FSPCA 2022 Virtual Annual Conference

Keeping Food Safe in an Increasingly Challenging Business Environment

October 19-20, 2022

Innovation Through Collaboration
IFSH | INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Welcome

Brian Schaneberg, PhD, Institute for Food Safety & Health (IFSH)

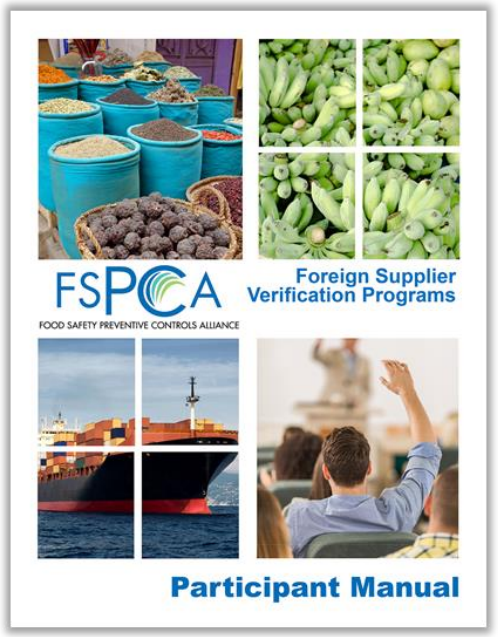
Day 1 Conference Agenda

MORNING SESSION			
START	**END**	**SESSION**	**PRESENTERS**
9:00 AM	9:05 AM	Welcome	**Presenter:** Brian Schaneberg
9:05 AM	9:15 AM	FSPCA Update	**Presenter:** Jason Wan
9:15 AM	11:00 AM	FDA Update: Implementing FSMA in a Post-Pandemic World	**Presenter:** Glenn Bass **Moderator:** Matthew Botos
MID DAY BREAK: LUNCH 11:00 – 11:45 AM / BREAKOUT SESSIONS 11:45 AM – 12:30 PM			
11:45 AM	12:30 PM	**Ask an Expert:** FDA Perspectives on Human Food	**Expert:** Glenn Bass **Moderator:** Jason Wan **Scribe:** Lillian Hsu
11:45 AM	12:30 PM	**Ask an Expert:** FDA Perspectives on Animal Food	**Experts:** Dianne Milazzo, Dave Fairfield **Moderator:** Matthew Botos **Scribe:** Dianne Milazzo
AFTERNOON SESSION			
12:30 PM	1:30 PM	2022 Industry Insights: What We've Learned and How It Will Impact 2023	**Panelists:** Stephen Posey, Martin Bucknavage, Katherine Simon **Moderator:** Jerry Wojtala
1:30 PM	2:25 PM	Fresh Produce Industry at the Intersection of Sustainability and Food Safety	**Presenter:** Max Teplitski **Moderator:** Jerry Wojtala
2:25 PM	2:30 PM	Closing Remarks	**Presenter:** Jason Wan

FSPCA Update

Jason Wan, Institute for Food Safety and Health (IFSH)

FSPCA Standardized and Core Curricula



FSPCA Update 2022

- Implementation of Policies & Procedures for Virtual Delivery of FSPCA Courses
  - Lead Instructors courses
  - Participants courses
- PCHF Curriculum Update
- FSPCA Quarterly Newsletters
- FSPCA Annual Conference
- In-progress – FSPCA Website Update
- FSPCA Training Highlights (as of October 4, 2022)

2022 FSPCA Lead Instructor Courses *(Since Oct 2021)*

Virtual PCHF Lead Instructor Courses

- October 25-29, 2021
- December 6-10, 2021
- February 7-11, 2022
- March 21-25, 2022
- April 11-15, 2022
- May 9-13, 2022
- July 18-22, 2022
- August 22-26, 2022
- September 19-23, 2022

2022 FSPCA Lead Instructor Courses *(Since Oct 2021)*

In-Person PCAF Lead Instructor Course

- August 16-18, 2022

Virtual FSVP Combination Course

- March 28-April 1, 2022

Virtual IAVA Combination Course

- October 5-6 & October 12-13, 2021

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FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

2022 FSPCA Training Highlights *(Oct 2021 – Oct 2022)*

	PCHF	PCAF	FSVP	IAVA
Lead Instructor Courses Completed	11	1	1	1
Lead Instructors Trained	133	14	14	9
Participants Courses Completed	1,561	170	217	165
Participants Trained	14,789	1,572	1,289	1,141

FSPCA Training Metrics: Participant

		PCHF	PCAF	FSVP	IAVA
Participant Certificates Issued	**Total**	**133,696**	**13,049**	**10,220**	**4,271**
	Domestic	78,344	11,677	8,688	2,204
	International	55,352	1,372	1,532	2,067
Participant Courses Completed	**Total**	**11,499**	**1,008**	**1,203**	**498**
	Domestic	6,380	880	1,015	277
	International	5,119	128	188	221

As of October 4, 2022

FSPCA Training Metrics: Lead Instructor

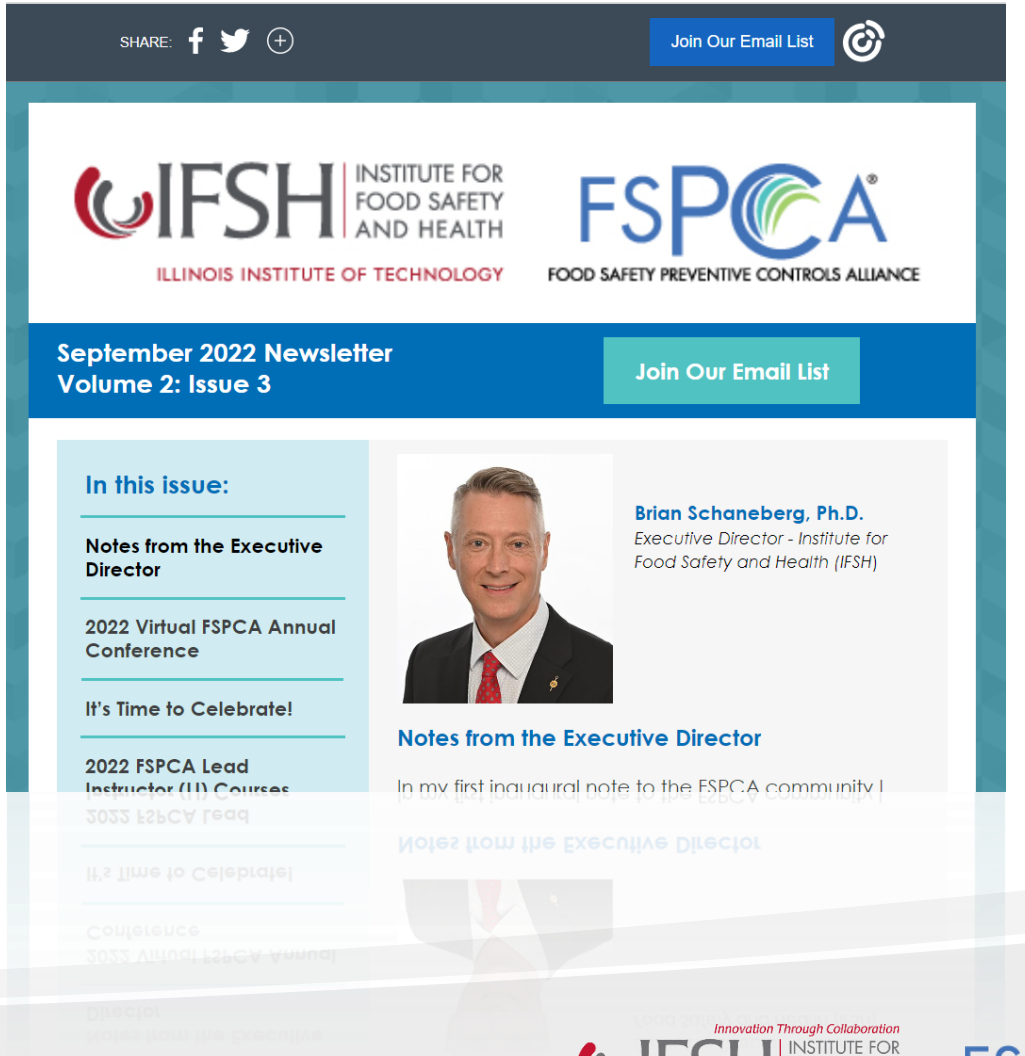
		PCHF	PCAF	FSVP	IAVA
Lead Instructors Trained	**Total**	**2,252**	**340**	**363**	**74**
	Domestic	1,339	268	306	54
	International	913	72	57	20
Lead Instructor Courses Completed	**Total**	**105**	**16**	**17**	**6**
	Domestic	68	12	11	6
	International	37	4	0	0

As of October 4, 2022

FSPCA Quarterly Newsletters

Read our latest newsletter or view a past newsletter

Join the listserv



FSPCA Annual Conferences

Innovation Through Collaboration
IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FSPCA Thank You

- FSPCA EAB Members
- FSPCA Committee Chairs and Members
- FSPCA Work Group Chairs and Members
- FSPCA Trainer-of-Trainers
- FSPCA Lead Instructors
- FSPCA Volunteers

FDA Update: Implementing FSMA in a Post-Pandemic World

Glenn Bass, FDA ORA

Moderator: Matthew Botos, ConnectFood

2022 FDA Update: Implementing FSMA in a Post-Pandemic World

Glenn Bass
Deputy Director
Office of Human and Animal Food – West
Office of Regulatory Affairs
U.S. Food & Drug Administration

2022 FSPCA Virtual Annual Conference| Oct 19, 2022

Agenda

- Impact of COVID-19
  - The Field Perspective

FDA Training Courses – FY 2017 – FY 2022

FD254 PC for HF Regulators (32+)	VM102 CGMP AF Regulators (20+)	VM220 PC for AF Regulators (16+)	FD226 Produce Safety for Regulators (20+)
Participants FDA = 600+ State = 300+	Participants FDA = 300+ State = 300+	Participants FDA = 200+ State = 200+	Participants FDA = 80+ State = 300+

Dynamic Workforce

What Have We Been Doing?

Re-thinking Field Activities

Impact of COVID-19: Re-thinking Field Activities

Challenges & Opportunities

Challenges:

- Limit the travel time and distance. Some inspections require staff to travel 5- 7 hours to get to the firm.
- As conditions on the ground changes and the impact of COVID-19 changes, we continue to revise the field instructions to meet the present conditions.
- Shifting to virtual working conditions such as training, managing new hires, and collaborative meetings (e.g., close-out inspections).

Impact of COVID-19: Re-thinking Field Activities

Challenges & Opportunities

Opportunities:

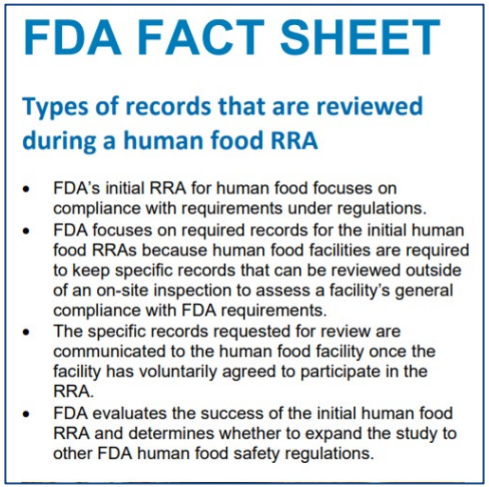
- Remote Regulatory Assessment (RRAs)
  - **VOLUNTARY**
  - Center for Food Safety & Applied Nutrition (CFSAN)
  - Center for Veterinary Medicine (CVM)
  - Does not replace onsite inspection (i.e., no change to inspection frequency)

Impact of COVID-19: FDA's Remote Oversight Tools

- Remote Regulatory Assessments (RRAs)
  - FDA may request establishments (e.g., food producers) participate in a Voluntary RRA.
    - These can be requesting and reviewing records;
    - Virtual meetings via livestream and/or secure email portal
  - Mandatory RRAs are defined in statue and regulation and currently include certain drug establishments and FSVP requests from Importers of an article of food.

Impact of COVID-19: FDA's Remote Oversight Tools

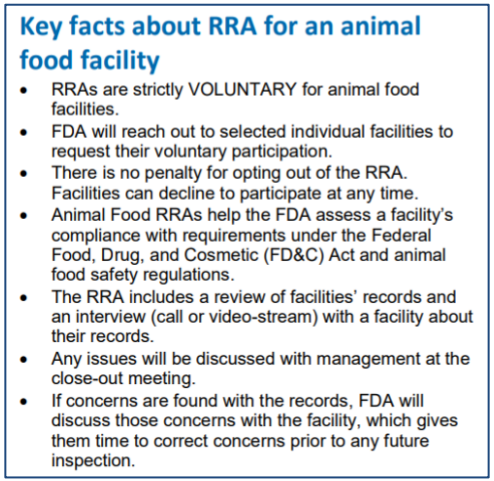
Remote Regulatory Assessment Fact Sheets



FDA FACT SHEET

Types of records that are reviewed during a human food RRA

- FDA's initial RRA for human food focuses on compliance with requirements under regulations.
- FDA focuses on required records for the initial human food RRAs because human food facilities are required to keep specific records that can be reviewed outside of an on-site inspection to assess a facility's general compliance with FDA requirements.
- The specific records requested for review are communicated to the human food facility once the facility has voluntarily agreed to participate in the RRA.
- FDA evaluates the success of the initial human food RRA and determines whether to expand the study to other FDA human food safety regulations.



Key facts about RRA for an animal food facility

- RRAs are strictly VOLUNTARY for animal food facilities.
- FDA will reach out to selected individual facilities to request their voluntary participation.
- There is no penalty for opting out of the RRA. Facilities can decline to participate at any time.
- Animal Food RRAs help the FDA assess a facility's compliance with requirements under the Federal Food, Drug, and Cosmetic (FD&C) Act and animal food safety regulations.
- The RRA includes a review of facilities' records and an interview (call or video-stream) with a facility about their records.
- Any issues will be discussed with management at the close-out meeting.
- If concerns are found with the records, FDA will discuss those concerns with the facility, which gives them time to correct concerns prior to any future inspection.

Draft Guidance: Conducting Remote Regulatory Assessments (RRAs) (posted 7/2022)

- Conducting Remote Regulatory Assessments Questions and Answers | FDA

Impact of COVID-19: Re-thinking Field Activities

Challenges & Opportunities

Opportunities:

- 2 Tier Inspection Program

Impact of COVID-19: Re-thinking Field Activities

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

Impact of COVID-19: Re-thinking Field Activities

- Official Establishment Inventory (OEI) Improvement
  - PSA: Re-registration end of 12/2022
- Limited Scope vs Full Scope-PCHF
- Routine Surveillance vs Compliance F/U;
- Announced vs Un-announced

Impact of COVID-19: Re-thinking Field Activities

- Outbreak Investigations
- For cause sampling
  - Product
  - Environmental

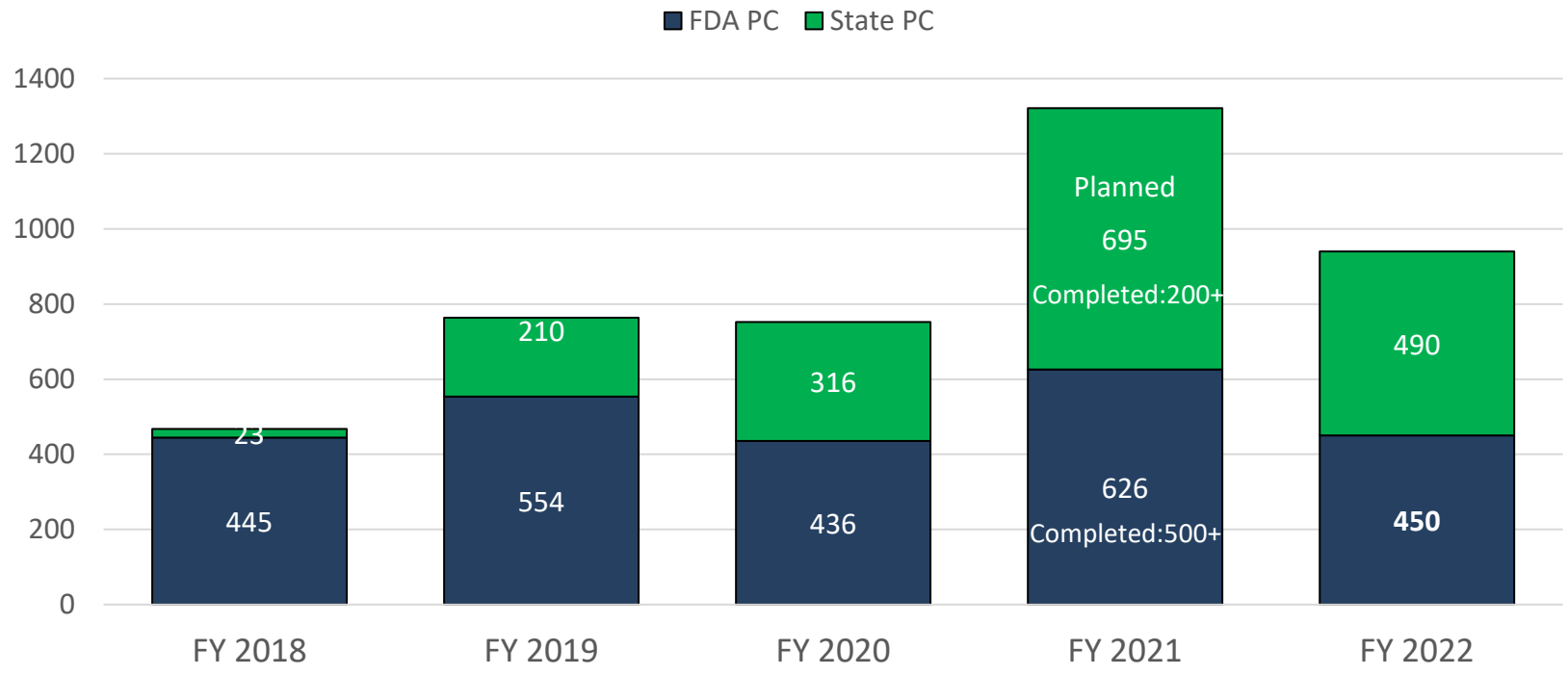
Impact of COVID-19: Re-thinking Field Activities

- Staff Development:
  - Formalized Program: PCHF & PCAF OJE
  - Coach-OJE (Division)
  - OHAFO/NEs: 1 day Webinar/Workshop
  - On-site Coach-OJE with CSO along with OHAFO/NE

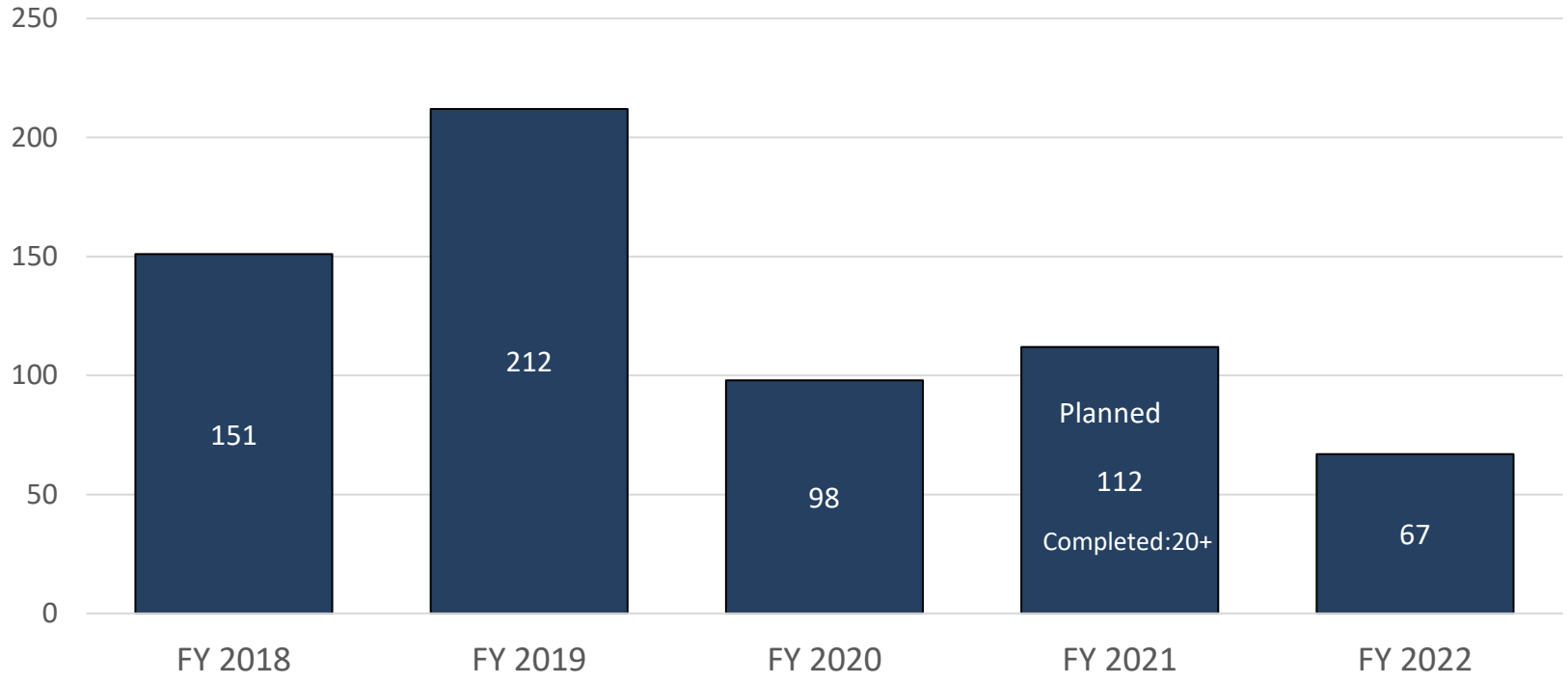
Impact of COVID-19: Re-thinking Field Activities

The Numbers

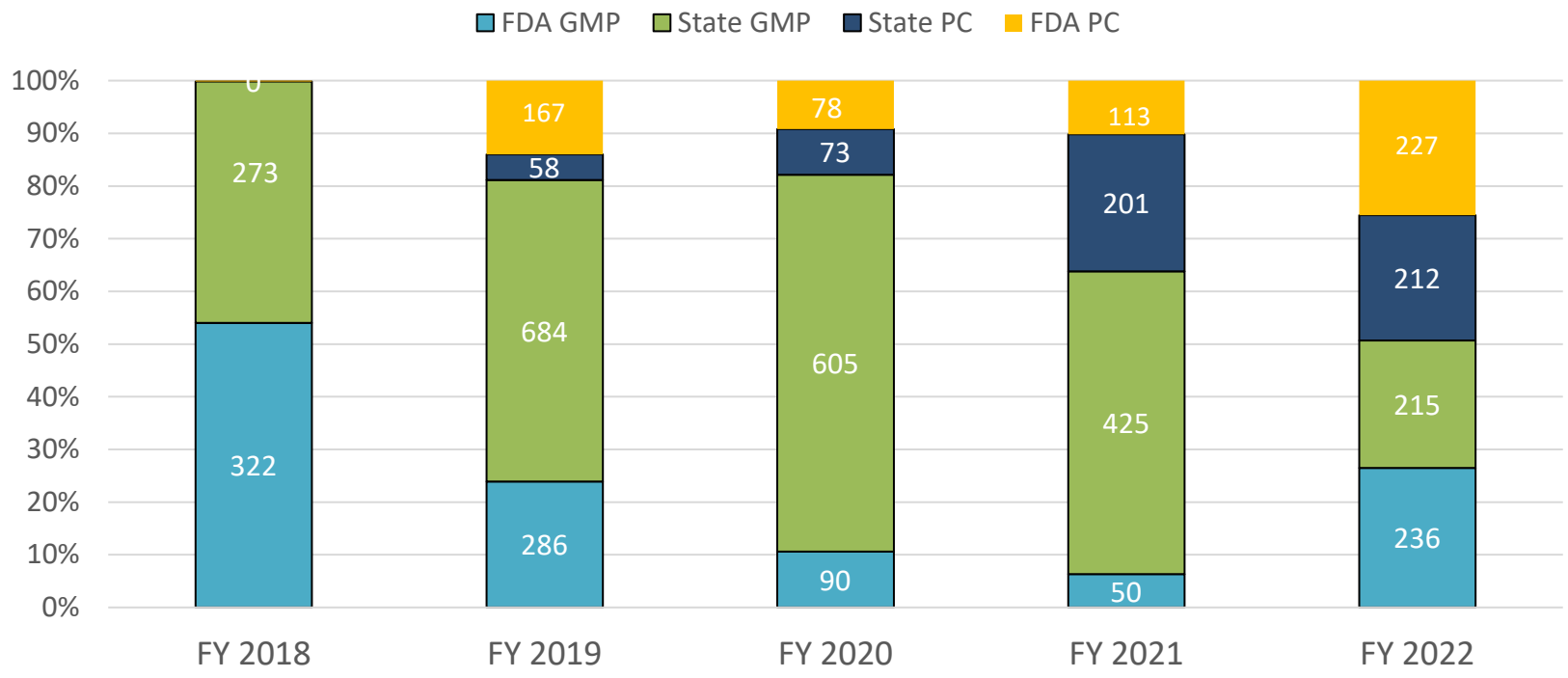
Domestic Inspections, FY 2018 – FY 2022
Preventive Controls for Human Food



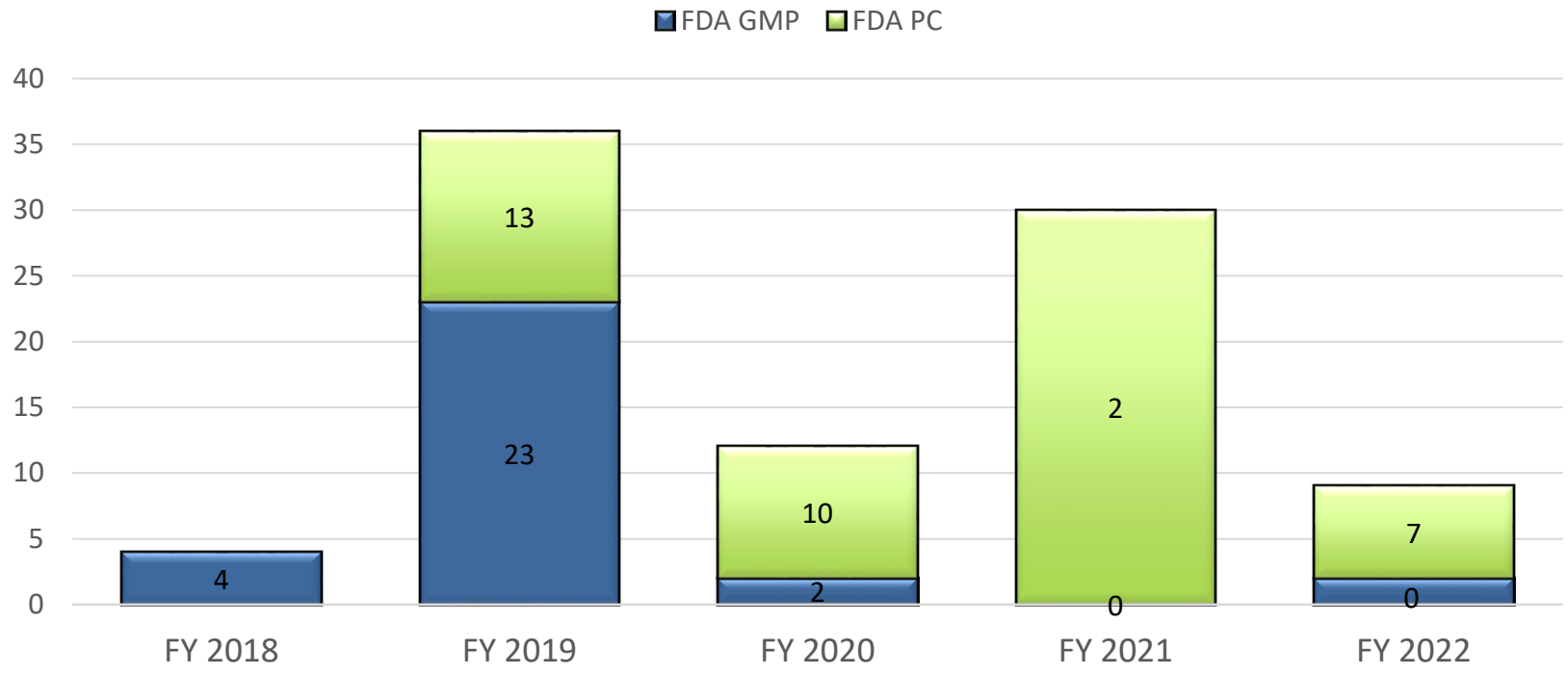
Foreign Inspections, FY 2018 – FY 2022
Preventive Controls for Human Food



Domestic Inspections, FY 2018 – FY 2022
Preventive Controls for Animal Food



Foreign Inspections, FY 2018 – FY 2022
Preventive Controls for Animal Food



FDA Data

Food-TRACK

- Preventive Controls and Imported Food Safety measures
- Additional measures in progress

- FDA Data Dashboard

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Welcome

Jason Wan, Institute for Food Safety and Health (IFSH)

Day 2 Conference Agenda

MORNING SESSION			
START	**END**	**SESSION**	**PRESENTERS**
9:00 AM	9:15 AM	Welcome Back! Review of Day 1	**Presenter:** Jason Wan
9:15 AM	9:45 AM	FSVP Update: Implementing FSVP in a Post-Pandemic World	**Presenter:** Selina Mata **Moderator:** Juan Silva
9:45 AM	10:30 AM	New Era of Food Safety	**Presenter:** Christopher J. Smith **Moderator:** Jennifer Thomas
10:30 AM	11:00 AM	FSPCA Products: What's Available and How to Use Them	**Presenters:** Jon Woody (IA), Kathy Gombas **Moderator:** Claudia Coles
MID DAY BREAK: LUNCH 11:00 – 11:45 AM / BREAKOUT SESSIONS 11:45 AM – 1:00 PM			
11:45 AM	1:00 PM	**FSVP Case Study:** The Real-World Implementation	**Experts:** Selina Mata, Bob Bauer **Moderator:** Hilary Thesmar **Scribe:** Dianne Milazzo
11:45 AM	1:00 PM	**PCHF Case Study:** The Real-World Implementation	**Experts:** Kathy Gombas, Lillian Hsu, Claudia Coles **Moderator:** Kathy Gombas **Scribe:** Ron Tanner

Day 2 Conference Agenda

AFTERNOON SESSION			
START	**END**	**SESSION**	**PRESENTERS**
1:00 PM	2:00 PM	What's New in the FSPCA Human and Animal Food Curricula	**Presenters:** Martin Bucknavage, Katherine Simon, David Fairfield **Moderator:** Kathy Gombas
2:00 PM	2:20 PM	Breakout Session Summaries from Days 1& 2	**Presenter:** Claudia Coles **Moderator:** Ron Tanner
2:20 PM	2:40 PM	Closing Remarks	**Presenter:** Brian Schaneberg

U.S. FOOD & DRUG ADMINISTRATION

Foreign Supplier Verification Programs (FSVP)

Presenter:

Selina Mata, Supervisory Consumer Safety Officer

Overview

- FDA Data Dashboard and TRACK
- Temporary use of UNK
- FSVP Remote inspections and RRAs
- FSVP Guidance for Industry

Enforcement Actions: Warning Letters

- Warning Letters issued = serious observations made; importer fails to comply
- Continued non-compliance after Warning Letter may result in placement on Import Alert
- FY19 - 1st Warning Letter issued
- FY20 – 45 Warning Letters issued
- FY21 – 58 Warning Letters issued
- FY22- approx 62 Warning Letters issued

Enforcement Action: Import Alert 99-41

- FSVP Import Alert 99-41 published on July 31, 2019
- Removal from IA 99-41 is non-traditional (i.e., private laboratory testing)
- Importer must demonstrate compliance through submission of documentation of corrective actions taken

FDA Data Dashboard

FDA Data Dashboard →

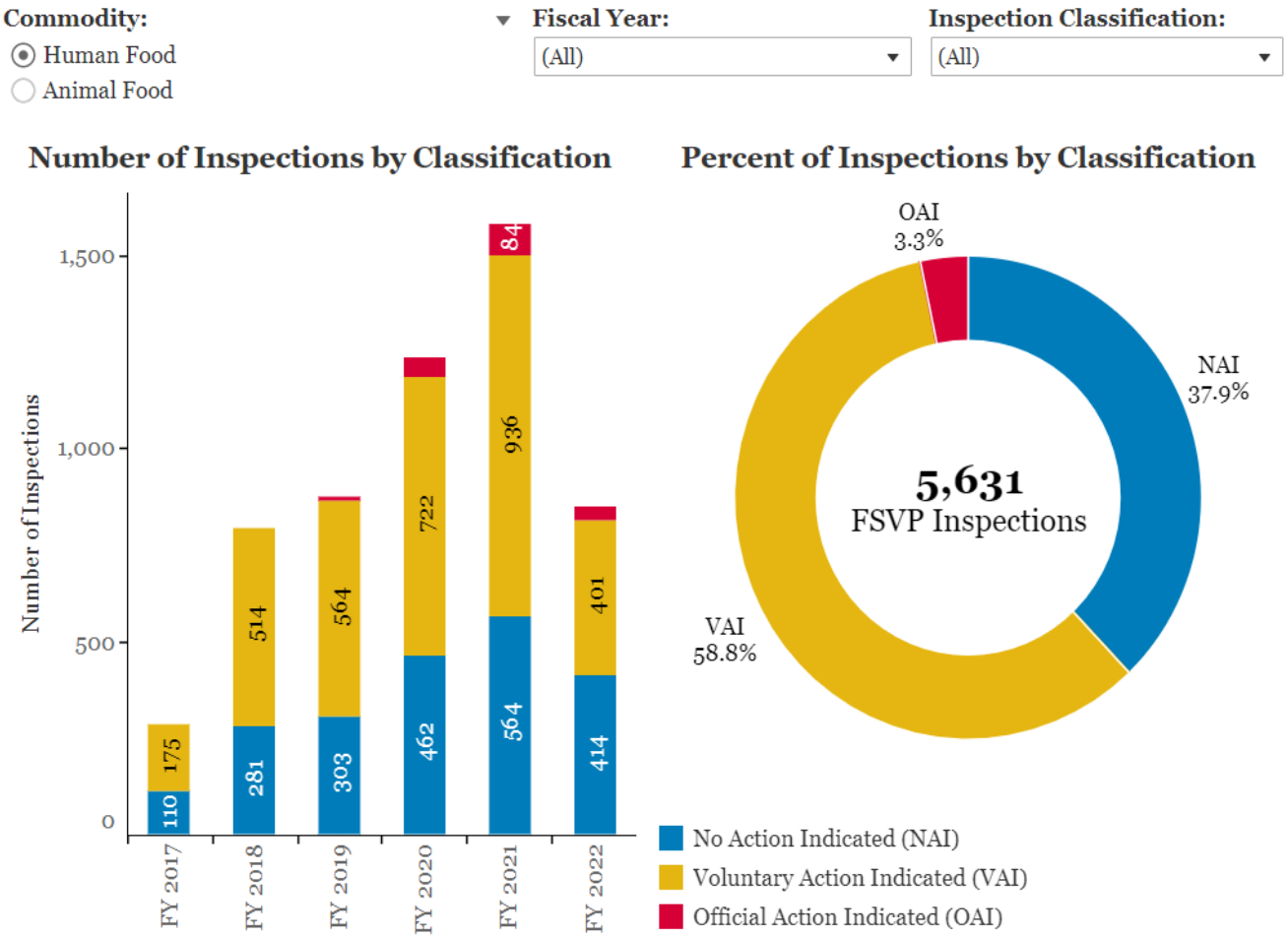
- External resource portal
- Intended for industry and stakeholder use
- Review compliance history of foreign supplier
- Determine approval and potential hazards

Firm/Supplier Evaluation Resources

The Firm/Supplier Evaluation Resources is:

- Located within the FDA Data Dashboard
- Used by importers and manufacturers/processors to perform evaluation for foreign supplier approval and compliance with FDA food safety regulations
- Compliance includes whether supplier is the subject of a warning letter, import alert, or other FDA compliance action (food safety)

Imported Food Safety Measures



https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/imported-food-safety-measures#3

Temporary Use of UNK

- Compliance with Providing an Acceptable UFI for the FSVP Regulation: GFI
  - Policy allowing temporary use of UNK. Updated Apr. 27, 2022
  - Developed to provide importers time to obtain DUNS
  - Avoid delays during entry process
- Importers must comply with section 1.509 (legal name, email address, and DUNS)

Industry Outreach: UNK

Outreach for impacted members of industry:

- April 2021: Monthly automated emails sent to FSVP importers and filers associated with UNK. Information includes:
  - Section 1.509 FSVP requirements
  - How to obtain a DUNS number
  - Potential repercussions for non-compliance
- Messages sent via CBP's CSMS- included 30 day notice before end- dating UNK
- Direct outreach to filers to encourage communication with FSVP importers to obtain or provide a DUNS

Remote FSVP Inspections

- April 3, 2020 – In response to COVID-19, FDA announced implementation of remote FSVP importer inspections
- Remote Regulatory Assessment vs. Remote FSVP Inspection
- Some situations have warranted an onsite inspection (i.e., foodborne illness outbreak)

Remote FSVP Inspections and RRAs

- Overall positive feedback received from both, FDA investigators and industry; examples include:
  - Convenient(i.e., elimination of travel)
  - Efficient (i.e., ability to conduct multiple inspections simultaneously)
  - Decrease in stress and intimidation factors

- What to expect moving forward

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

FSVP Guidance for Industry and other items

- Expected issuance date of February 2022
- Reminders for industry?
- How can we partner together?

Questions?

New Era of Food Safety

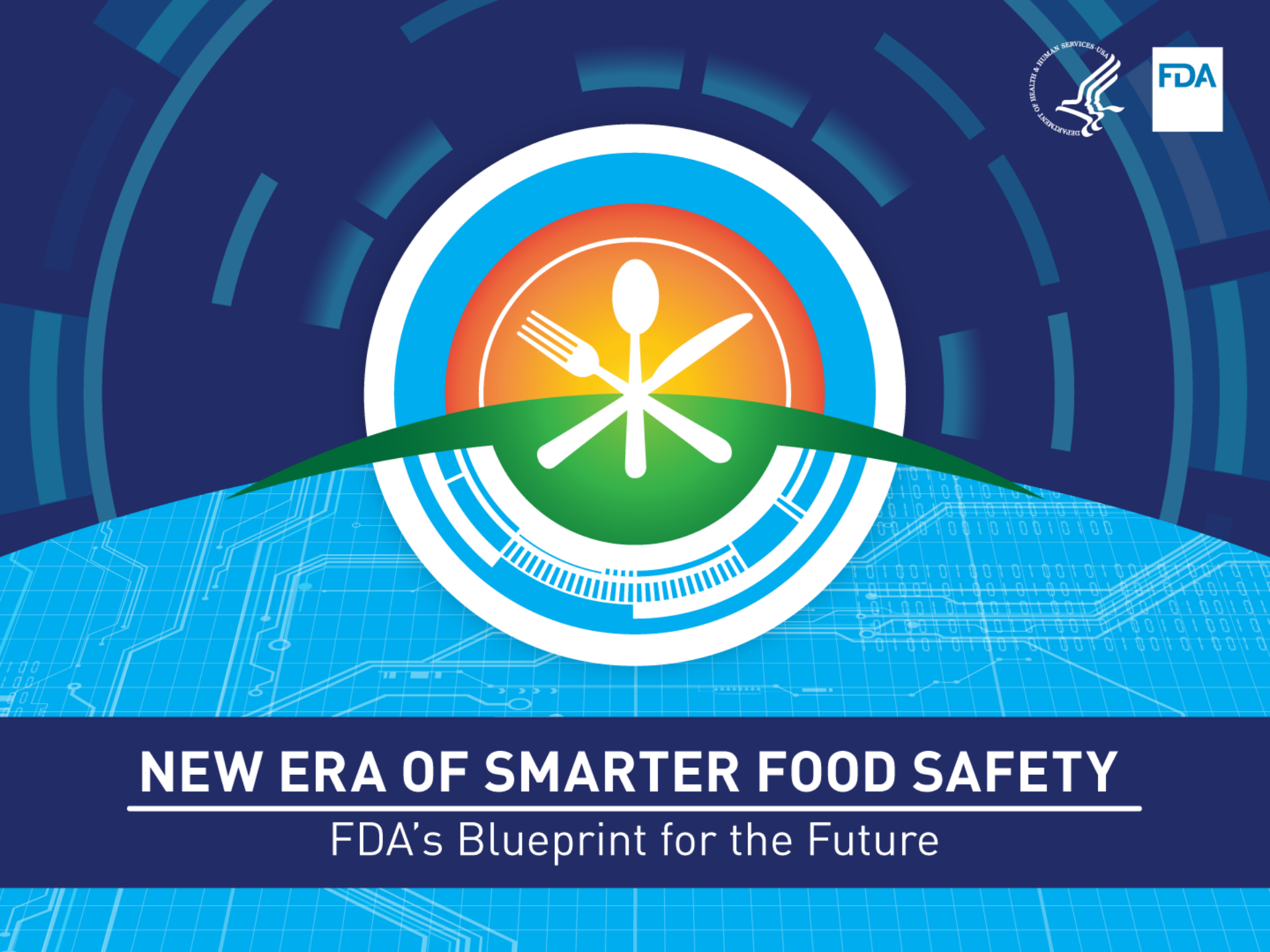
Christopher J. Smith, FDA Office of Food Policy and Response

Moderator: Jennifer Thomas, FDA CFSAN

New Era of Smarter Food Safety

FDA's Blueprint for the Future

Christopher J. Smith
Acting Senior Advisor for Policy
U.S. Food & Drug Administration
Office of Food Policy & Response


NEW ERA OF SMARTER FOOD SAFETY
FDA's Blueprint for the Future

Tech-enabled Traceability

Smarter Tools and Approaches for Prevention and Outbreak Response

Welcome to FDA's New Era of Smarter Food Safety

New Business Models and Retail Modernization

Food Safety Culture

Tech-Enabled Traceability

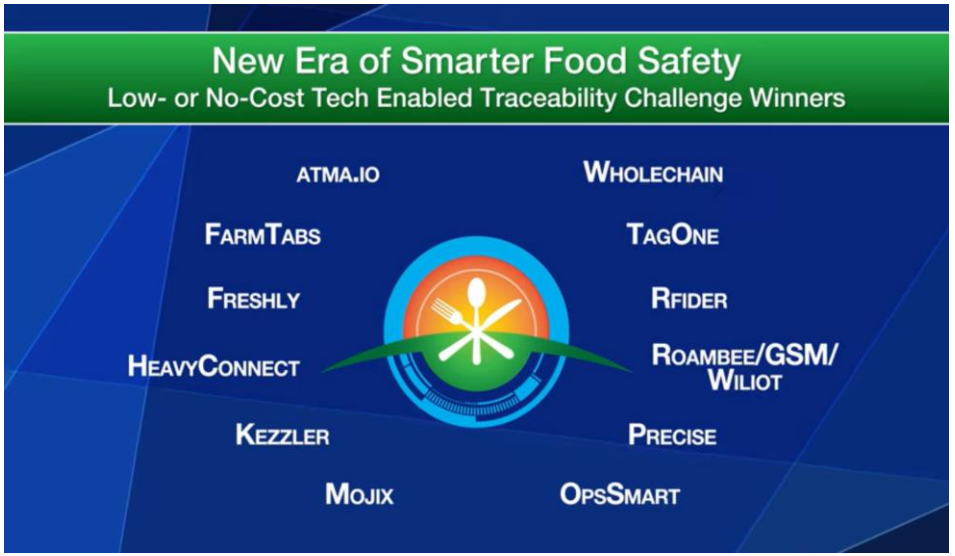
Tech-Enabled Traceability

1.1 Develop Foundational Components

1.2 Encourage & Incentivize Industry Adoption of New Technologies

1.3 Leverage the Digital Transformation

Low or No Cost Tech Enabled Traceability Challenge



https://www.fda.gov/food/new-era-smarter-food-safety/meet-winners-fdas-low-or-no-cost-food-traceability-challenge

FDA Tech Talk on Traceability

TechTalk Podcast Episode 1: Tech-enabled Traceability in the New Era of Smarter Food Safety

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From left to right: Angela Fernandez (GS1 US); Alison Grantham, Ph.D. (IFT); Hilary Thesmar, Ph.D., RD, CFS (FMI)

Content current as of:
04/29/2021

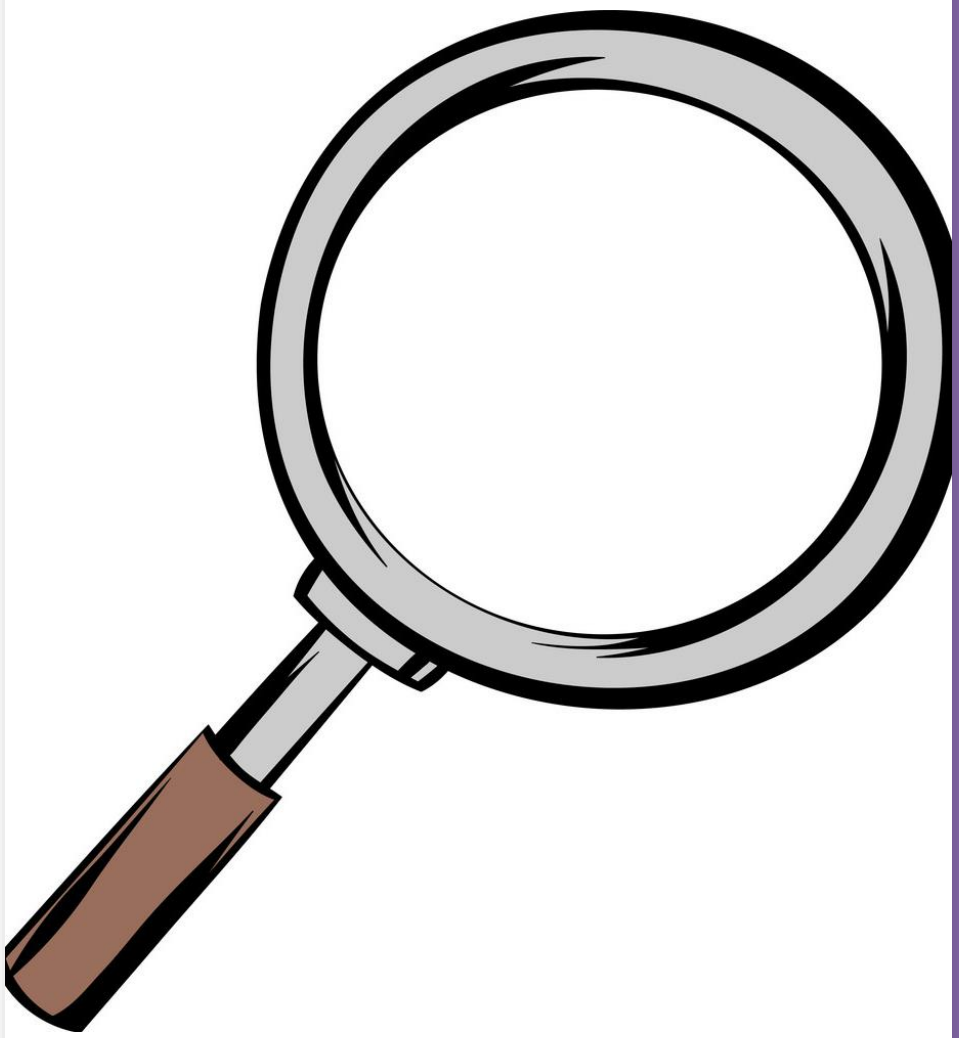
Regulated Product(s)
Food & Beverages

https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-techtalk-podcast

Smarter Tools and Approaches for Prevention and Outbreak Response

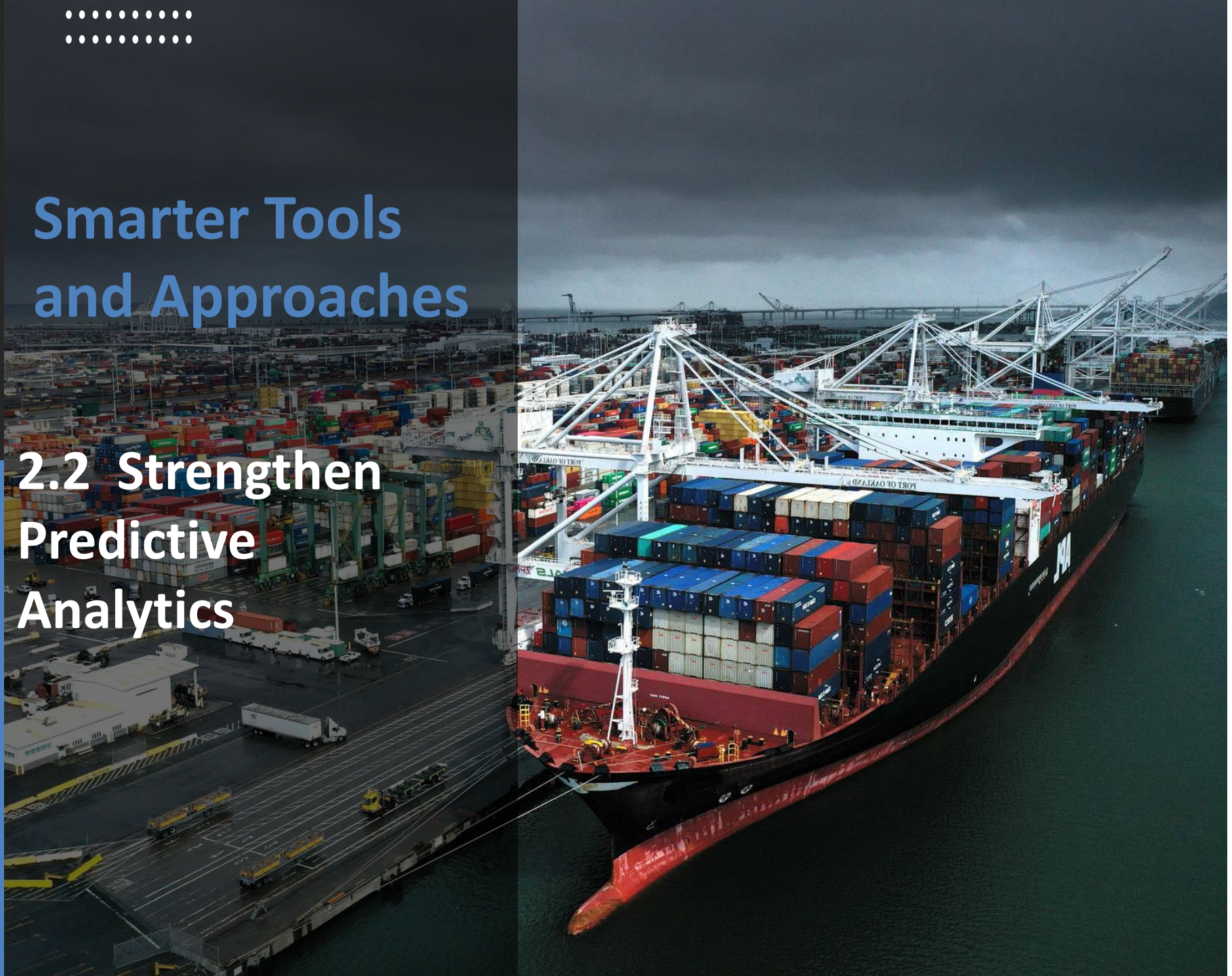
Smarter Tools and Approaches

2.1 Invigorate Root Cause Analyses



Smarter Tools and Approaches

2.2 Strengthen Predictive Analytics



[The FDA Moves into Third Phase of Artificial Intelligence Imported Seafood Pilot Program | FDA]

FDA Tech Talk on Artificial Intelligence

TechTalk Podcast Episode 3: Artificial Intelligence in the New Era of Smarter Food Safety

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TechTalk Podcast Main Page

From left to right: Cronan McNamara (Creme Global), Maria Velissariou (Global Corporate Research & Development), Nikos Manouselis (Agroknow)

Content current as of:
03/21/2022

Regulated Product(s)
Food & Beverages

https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-techtalk-podcast

FDA Tech Talk on Artificial Intelligence

TechTalk Podcast Episode 4: Data Exchange in the New Era of Smarter Food Safety

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TechTalk Podcast Main Page

From left, Jennifer Pierquet (AFDO); Kristen Lozinak (Maryland Department of Health); Phillip Fruechting (Arkansas Department of Health)

TechTalk Podcast Episode 4: Data Exchange in the New Era of Smarter Food Safety | FDA

Smarter Tools and Approaches

2.3 Domestic Mutual Reliance

Smarter Tools and Approaches

2.4 Inspection, Training, and Compliance Tools

Smarter Tools and Approaches

2.5 Outbreak Response

Foodborne Outbreak Response Improvement Plan

Webinar Recording

https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-foodborne-outbreak-response-improvement-plan-04132022

New Era of Smarter Food Safety: FDA's Foodborne Outbreak Response Improvement Plan

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Tackling foodborne outbreaks faster and revealing the root cause are essential for the prevention of future outbreaks. We have a plan to do that.

Foodborne disease remains a significant public health problem in the United States. The FDA's Foodborne Outbreak Response Improvement Plan (FORIP), described in this document, is an important step that the FDA is taking to enhance the speed, effectiveness, coordination, and communication of outbreak investigations. (Unless stated otherwise, this report focuses exclusively on the response to human food and not animal food.)

- New Era of Smarter Food Safety: FDA's Foodborne Outbreak Response Improvement Plan (PDF: 902KB)

Content current as of:
03/23/2022

Regulated Product(s)
Food & Beverages

https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-fdas-foodborne-outbreak-response-improvement-plan

Prevention Strategies

FDA Releases New, Prevention Strategies to Enhance Food Safety

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FDA Voices

Content current as of:
10/13/2022

Regulated Product(s)
Food & Beverages

[FDA Releases New, Prevention Strategies to Enhance Food Safety | FDA]

Smarter Tools and Approaches

2.6 Recall Modernization

← **Thread**

U.S. FDA Recalls ✓
@FDArecalls

The Enforcement Report Subscription Service enables consumers/industry to sign up for e-mail alerts using keywords for new/updated #recalls. Subscribe TODAY to help protect #PublicHealth!
accessdata.fda.gov/scripts/ires/i...

10:09 AM · Sep 27, 2022 · Twitter Web App

1 Retweet **1** Like

[Enforcement Reports | FDA]

New Business Models and Retail Modernization

New Business Models and Retail Modernization

3.1 Ensure Safety of Food Produced or Delivered Using New Business Models

Online Share of

Grocery Basket

retail grocery

80%

20

online grocery

By **2023**, could reach

$100 Billion

annually

Source: The Digitally Engaged Consumer, FMI & Nielsen

New Business Models and Retail Modernization

3.2 Modernize Traditional Retail Food Safety Approaches

Modernizing through Partnership

The Collaborative

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

FDA U.S. FOOD & DRUG ADMINISTRATION

NACCHO
National Association of County & City Health Officials

AFDO
CONNECT · SHARE · PROTECT · IMPACT

PROMOTING FOOD SAFETY THROUGH COLLABORATION

NATIONAL ENVIRONMENTAL HEALTH ASSOCIATION

Members of these organizations make up the
Retail Food Safety Regulatory Association Collaborative.

[Home - Retail Food Safety Collaborative]

Food Safety Culture

Food Safety Culture

4.1 Promote Food Safety Throughout the Food System

Food Safety Culture

4.2 Further Promote Food Safety Throughout the Agency

Food Safety Culture

4.3 Develop and Promote a Smarter Food Safety Consumer Education Campaign

Webinar Series

Promote and discuss best practices, gaps, opportunities in improving food safety culture

Webinar Series

[About our Food Safety Culture Webinar Series - Stop Foodborne Illness]

For more information:

- www.fda.gov/SmarterFoodSafety
  - Subscribe to Updates
- Contact us: smarterfoodsafety@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION



FSPCA Products: What's Available and How to Use Them

Kathy Gombas, FSPCA Executive Advisory Board

Jon Woody, FDA CFSAN

Moderator: Claudia Coles, Seafood Products Association

FSPCA Training Offered by FSPCA-trained Lead Instructors

	Instructor Led			
FSPCA Participant Courses	**In-person, live**	**Virtual-online, web based live**	**Blended Course Part 2 Instructor Led**	**Asynchronous: 100% online, self-paced**
Preventive Controls for Human Food	X	X	X	X
Preventive Controls for Animal Food	X	X	X	
Foreign Supplier Verification Programs	X	X	X	X
Intentional Adulteration Vulnerability Assessments	X	X		

FSPCA Participant Courses

Registered and Approved Public Participant Courses
https://fspca.force.com/FSPCA/s/courselist?language=en_US

- Course Type
- Lead Instructor Name
- Course Date
- Web Address to Register
- Cost
- Address
- Language, e.g., English, Spanish
- Format, e.g., virtual-online, web based live

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FSPCA Preventive Controls for Human Food

Materials and Resources

- Participant Course Manuals
  - FSPCA PCHF Course Participant Manual V1.2 (English)
    - **Hardcopy:** Available on the FSPCA Bookstore and Amazon Bookstore
  - FSPCA PCHF Course Participant Manual V1.2 (Chinese)
  - FSPCA PCHF Course Participant Manual V1.2 S1 (Spanish)
    - **Hardcopy:** Available on the Amazon Bookstore

FSPCA Preventive Controls for Human Food

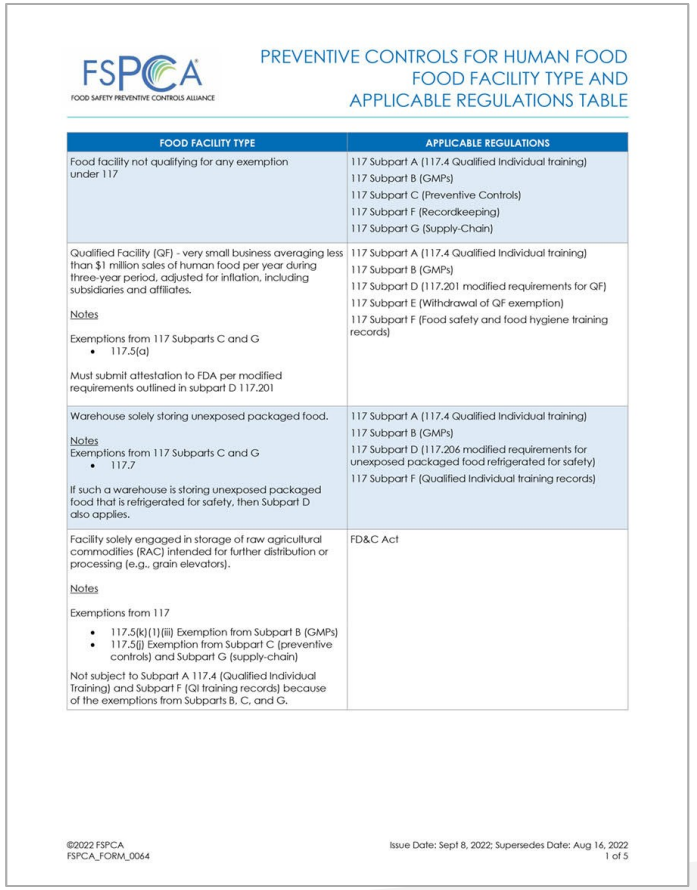
Materials and Resources

- PCHF Workaids - forms that help a PCQI develop a food safety plan & recall plan
  - Food Safety Plan Worksheets - Fillable PDF, Word Document
  - Recall Plan Template

- PCHF Food Facility Type and Applicable Regulations Table (FSPCA FORM_0064) - a valuable resource for determining which regulations and subparts of 21 CFR 117 are applicable to a specific food facility type

PCHF Food Facility Type and Applicable Regulations Table *(FORM_0064)*

- Updated Oct 7, 2022
- Available on FSPCA website and PCHF Lead Instructor Portal
- PDF can be shared with course participants



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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 Qualified Individual training) 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 Qualified Individual training) 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 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart D (117.206 modified requirements for unexposed packaged food refrigerated for safety) 117 Subpart F (Qualified Individual 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) Not subject to Subpart A 117.4 (Qualified Individual Training) and Subpart F (QI training records) because of the exemptions from Subparts B, C, and G.	FD&C Act

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Issue Date: Sept 8, 2022; Supersedes Date: Aug 16, 2022
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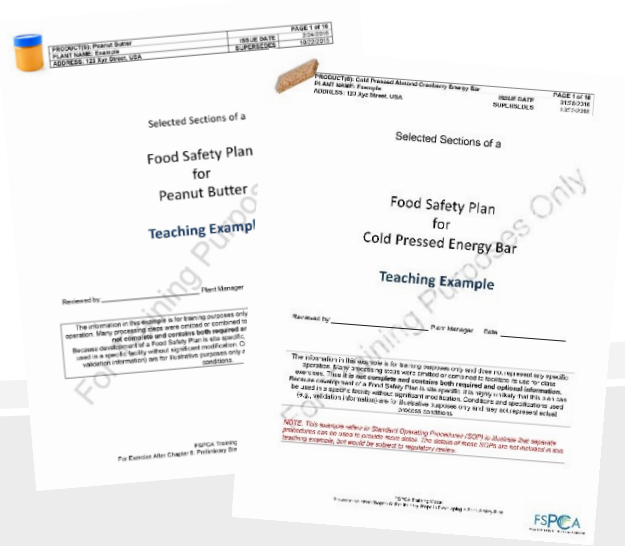
FSPCA Food Safety Plan Teaching Examples

Available on [PCHF Lead Instructor Resource Portal]

- Peanut Butter
- Cold Pressed Energy Bar
- Ground Black Pepper
- Broccoli, Carrot, Pecan Salad
- Fettuccini Marinara with Broccoli
- Pepper Jack Cheese
- Fresh Blueberries
- Mature Green Round Tomatoes
- Leafy Greens Salads

- Submit new teaching examples to FSPCA for approval to be added to PCHF Lead Instructor Resource Portal
  - FSPCA Guidelines for Industry-specific Food Safety Plan Teaching Examples
  - FSPCA Food Safety Plan Template



FSPCA Preventive Controls for Animal Food

Materials and Resources

- Participant Course Manuals
  - FSPCA PCAF Course Participant Manual V1.1 (English)
    - **Hardcopy:** Available on the FSPCA Bookstore and Amazon Bookstore
  - **NEW!** FSPCA PCAF Course Participant Manual V1.1 (Spanish)
    - **Hardcopy:** Available on the Amazon Bookstore

- FSPCA Guide for Creating a Livestock Food Safety Plan

- Current Good Manufacturing Practices for Animal Food Online Course

FSPCA Foreign Supplier Verification Programs

Materials and Resources

- Participant Course Manual
  - FSPCA FSVP Course Participant Manual V1.1 (English)
    - **Hardcopy:** Available on the FSPCA Bookstore and Amazon Bookstore

- FSVP Awareness Module for Foreign Suppliers (English)

FSPCA Foreign Supplier Verification Programs

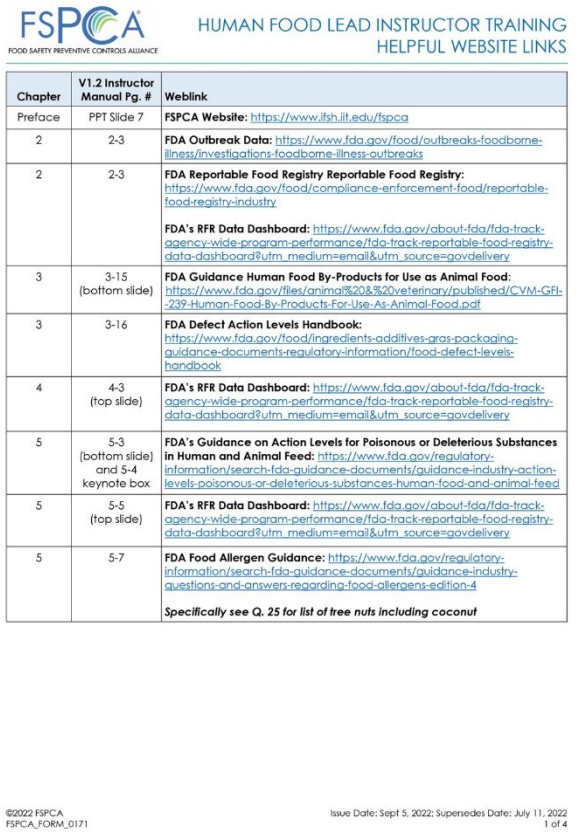
Materials and Resources

- FSVP Workaids – forms that can help an FSVP Importer develop an FSVP
  - **Workaid A:** Determining the FSVP Importer (PDF) (Word)
  - **Workaid D:** FSVP Hazard Analysis Form Example (PDF) (Word)
  - **Workaid E:** FSVP Foreign Supplier Evaluation Form Example (PDF) (Word)
  - **Workaid F:** FSVP Foreign Supplier Performance/Food Product Approval Worksheet Example (PDF) (Word)
  - **Workaid G:** FSVP Foreign Supplier Reevaluation Form Example (PDF) (Word)

Lead Instructor Resources

Lead Instructor Resource Portal

- Materials for hosting your participant courses
- **UPDATED!** FSPCA Course Advertising Requirements for Lead Instructors
  - Referencing certification in your advertisement – FSPCA courses are not certification courses
- **NEW!** PCHF Lead Instructor Website List for Participant Courses (FSPCA FORM 0171)



FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

HUMAN FOOD LEAD INSTRUCTOR TRAINING
HELPFUL WEBSITE LINKS

Chapter	V1.2 Instructor Manual Pg. #	Weblink
Preface	PPT Slide 7	**FSPCA Website:** https://www.ifsh.iit.edu/fspca
2	2-3	**FDA Outbreak Data:** https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks
2	2-3	**FDA Reportable Food Registry Reportable Food Registry:** https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry **FDA's RFR Data Dashboard:** https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard?utm_medium=email&utm_source=govdelivery
3	3-15 (bottom slide)	**FDA Guidance Human Food By-Products for Use as Animal Food:** https://www.fda.gov/files/animal%20&%20veterinary/published/CVM-GFI-239-Human-Food-By-Products-For-Use-As-Animal-Food.pdf
3	3-16	**FDA Defect Action Levels Handbook:** https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook
4	4-3 (top slide)	**FDA's RFR Data Dashboard:** https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard?utm_medium=email&utm_source=govdelivery
5	5-3 (bottom slide) and 5-4 keynote box	**FDA's Guidance on Action Levels for Poisonous or Deleterious Substances in Human and Animal Feed:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed
5	5-5 (top slide)	**FDA's RFR Data Dashboard:** https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard?utm_medium=email&utm_source=govdelivery
5	5-7	**FDA Food Allergen Guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4 ***Specifically see Q. 25 for list of tree nuts including coconut***

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Issue Date: Sept 5, 2022; Supersedes Date: July 11, 2022
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IA Rule Training, Education, Experience

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under subpart C of this part, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, and employee of the establishment.

Guidance: Education, Training, or Experience

FSPCA Training Course	Delivery Method	Intended Audience
Food Defense Awareness	Online Training	• 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)
Overview of IA Rule	Online Training	• Any stakeholder interested in learning more about the IA rule requirements • This course is not associated with any IA rule training requirement

Food Defense Qualified Individuals

- Preparation of the FDP
- Conduct of the VA
- Identification and explanation of mitigation strategies
- Performance of the reanalysis

"You have flexibility to determine how many and which people will be food defense qualified individuals at your facility."

Guidance: Education, Training, or Experience

FSPCA Training Course*	Delivery Method	Intended Audience – Food Professionals who do the following:
Conducting Vulnerability Assessments (VAs) using Key Activity Types (KAT)	Online Training	• Conduct VAs using the KAT Method only
Conducting Vulnerability Assessments (IAVA)	Live, Instructor-led	• Conduct VAs using the 3 Fundamental Elements • This 1-day course must be taught by trained FSPCA VA Lead Instructors
Identification and Explanation of Mitigation Strategies	Online Training	• Identify Mitigation Strategies to implement at Actionable Process Steps
Food Defense Plan Preparation and Reanalysis	Online Training	• Prepare the Food Defense Plan • Conduct Reanalysis activities

**These courses satisfy the requirements in §121.4 of the IA rule*

Food Defense Qualified Individuals

"We are not establishing minimum standards for competency and do not intend routinely to directly assess qualifications of persons who function as the food defense qualified individual, whether by training or job experience. Instead, we intend to focus our inspections on the *adequacy of the food defense plan*."

FSPCA Intentional Adulteration

Materials and Resources

- FSPCA IA Training Cheat Sheet
- Participant Course Manual
  - FSPCA Conducting Vulnerability Assessments Participant Course Manual v1.0 (Public Version) – pdf on FSPCA website
    - **Hardcopy:** Available on the FSPCA Bookstore and Amazon Bookstore
  - FSPCA Conducting Vulnerability Assessments Exercise Workbook v1.0
    - **Hardcopy:** Available on the FSPCA Bookstore and Amazon Bookstore
- FSPCA IA Online Course PDFs

Version 2.0

Breakout Sessions

Breakout Room 1

FSVP Case Studies: Real-World Implementation

- **Experts:** Selina Mata, Bob Bauer
- **Moderator:** Hilary Thesmar
- **Scribe:** Dianne Milazzo

Breakout Room 2

PCHF Case Studies: Real-World Implementation

- **Experts:** Kathy Gombas, Lillian Hsu, Claudia Coles
- **Moderator:** Kathy Gombas
- **Scribe:** Ron Tanner

Breakout Sessions begin at 11:45 AM and end promptly at 1:00 PM CDT




FSVP Case Studies

Expert: Selina Mata, FDA ORA
Expert: Bob Bauer, AFI
Moderator: Hilary Thesmar, FMI
Scribe: Dianne Milazzo, FDA CVM

SCENARIO 1

Perpetual French

- Very Small Importer (VSI)
- Imports French inspired foods (i.e., chocolates, liquors, beef jerky) from supplier, Bleu Chateau
- Packaged individually in cellophane bags & 5-10 randomly selected foods are placed in boxes prior to importation to VSI for distribution to paying subscribers
- Contents of subscription boxes vary each month; same products are not consistently imported; small amounts imported
- Average annual sales: $1.3 million

Very Small Importer

- May choose to comply w/ modified FSVP requirements under 21 CFR 1.512 if importer meets definition of VSI
- Importer averaging <$1 million/yr., adjusted for inflation, during the 3-yr period preceding the applicable calendar yr., in sales of human food + the U.S. market value of human food imported, manufactured, processed, packed, or held w/o sale.

Question: Does Perpetual French meet the definition of a very small importer? Why or why not?

SCENARIO 1

- Answer: No, Perpetual French does not meet the definition of a very small importer
- Sales calculations to determine eligibility to importer as a very small importer must include all human foods, including:
  - Foods that are imported, manufactured, processed, packed, or held by all subsidiaries and affiliates regardless of what U.S. food safety regulations the food is subject to (i.e., Preventive Controls and Produce Safety regulations)
  - Alcoholic beverages, dietary supplements, fish and fishery products, juice
  - Raw agricultural commodities, grains, milk, raw milk, shell eggs
  - Foods under USDA jurisdiction (i.e., certain meat and egg products)
- Very small importers of human foods will not include animal foods or other products that are not human food in the sales calculation

SCENARIO 2

Integral Imports

- Buys many products from many suppliers around the world.
- Dutiful Distributors, based in Germany, supplies, from various manufacturers, a handful of products to Integral.
- Dutiful Distributors collects all the needed food safety documentation.
- Some items require temperature control and are stored at Dutiful's warehouse.
- Dutiful Distributors collects and reviews the required food safety information and has temperature control records for all products with that issue. Dutiful Distributors informs the importer to list it as the foreign supplier on all products it provides.

Question 1: Does Dutiful Distributors meet the definition of a foreign supplier for any, some or all of the products?

Question 2: What documentation does the FSVP importer need and from which entity(ies)?

Question 3: What problems might the FSVP importer encounter in terms of document collection?

SCENARIO 2

Answer 1: No. Dutiful Distributors does not meet the definition of a foreign supplier because it is not 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.

Answer 2: The FSVP importer needs the same documentation it would collect as if it was importing directly from the foreign supplier. In short, it needs all information related to the preventive control plan and the verification steps it calls for. Integral still needs to review and assess all information it receives from this and any other entity.

Answer 3: The FSVP importer needs to educate Dutiful Distributors about the definition of foreign supplier. To protect its relationship with its suppliers and keep Integral and others from buying direct, Dutiful might not want to share the food safety documentation. It's among the tough conversations it'll take for Integral to properly handle its FSVP requirements. Assuming Dutiful agrees, it's in the best position to (continue to) collect the food safety documentation.

SCENARIO 3

Yum Yum Teas, Taiwan

- Headquarters based in Taiwan; allows for U.S. entities to purchase franchise
- Maintains >100 franchises; indicates each responsible for complying w/FSVP
- Average annual sales: $2.2 million

Yum Yum Teas, USA (Franchise)

- Yum Yum Teas USA claims to meet the definition of VSI based on sales for previous 3 years
- Provided tax records and supplier written assurances, but no eligibility records
- Average annual sales: $765,000

Question 1: Was the investigator correct in conducting the inspection against the standard FSVP requirements? Why or why not?

Question 2: Can a franchisee meet the definition of "very small importer" even if the franchisor company is not a very small importer?

SCENARIO 3

- Very small importers must consider their sales as well as sales of any subsidiaries and affiliates to determine eligibility
- If franchisor is neither same business entity as franchisee, affiliate or subsidiary, the franchisee would not consider franchisor's sales when calculating average sales during applicable 3-yr period
- Thus, it is possible that a franchisee can be a very small importer even if the franchisor is not a very small importer
- If franchisee and franchisor are the same business entity, affiliate, or subsidiary, the franchisee would include franchisor operations in sales calculation
- Answer 1: No, the importer chose to comply with section 1.512 and meets the definition of a very small importer
- Answer 2: Yes, in this scenario, the franchisee and franchisor are separate entities, so the franchisee meets the definition of a very small importer

SCENARIO 4

Roundabout Imports

- Mega Manufacturer, with offices and facilities in the U.S., also has production facilities in other countries.
- Double Distribution doesn't buy directly from Mega.
- Roundabout Imports buys Mega's product from Double Distribution.
- Roundabout is the FSVP importer.

Question 1: How can Roundabout meet its FSVP responsibilities?

Question 2: What problems might the FSVP importer encounter in terms of document collection?

Question 3: Any advice to Mega on how to avoid this scenario?

SCENARIO 4

Answer 1: It's unlikely Roundabout will be able to comply; in order to do so, it will need Mega's food safety information.

Answer 2: To comply with the FSVP regulation, Roundabout would need Double Distribution to get all of the needed information from Mega Manufacturer – or get it directly from Mega. That's unlikely to happen because there's almost no change Mega will provide that.

Answer 3: Mega has to educate anyone it sells to about the FSVP requirements and put everything in writing in contracts, etc. The regulation might actually help Mega tighten its distribution by eliminating these resellers.

SCENARIO 5

Animal Pet Favorite Treats, LLC

- Imports dog and cat treats (i.e., biscuits, semi-moist morsels, dried beef, lamb, & chicken jerky)
- Suppliers located in Canada or Australia
- Some treats are imported in bulk for repacking in U.S.; some are imported in final packaging for retail sale at pet stores in U.S.
- Average annual sales: $5 million
- FSVPI claims to meet modified requirements under section 1.513 because foods are included in systems recognized agreements w/ Canada and Australia
- No FSVP for jerky treats; USDA jurisdiction

Question 1: Does this animal food FSVPI, Animal Pet Favorite Treats, LCC, fall under the system recognized agreement? Why or why not?

Question 2: Does the jerky fall under USDA jurisdiction? Why or why not?

Question 3: Is there anything else that you must consider when looking at animal food products going for further processing?

SCENARIO 5

Answer 1: No, imported products are animal food, which do not have any system recognized agreements. FSVPI must develop, maintain, and follow an FSVP to provide adequate assurances that the foreign supplier is producing a food in compliance with processes and procedures w/applicable food safety regulations. Products not undergoing further processing are subject to the FSVP

Answer 2: No, although some products are dried meat treats, they are not exempt from FSVP. These animal foods are not under the jurisdiction of the USDA and should be included in the FSVP.

Answer 3: Yes, the FSVPI receives some products that will be further processed (repackaged) at a receiving facility and would be deemed in compliance with FSVP if they meet one of the following:

- Implemented preventive controls for the hazards in the food in accordance with preventive control requirements (507.34)
- Followed the customer provisions in 507.36 or
- Established and implemented a risked-based supply chain program as a supply-chain-applied control has been identified by the facility (21 CFR 507 Subpart E).

SCENARIO 6

International Imports

- International Imports, an FSVP importer, buys many products from many suppliers around the world.
- One of its suppliers says its products are FDA-certified.
- One of its customers says it will accept only FDA-certified products.

Question 1: What's the likelihood of the supplier's products being FDA-certified?

Question 2: Is it likely the customer will get FDA-certified product?

Question 3: How is all this going to be worked out?

SCENARIO 6

Answer 1: Almost nil. It's very likely a case of the supplier thinking that because its facility is registered with FDA that it's FDA-certified.

Answer 2: No. In this case, it's likely the customer has heard about but doesn't really understand the Voluntary Qualified Importer Program, so it thinks FDA-certified product is something an importer can easily arrange.

Answer 3: Communication! In order to do FSVP compliance correctly, FSVP importers have to have educate all other entities in their supply chain about the requirements and they often have to correct misinterpretations by those entities. The FSVP importer must be proactive; doing so will reduce the chance of any misunderstandings – which often lead to delays and/or added costs.

SCENARIO 7

Tasty Imports

- Tasty Imports buys many products from several suppliers around the world.
- It hears about the FSPCA FSVP training.
- It also receives something from a vendor that says "The FSMA-FSVP Certification program consists of three levels: Level 2 (Basic), Level 2 (Enhanced), and Level 2 (Advanced)."
- Tasty Imports' owner decides to have its traffic manager/quality control person take the FSPCA course.
- After receiving the certificate for completing the course, the attendee asks the instructor about the levels listed above.

Question 1: Individual reaches out to FSPCA instructor and says, "I'm certified but at what level?" What's the reply?

Question 2: How might this question be avoided?

SCENARIO 7

Answer 1: Almost nil. It's very likely a case of the supplier thinking that because its facility is registered with FDA that it's FDA-certified.

Answer 2: Since certification questions and misunderstandings are somewhat prevalent, instructors might need to spend a little more time explaining certifications – and the lack thereof.




BREAKOUT SESSION: PCHF CASE STUDIES

Expert: Kathy Gombas, FSPCA Executive Advisory Board

Expert: Lillian Hsu, FDA CFSAN

Expert: Claudia Coles, Seafood Products Association

Scribe: Ron Tanner, Tanner Food Group

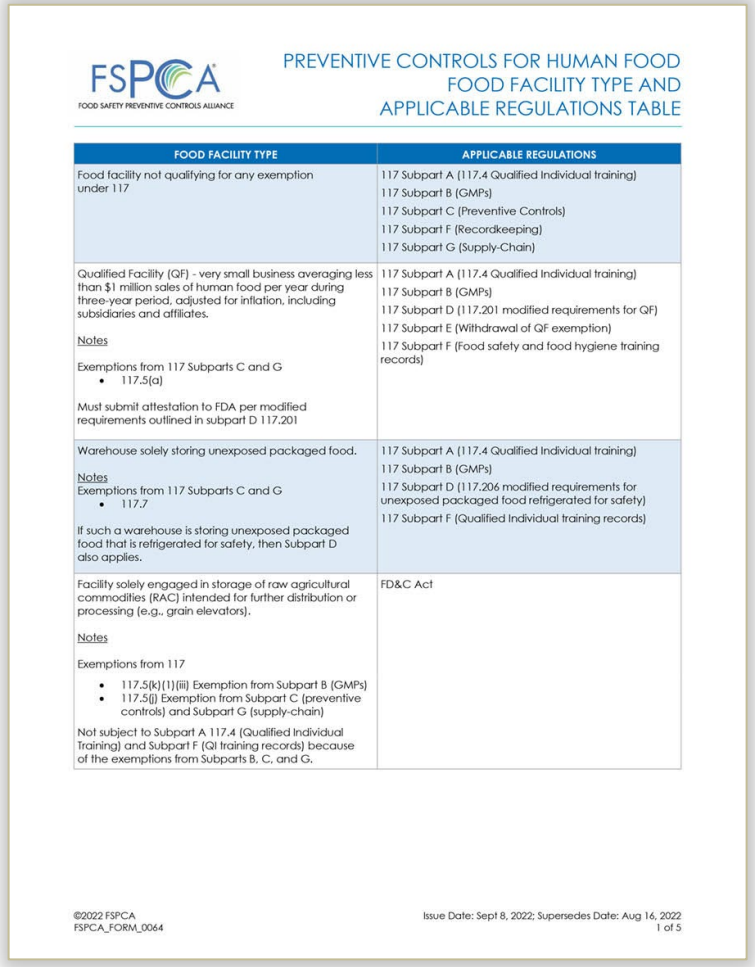
To Whom do 21 CFR 117 Subparts Apply?

Subpart A	117.4 Qualified Individual Training
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)

PCHF Food Facility Type and Applicable Regulations Table (FORM_0064)

- Updated Oct 7, 2022
- Available on FSPCA website and PCHF Lead Instructor Portal
- Post in the chat



PREVENTIVE CONTROLS FOR HUMAN FOOD
FOOD FACILITY TYPE AND
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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) Not subject to Subpart A 117.4 (Qualified Individual Training) and Subpart F (QI training records) because of the exemptions from Subparts B, C, and G.	FD&C Act

FSPCA_FORM_0064

Issue Date: Sept 8, 2022; Supersedes Date: Aug 16, 2022
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SCENARIO 1

PBnJay Corporation

- Processing facility located on berry farm in Lehigh Acres, FL
- Manufacturer of fruit juice-based jellies, sugar-free jellies, peanut butter, cashew butter, and sunflower seed butter
- No related companies
- Incoming raw materials for the various butters are received through interstate commerce including the jars and lids
- Incoming raw materials for the jelly products are sourced locally including the jars and lids
- Distribution of jelly and butter products to retailers in AL and MS
- Total sales $800,000 annually

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

- Very small farm mixed-type facility averaging < $1 million sales of human food per year during three-year period, adjusted for inflation
- Does not get 117.5(h)(3) exemption b/c not conducting low-risk manufacturing/processing activity/food combinations
- Subject to modified PC requirements outlined in 21 CFR 117.201 (Subpart D) (submitting attestations to FDA)

SCENARIO 2

Healthy Food Markets, Inc.

- Central Kitchen in Oakland, CA
- Produces variety of nut butters and sliced produce items
- Distribution to 3 company-owned retail stores in Bay Area
- The Central Kitchen has 50 full-time employees and 30 part-time employees
- Total employees at Corporate, the Central Kitchen and 3 stores equal 512 FTEs
- Company human food sales including all retail human food sales is > $5,000,000 annually

21 CFR 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	

Central Kitchen is a Food Facility

- Central Kitchen is subject to 117 including Subparts C and G. It is NOT a qualified facility.
- Does not meet definition of very small business averaging < $1 million sales of human food per year during three-year period, adjusted for inflation (including any subsidiaries and affiliates)
- Does not meet definition of small business, a business (including any subsidiaries and affiliates) employing fewer than 500 FTE employees

SCENARIO 3

The People's Pickled Peppers

- Cooperative company in Pittsburgh, PA
- Produces variety of pickled peppers, packaged in glass jars
- Raw peppers are received from growers in CA
- Distribution to supermarkets throughout Midwest U.S.
- Sales of pickled peppers > $5,000,000 annually

21 CFR 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	

Acidified Food Processor

- 21 CFR 108/114 are regulations specific to Acidified Foods
- No exemptions from any subparts of 117

SCENARIO 4

PNW Fish Company LLC

- Seafood company in Seward, AK
- Produces salmon fillets, and fishmeal and fish oil from fish by-products
- Sockeye salmon received from harvesters in AK
- Distribution of salmon fillets to restaurants and supermarkets throughout U.S.
- Fish oil is distributed to a co-packer to be encapsulated as a dietary supplement
- Fishmeal is distributed for Animal Food use

21 CFR 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

Fish fillets and fish oil

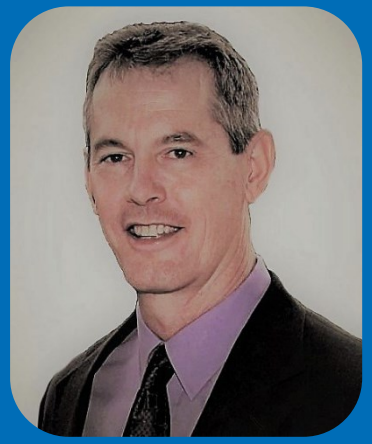
- 21 CFR 123: Fish and Fishery Products
- 21 CFR 117: Subparts A, B, and F

Fishmeal for animal food

- 21 CFR 507 (cGMP & PC): regulation specific to Animal Foods
  - PNW Fish Company may choose to follow GMPs in either Part 117 or Part 507

CLOSING






What's New in the FSPCA Human and Animal Food Curricula

Martin Bucknavage, Penn State University
Katherine Simon, Minnesota Department of Agriculture
Dave Fairfield, National Grain and Feed Association (NGFA)
Moderator: Kathy Gombas, FSPCA Executive Advisory Board

Update of FSPCA Preventive Controls for Human Foods

Goals for Updated Version

- Address new regulatory guidance including the FDA Hazards Draft Guidance
- Reflect updated information, update references, e.g., RFR, CDC
- Streamline sections, reduce redundancy
- Support development of key concepts
- Increase small- and mid-sized producer applications
- Gain recognition as an approved HACCP-based curriculum

Recognition as HACCP-based Curriculum

The course materials will:

- State this is a HACCP-based curriculum
- Show the development of PCHF from the traditional HACCP model
- Cover the 7 principles of HACCP focusing on CCPs / Process Preventive Controls in consecutive order (plus the preliminary steps which constitute the 12 steps of HACCP)
- Include instructor notes that help the instructors address facilities that have HACCP plans already in place

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 – 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**
- **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

Preface and Chapter 1

Preface and Chapter 1

- Combines Chapters 1and 2 of previous version
- Introduces the Food Safety Plan
- Connect PCHF to HACCP
- Streamlined to reduce redundancy
- Moves course management information to the Preface

Chapter on GMPS

Chapter 2 – Good Manufacturing Practices and Other Prerequisite Programs

- First, GMPs from 21 CFR 117 Part B are listed
- Then, the policies and procedures used by food operations to implement GMPs and other pre-requisite programs are covered
- Instructors are encouraged to emphasize elements that are most appropriate for the audience

Chapters on Hazards and Preventive Controls

Chapter 5 – Hazard Analysis

- Combines elements of previous Chapter 7 (resources)
- Clarifies distinction between hazard identification and evaluation
- Incorporates potential hazard info from the FDA Hazards Guidance

Chapter 6 – Determination of Preventive Controls

- This was split out from the previous Hazard Analysis chapter (8) to make covering this chapter more manageable
- Introduces the types of Preventive Controls
- Covers Preventive Controls exemptions

Process Preventive Controls

Chapters 8, 9 and 10

- Process Preventive Controls was broken up to provide more clarity and attention to each of the HACCP-based principles

Ch 8 – Process Preventive Controls, Critical Limits, and Operating Limits

- Operating Limits was moved to follow Critical Limits

Ch 9 – Monitoring and Corrective Action

- Added examples for both monitoring and corrective action

Ch 10 – Verification and Record Keeping

- These elements are introduced and here, they focus on CCPs

Allergen, Sanitation, & Supply Chain Preventive Controls

Chapters 11, 12, and 13

- **Allergen, Sanitation, and Supply Chain Preventive Controls**
  - With verification and record keeping introduced in Chapter 10, these sections will cover all management components (parameters, corrective action, verification, and record keeping)
  - Improved focus on control using GMPs vs Preventive Controls
  - Better delineation between Supplier Approval and Supplier Verification activities

Program Management

Chapter 14

- **Program management and long-term verification**
  - Plan management and training will be address in this Chapter
  - Long term verification will be discussed with requirements for overall plan review

Recall & Regulation/Regulatory Oversight Chapters

Chapter 15 and 16

- **Recall and Regulatory Chapters**
  - Recall Chapter streamlined to focus on regulatory requirement
  - Regulatory Chapter streamlined to provide overview of Regulation and introduce information on FDA regulatory oversight (what to expect)

What's Next?

Development

- Review of Appendices including E.G. Food Company
- Review of applicable chapter exercises
- Addition of knowledge checks at the end of each chapter
- Addition of new food safety plan teaching examples

Reviews

- Walk-through
- Pilots
- FDA Review

Thank You

See you next year!

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