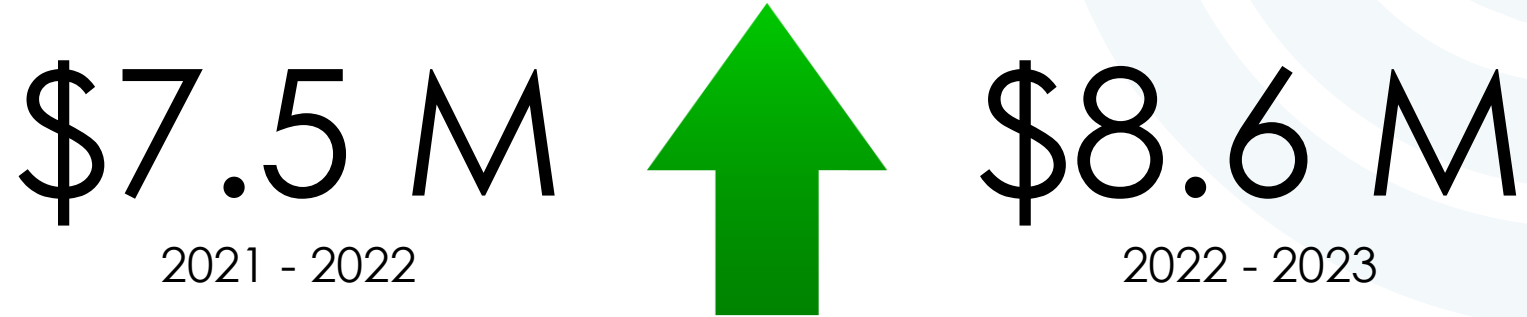
FMC Corporation
\$100,000

Wm. Wrigley Jr. Company
\$100,000

NCFST Year 1 = \$700,000

Year-in-Review

by the numbers



Membership



FSPCA



Grants / Projects





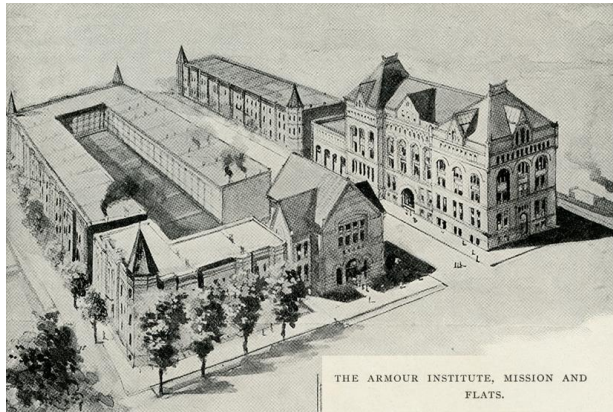
The Future

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.



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.

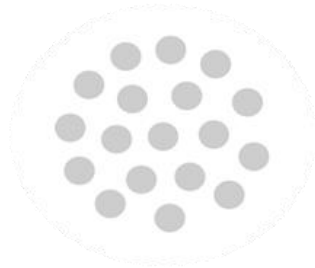
Challenges → Opportunities

- ✓ **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...

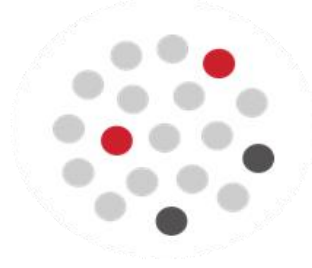
Convene

Convene conversations between academia, industry and government



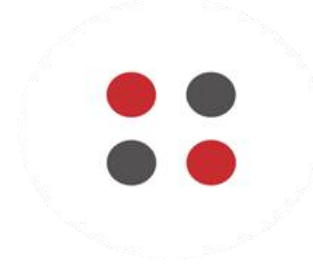
Curate

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



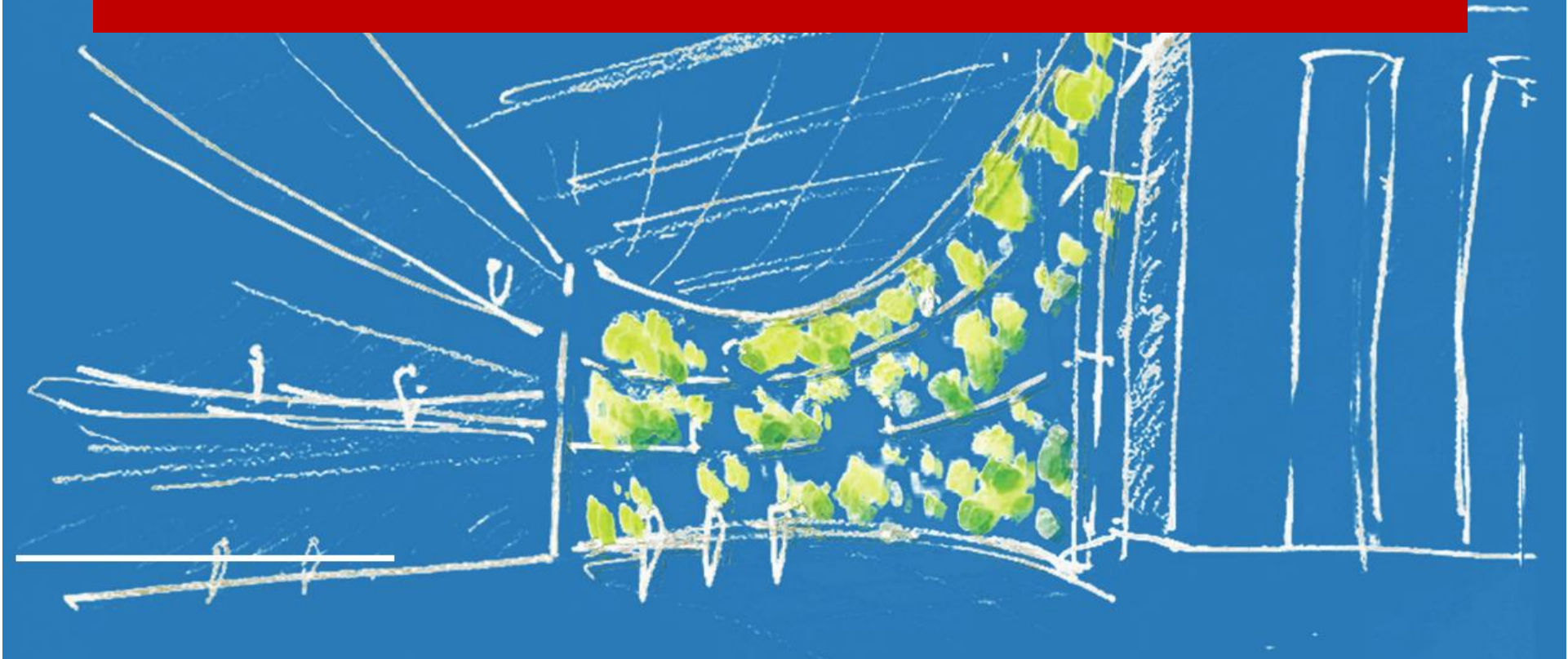
Strategic Goals... We Will...

•• 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

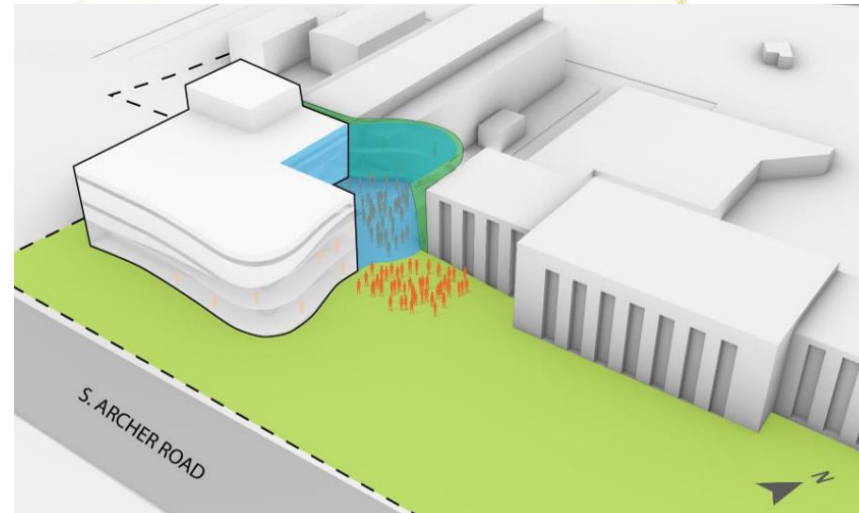
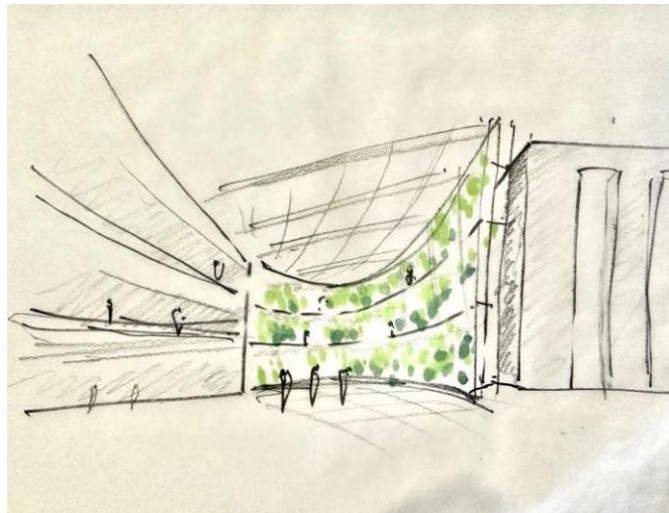
a vision towards the future



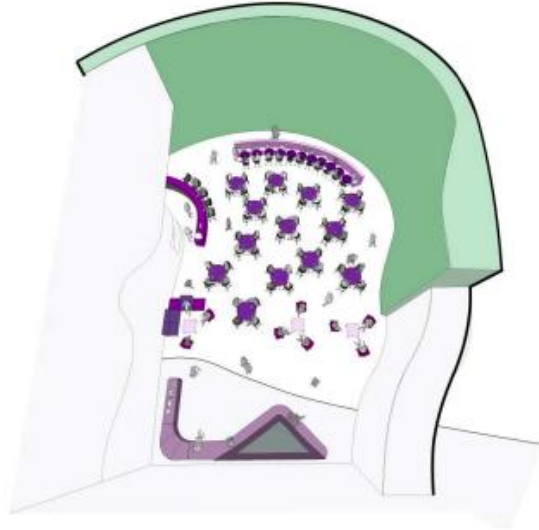


"IFSH is a collaborative environment where scientists from industry, academia, and government pool their scientific expertise and institutional perspectives to ensure the production of safe, wholesome foods."

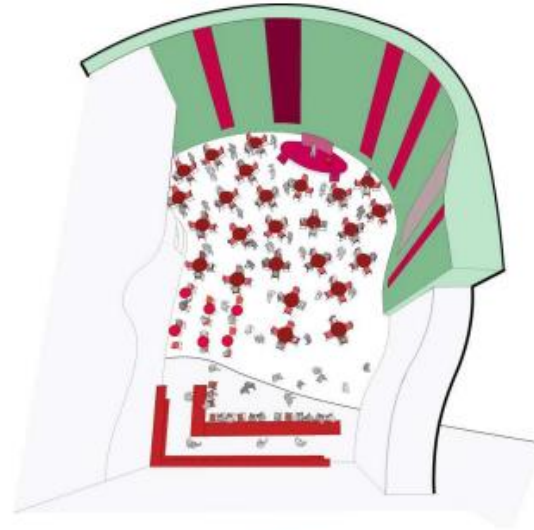




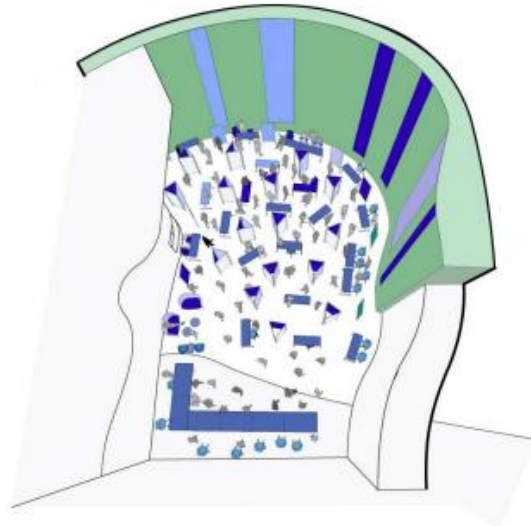
Everyday Life
Meeting Space



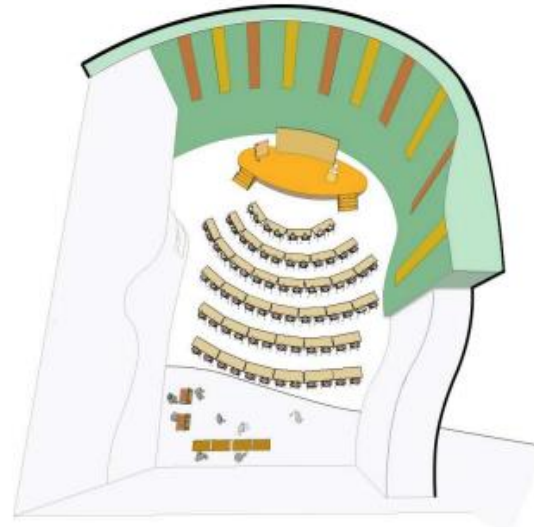
Fundraiser Event
The Ballroom



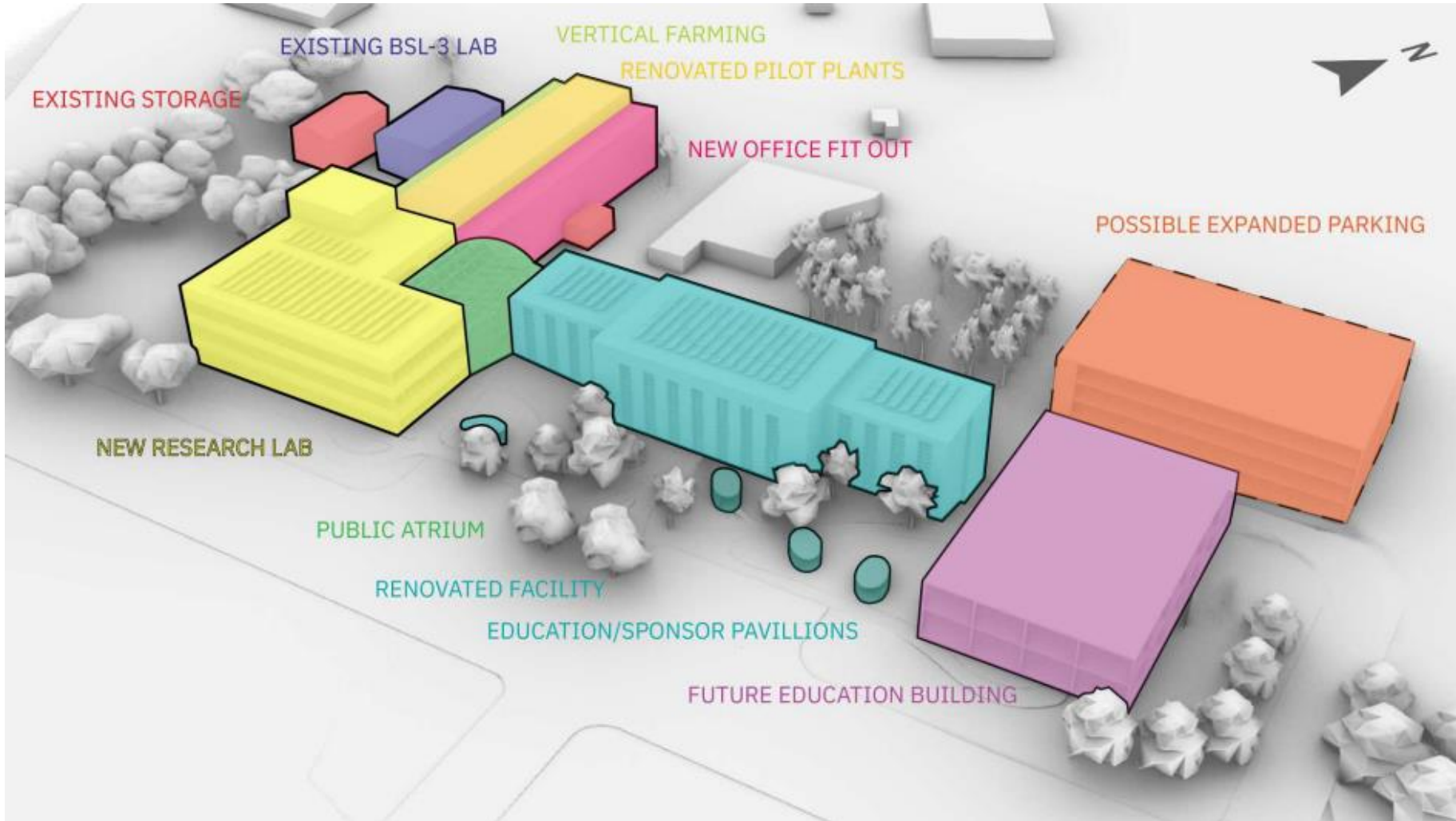
Science Fair
Scientific Industry



Seminar Space
Industry Partners









Thank You



FEATURED SPEAKER VIDEO

SEAN CASTEN
U.S. CONGRESSMAN



FSPCA OPERATIONAL HIGHLIGHTS

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

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)

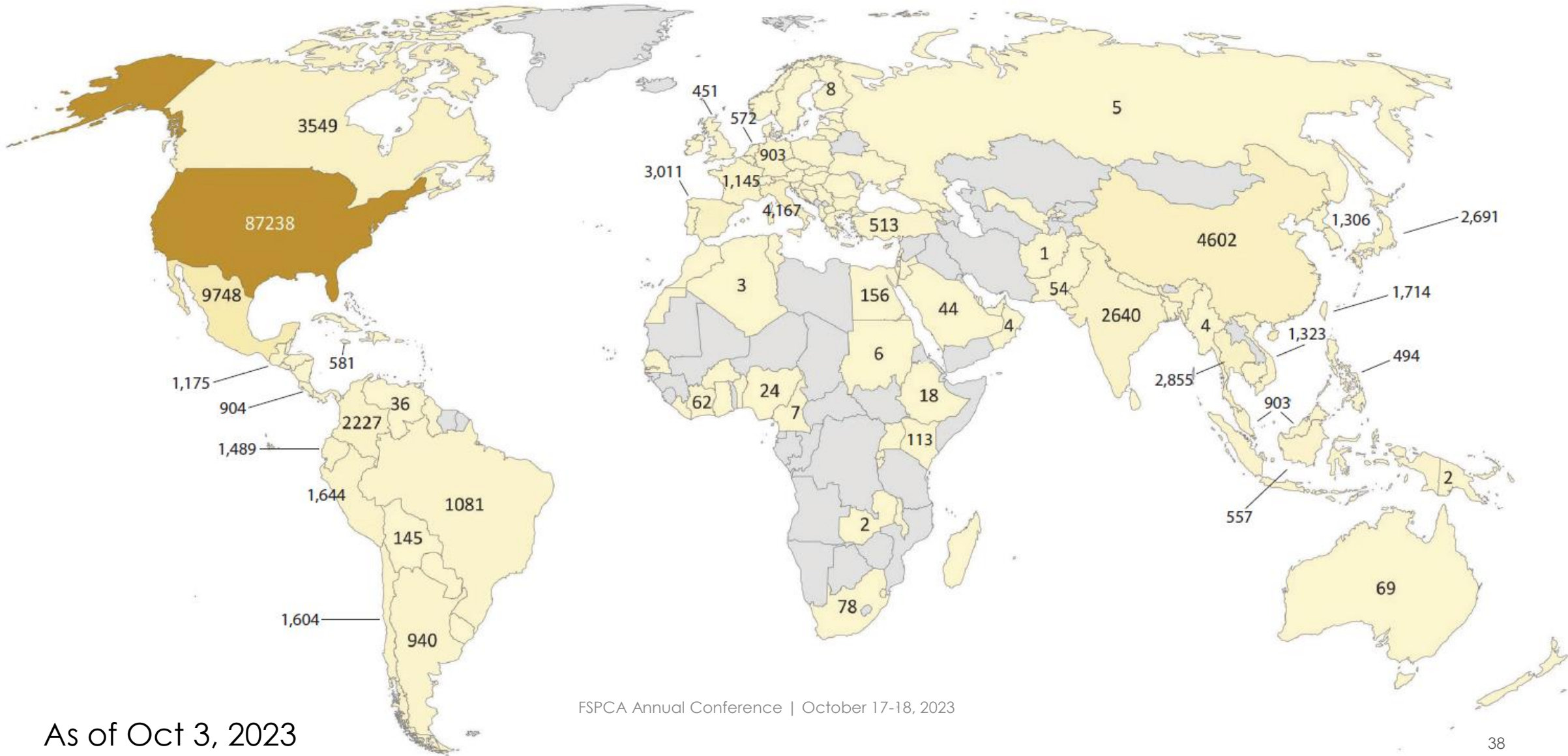


Updated FSPCA Website, October 2023

- 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

PCHF PCQI Certificates Issued by Country: Total 149,634



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

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



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

GLENN BASS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: MATTHEW BOTOS

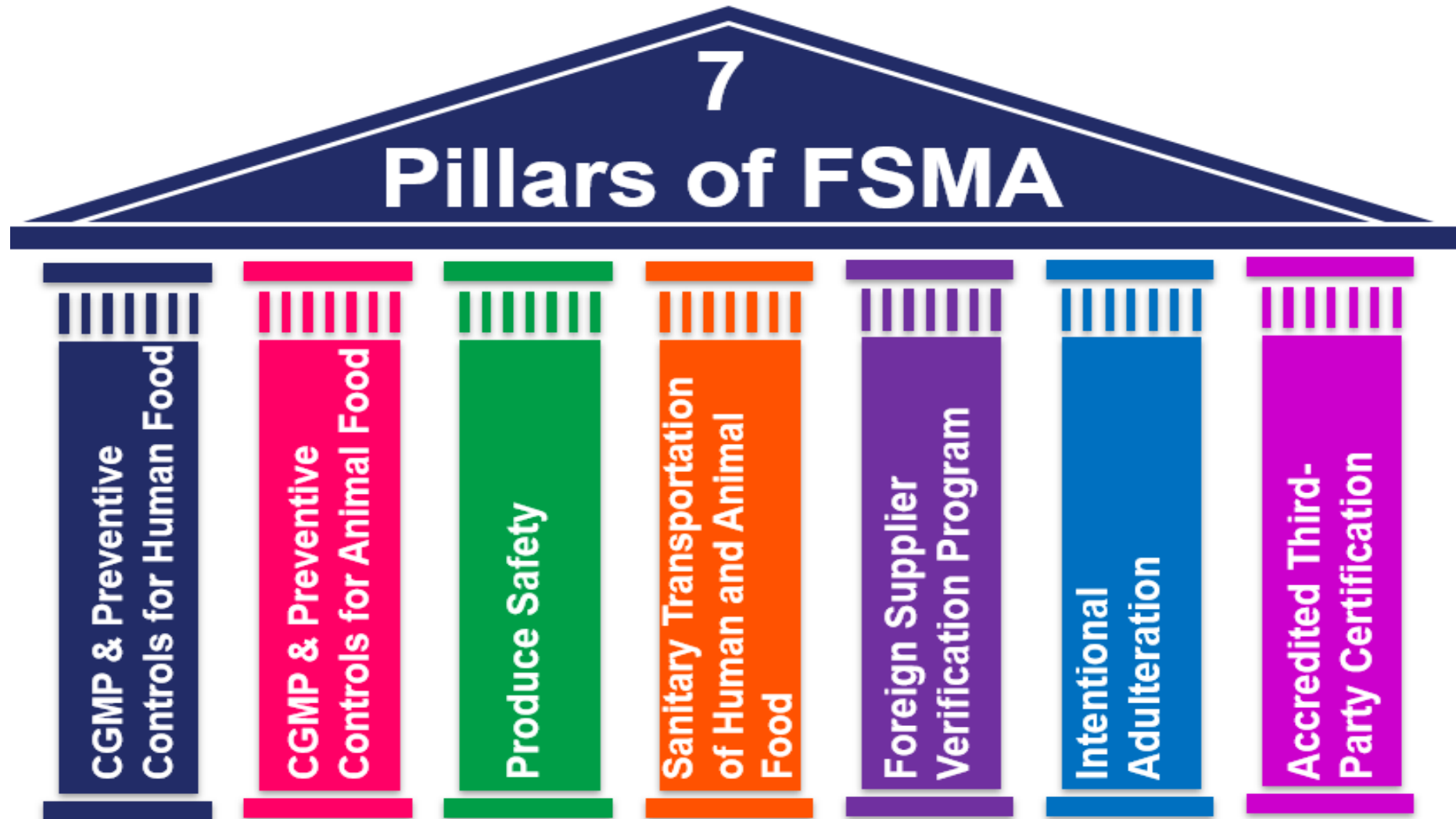


The Past, Present and Future of FSMA Implementation

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)



FOODS PROGRAM GOVERNANCE BOARD



FSMA PHASE 2 STEERING COMMITTEE



**IMPORT
CONTROLS**

**PCHF
PCAF**

**PRODUCE
SAFETY**

**INTENTIONAL
ADULTERATION**

**LABORATORY
ACCREDITATION**

**SANITARY
TRANSPORTATION**

**SPROUT
SAFETY**

**ORA, CFSAN, CVM and State
representation**

2012

FDA Training Courses – FY 2018 – FY 2023

FD254
PC for HF
Regulators
(47)

VM102
CGMP AF
Regulators
(23)

VM220
PC for AF Regulators
(21)

Participants

FDA = 550+
State = 490+

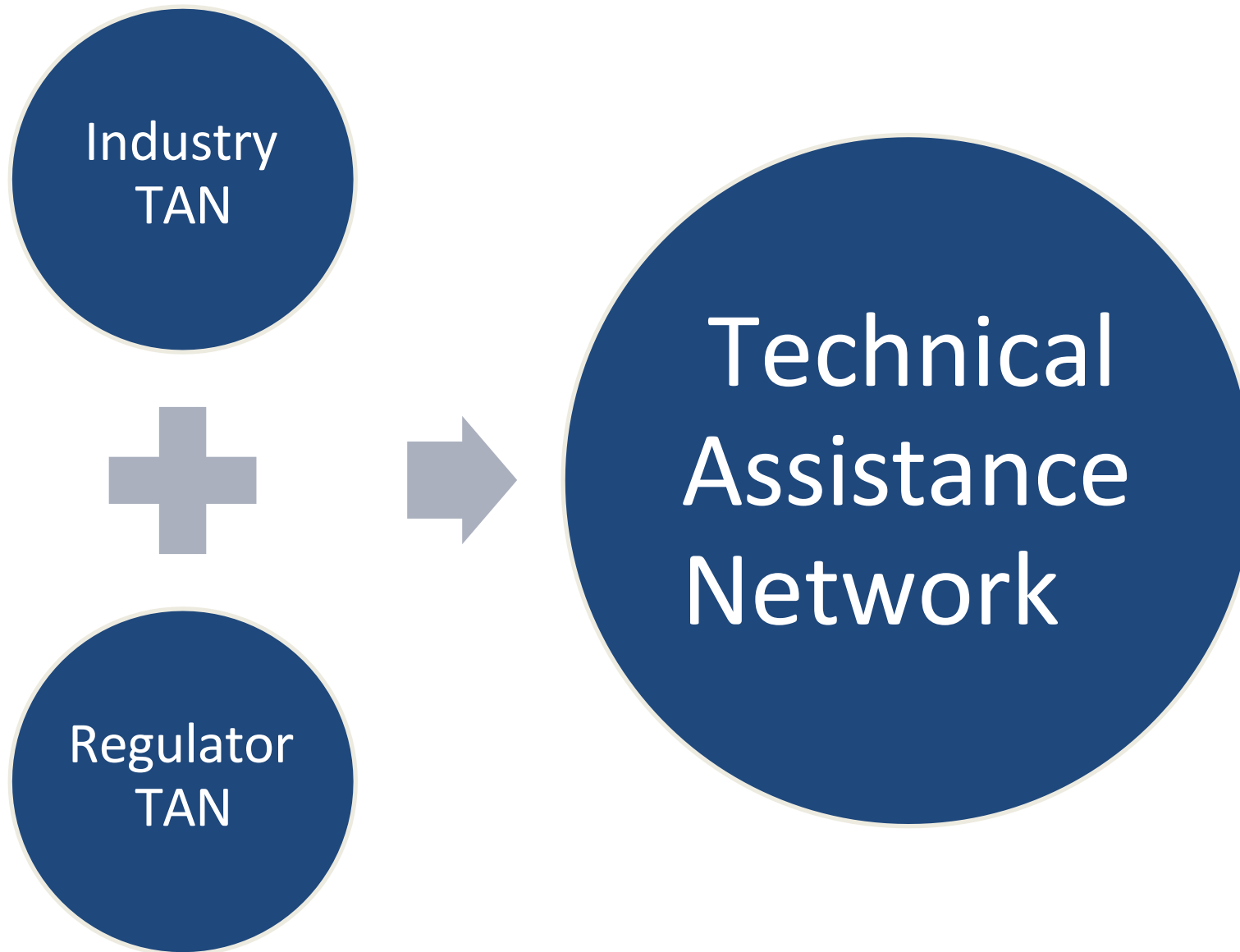
Participants

FDA = 267+
State = 210+

Participants

FDA = 208+
State = 179+

Dynamic Workforce



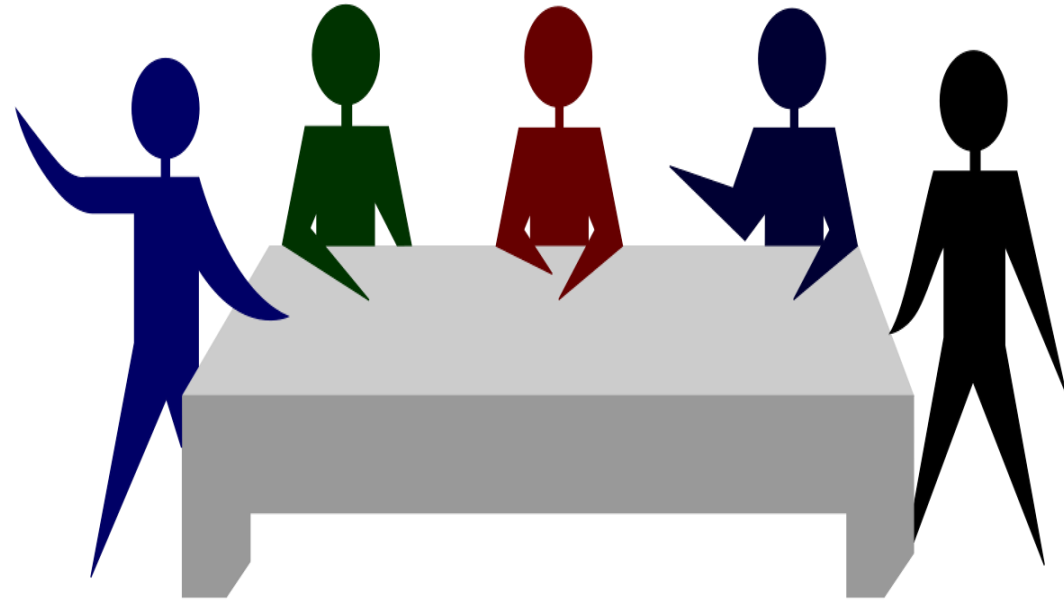
FSMA Chats



- 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

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

- | | |
|---|---|
| <ul style="list-style-type: none"> • Documented observations • Geographic location • Active registration • Total number of facilities applying • Categories/types of products • Inspection and compliance history | <ul style="list-style-type: none"> • 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

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)

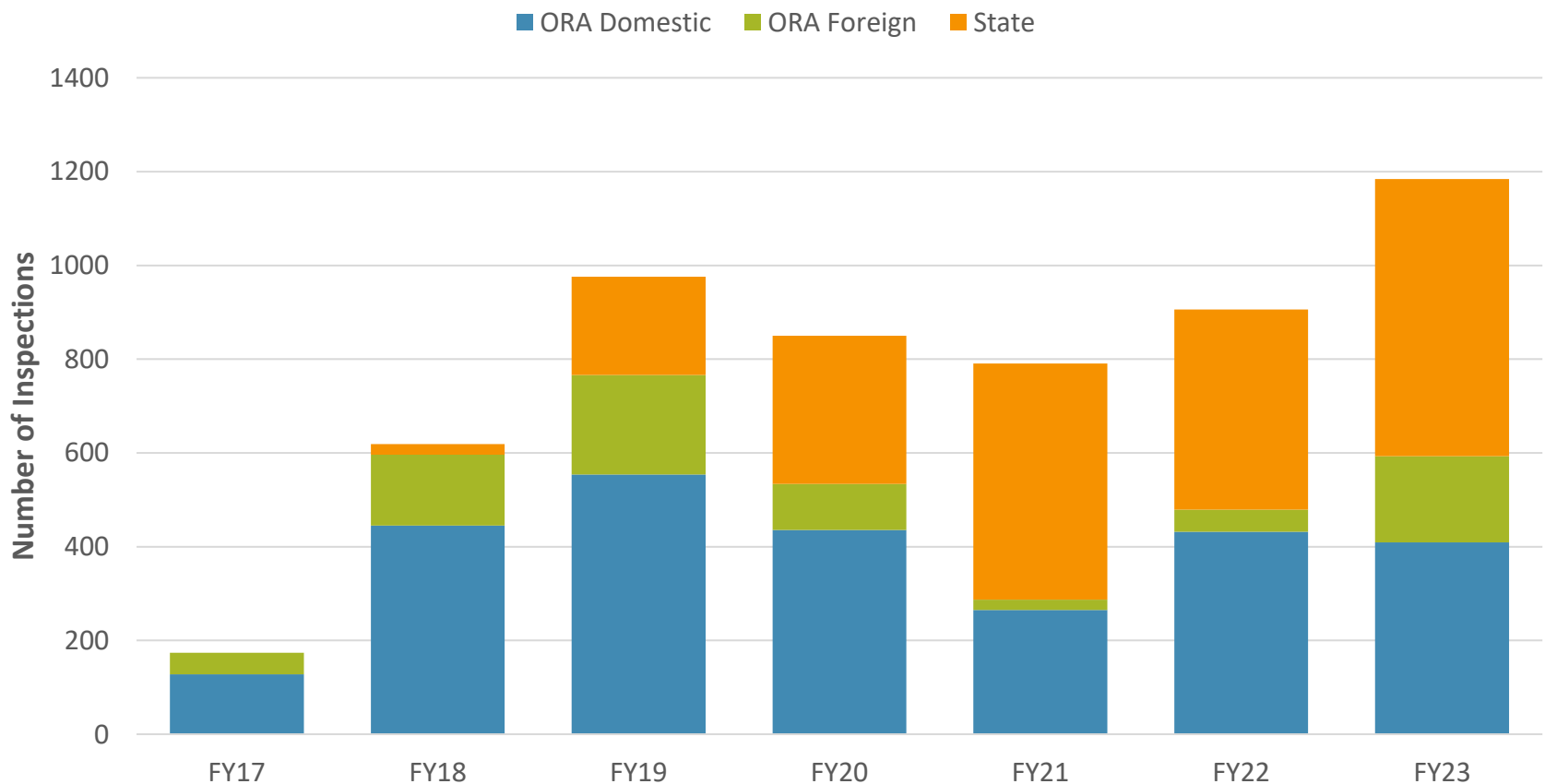


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LILLIAN HSU

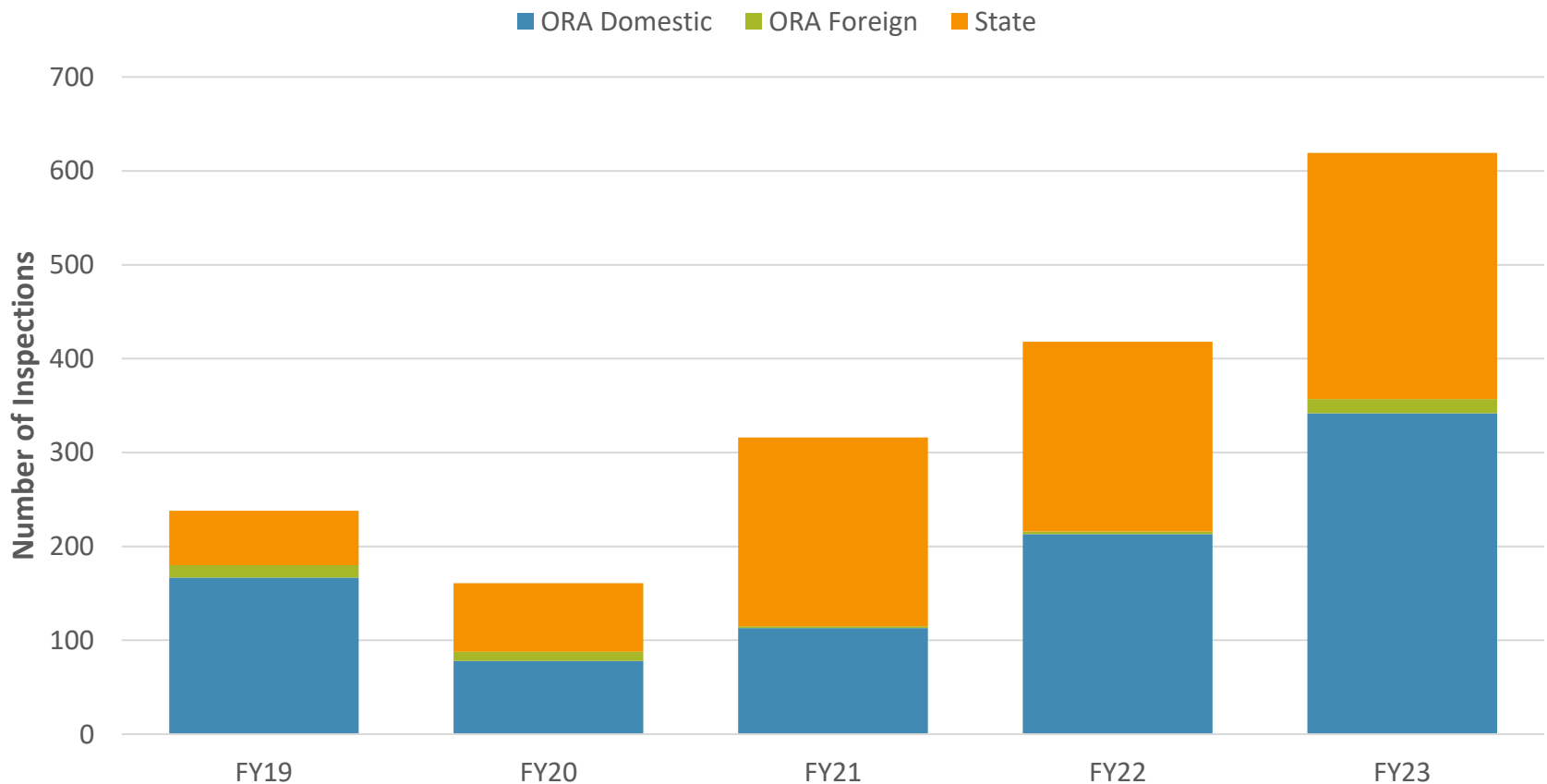
U.S. FOOD AND DRUG
ADMINISTRATION
(FDA)

FSMA Inspection Numbers

Preventive Controls – Human Food



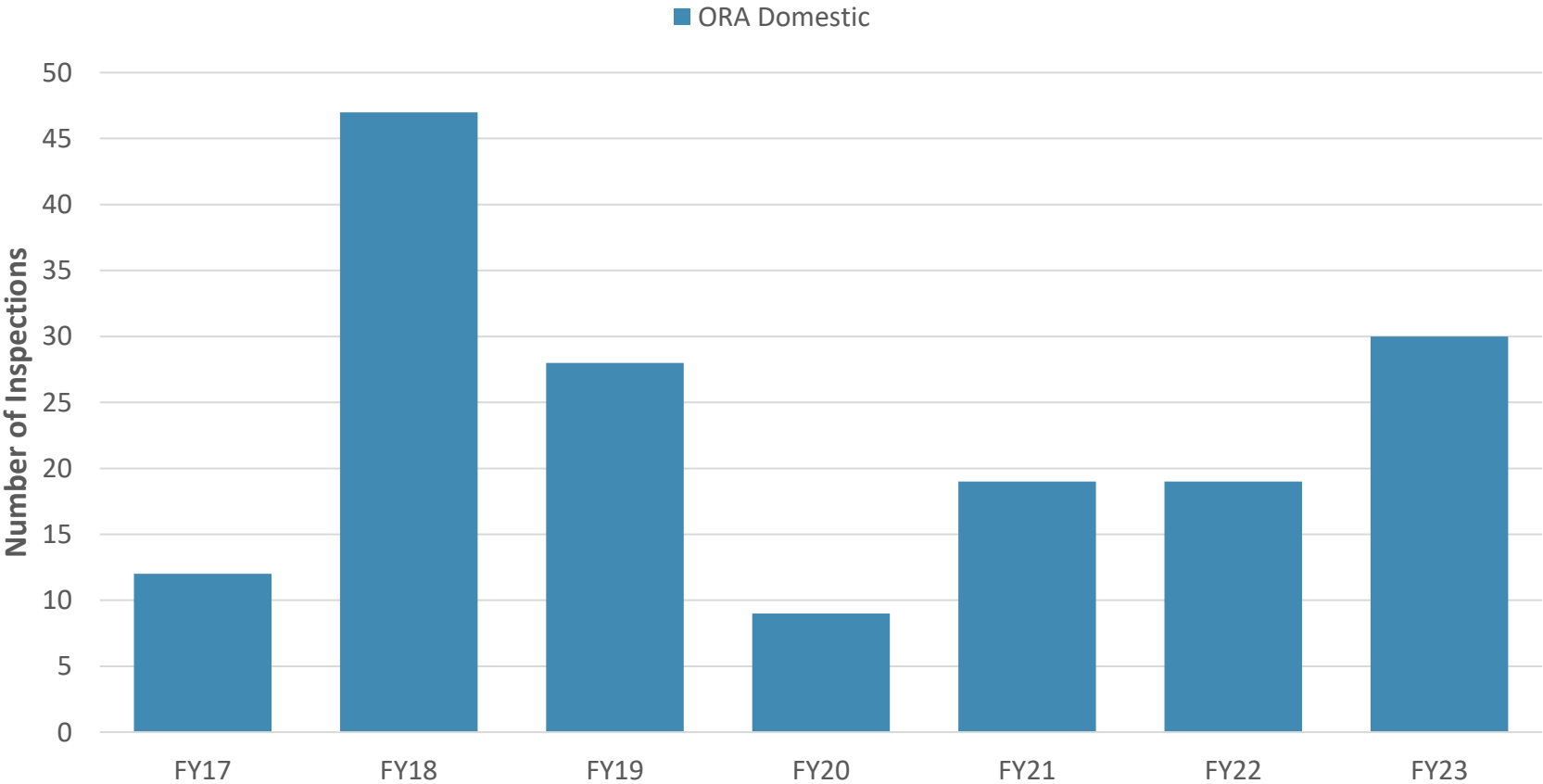
Preventive Controls – Animal Food



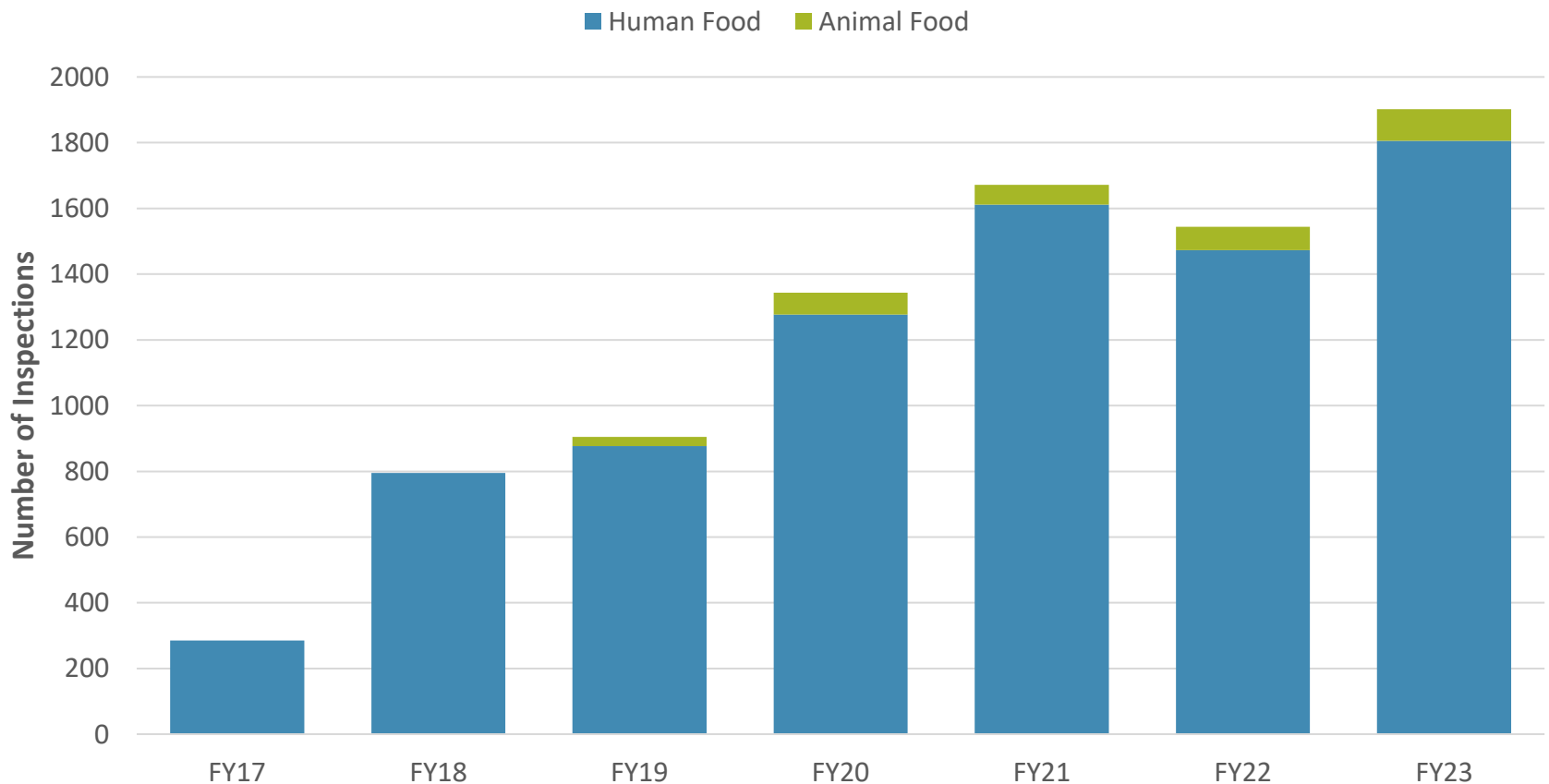
Sanitary Transportation Inspections



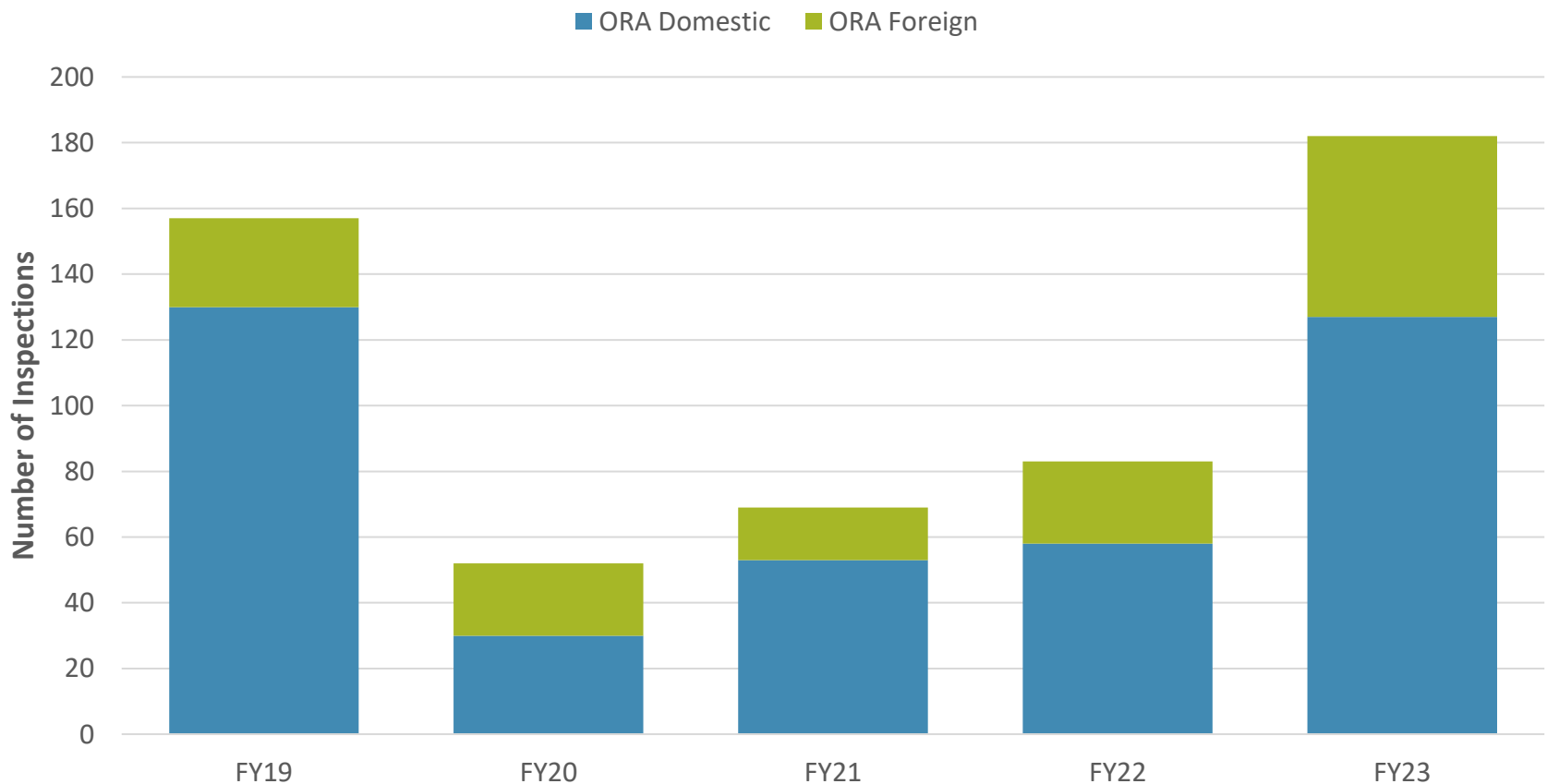
Sprout Safety



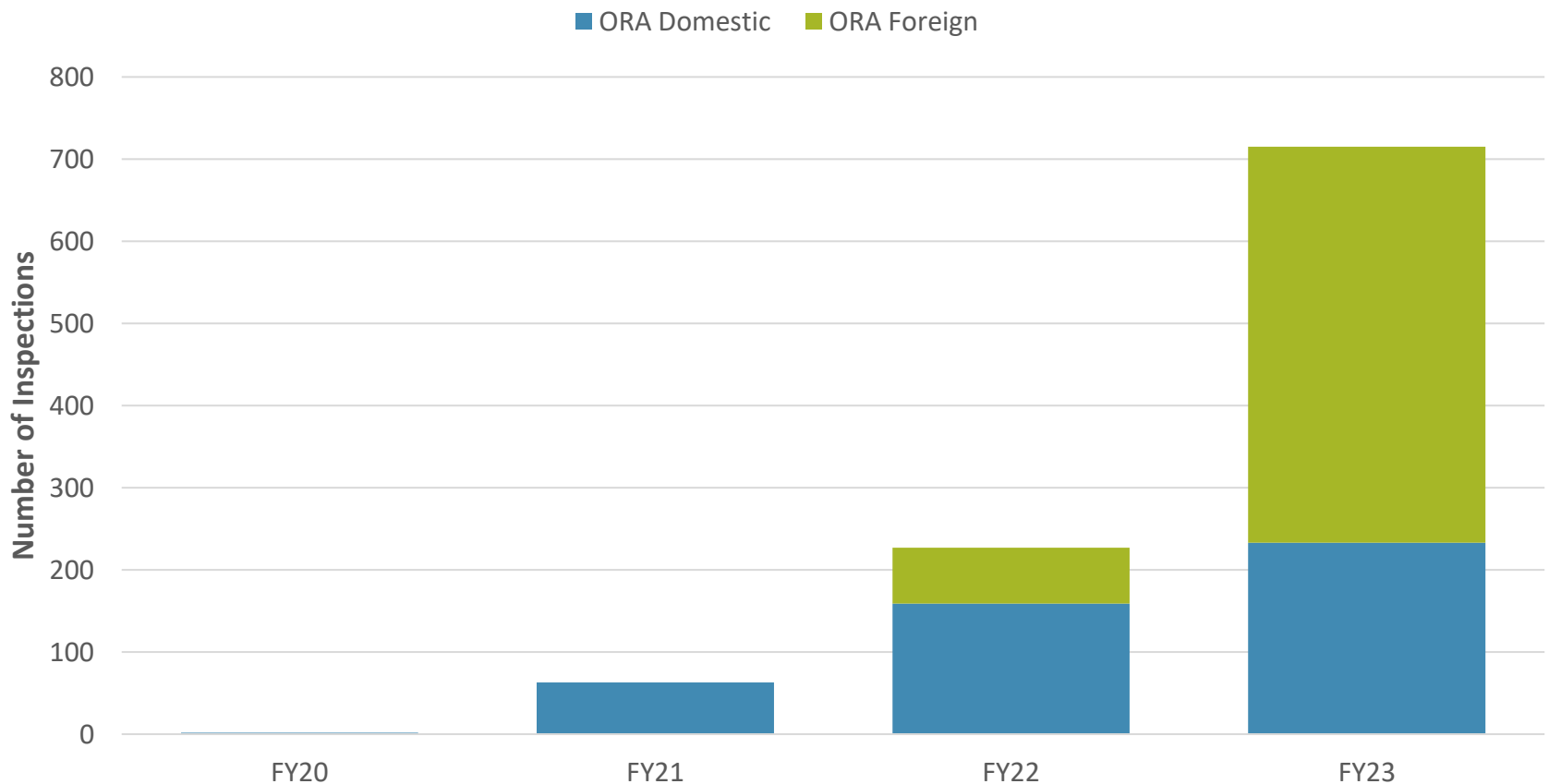
Foreign Supplier Verification Program



Produce Safety

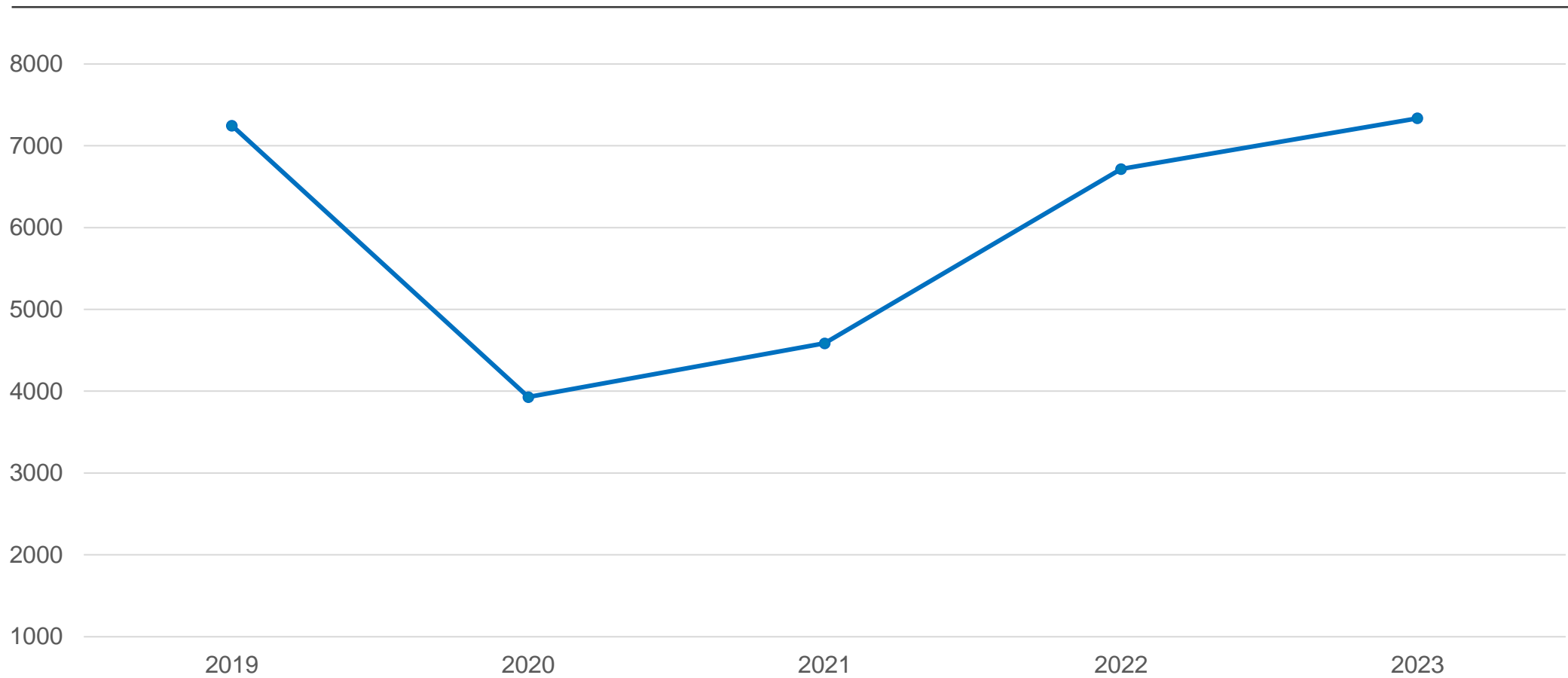


Intentional Adulteration





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**

21 CFR 117.35(c) Pest control	21 CFR 117.35(a) Sanitary operations - Plant maintenance	21 CFR 117.130(a)(1) Hazard Analysis - Identification of Hazard	21 CFR 117.40 Equipment and utensils - Design and maintenance
21 CFR 117.80(c) Manufacturing, processing, packing, holding - Controls	21 CFR 117.10 Personnel	21 CFR 117.20(b) Plant construction and design	21 CFR 117.35(d) Sanitation of food-contact surfaces - Frequency
		21 CFR 117.35(a) Sanitary operations - Plant sanitation	21 CFR 117.37 Sanitary facilities and controls

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)



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

- 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>



FDA Resources for Animal Food Businesses

(Recursos de la FDA para empresas de alimentación animal)



Register with FDA:
Animal Food Facility
Registration and Qualified
Facility Attestation: Frequently
Asked Questions | FDA



Start an Animal Food Business:
How do I Start an Animal Food
Business? | FDA

FSPCA Animal Food Curriculum



FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

**Preventive Controls
for Animal Food**

Version 1.1 – 2017



Participant Manual

QUESTIONS?







FDA FSVP UPDATE

LORIE S. HANNAPPEL

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: HILARY THESMAR



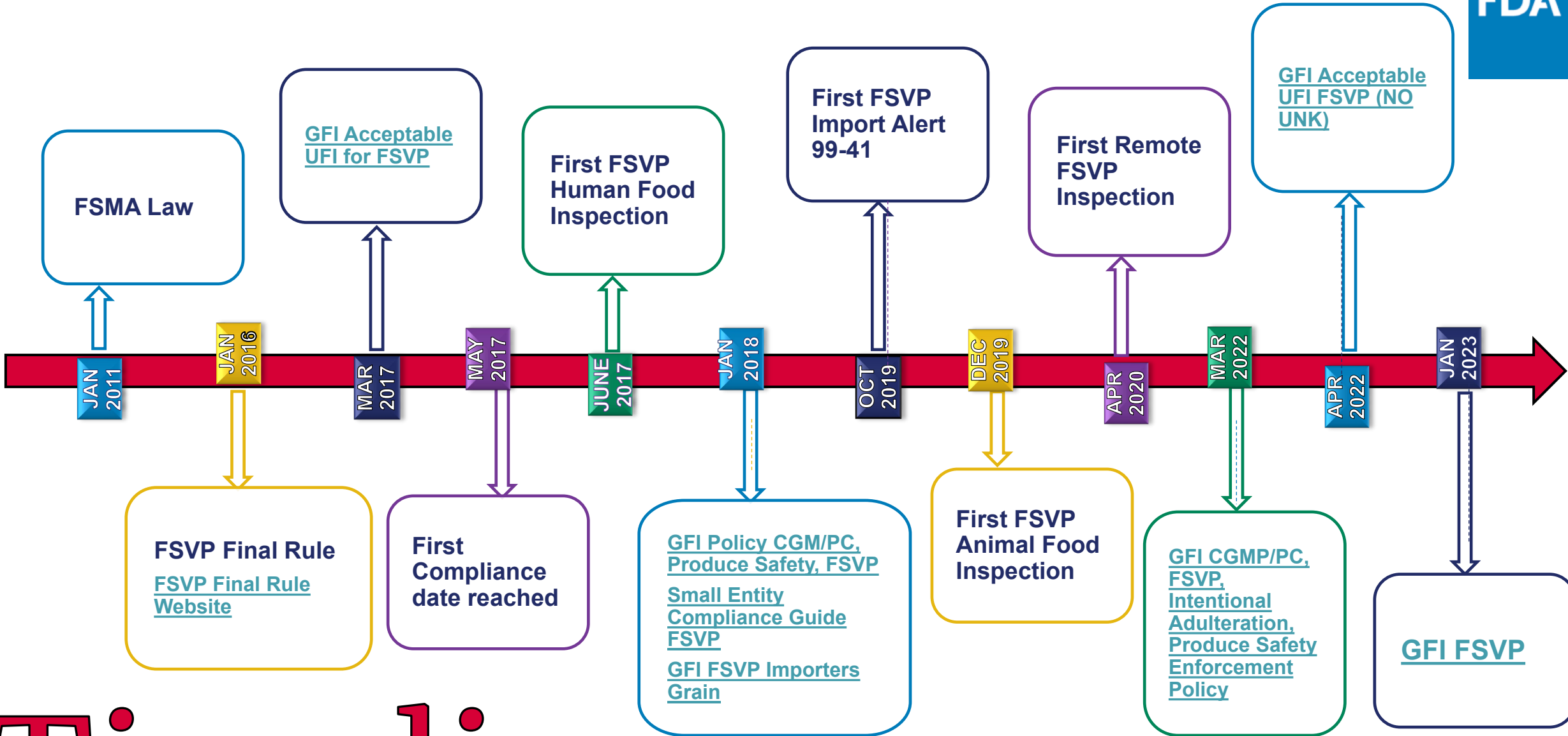
FDA

U.S. FOOD & DRUG
ADMINISTRATION

FSVP, Where are We?

(Foreign Supplier Verification Programs)

Consumer Safety Officer Lorie Hannappel
October 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



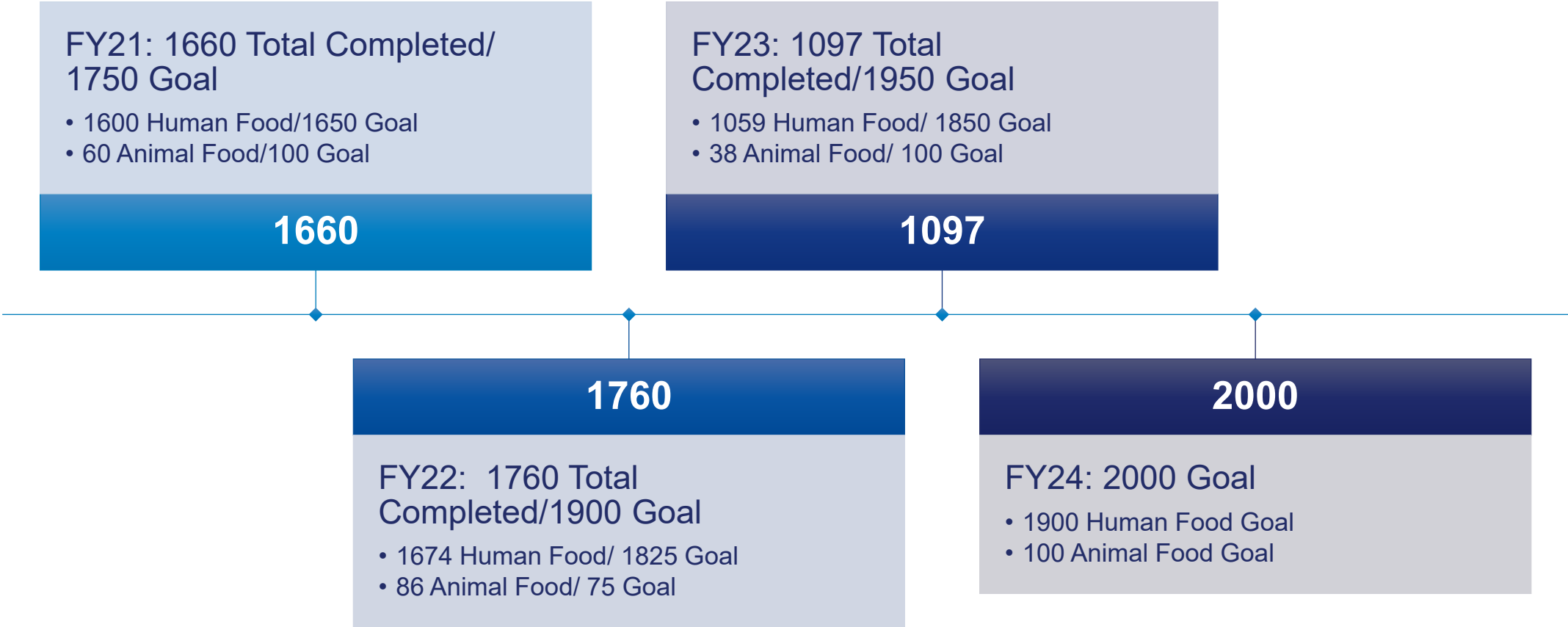
FSVP GFI:

Guidance for Industry
(GFI) Highlight's



Inspections

FY21-FY23 FSVP Inspection



❖ Numbers from [FDA TRACK](#)

Remote vs Onsite

Remote Start: April
3, 2020, 1.510(b)(3)

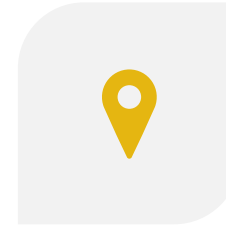


Today: Both
Remote & Onsite

FSVP Importer Portal for FSVP Records Submission



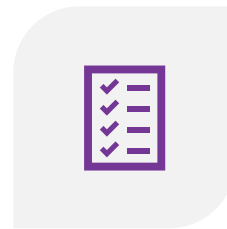
**PROGRAM
EFFICIENCY**



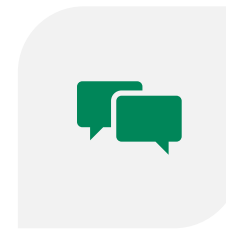
**CENTRALIZED
LOCATION TO
COMMUNICATE**



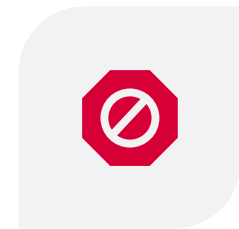
**ALLOW USERS
TO SUBMIT
LARGE SIZE
DOCUMENTS**



**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

- 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%)

FY22

- 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%)

FY23*

- 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

FSMA Data Search

Find firm compliance and enforcement information.

[Search Firm Information](#)

[LAAF Participants](#)

[TPP Participants](#)

[Approved VQIP Importers](#)

FDA Data Dashboard

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

[Dashboard](#) has been added to serve as the online public registry listing for information on participants in the Laboratory Accreditation for Analyses of Foods (LAAF) Program.

Receive notifications about FDA Data Dashboard updates and information.

Inspection actions data is now available through [RESTful APIs](#) on the FDA Data Dashboard.

FDA-TRACK: Imported Food



Commodity:

- Human Food
- Animal Food

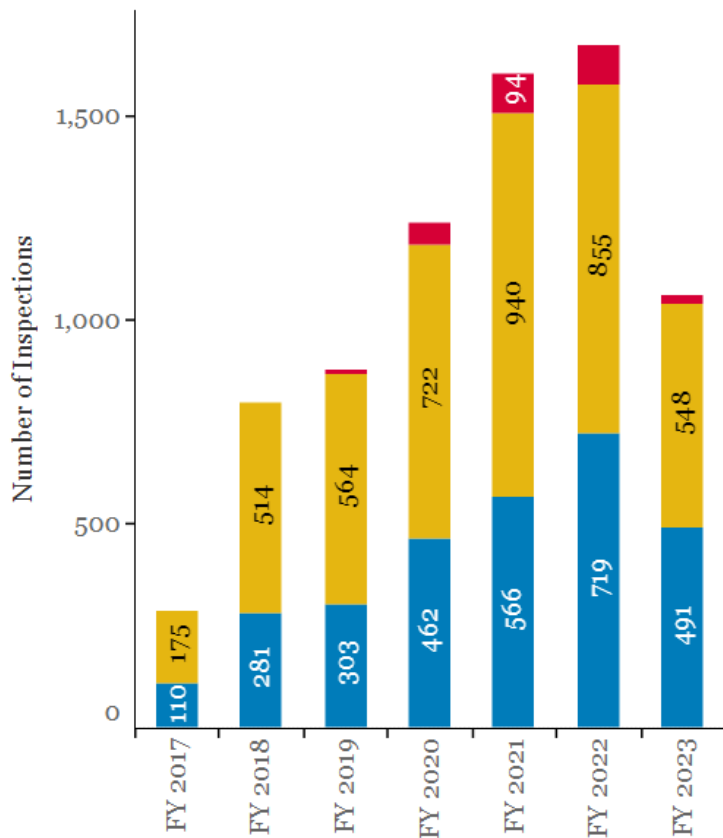
Fiscal Year:

(All) ▼

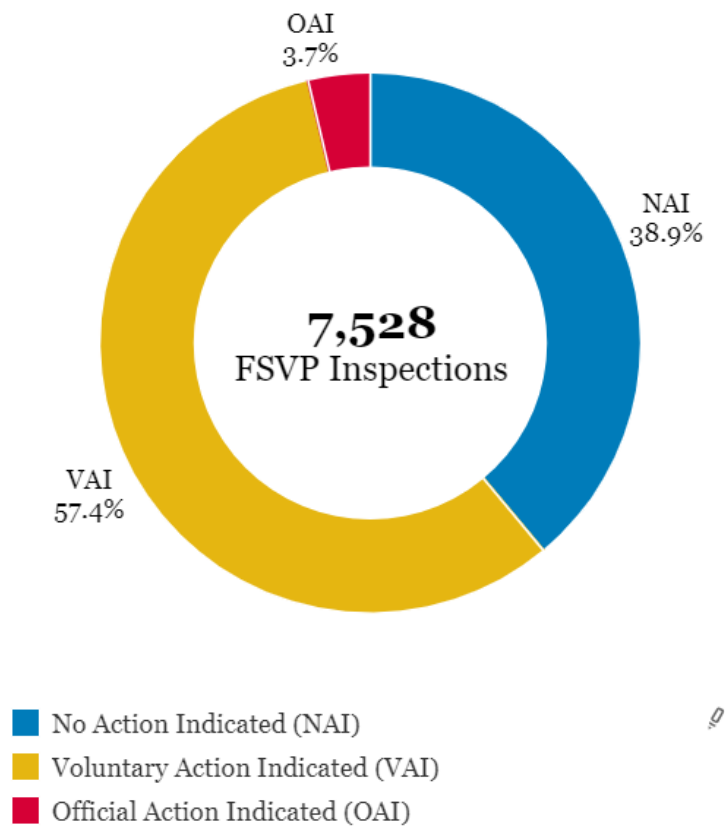
Inspection Classification:

(All) ▼

Number of Inspections by Classification



Percent of Inspections by Classification



FSVP
Inspections
Classifications



FSVP Guidance for Industry (GFI) Highlight's

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

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

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](#)

Content current as of: 07/13/2023

Regulated Product(s)
Food & Beverages

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

[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](#)

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



U.S. FOOD & DRUG
ADMINISTRATION



HACCP AND PREVENTIVE CONTROLS

MARTIN BUCKNAVAGE
PENN STATE

TANIA MARTINEZ
DEMOS GLOBAL GROUP, INC.

MODERATOR: CLAUDIA COLES

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 part 117
 - 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 stand out 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...”



AWARDS PRESENTATION

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

LIFETIME ACHIEVEMENT AWARD

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



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 she 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.

