



FSPCA 2021 VIRTUAL ANNUAL CONFERENCE

OPERATING AT THE CROSSROADS OF PRE- AND POST-COVID

October 20-21, 2021: Day 1



WELCOME

Jason Wan

Interim Executive Director, FSPCA

Interim Director, Institute for Food Safety and Health (IFSH)

DAY 1 CONFERENCE AGENDA

MORNING SESSION			
START	END	SESSION	PRESENTERS
9:00 AM	9:15 AM	Welcome and FSPCA Update	Presenter: Jason Wan
9:15 AM	11:00 AM	2021 FDA Update: Implementing FSMA in an Almost-post-COVID-19 World	Presenter: Glenn Bass Moderator: Jason Wan
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	Experts: Glenn Bass (HF/AF), Selina Mata (FSVP) Moderator: Claudia Coles Scribe: Ron Tanner
11:45 AM	12:30 PM	Ask an Expert: Animal Food	Expert: Dave Fairfield Moderator/Scribe: Dianne Milazzo
AFTERNOON SESSION			
12:30 PM	1:30 PM	2021 Industry Insights and Impacts	Panelists: John Hoffman, Loralyn Ledenbach, Maria Wedel Moderator: Juan Silva
1:30 PM	2:25 PM	The Pandemic - Continuing Challenges	Panelists: Elizabeth Fawell, Kevin Myers, Jennifer Thomas, Roberta Wagner Moderator: Matt Botos
2:25 PM	2:30 PM	Closing Remarks	Presenter: Jason Wan

FSPCA UPDATE

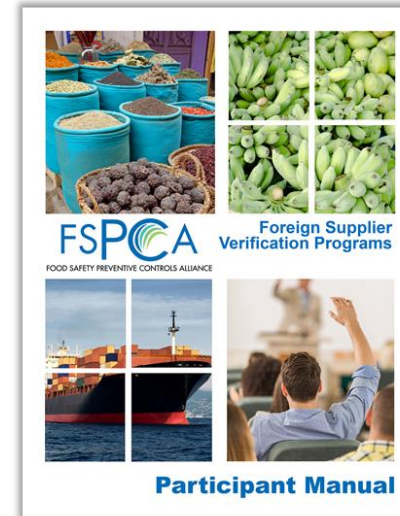
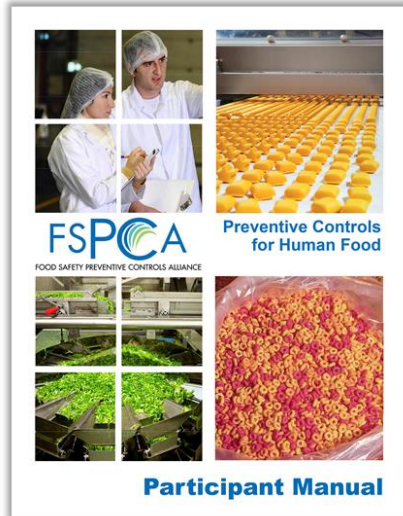


PRESENTER

Jason Wan

Illinois Institute of
Technology (IIT),
Institute for Food
Safety and Health
(IFSH)

FSPCA STANDARDIZED CURRICULA



FSPCA UPDATE 2021

- FSPCA EAB, Subcommittees, Work Groups
- Policies & Procedures for Virtual Delivery of FSPCA Courses
 - Lead Instructors courses
 - Participants courses
- PCHF curriculum update
- FSPCA manuals and materials on Amazon
- FSPCA Quarterly Newsletters
- FSPCA Annual Conference
- Training metrics for PCHF, PCAF, FSVP and IAVA (as of October 5, 2021)

2021 FSPCA LEAD INSTRUCTOR COURSES

- Virtual Human Food Lead Instructor Course
 - August 2-6, 2021
 - September 13-17, 2021
 - October 25-29, 2021 (SOLD OUT)
 - December 6-10, 2021 (SOLD OUT)
- In-Person Animal Food Lead Instructor Course
 - August 3-5, 2021
- Virtual Intentional Adulteration Vulnerability Assessment Combination Course (Participant Course + Lead Instructor Course)
 - May 25-26 & June 1-2
 - October 5-6 & October 12-13

FSPCA TRAINING METRICS: PARTICIPANT

		PCHF	PCAF	FSVP	IA VA
Participant Certificates Issued	Total	118,907	11,477	8,931	3,130
	Domestic	69,731	10,312	7,614	1,728
	International	49,176	1,165	1,317	1,402
Participant Courses Completed	Total	9,938	838	986	333
	Domestic	5,444	708	825	184
	International	4,494	130	161	149

As of October 5, 2021

FSPCA TRAINING METRICS: LEAD INSTRUCTOR

		PCHF	PCAF	FSVP	IA VA
Lead Instructors Trained	Total	2,119	326	349	65
	Domestic	1,249	255	296	50
	International	870	71	53	15
Lead Instructor Courses Completed	Total	94	15	16	5
	Domestic	58	11	16	5
	International	36	4	0	0

As of October 5, 2021

Sign Up for Illinois Tech's, Institute for Food Safety and Health Updates

Thanks for your interest in joining Illinois Tech's, Institute for Food Safety and Health mailing list, which will give you access to institute news and activities, including the Food Safety Preventive Controls Alliance (FSPCA), Sprout Safety Alliance (SSA), and more. Please complete the information below and click Sign Up.

* Email Address

* First Name

* Last Name

* Phone Number

* Address
Select a country

Street


City

Select a state/province Zip Code

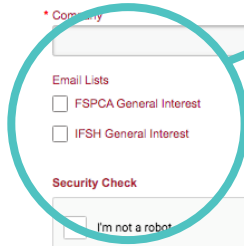
* Job Title

* Company

Email Lists
 FSPCA General Interest
 IFSH General Interest

Security Check
 I'm not a robot 

By submitting this form, you are consenting to receive marketing emails from: . You can revoke your consent to receive emails at any time by using the [SafeUnsubscribe!](#) link, found at the bottom of every email. [Emails are serviced by Constant Contact.](#)



STAY CONNECTED

- Sign up to receive FSPCA updates by joining the [FSPCA Listserv](#)
- Visit the FSPCA Website and look for the link under the “**Stay Connected**” heading
- Fill out the form and check “FSPCA General Interest”
- Now you will receive all future FSPCA updates!



PRESENTER

Glenn Bass

U.S. Food and Drug
Administration
(FDA)



MODERATOR

Jason Wan

Illinois Institute of
Technology (IIT),
Institute for Food
Safety and Health
(IFSH)

2021 FDA UPDATE: IMPLEMENTING FSMA IN AN ALMOST-POST-COVID-19 WORLD



U.S. Food and Drug Administration

Glenn Bass, Deputy , HAF West

Office of Regulatory Affairs

Office of Human and Animal Food Operations

U.S. Food & Drug Administration | FDA

**FSPCA: Implementing FSMA in an Almost-post-COVID-19
World**

October 20, 2021



- Mission Critical Inspections
 - Never stopped: domestic & foreign
- Prioritized Domestic Surveillance Inspections
 - Foreign –abeyance
 - Pre-announced Approach up to ~~5 day~~ –as appropriate
- State Contract Inspections

FSPCA: Implementing FSMA in an Almost-post-COVID-19 World

- Week of March 16, 2020; Suspended all **Surveillance** inspections (domestic & Foreign)
- June 17, 2020: Lifted Stop Work Order- for state contracts
- Week of July 10, 2020 – FDA resumed **Prioritized Surveillance Domestic** inspections



to Favorites Help



Resiliency Roadmap for FDA Inspectional Oversight: May 2021

Full-screen Snip

Resiliency Roadmap for FDA Inspectional Oversight



FDA U.S. FOOD & DRUG
ADMINISTRATION



FSPCA: Implementing FSMA in an Almost-post-COVID-19 World

COVID Advisory Matrix

1. Red

2. Yellow

3. Green

- Selection
- Pre-announce
- Day of inspection

FSPCA: Implementing FSMA in an Almost-post-COVID-19 World



ORA Field Instruction:

- *You are FDA's greatest resource.*
- *Take care of yourself first.*
- *If you feel you are at risk, get out and get safe.*
- *Afterwards and as soon as you can, contact your supervisor.*



Assignment Process (3 steps):

- Pre-Assignment:
- During Assignment:
- Close Out and Post Assignment:

FSPCA: Implementing FSMA in an Almost-post-COVID-19 World

Challenges & Opportunities

Challenges:

- Trying to limit the local travel time. 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;
- Social unrest- unpredictable but must be considered when providing the final Go or No Go for the inspection

FSPCA: Implementing FSMA in an Almost-post-COVID-19 World

Challenges & Opportunities

Opportunities:

- **Voluntary** Remote Regulatory Assessment (VRRRA) & Program Evaluation
 - CFSAN
 - CVM
 - Audit Staff

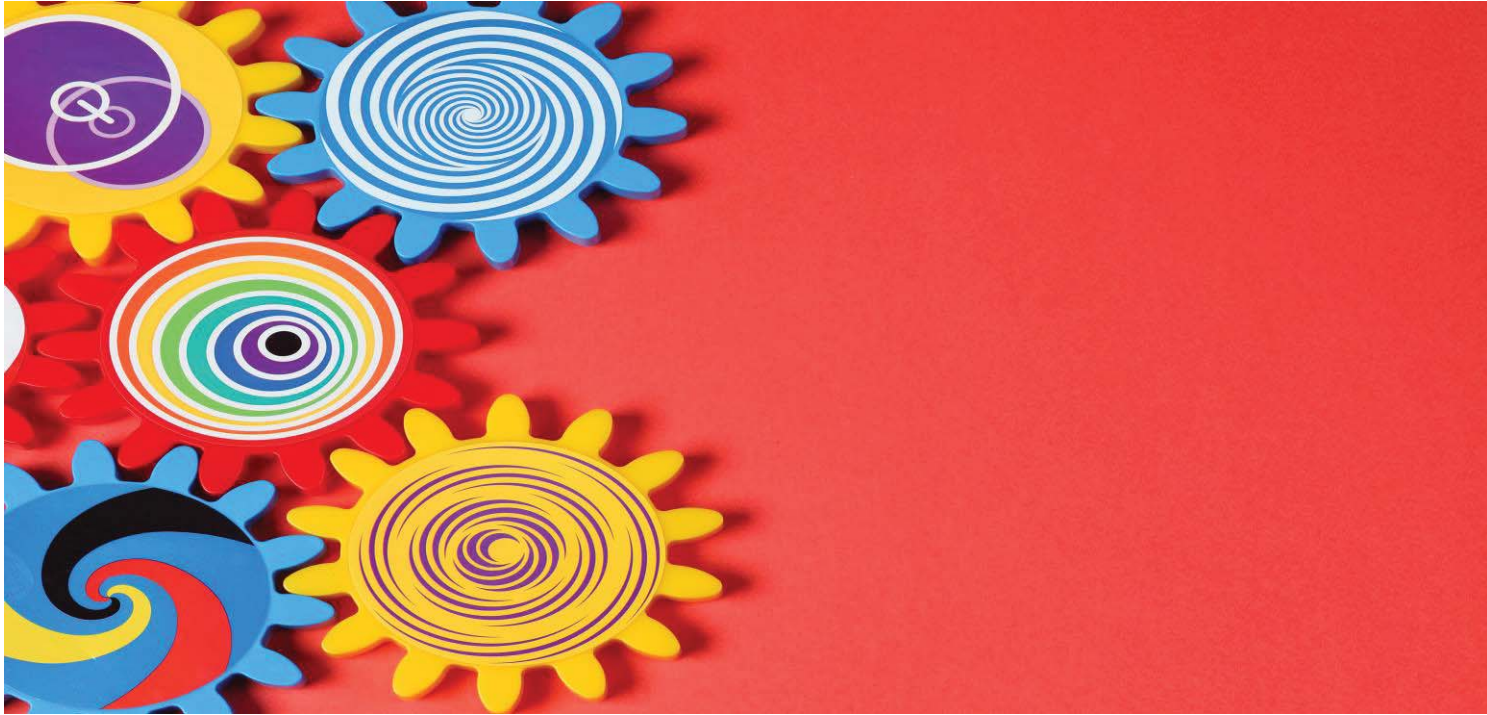


FSPCA: Implementing FSMA in an Almost-post-COVID-19 World

Regulatory Remote Assessments (RRA)

- FDA Remote Oversight Tools: FACT Sheets: Human and Animal Food Inspections
- <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fdas-remote-oversight-tools>

Accomplishments





FDA Training Courses – FY 2017 – FY 2020

FD254
PC for HF
Regulators
(26)

VM102
CGMP AF
Regulators
(14)

VM220
PC for AF
Regulators
(10)

FD226
Produce Safety
for Regulators
(14)

Participants

FDA = 467
State = 294

Participants

FDA = 261
State = 220

Participants

FDA = 167
State = 116

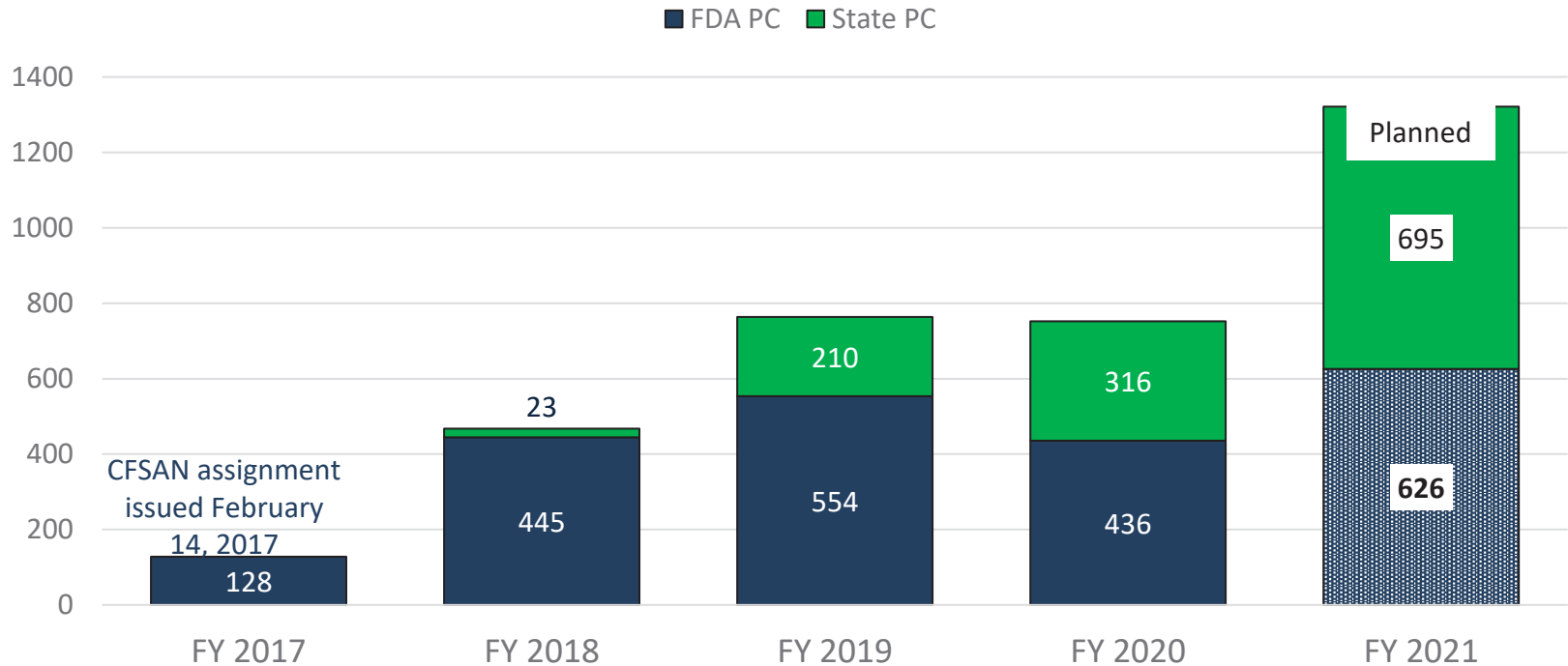
Participants

FDA = 51
State = 307



Domestic Inspections, FY 2017 – FY 2021

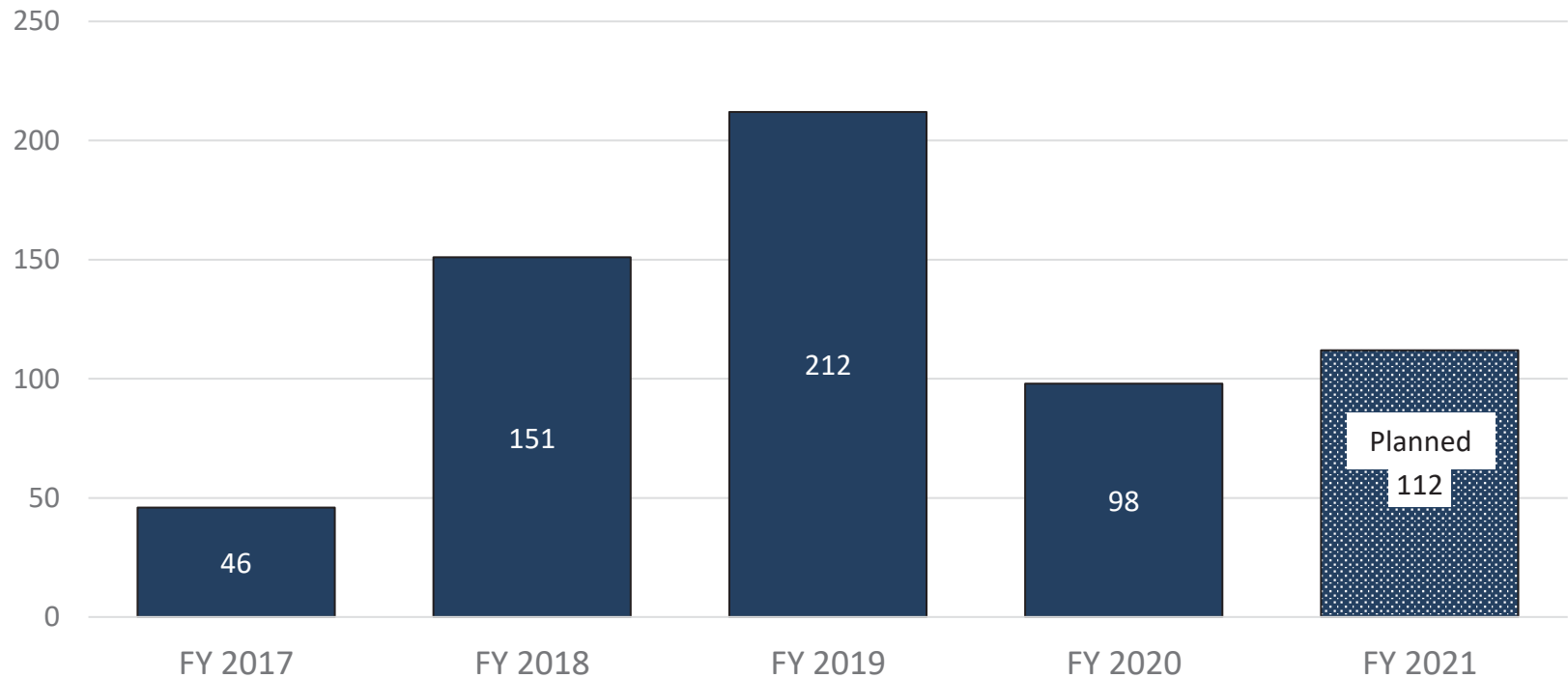
Preventive Controls for Human Food



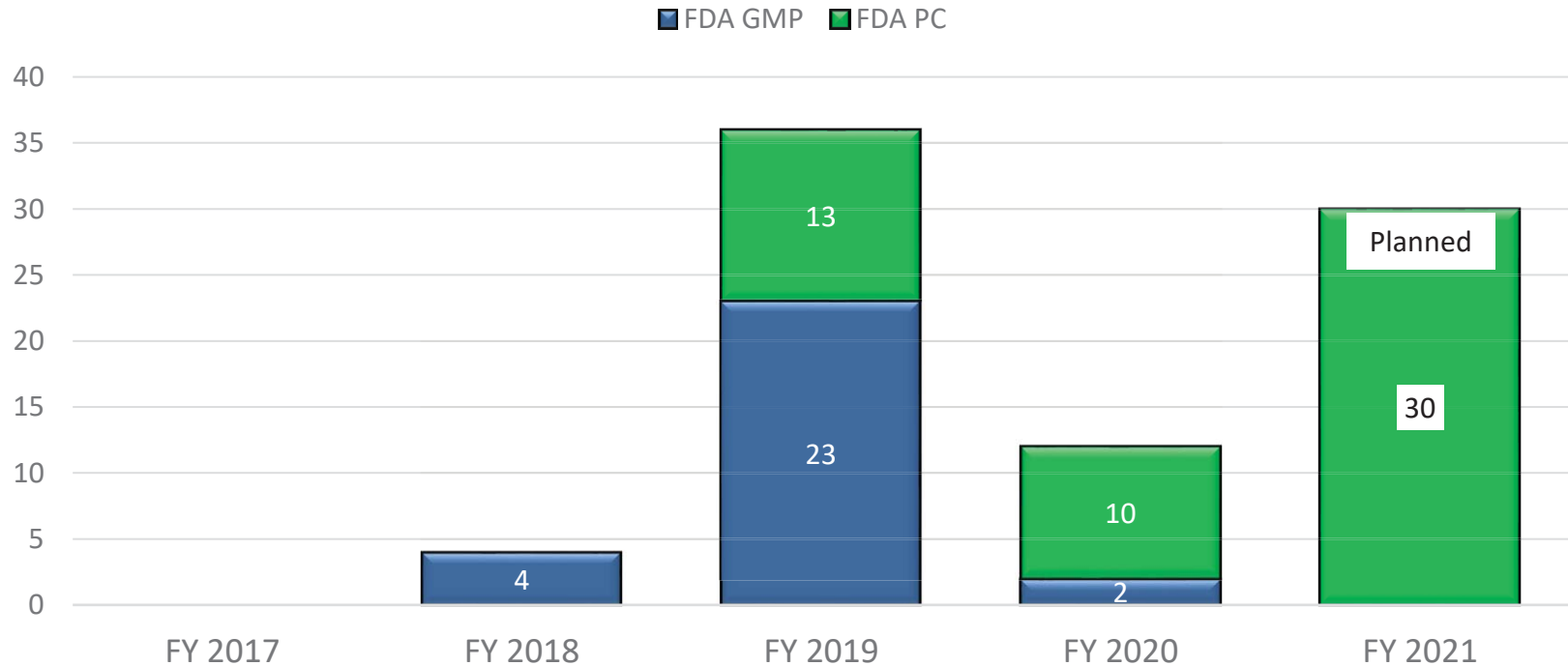


Foreign Inspections, FY 2017 – FY 2021

Preventive Controls for Human Food

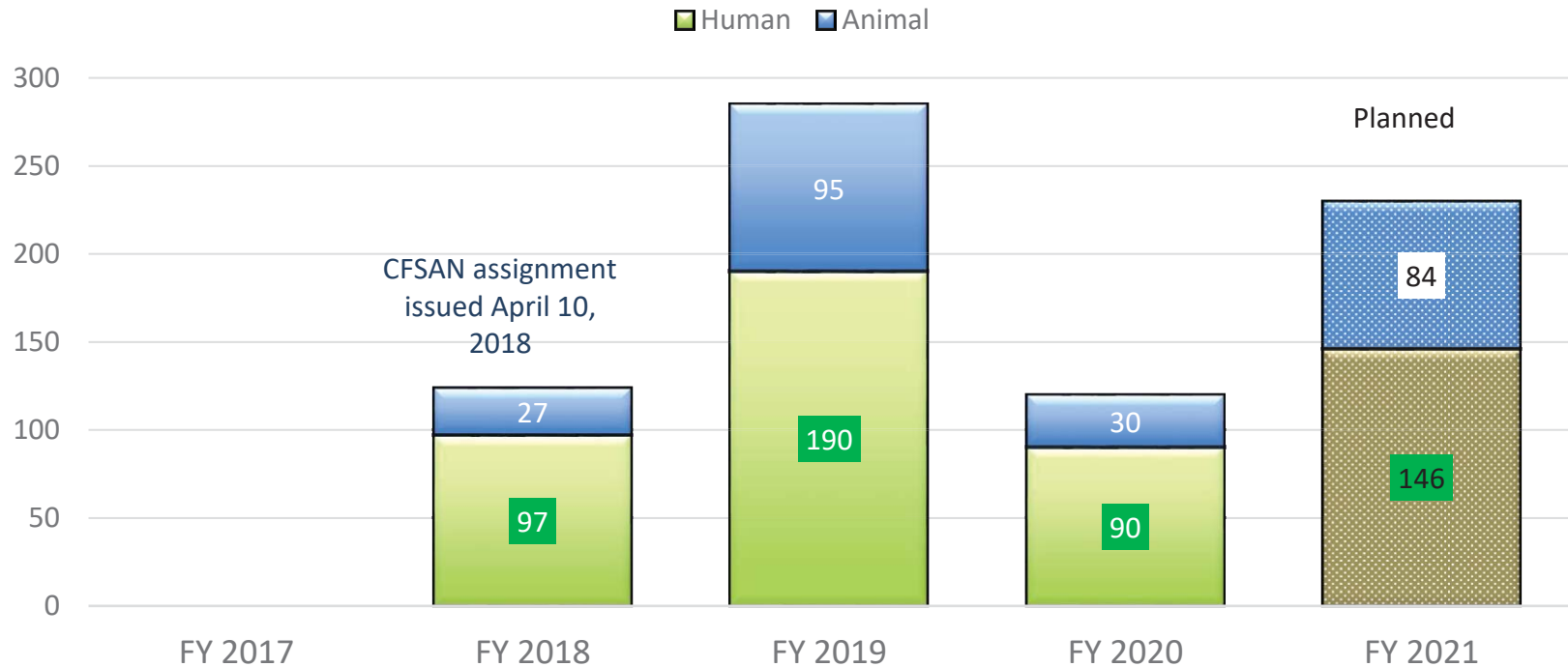


Foreign Inspections, FY 2017 – FY 2021 Preventive Controls for Animal Food



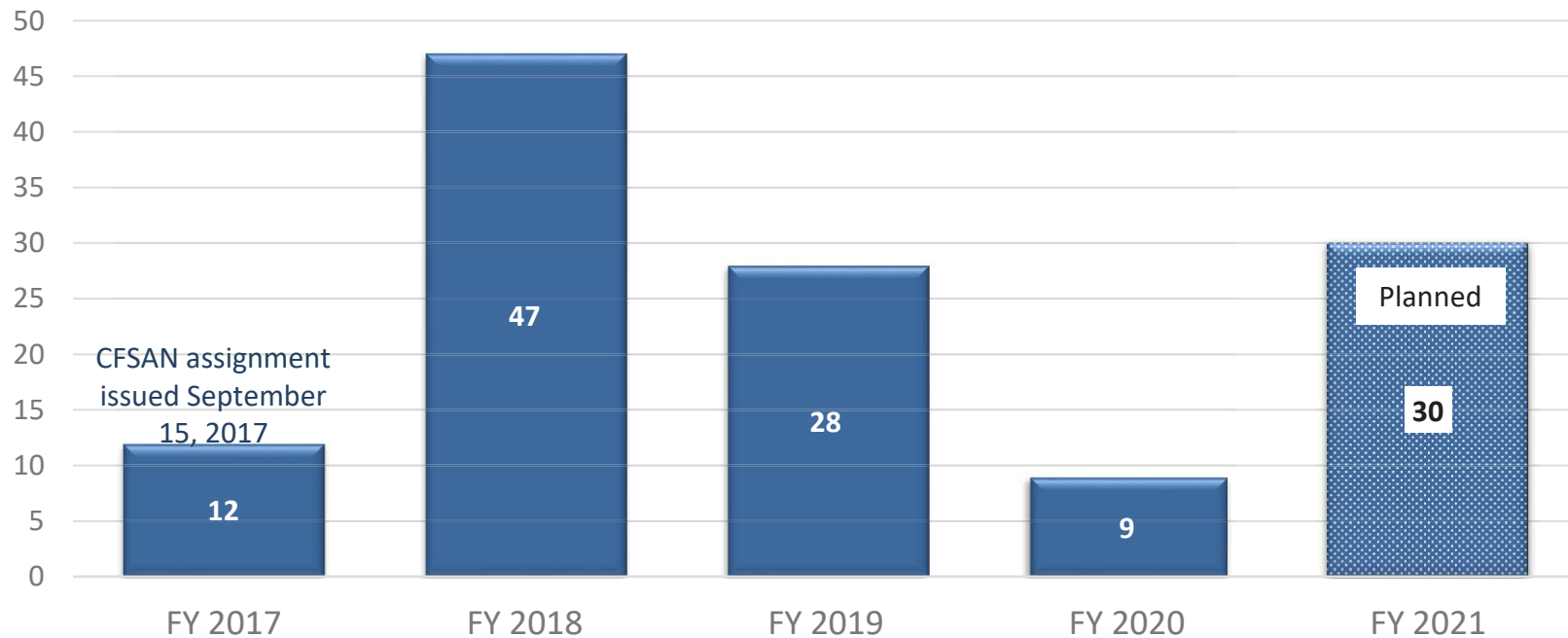
FDA Domestic Inspections, FY 2017 – FY 2021

Sanitary Transportation for Human and Animal Food



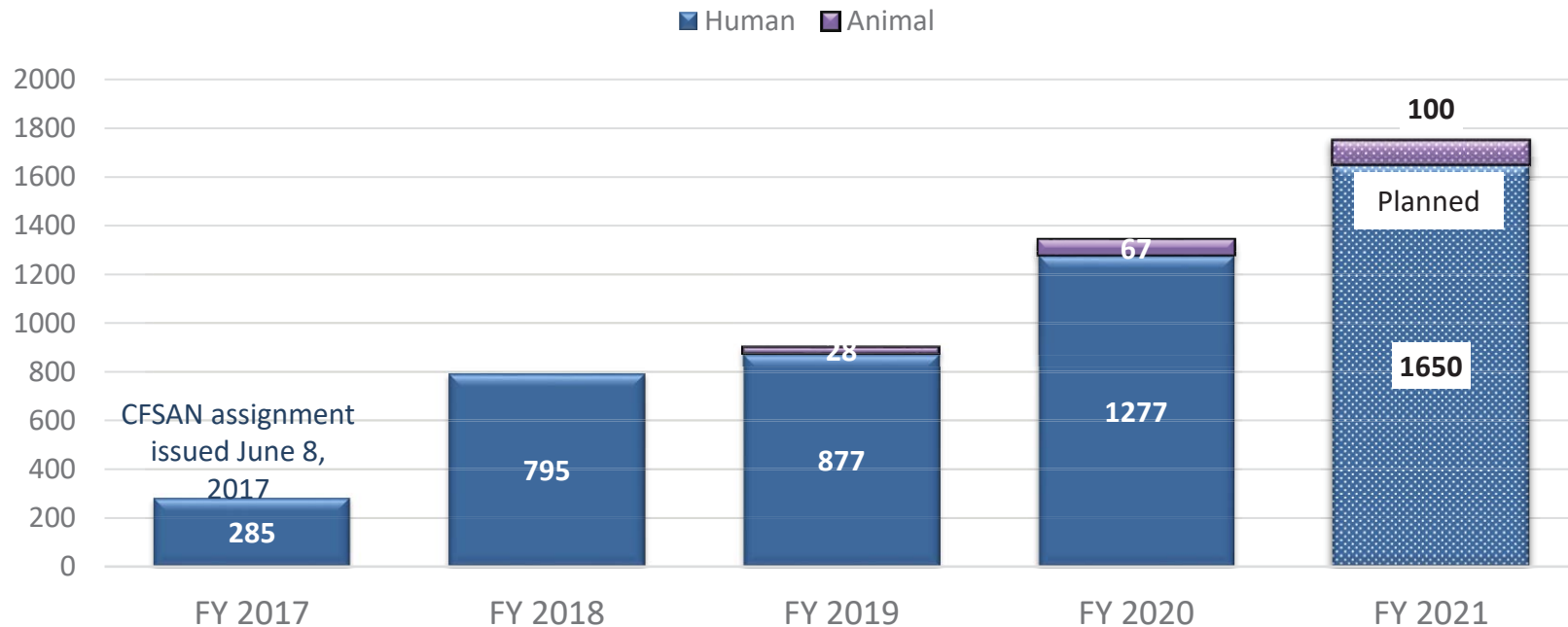
FDA Domestic Inspections, FY 2017 – FY 2021

Sprout Safety



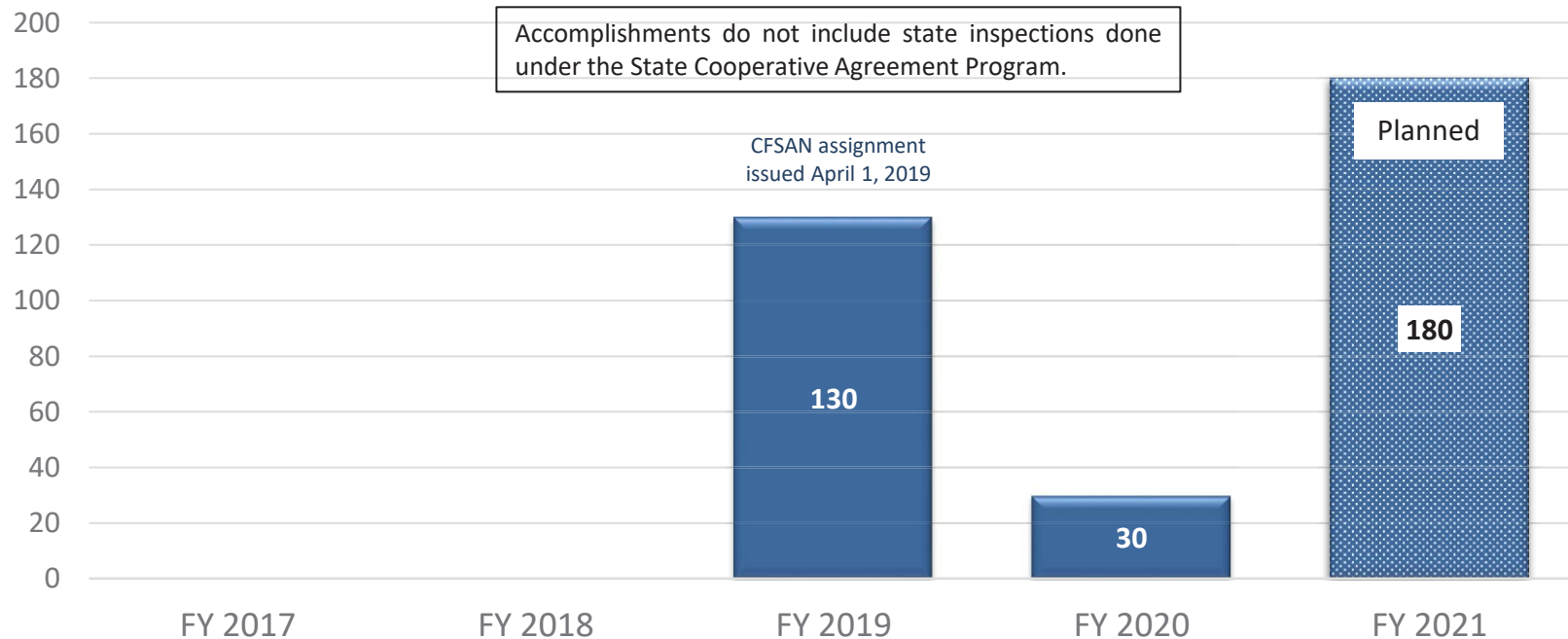
FDA Domestic Inspections, FY 2017 – FY 2021

Foreign Supplier Verification Program (FSVP)



FDA Domestic Inspections, FY 2017 – FY 2021

Produce Safety



FDA Domestic Inspections, FY 2020 – FY 2021

Intentional Adulteration

Assignment Issued
March 2020

FY2020 = 2
Quick Checks

FY2021

Performance Data

- FDA-Track: Food Safety Dashboard
 - Preventive Controls and Imports data posted
 - Additional measures in progress
- FDA Data Dashboard
 - Provides data on inspections, VQIP and TPP participants
 - Resource for manufacturers and importer to research suppliers



FY 18,19,20: Most Frequent Citations Limited Scope (HF): Domestic and Foreign

1. 21 CFR 117.35(c): Pest Control
2. 21 CFR 117.10: Personnel
3. 21 CFR 117.80(c): Manufacturing, Processing, Packing, Holding – Controls
4. 21 CFR 117.35(a): Sanitary Operations - Plant Maintenance
5. 21 CFR 117.40: Equipment and Utensils - Design and Maintenance



FY 18,19,20: Most Frequent Citations Full Scope (HF): Domestic and Foreign

1. 21 CFR 117.130(a)(1): Hazard Analysis
2. 21 CFR 117.126(a)(1): Food Safety Plan
3. 21 CFR 117.135(a)(1): Preventive Controls
4. 21 CFR 117.165(b): Sanitation Controls Verification Procedures
5. 21 CFR 117.145(a): Sanitation Controls Monitoring Procedures

FY 18, 19 ,20: Most Frequent Citations
cGMP & PC (AF): Domestic and Foreign



1. 21 CFR 507.34(a)(1): Preventive Controls
2. 21 CFR 507.33(a): Hazard Analysis
3. 21 CFR 507.31(a): Food Safety Plan
4. 21 CFR 507.49(a)(3): Environmental Monitoring



EXPERT (HF/AF)

Glenn Bass

U.S. Food and Drug
Administration
(FDA)



EXPERT (FSVP)

Selina Mata

U.S. Food and Drug
Administration
(FDA)



MODERATOR

Claudia Coles

Seafood Products
Association (SPA)



SCRIBE

Ron Tanner

Tanner Food
Group

BREAKOUT SESSION

Ask an Expert: FDA Perspectives



EXPERT

David Fairfield
National Grain and
Feed Association
(NGFA)



MODERATOR/SCRIBE

Dianne Milazzo
U.S. Food and Drug
Administration (FDA)

BREAKOUT SESSION

Ask an Expert: Animal Food



PANELIST
Loralyn Ledenbach
Kraft Heinz
Company



PANELIST
Maria Wedel
Cargill



PANELIST
John Hoffman
Food Protection
and Defense
Institute



MODERATOR
Juan Silva
Mississippi State
University

2021 INDUSTRY INSIGHTS AND IMPACTS

Panel Discussion



THE KRAFT HEINZ COMPANY

Managing FSMA through the Pandemic – Industry Insight and Impacts

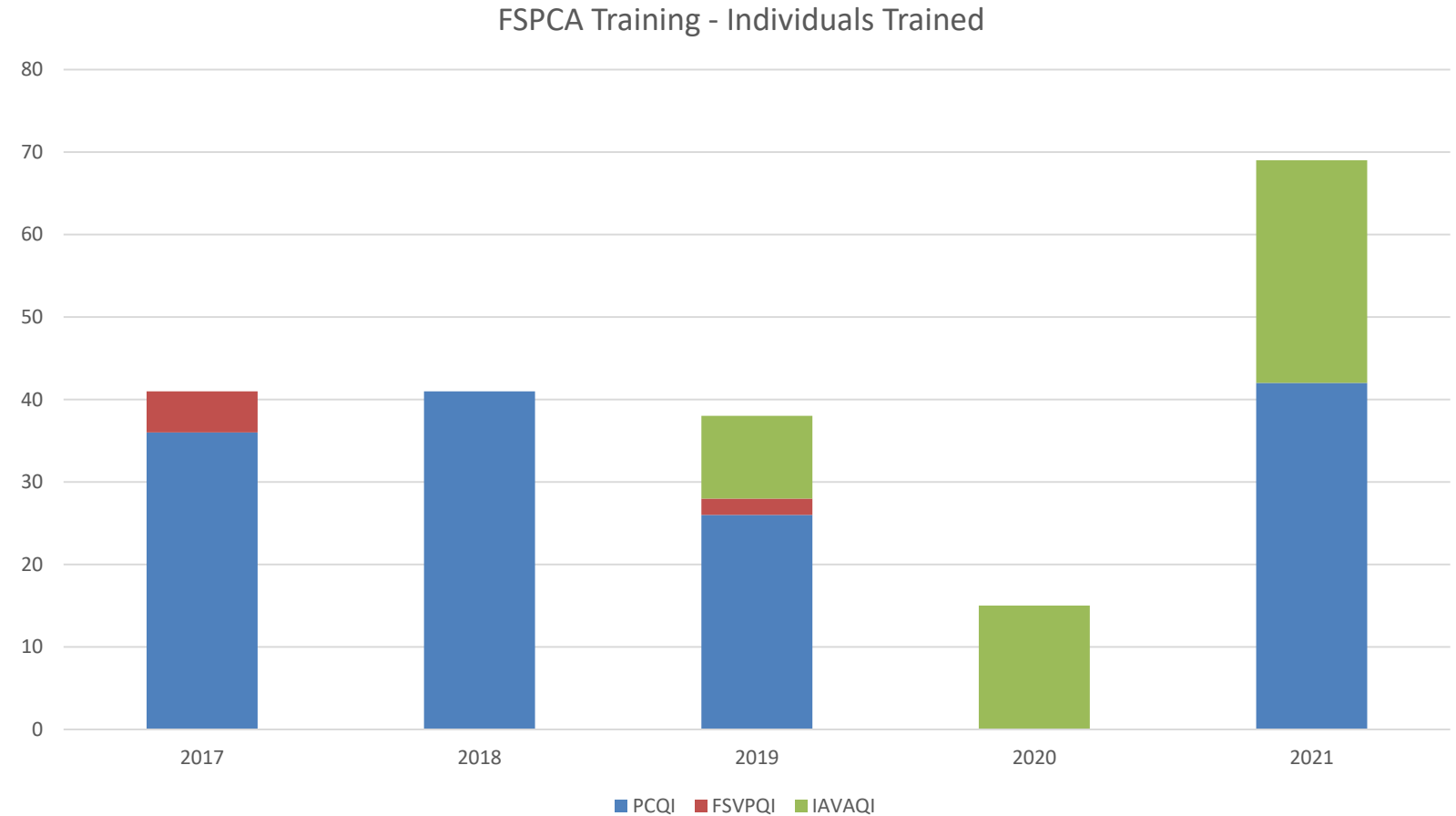
Loralyn Ledenbach
FSPCA Annual Conference 2021

FSPCA Training Efforts



FSPCA Internal Training

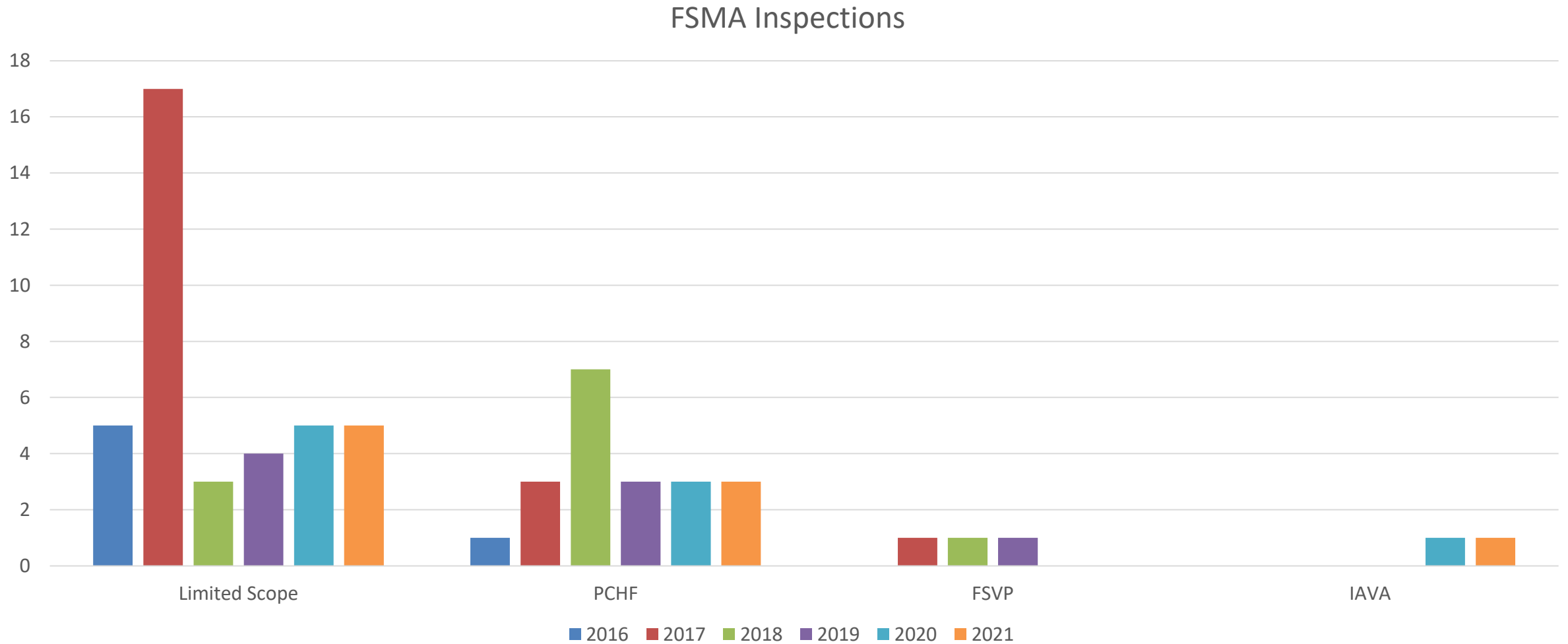
- Lead Instructors:
 - Two LI's for PCHF
 - One LI for FSVP
 - Two LI's for IAVA
 - One ToT for PCHF
- Cover full FSPCA curriculum, model plan examples, and how they work within KHC policy
- All 2020 and 2021 sessions have been virtual



FSMA Impact: What Investigations (Inspections) Look Like

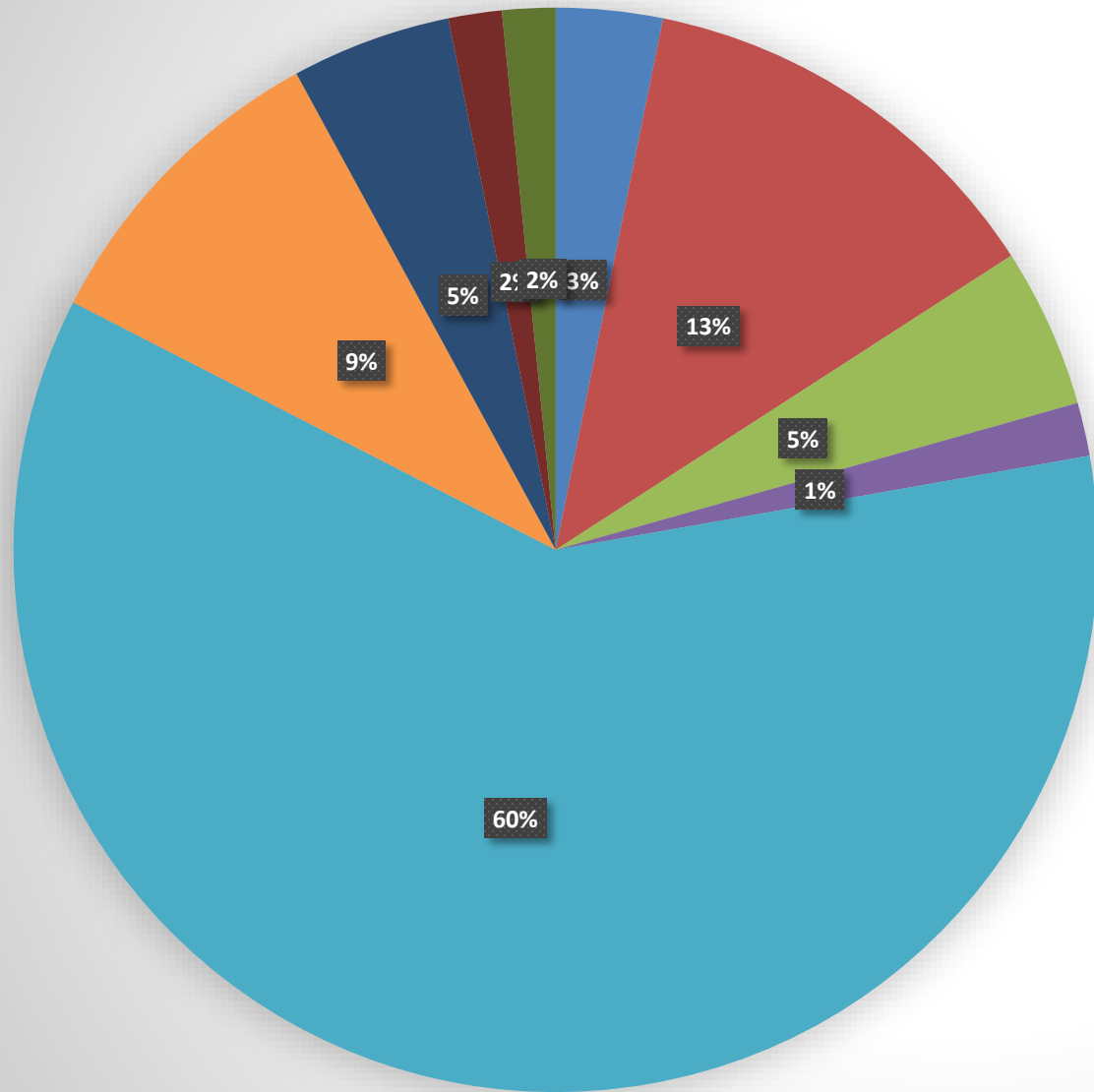


FSMA Inspections 2016-2021 by Type



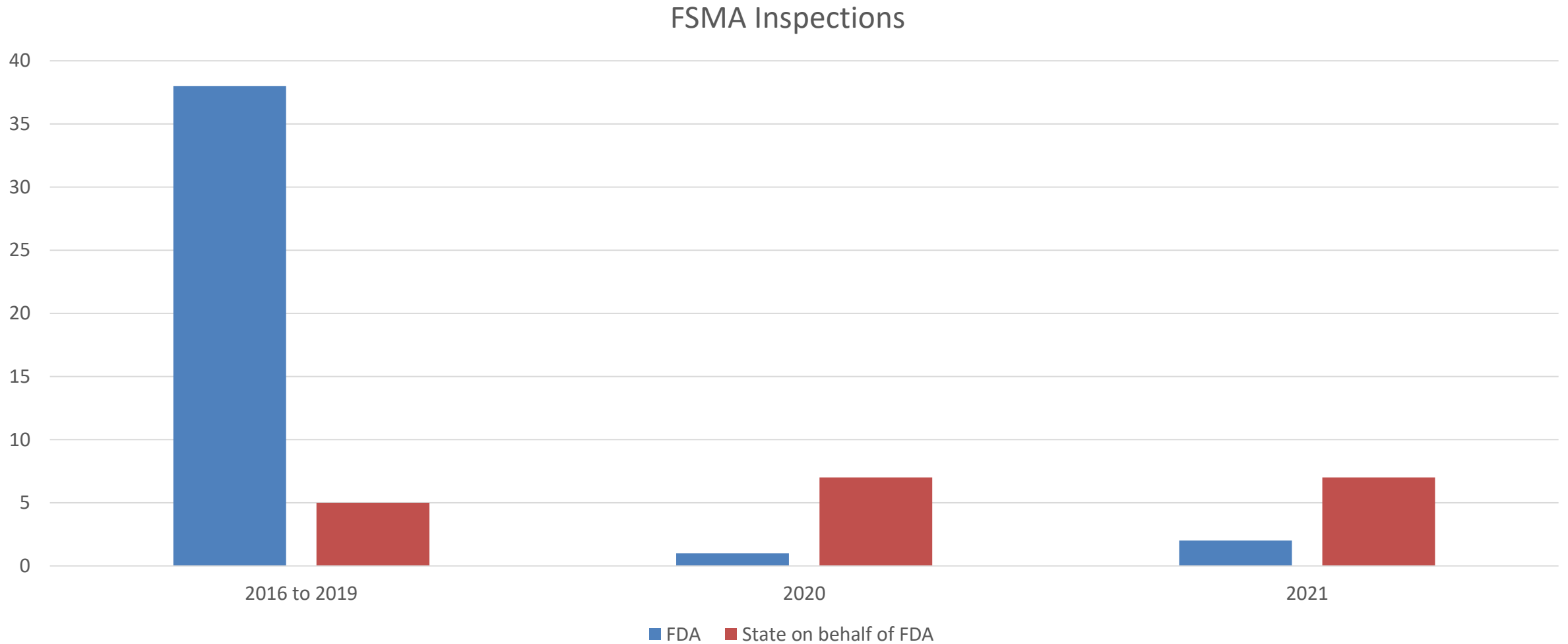
**Also had one state inspection in 2020 to check on best practices for Covid prevention

FSMA Investigations (Inspections): Total = 62



- Full Scope + LACF
- Full Scope
- Full Scope + Swabbing
- Full Scope + LACF + Swabbing
- Limited Scope
- Full Scope switched to Acidified/Juice/Seafood HACCP
- FSVP
- IA Quick Check
- IA Full

FSMA Inspections 2016-2021 by Investigator



**Also had one state inspection in 2020 to check on best practices for Covid prevention

FSMA Inspections and Kraft Heinz (since 2016)

# FDA Personnel:	Average of 1-2 investigators: typically 1 trainer, 1 trainee (less often in 2019), increasing State involvement
Length:	1-5 days
Products:	Whipped Topping, Meal Kits, Cream Cheese, Process Cheese, Natural Cheese, Spice Blends, Boxed Pasta Products, Bagel Bites, Grated Parmesan, RTD Juice, Frozen Meals & Soups, Potatoes, Pickles, Nuts, Sauces/Condiments, Ketchup, Cultures

Voluntary Remote Regulatory Assessment

- The RRA was intended to be a document review
- The facility that underwent this RRA had generally good compliance standing with one specific follow-up that was needed
- Document sharing occurred live with no screen captures taken versus emailing documents ahead of time
- Investigator did a very thorough review of the food safety plan, with an emphasis on the hazard analysis
- Investigator did not request any video tour

FSMA Compliance Impacts

- No real impact to food safety plan preventive controls
- Increased need to implement supply chain verification activities for new suppliers
 - Capacity issues at certain suppliers meant alternates had to be identified and approved
- Supplier audits have to be performed virtually as desk top audits
- Food safety plan re-analysis activities have to be performed virtually
 - Most work can be completed online through video-conferencing
 - Facility walk throughs and process flow confirmations are done by onsite employees
 - Some experimentation with use of smartphones/other technologies to show corporate employees what was happening at the facilities
- New plan start up and validation activities are still performed in-person
 - Travel has been limited to within countries (U.S. vs Canada)



Keeping the Food Supply Chain Strong: Industry Insights and Impacts in 2021

Maria Wedel

Food Safety, Quality and Regulatory Lead for Cargill, Animal Nutrition and Health



Our purpose is to nourish the world in a safe, responsible and sustainable way.

At a glance

155,000 employees

Working in 70 countries

More than 155 years of experience

A trusted partner for food, agriculture, financial and industrial customers in more than 125 countries.



Agriculture



Food



Animal nutrition and protein



Financial and industrial



Our business



For farmers

We supply feeds, other inputs and expertise to farmers, and buy crops and livestock from them

We provide insights to our partners



Data analytics



Market expertise



Risk management



Financial solutions

We transform raw materials into finished goods



Animal nutrition



Food ingredients



Animal protein



Branded foods



Bioindustrials

We move products around the world



Roads



Rail



Rivers



Oceans



For customers

We deliver finished goods to customers in the foodservice, retail, consumer packaged goods and industrial sectors

How Cargill confronted COVID challenges to operate and produce food in a safe environment...



Value-driven organization



Cross-functional crisis management



Kept focus on talent development



Streamlined and simplified



Took advantage of technology

Cyber Hygiene

Building a layered Cyber Defense



John T. Hoffman

Colonel, USA, Retired
Senior Research Fellow
FPDI
hoffm584@umn.edu

Recent Cyber Attacks in the Food Sector

Some Cyber Crime is by Nation States

The 2020 exploitation of the SolarWinds software gave the Russian Government access to hundreds of U.S. firms

2017 Malware attack on Mondelez

Cost the firm \$150 Million and cut international sales by 2.3%!

2021 Molson Coors Cyber Attack

This March 2021 attack severely disrupted production and distribution of its products

2021 JBS Ransomware attack

This ransomware attack impacted global protein production and the firm paid a \$11 Million ransom

2021 Ransomware attack on Kaseya

This attack impacted 1500 firms across the globe to include food retail firms

Forms of Attack:

- Ransomware
- Extortion
- Denial of Service
- Penetrations
- Malware
- Mal-advertising
- BEC
- Web attacks
- Cryptojacking
- Exploit kits
- Theft of IP
- Destruction of Data
- Penetration of ICS
- Co-opting SCADA

Your People Are A Hacker's Lowest Hanging Fruit

- Social Engineering Works!
- While comprehensive and monitored computer systems security infrastructure may defeat most exploits....

Hackers go after your people!

- Humans are the easiest, cheapest and safest compromise strategy.....and it works!
- Network hacking has six decades of practice to prove this!
- Simple mistakes in judgement can be catastrophic

Your best defense against this strategy is Education!



Cyber Hygiene – Principles

Hazard Identification

Identify and continuously assess networks, email system and the most critical or sensitive industrial control system components (cyber and physical) system and software updating/patch controls

Hazard Assessment

Conduct a hazard (vulnerability) assessment for the critical and sensitive industrial control system components identifying areas requiring security controls (automate as necessary) and all cyber supply chain functions (patches/updates/changes)

Preventive Controls

Develop and deploy preventive controls/mitigation strategies to reduce hazards

- Segregating networks (DMZs)
- Restrict access – both users and external device connections
- Hardware and software configuration settings
- Minimize administrator controls
- Require multi-factor authentication for all network access and Email
- Automated but Active virus, spyware, and malware detection
- Layered defenses with firewalls and port filtering
- Internet isolation for select components
- Operating system currency and software updating/patch controls
- Recurrent Training



Cyber Hygiene – Principles

Monitor



Establish an active monitoring program

- Maintain and validate audit logs
- Active intrusions detection
- Monitor data transactions (inbound and outbound)
- Active account usage surveillance
- Configuration requirements are followed
- All patches and updates applied and current

Corrective Actions

Develop an incident response and management procedure

- Regularly review with senior management IT security status and events
- Capture and document failures and adverse events
- Establish formal authorized user reporting mechanism for irregularities or observed security violations to facilitate rapid assessment and response
- Assess and Learn from near misses
- Set time limits on reporting anomalous events
- Hire or establish a retainer with third-party incident response providers and technical advisors
- Conduct incident scenario review sessions
- Recurrent Cyber Security Training for all users

Cyber Hygiene – Principles

Verification



Test the overall strength of security system

- Conduct external and internal penetration tests
- Workforce testing and performance monitoring
- Conduct periodic red team exercises
- Re-evaluate hazard identification and hazard assessment on a time based program
- Consider engaging an outside, third-party IT security firm as a partner in your layered IT defense

Training

Develop security skills in employees necessary for support of security program, test these skills and conduct periodic security policy and procedure retraining

Records

Maintain all network records and event logs. Establish a secure, isolated data storage, backup and recovery system for software, data, user access records and security logs

Contractually require all vendors, customers and contractors to maintain the same level of network security as yours for any system or network that will connect to your network

Resources

DHS/CISA: <https://us-cert.cisa.gov> and <https://us-cert.cisa.gov/report>

FBI Cyber: [Internet Crime Complaint Center\(IC3\) | Home Page](#)

FBI Field Offices: [Field Offices — FBI](#)

NIST: <https://csrc.nist.gov/publications/detail/sp/800-53/rev-5/final>

FPDI: [FPDI Food and cybersecurity](#)

A few useful Cyber Security Firm Contacts: (not an endorsement)

[Managed Detection and Response with ThreatOps for IT Resellers | Huntress](#)

[CrowdStrike: We Stop Breaches](#)

[Threat Detection and Response | Trustwave](#)

[Mandiant | FireEye](#)

Cyber Hygiene

Thank You



John T. Hoffman

Colonel, USA, Retired
Senior Research Fellow
FPDI
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PANELIST
Roberta Wagner
Consumer Brands
Association



PANELIST
Elizabeth Fawell
Hogan Lovells US
LLP



PANELIST
Kevin Myers
Hormel Foods
Corporation



PANELIST
Jennifer Thomas
U.S. Food and
Drug
Administration



MODERATOR
Matt Botos
Connect Food

THE PANDEMIC - CONTINUING CHALLENGES

Panel Discussion

FSPCA ANNUAL CONFERENCE

The Pandemic - Continuing Challenges

October 20, 2021

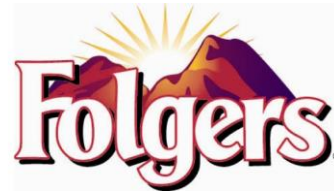
Roberta F. Wagner, B.S., M.S.
Vice President, Regulatory and Technical
Affairs
Consumer Brands Association





Consumer Brands Association (CBA)

Who We Are and our Advocacy Priorities



Consumer Brands Advocacy Priorities

**Enhancing
Packaging Sustainability**

**Creating
Frictionless Supply Chains**

**Championing
Smart Regulation**

**Building Trust in Brands,
Shaping a Powerful
Industry Narrative**

Smart Regulation

The Consumer Brands Association advocates for smart regulatory frameworks that maintain affordability, promote choice and build consumer trust.

RESULT IN
UNIFORM
REGULATORY
FRAMEWORK

Are informed by
risk-based
science

Consider
consumer benefit
and expectations

Enhance trust in
consumer
package goods

Empower
consumers to make
informed choices

Achieve
outcomes
efficiently

Stand the test
of time



Consumer Brands Perspectives

The Pandemic - Continuing Challenges

The Pandemic – *We Are Still In It!*

- Labor Shortages
- Transportation Issue
- Ingredient Shortages & Delivery Delays
- Packaging Material Shortages & Delivery Delays
- Labeling Film Shortages
- Vaccine Mandates for Workers



Supply Chain Pressures, Although Different From the Beginning of the Pandemic Persist, While Consumer Demand for CPG Products Remains Elevated



Supply Chain Pressures & Changes in Consumer Demand & Ways of Shopping

- Companies have no supply chain slack and are out of options, need government to play its role;
- Federal office of supply chain to coordinate policy across the federal government; Congress is working on similar proposal in reconciliation bill, we need to move faster
- Reports of ingredient and packaging shortages and stories of schools having to change lunch menus because of late deliveries abound
- While consumers will not lose access to essentials, may face reduced options, changed products or more limited stocks



Recommendations to Relieve Supply Chain Pressures Provided by Consumer Brands to White House

- Increase labor pool through incentives, temporary visas and, if needed, targeted use of the National Guard;
- Maintain regulatory flexibility, pause regulations that would hamper industry's ability to deliver essentials; and
- Create a constant communication channel by establishing a supply chain war room, comprised of public and private sectors, to identify problems and find solutions in real-time.



Changes in Consumer Demand for CPG Products

- In Q2 of 2021, 8.7% increase in demand for CPG goods over the previous year
- Expect at-home consumption spikes to moderate, but evidence indicates that consumers made permanent changes during the pandemic and those changes will last beyond the pandemic



Changes in the Way Consumers Shop

- Pandemic made curbside pickup, delivery, an on-demand lifestyle part of consumers' ongoing expectations
- Nearly half of consumers used online ordering for groceries during the pandemic, almost eight-in-ten of them plan to continue using it afterwards
- This sea change will mean faster-paced hiring to fill technology positions, a particularly competitive category in the talent marketplace



Pandemic: How Consumer Brands Kept Industry Up and Running

- Secured DHS essential worker designation for all CPG industry employees; drove state/local alignment with federal worker designations.
- Worked with EPA to expedite scientific reviews of disinfectants.
- Solidified waive of hours-of-service and truck weight limits with dot.
- Launched critical infrastructure supply chain council, over 40 trade associations committed to addressing state supply chain issues, working toward nationwide uniformity for workforce/transportation movement.
- Initiated state department's development of a private sector portal for industry to report and receive assistance with international supply chain disruptions in real time.
- Advocated for FDA labeling flexibility for minor product substitutions resulting in issuance of temporary pandemic guidance by FDA.
- Worked with AFDO to inform protocol for state inspectors on remote/virtual document reviews/inspections to promote consistency in inspection approach.
- Advocated for alternative supplier verification methods, in lieu of annual third-party audits/certifications, to meet existing regulatory requirements; led to FDA's temporary pandemic policy for supplier verification.



CBA Survey with 23 CPG Company Respondents in October 2020, Showed the Following

- **CPG industry provided a united response regarding** its need for speed/clarity from the government. Respondents flagged opportunities to enhance efficiency and timeliness of response that will serve country as it continues to fight the pandemic
- **100% of respondents** agreed that best practice documents created by relevant third parties – trade associations or alliances – then reviewed/”blessed” by government, allowed companies to be responsive to the rapidly changing situation
- **79% of respondents** stated that remote inspections/audits reduced person-to-person contact while maintaining same level of oversight and safety





***Pandemic Proves Smart, Nimble
Regulatory Change is Possible***

***Consumer Brands & Members Identify Ten
Regulatory Policies Established During the
Pandemic that Should Be Made Permanent***

Inspections

3. Develop and Implement Modernized Routine Inspection and Third-Party Audit Models

4. Expand Government Capabilities to Provide "Speed of Business" Regulatory Response to Stakeholders

5. Expedite Creation of Just-In-Time Best Practice Documents

Labeling Disclosure

6. Expand Digital Disclosure of Product Information

7. Accelerate Process to Substantiate Product Efficacy Claims

8. Maintain Food Labeling Flexibility

9. Remain Solution-Focused to Ensure Accurate Information is Available to Consumers

Manufacturing

10. Adopt "Switch and Notify" for Supplier Changes

Role of Remote Regulatory Activities Pre and Post Pandemic

- During the pandemic, available technology used to perform remote audits/inspections and/or regulatory document review
- Consumer Brands established principles and a draft protocol for remote regulatory document review; used by FDA/AFDO to draft procedures for this type of work by State inspectors/FDA Consumer Safety Officers
- CBA and FBIA hosted a roundtable discussion on remote regulatory activities
 - FDA shared results of its remote regulatory assessment pilot
 - Role of remote regulatory oversight activities post pandemic, as a tool for the efficient use of technology and resources and to modernize inspection models to align with current industry practices, discussed



Questions?

rwagner@consumerbrandsassociation.org

VISIT US AT

CONSUMERBRANDSASSOCIATION.ORG



@ConsumerBrands

The Pandemic: Continuing Challenges

A few legal and regulatory considerations

- “Normal” FDA on-site inspections will resume eventually. Don’t forget that PCHF records access goes back 2 years!
- New risks to consider:
 - Have your suppliers reconfigured supply chains?
 - Does a frazzled work force present a risk of intentional adulteration?
 - Balancing supply chain disruptions with production demands
 - Labor shortages and workforce training
- Remote supplier audits – the wave of the future?

Elizabeth Barr Fawell

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The Pandemic: Looking forward

A few legal and regulatory considerations

- Creating an administrative record
- Expanding the regulatory tool box
- Enforcement discretion timeframe and wind down
- Measuring effects of regulatory actions
- Knowing ahead of time what might be “waived”
- Outlining an approach to the DPA
- Interacting with state and local authorities
- Importance of trust and shared goals

Elizabeth Barr Fawell

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Kevin Myers

Hormel Foods





COVID Mitigation – initial efforts

- Decision Tree
- Constant and consistent communication to all employees
- Common platform to broadcast/share information between facilities
- Created [keepcovidout.org/](https://www.keepcovidout.org/)



COVID Mitigation – Year 2

- Constant and consistent communication to all employees
- Use of doctors and experts to share COVID/Vaccine info
- Vaccine clinics in all facilities
- Evolving CDC and OSHA guidance/regulations



COVID Mitigation – Ongoing/Future

- Supply Chain challenges
- Changes in COVID protocols
- Employee Feedback & Engagement
- Future: Vaccine Mandate/Testing Unvaccinated?



THE PANDEMIC - CONTINUING CHALLENGES

Jennifer Thomas

U.S. Food and Drug Administration

The Pandemic – Continuing Challenges

Jennifer Thomas

FDA/CFSAN

October 2021

Worker Challenges

- Vaccine hesitancy among the food/agriculture workforce
- Shortage of workers
- Difficulty in industry obtaining PPE – gloves, masks

Supply Chain Challenges

- Shortages in packaging materials – retail and food processing facilities
- Shortage of shipping containers
- Use of alternative ingredient sources



FDA On-Site Challenges

- Activities
 - Investigations
 - Inspections
 - Sampling
- Considerations
 - Mission-critical
 - Disease rates
 - Firm requirements
 - Travel restrictions

Resource: Resiliency Roadmap

International Challenges

- Export restrictions
- Testing
- Remote audits

FDA Resources

- FDA Coronavirus website:

<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

- FDA foods specific information:

<https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19>

- Resiliency Roadmap

<https://www.fda.gov/media/148197/download>





CLOSING REMARKS

Jason Wan

Interim Executive Director, FSPCA

Interim Director, Institute for Food Safety and Health (IFSH)

FSPCA 2021 VIRTUAL ANNUAL CONFERENCE

OPERATING AT THE CROSSROADS OF PRE- AND POST-COVID

October 20-21, 2021: Day 2



WELCOME BACK

Jason Wan

Interim Executive Director, FSPCA

Interim Director, Institute for Food Safety and Health (IFSH)

DAY 2 CONFERENCE AGENDA

MORNING SESSION			
START	END	SESSION	PRESENTERS
9:00 AM	9:15 AM	Review of Day 1 and outline of Day 2	Presenter: Jason Wan
9:15 AM	10:30 AM	FSVP Update	Presenters: Selina Mata, Hilary Thesmar Moderator: Claudia Coles
10:30 AM	11:00 AM	Lead Instructor Policy Refresher and Updates	Presenter: Claudia Coles Moderator: Jerry Wojtala
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: Intentional Adulteration	Experts: Ryan Newkirk, Jon Woody Moderator: Debra Freedman Scribe: Caitlin Hickey
11:45 AM	12:30 PM	Ask an Expert: Virtual Training Tips	Experts: Jeff Chilton, Art Johnstone, Juan Silva, Jennifer van de Ligt Moderator: Juan Silva
AFTERNOON SESSION			
12:30 PM	1:30 PM	Update on the FSPCA Preventive Controls for Human Food Curriculum	Presenters: Martin Bucknavage, Katherine Simon Moderator: Jerry Wojtala
1:30 PM	2:25 PM	Breakout Session Summaries from Day 1 & 2	Presenters: Claudia Coles, Ron Tanner, David Fairfield, Dianne Milazzo, Debra Freedman, and Juan Silva Moderator: Matt Botos
2:25 PM	2:30 PM	Closing Remarks	Presenter: Jason Wan

FSVP UPDATE



PRESENTER
Selina Mata
U.S. Food and Drug
Administration
(FDA)



PRESENTER
Hilary Thesmar
Food Marketing
Institute (FMI)



MODERATOR
Claudia Coles
Seafood Products
Association (SPA)



FSVP UPDATE

Selina Mata

U.S. Food and Drug Administration (FDA)

Foreign Supplier Verification Programs (FSVP)

Presenter:

Selina Mata, Supervisory Consumer Safety Officer

Overview

- FSVP FY21 and FY22 inspection statistics
- Inspection classifications and top citations
- FDA Data Dashboard and TRACK
- Temporary use of UNK
- FSVP Remote inspections
- FSVP Importer Portal for FSVP Records Submissions



FY22 FSVP Inspection Statistics

FY22 Work Plan Goal → 1900 FSVP Inspections

- Human Food Goal: 580 (505 human food; dietary supplements: 50)
- Animal Food Goal: 75
- Re-inspections: 1320

FY21 Top Human and Animal Food Citations



21 CFR 1.502(a)	Develop FSVP	You did not develop an FSVP. Specifically, ***	794
21 CFR 1.504(a)	Hazard analysis written	You did not have a written hazard analysis. Specifically, ***	78
21 CFR 1.505(a)(2)	Evaluation - performance, risk	You did not document that you conducted an evaluation or reviewed and assessed an evaluation conducted by another entity to determine [a foreign supplier's performance] [the risk posed by a food]. Specifically, ***	74
21 CFR 1.505(b)	Supplier approval - document	You did not document that you approved a foreign supplier based on an evaluation that you conducted of the foreign supplier's performance and the risk posed by a food or based on a review and assessment of another entity's evaluation of a foreign supplier's performance and the risk posed by a food. Specifically, ***	71
21 CFR 1.506(a)(1)	Approved supplier procedures - importer established	You did not establish written procedures to ensure that you import foods only from approved foreign suppliers. Specifically, ***	69

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

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



Outcome: More Effective Oversight of Foreign Suppliers by Importers (FSVP)

I. Number and Percent of FSVP inspections classified NAI, VAI, OAI

The inspection classification is based on the FSVP citations and rankings documented in the Establishment Inspection Report (EIR). FDA classifies inspections in terms of significance of observations and monitors trends at the firm and aggregate level. This information will allow FDA to identify areas of industry in need of outreach and education in coming into compliance with the Foreign Supplier Verification Programs (FSVP) provision.

[Glossary](#)
(click here)

Note: Current Fiscal Year represents performance year-to-date.

Commodity:

- Human Food
 Animal Food

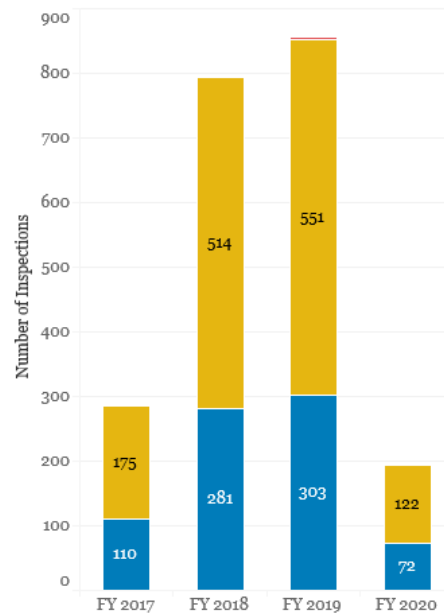
Fiscal Year:

(All)

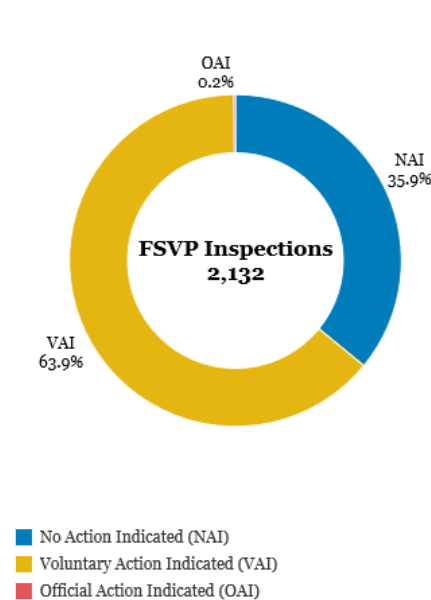
Inspection Classification:

(All)

Number of Inspections by Classification



Percent of Inspections by Classification



Temporary Use of UNK

- Compliance with Providing an Acceptable UFI for the FSVP Regulation: GFI
 - Policy allowing temporary use of UNK
 - 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)

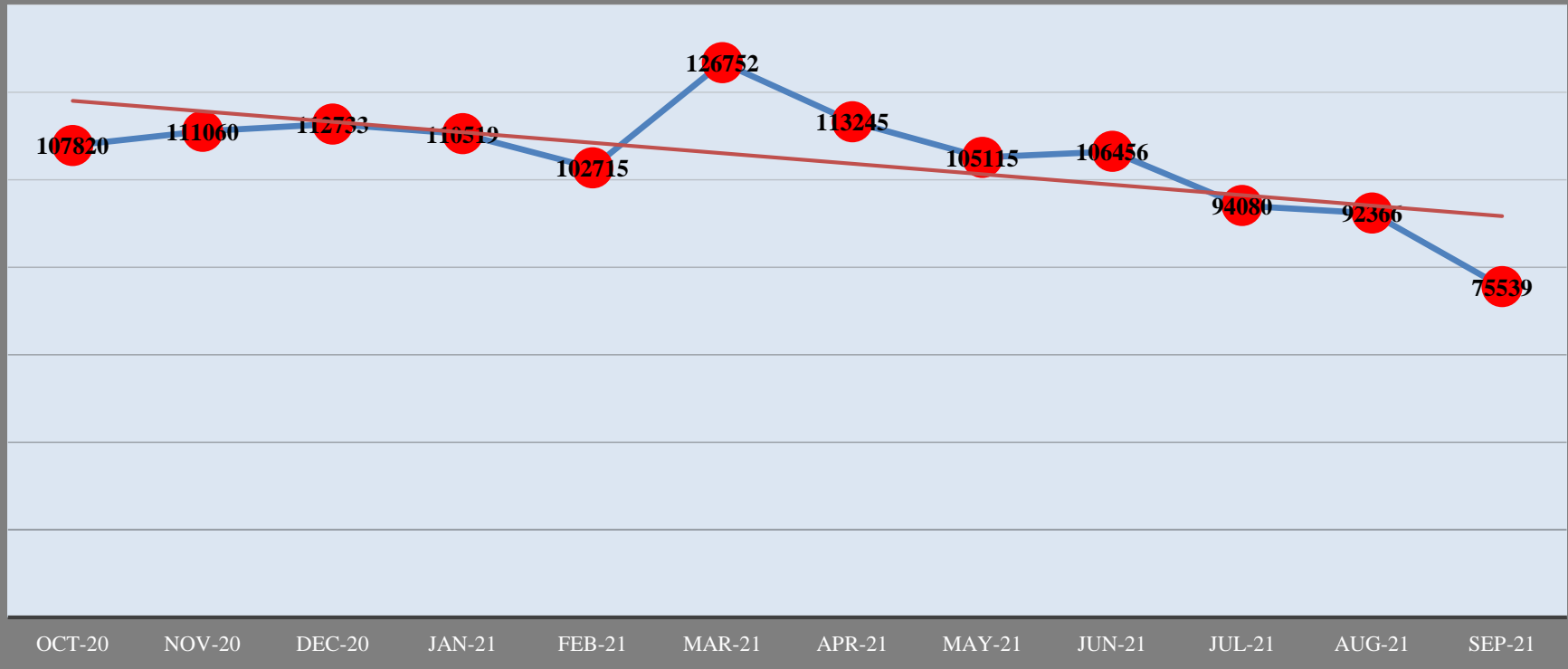
Industry Outreach: UNK

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
- Direct outreach to filers to encourage communication with FSVP importers to obtain or provide a DUNS

FY21 UNK Transmission Trends

FY21 FSVP Total UNK (no DUNS #)



- October 1, 2020 –September 30, 2021
- Q1-Q3: Trends consistently high; averaging 100k/month
- Q4: Notable decrease as a result of industry outreach efforts

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)
- Once COVID restrictions have lifted, we will resume conducting both onsite and remote FSVP inspections



Remote FSVP Inspections, cont.

- Since implementation, FDA has conducted ~2300 remote inspections
- 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



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 UPDATE

Hilary Thesmar
Food Marketing Institute (FMI)

TOPICS

- **FSVP Participant Courses**
 - Instructor-led course
 - Blended course
- **Virtualization of the FSVP Combination Course**
- **FSVP Awareness Module**
- **Where to go for information/questions**
 - FSPCA Website
 - FSPCA Community
 - FSVP Lead Instructor Chatter Group

FSVP PARTICIPANT COURSES

Instructor-led

- Entire participant course is provided by an FSPCA FSVP Lead Instructor

Blended

- Part 1 is online
- Part 2 is instructor-led

FSVP PARTICIPANT COURSES

Online or Virtual Delivery

- FSVP Instructor-led and Part 2 of FSVP Blended Course can be delivered virtually

Requires:

- Registering the course as a modification
- Meeting virtual course criteria as outlined in Policy 0017

Food Safety Preventive Controls Alliance (FSPCA) Policies and Guidelines		Document #: FSPCA POL 0017	Page 1 of 7
		Author: FSPCA Trainer of Trainers Work Group	
Title: FSPCA Participant Course Registration and Delivery Policy		Scope: All FSPCA Lead Instructors, Association of Food and Drug Officials (AFDO), Trainer of Trainers Work Group, Monitoring and Evaluation Work Group	
		Distribution: All FSPCA Lead Instructors, Committees, Subcommittees, Work Groups and/or Staff	
Issue Date: August 27, 2021	Supersedes Date: August 27, 2020	FSPCA ED Approval Date: August 30, 2021	Status: FINAL
Related Documents: FSPCA_POL_0018; FSPCA_POL_0017a			

1. Summary of Revisions:

1.1. Previous version of this policy stated that FSPCA would allow virtual delivery for a limited time of the FSPCA Intentional Adulteration Vulnerability Assessments (IAVA) participant course. This policy and FSPCA Policy 0017a were revised to permanently allow virtual instructor led IAVA participant courses, provided the audit policy and class size limits are kept in place. Exceptions and additional criteria/requirements for the virtual delivery of FSPCA Intentional Adulteration Vulnerability Assessments (IAVA) participant courses, can be found in FSPCA_POL_0017a, were updated.

2. Title: FSPCA Participant Course Registration and Delivery Policy

3. Scope: Relevant FSPCA Committee/Subcommittee

All FSPCA Lead Instructors, Association for Food and Drug Officials (AFDO), Trainer of Trainers Work Group, Monitoring and Evaluation Work Group

4. Purpose/Objectives/Goals: This policy outlines the requirements FSPCA Lead Instructors must follow to register and deliver the following FSPCA participant courses:

VIRTUALIZATION OF THE FSVP COMBINATION COURSE IN DEVELOPMENT

- The FSPCA FSVP Combination Course combines the FSVP participant course and FSVP Lead Instructor training
- Virtualization of the FSVP Combination Course is scheduled for November 30th & December 1st
- Stay tuned for more information on virtual delivery of the FSVP Combination Course

FSVP AWARENESS MODULE

- Module that can be used to introduce the FSVP rule to other training audiences and to foreign suppliers so they are aware of the requirements of importers
- 36 slides

FSVP Module Description and Target Audience

- **Module Description:** This module will provide participants with an understanding of the requirements of the “Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals” regulation.
- **Target Audience:** This module is designed specifically for the foreign suppliers that manufacture, process, pack, or hold food intended for human or animal consumption in the U.S.
- The FSVP rule requirements are directed at importers, not foreign suppliers.



WHAT HAS CHANGED?

Records submission process

[Food and Dietary Supplements](#) / [Food Imports & Exports](#) / [Importing Food Products into the United States](#) / [Foreign Suppliers Verification Programs \(FSVP\) - Importer Portal for Records Submission](#)

Foreign Suppliers Verification Programs (FSVP) - Importer Portal for Records Submission

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The Foreign Suppliers Verification Programs (FSVP) Importer Portal for FSVP Records Submission is a means for importers to upload FSVP records electronically to the Agency, after receiving a written request from FDA for the records.

The [FSMA Final Rule on FSVP](#) 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).

[Launch the Portal*](#)

[Download the User Guide](#)

Content current as of:
06/16/2021

Regulated Product(s)
Food & Beverages

Topic(s)
Import

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

WHERE TO GO FOR MORE INFORMATION?

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Menu

Foreign Supplier Verification Programs (FSVP)

FOREIGN SUPPLIER

- Materials and Resources
 - [FSVP Awareness Module for Foreign Suppliers \(English\)](#)
 - This module is specifically designed for the foreign suppliers that manufacture, process, pack, or hold food intended for human or animal consumption in the U.S. The FSVP rule itself imposes requirements on importers, not foreign suppliers. Nevertheless, importers may make requests of foreign suppliers to assist in meeting the importers obligations. This module will explain the requirements of the FSVP rule.

U.S. FSVP IMPORTER

« FSPCA HOME

- THE ALLIANCE
- COURSES
- FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP)
 - FSVP MEETING SUMMARIES
 - INTENTIONAL ADULTERATION
 - FSPCA IA VULNERABILITY ASSESSMENT LEAD INSTRUCTOR CRITERIA AND ONLINE APPLICATION
 - FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD
 - FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Search for Knowledge Articles

SEARCH LOGIN

COURSE LIST LEAD INSTRUCTOR LIST SPROUTS PRODUCE INSTRUCTOR HELP ABOUT FSPCA GROUPS

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE (FSPCA) COMMUNITY

The FSPCA Community is a place where you can find PCQI Courses, and ask questions related to the Food Safety Modernization Act (FSMA). To submit a technical question connected with FSMA implementation, or to ask a question about FSPCA Lead Instructor activities, use the "Submit An Inquiry" button below.

SUBMIT AN INQUIRY

Open Discussion Forum and Knowledge Articles

To submit a FSMA-related scientific question to the FSPCA's Technical Assistance Network that is comprised of Food Safety Experts located throughout the United States, use the "Submit An Inquiry" button above. To participate in an open discussion forum, and to find knowledge articles related to your topic, select one of the content blocks below.

FEATURED DISCUSSIONS TRENDING ARTICLES

LEAD INSTRUCTOR APPLICATION RESOURCES CURRENT LEAD INSTRUCTOR RESOURCES PREVENTIVE CONTROLS RESOURCES

How to Register a Course on the FSPCA Community Course List

How to Resubmit a FSPCA Lead Instructor Application

How to Submit a Question to the FSPCA Community's Technical Assistance Network

How to Create a FSPCA Lead Instructor Application

- FSPCA Website

- FSPCA Community
- FSVP Lead Instructor Chatter Group

LEAD INSTRUCTOR POLICY REFRESHER AND UPDATES



PRESENTER

Claudia Coles
Seafood Products
Association (SPA)



MODERATOR

Jerry Wojtala
International Food
Protection Training
Institute (IFPTI)



LEAD INSTRUCTOR POLICY REFRESHER AND UPDATES

Claudia Coles
Seafood Products Association (SPA)



FSPCA Lead Instructor Policy Refresher and Updates

CLAUDIA COLES

Requirements for Successfully Advertising FSPCA Participant Courses

- Preventive Controls for Human Food (form 0028)
- Preventive Controls for Animal Food (form 0031)
- Foreign Supplier Verification Programs (form 0030)
- Intentional Adulteration Vulnerability Assessments (form 0073)

Lead Instructor Resource Portals: <https://lms.ifpti.org>

FSPCA Homepage: <https://www.ifsh.iit.edu/fspca>

Requirements for Successfully Advertising FSPCA Participant Courses

- Referencing your distinction as a Lead Instructor
- Use of the FSPCA logo
- Referencing FDA recognition of the FSPCA curriculum
- Implying the course is required

Lead Instructor Resource Portal: <https://lms.ifpti.org>

FSPCA Homepage: <https://www.ifsh.iit.edu/fspca>

Requirements for Successfully Advertising FSPCA Participant Courses

- Adding requirements for obtaining a certificate
- Referencing regulator attendance in your course
- Requirements for delivering and registering an FSPCA PCHF participant course

Lead Instructor Resource Portal: <https://lms.ifpti.org>

FSPCA Homepage: <https://www.ifsh.iit.edu/fspca>

Requirements for Successfully Advertising FSPCA PCHF and PCAF Courses

- Referencing “qualified Individual” in your advertisement
- Responsibilities of a Preventive Controls Qualified Individual
- “Preventive” not “Preventative”
- Avoid use of the acronym “HARPC”

Human Food and Animal Food Lead Instructor Resource Portal:

<https://lms.ifpti.org>

FSPCA Homepage: <https://www.ifsh.iit.edu/fspca>

Reporting Advertising Issue

Consequences for not adhering to the FSPCA advertising requirements

1. A friendly reminder by email from the FSPCA
2. A request for correction
3. A warning
4. A suspension of Lead Instructor status (or possibly all Lead Instructors associated with the advertiser)

Requirements for Successfully Advertising FSPCA Participant Courses

- Communicate the FSPCA Advertising Requirements to your Administrative and Marketing Staff
- Bottomline, FSPCA Lead Instructors will be held responsible for any violations and consequences
- **REMINDER:** FSPCA Participant Courses are NOT certification courses



**FSPCA POLICY 0017 OVERVIEW:
FSPCA PARTICIPANT COURSE DELIVERY &
REGISTRATION REQUIREMENTS**

FSPCA Policy 0017

- **Title:** FSPCA Participant Course Registration and Delivery Policy
- **Scope:** All FSPCA Lead Instructors
- **Purpose:** This policy outlines the requirements FSPCA Lead Instructors (LIs) must follow to register and deliver face to face and virtual (on-line, web-based, live) FSPCA participant courses
- **Reissued** August 27, 2021

Policy is available in the FSPCA Instructor Resource Portals

<https://lms.ifpti.org>

FSPCA Policy 0017: Section 1

- Policy 0017 may be revised from time to time
- A summary of revisions is listed in Section 1
- Check the FSPCA Instructor Resource Portals for most current version of policy

Food Safety Preventive Controls Alliance (FSPCA) Policies and Guidelines		Document #: FSPCA POL 0017	Page 1 of 7
		Author: FSPCA Trainer of Trainers Work Group	
Title: FSPCA Blended Course Registration and Delivery Policy		Scope: All FSPCA Lead Instructors, Association of Food and Drug Officials (AFDO), Trainer of Trainers Work Group, Monitoring and Evaluation Work Group	
		Distribution: All FSPCA Lead Instructors, Committees, Subcommittees, Work Groups and/or Staff	
Issue Date: August 27, 2020	Supersedes Date: February 19, 2019	FSPCA ED Approval Date: August 31, 2020	Status: FINAL
Related Documents: FSPCA_POL_0014; FSPCA_POL_0017a			

1. Summary of Revisions:

- 1.1. Section 5.3 was revised to define “contact hours”.
- 1.2. Section 5.7 was revised to clarify which training materials can be shared electronically with participants.
- 1.3. Section 5.9 was added to require course evaluations for all FSPCA participant courses.
- 1.4. Section 5.10 was revised to:
 - 1.4.1. Allow virtual delivery of FSPCA Blended Course Part 2 for Preventive Controls Animal Food (PCAF) and Foreign Supplier Verification Programs (FSVP),
 - 1.4.2. allow virtual delivery for a limited time of the FSPCA Intentional Adulteration Vulnerability Assessments (IA VA) course, and
 - 1.4.3. require Hybrid Courses, e.g. a course that includes virtual and in-person participants, to be registered as a modified course.
- 1.5. Section 5.11 was revised by:
 - 1.5.1. Removing the requirement for recordings of virtual deliveries, and
 - 1.5.2. adding virtual course criteria examples to the recommendation column.
- 1.6. Section 5.11, item 6, was revised to define “contact hours”.
- 1.7. Section 5.11, item 8, added provisions that the FSPCA has the right to audit a virtual course at their discretion.
- 1.8. Exceptions and additional criteria/requirements for the virtual delivery of FSPCA Intentional Adulteration Vulnerability Assessments (IA VA), as found in FSPCA_POL_0017a, were added to Sections 5.9, 5.10, 5.11 and 5.12.

FSPCA Policy 0017: Section 5

- Section 5 lists FSPCA Participant Course Requirements
- Recommendations and comments are also provided
- If Lead Instructors use administrators to register their courses, please make them aware of the policy requirements

5. FSPCA Participant Course Requirements

	Requirements	Recommendations/Comments
5.1	In order to issue FSPCA participant certificates, all FSPCA Participant Courses must be registered on the FSPCA Community at: https://fspca.force.com/FSPCA/s/courselist?language=en_US	Course review takes up to 5 <u>business days</u> depending on the number of courses in the queue <ul style="list-style-type: none">■ Modified course submissions may require additional time for review■ Once a course is approved, and if the course is public, the listing is added to the online FSPCA course list in the FSPCA Community<ul style="list-style-type: none">• Invitation Only courses are NOT listed on the FSPCA Community
5.2	All FSPCA Participant Courses must be registered with AEDC at least <u>two (2) weeks</u> in	Scheduling and registering trainings far in advance will allow AEDC and the FSPCA to ensure the course

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.1 In order to issue FSPCA participant certificates, all FSPCA Participant Courses must be registered on the FSPCA Community at: https://fspca.force.com/FSPCA/s/courselist?language=en_US</p>	<p>Course review takes up to 5 <u>business days</u> depending on the number of courses in the queue</p> <ul style="list-style-type: none">▪ Modified course submissions may require additional time for review▪ Once a course is approved, and if the course is public, the listing is added to the online FSPCA course list in the FSPCA Community<ul style="list-style-type: none">▪ Invitation Only courses are NOT listed on the FSPCA Community

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.2 All FSPCA Participant Courses must be registered with AFDO at least two (2) weeks in advance.</p>	<p>Scheduling and registering trainings far in advance will allow AFDO and the FSPCA to ensure the course information is thoroughly reviewed and approved in advance of the Lead Instructors' participant course.</p> <p><i>NOTE:</i> Course review takes up to 5 business days. If courses are modified, review may take longer.</p>

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p data-bbox="112 396 1043 525">5.3 All FSPCA Participant Courses must be delivered with the minimum contact hours, as shown below:</p> <ul data-bbox="208 578 1043 1013" style="list-style-type: none"><li data-bbox="208 578 840 614">• Human Food: 20 Contact Hours<li data-bbox="208 621 1043 699">• Human Food Part 2 of the Blended Course: 8 Contact Hours<li data-bbox="208 706 840 742">• Animal Food: 20 Contact Hours<li data-bbox="208 749 1043 828">• Animal Food Part 2 of the Blended Course: 8 Contact Hours<li data-bbox="208 835 685 871">• FSVP: 12 Contact Hours<li data-bbox="208 878 917 956">• FSVP Part 2 of the Blended Course: 8 Contact Hours<li data-bbox="208 963 724 1013">• IA VA: 6.5 Contact Hours	<p data-bbox="1091 396 1796 571">Lead Instructors should use participant course agenda templates provided in the Lead Instructor Resource Portals at https://lms.ifpti.org</p> <p data-bbox="1091 621 1632 699">Contact Hours do not include breaks/lunch</p>

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.4 All FSPCA Participant Courses must have at least one FSPCA Lead Instructor who is physically present through the entire course. Additionally, all assistant instructors planning to deliver FSPCA Curriculum Modules must have already successfully completed FSPCA Lead Instructor or applicable Participant course. For example, in order to deliver an FSVP curriculum, the assistant instructor must be either an FSVP Lead Instructor or have successfully completed the FSVP Participant course. AFDO will confirm that all instructors have an appropriate FSPCA certificate before the requested participant course is approved.</p>	<p>Having more than one FSPCA Lead Instructor or FSPCA Assistant Instructor is ideal, as delivering multiple modules by only one instructor may reduce instructor/student interaction and increase instructor fatigue.</p>

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.5 FSPCA Lead Instructors must not electronically share the FSPCA Curriculum PowerPoint slide decks with non-Lead Instructors and participants. The PowerPoints are intellectual property of the FSPCA.</p>	<p>Request non-Lead Instructors to review the slide sets in their participant manuals and handouts provided for the chapters they will teach so they can be familiar with the content.</p>

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.6 Translation Requirements: (FSPCA_POL_0018) Lead Instructors must use the <u>official</u> English version or other FSPCA <u>endorsed</u> language version of training materials in the FSPCA Lead Instructor Resource Portal, e.g., Spanish.</p> <ul style="list-style-type: none">• participant manual• exercise workbook• food safety plan teaching examples <p>If there is no officially reviewed translation in the Lead Instructor Resource Portal, Lead Instructors can use their own translated materials, but must:</p> <ul style="list-style-type: none">• Be bilingual in English and the foreign language• Ensure the accuracy of the delivery of FSPCA training curriculum• Inform course participants that the translation is unofficial, e.g., mark materials as “unofficial version”• Provide course participants access to the official English materials, e.g., hard copy or electronic	<p>FSPCA endorsed (official) versions can be found on the Lead Instructor Resource Portal at https://lms.ifpti.org/</p>

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.7 All FSPCA Participant Course attendees must be provided with a copy of the <u>current</u> version of the training materials.</p>	<p>Participants can download a public version of the participant manual on the FSPCA website OR all current versions are located on the Lead Instructor Resource Portal located at https://lms.ifpti.org/</p> <ul style="list-style-type: none">• Human Food: FSPCA Human Food Preventive Controls Participant Manual, Exercise Workbook, and Food Safety Plan Teaching Examples• Animal Food: FSPCA Animal Food Preventive Controls Participant Manual and Exercise Workbook• FSVP: FSPCA FSVP Participant Manual and Exercise Workbook• IA VA: FSPCA IA VA Participant Manual and Exercise Workbook

Reminder - Virtual Course Materials

We have been receiving many inquiries asking what course materials can be shared electronically with students.

- Participants can download a public version of the participant manual on the FSPCA website **OR**
- Lead Instructors can download the FSPCA Participant Manual, Exercise Workbook, and PCHF Food Safety Plan Teaching Examples and electronically share with students
- All electronic course materials can be found on the Instructor Resource Portals
- Course participants may also purchase hard copies of course materials from the [FSPCA bookstore](#)

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.8 Participants must be present for the entire course in order to receive an FSPCA participant certificate. The Lead Instructor may use discretion to cover missed course materials prior to issuing a certificate, if a participant steps away for a short period of time.</p>	<p>Use an attendance sheet to confirm that each participant is present for all the required modules. Attendance sheet template is available on the Lead Instructor Resource Portals at https://lms.ifpti.org/</p>

FSPCA POLICY 0017: Section 5

	Requirements	Recommendations/Comments
5.9	<p>Lead Instructors are required to provide course evaluations to their participants. Course evaluations must be retained by Lead Instructors for at least <u>one</u> year.</p> <p>EXCEPTION: Refer to FSPCA_POL_0017a; Item 5.4. for IA VA virtual course evaluation requirements.</p>	<p>Lead Instructors may use their own course evaluation in lieu of FSPCA's course evaluation. FSPCA course evaluation is located on the Lead Instructor Resource Portal located at https://lms.ifpti.org/.</p> <p>FSPCA has the right to request course evaluations at their discretion.</p>

FSPCA POLICY 0017: Section 5

	Requirements	Recommendations/Comments
5.10	<p>Course modifications must be identified during the course registration process using the FSPCA participant course registration form. <u>Course modifications include:</u></p> <ul style="list-style-type: none">a. Courses delivered over a longer period of time (e.g., one chapter or lesson per week)b. Registering a previously approved modified coursec. Virtual (web-based, live) courses: PCHF, HF Part 2, PCAF, AF Part 2, FSVP; FSVP Part 2; and IA VAd. Hybrid Course, e.g. a course that includes virtual and in-person participantse. Other (describe)	<p>The REVISED course registration form is available at https://fspca.force.com/FSPCA/s/courselist?language=en_US</p> <p>When identifying a previously-approved modified course, enter course registration number (REG-000000)</p> <p>See 5.3 for required contact hours</p>

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.11 Virtual (web-based, live) delivery is considered a course modification and must be indicated on your course registration form. See virtual course criteria (next slide).</p> <p>NOTE: Refer to FSPCA_POL_0017a for <u>additional</u> requirements for virtual delivery of the FSPCA Intentional Adulteration Vulnerability Assessment (IA VA) course</p>	

FSPCA POLICY 0017: Section 5

Requirements

Recommendations/Comments

5.11 Virtual Course Criteria

- 1) Instructors must have visual contact with course participants throughout the entire course.
- 2) Remote participation identification and verification must take place.
- 3) Interactive-participation strategies must be used by the Lead Instructor to engage attendees using multiple engagement tools.
- 4) Interaction between the participants and instructor should be assured, and demonstration of using course materials verified.

- 1) Visual contact platforms such as Zoom, Blue Jeans, Microsoft Meetings, etc.
- 2) Participants can provide visual identification (driver's license, passport, etc.) during the course, or you may request that they send identification in advance of the course
- 3) Use of active icons, questions & answers, polling, group discussion, breakouts, discussion boxes, and chat boxes
- 4) Use of knowledge checks (see hand icon in LI Guide for engagement and knowledge check opportunities), use of workbooks, discussion of workgroup activities

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.11 Virtual Course Criteria (continued)</p> <p>5) Group work and exercises must be conducted ensuring that all course content is delivered and there <u>is interaction between participants and instructor.</u></p> <p>6) <u>Contact hours</u> must meet FSPCA minimums as indicated in item 5.3.</p> <p>7) Administrative and/or electronic monitoring tools must be used to ensure participant activity during the course.</p> <p>8) FSPCA has the right to audit a virtual course at their discretion.</p> <p>9) A course evaluation completed by your course participants is required. Course evaluations must be retained by Lead Instructors for at least one year.</p>	<p>5) Breakout groups in chat rooms, LI checks on each breakout group periodically, have each group report out to the entire class.</p> <p>6) Contact Hours do not include breaks/lunch</p> <p>7) Platform has the capability to monitor participants at all times. A course monitor is helpful.</p> <p>8) Lead Instructors will be notified prior to any audit.</p> <p>9) FSPCA has the right to request course evaluations at their discretion.</p>

FSPCA POLICY 0017: Section 5

	Requirements	Recommendations/Comments
5.12	<p>There is no maximum course size.</p> <p>EXCEPTION: Refer to FSPCA_POL_0017a for IA VA virtual course instructor to student ratio requirements.</p>	<p>A trainer to student ratio of no more than 1:15 is strongly suggested for quality instruction and to reduce instructor fatigue.</p>

FSPCA POLICY 0017: Section 5

Requirements	Recommendations/Comments
<p>5.13 Course cancellations must be requested via the FSPCA Technical Assistance Network (TAN).</p> <p>To submit a course cancellation, follow the below steps:</p> <ol style="list-style-type: none">1. Visit https://fspca.force.com/FSPCA/s/?language=en_US2. Click "Submit an Inquiry" (blue button)3. Under "Case Reason," choose "Training / FSPCA Courses"4. Under "Description," type in the request for cancellation5. The course registration number is required (REG-000000), no cancellations can be accommodated without this number6. Click submit	<p>After course registration, very few edits will be allowed. In most instances, you will be required to cancel the course in question and resubmit a new course registration form.</p> <p>In extenuating circumstances, please contact the FSPCA Technical Assistance Network. We will assess the situation and determine if changes can be accommodated.</p>

FSPCA Policy 0017: Section 6

- Section 6 describes the do's and do not's for modifying and delivering the course materials
- Educational materials, specifically, PowerPoints that can be modified by the Lead Instructor without FSPCA prior approval include the following:
 - a. You **MAY** add photos or graphics. You should have permission to use all photos, respect copyright laws!
 - b. You **MAY** split bullets on slides to make 2 slides out of one
 - c. You **MAY** add extra slides using your own template and/or logo but do not use the FSPCA logo on your extra slides using your own template

NOTE: You are **NEVER** allowed to subtract/delete existing information from FSPCA slides.

FSPCA Policy 0017: Section 6

- Course delivery methods that can be conducted without FSPCA prior approval, include the following:
 - a. You **MAY** customize an exercise to suit a particular audience (exception is IA VA)
 - b. You **MAY** change the order of chapters / lessons
 - c. You **MAY** require prerequisites
 - d. You **MAY** add an assessment or knowledge checks
 - e. You **MAY** use your own course evaluation in lieu of FSPCA's course evaluation

FSPCA Policy 0017a for IAVA

- Reissued August 23, 2021
- Reason for reissue: Permanently allowing virtual instructor led IAVA participant courses, provided the audit policy and class limits are in place
 - An instructor to student ratio of ≥ 1 to 8 is **required**
 - For auditing purposes, IAVA LIs must share access to the virtual course with FSPCA, if requested. Audits will be announced by FSPCA at least 24 hours prior to the start of the course.



EXPERT

Ryan Newkirk

U.S. Food and Drug
Administration
(FDA)



EXPERT

Jon Woody

U.S. Food and Drug
Administration
(FDA)



MODERATOR

Debra Freedman

Food Protection
and Defense
Institute



SCRIBE

Caitlin Hickey

U.S. Food and Drug
Administration
(FDA)

BREAKOUT SESSION

Ask an Expert: Intentional Adulteration



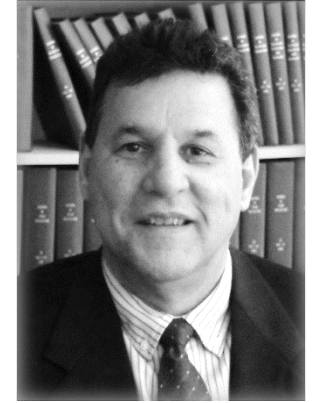
EXPERT
Jeff Chilton
Intertek Alchemy



EXPERT
Art Johnstone
Public Health
Partners



EXPERT
Jennifer van de Ligt
Food Protection
and Defense
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EXPERT/MODERATOR
Juan Silva
Mississippi State
University

BREAKOUT SESSION

Ask an Expert: Virtual Training Tips



PRESENTER
Martin Bucknavage
Penn State



PRESENTER
Katherine Simon
Minnesota
Department of
Agriculture,



MODERATOR
Jerry Wojtala
International Food
Protection Training
Institute (IFPTI)

UPDATE ON THE FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD CURRICULUM

WELCOME

Martin Bucknavage and Katherine Simon

Co- Chairs, PCHF Curriculum Update Work Group

OUTLINE

	Description:	Presenter(s):
1	Review of Approach and Process	Katherine Simon
2	Project Status	Katherine Simon
3	Key changes and examples	Martin Bucknavage
4	Next Steps	Katherine Simon
5	Questions?	Attendees

CURRICULUM UPDATE – APPROACH AND PROCESS

Katherine Simon

Co- Chair, PCHF Curriculum Update Work Group

WHY?

FSPCA Strategic Plan (July 26, 2018)

“Excellence”

- The FSPCA should ensure that core curricula and training materials remain up-to-date, being cognizant of all changes to the Food Safety Modernization Act implementing rules and issuance of relevant guidance documents”
- Necessary that curriculum be updated and changed to reflect current information and approaches

GOALS

- Address new regulatory 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 acceptance from third-party organizations as approved HACCP-based curriculum *

SCOPE

What is being updated

- Course PowerPoints
- Participant manual
- Participant workbook
- Instructor delivery notes
- Appendices in manual

Focus of changes

- Technical updates
- Increase effectiveness of instructor delivery

COMPLETED ACTIONS

- Existing Instructor Input Compiled - **DONE**
 - Lead Instructor Trainings
 - Feedback to FSPCA Admin
 - Survey of Changes Recommended by Lead Instructors
- Work Group established - **DONE**
- Curriculum organizational change - **DONE**
- Content update – **ONGOING**
 - >21 meetings since January 2021**

PC-HF WORKGROUP

FSPCA Executive Advisory Board

Co-Chair: Martin Bucknavage – Penn State
Co-Chair: Katherine Simon – MN Dept. of Ag.
Claudia Coles - Seafood Products Association
Kathy Gombas - FSMA Solutions
Tania Martinez - Demos Global Group, Inc.
Juan Silva - MS State
Jason Wan – IIT

FDA Reviewers

Lillian Hsu - FDA
Deb DeVlieger - FDA
Jenny Scott - FDA

Additional Members

Lynette Johnston - NC State
Wendy White - GA Tech
Kimberly Anderson - Iowa State
Richard Kralj - Penn State Extension
Warren Stone - Zone One Consulting, LLC
Sergio Neito-Montenegro - Food Safety CTS
Joshua Sams - GHD Digital
Elise Forward - Forward Food Solutions

Editor

Ruth Petran, Ruth Petran Consulting

GENERAL PROCESS

- Co-chair drafts changes in PowerPoint
 - Reviewed by workgroup and discussed
 - Modification made based on input
 - Instructor clarification needs identified
 - Final review by workgroup
- **OUTPUT -**
 - **PowerPoint Content Updated per Chapter**
 - **Instructor Delivery Notes Drafted**

GENERAL PROCESS

- Manual editor drafts text changes
 - Participation in workgroup discussions
 - Identification of manual text updates
 - Final review by workgroup – *end of process*
- **OUTPUT –**
 - **Participant Manual Updated per Chapter**
 - **Instructor Notes Updated per Chapter**
 - **Change Log Populated**

KEY UPDATES AND EXAMPLES

Martin Bucknavage

Co- Chair, PCHF Curriculum Update Work Group

PC-HF CHAPTER OVERVIEW

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

PREFACE AND CHAPTER ONE

Preface

- Contains items pertaining to the course management.
- Moved elements from Chapter one to this section.

Chapter 1

- Combines Chapter One and Two of previous version.
- Streamline to reduce redundancy
- Connect PCHF to HACCP

CHAPTER ONE

UPDATED VERSION

Preventive Controls

Preventive Controls as determined by the Hazard Analysis

Allergen Preventive Control

- Prevention of cross-contact
- Prevention of mis-labeling

Sanitation Preventive Control

- Prevention of contamination in the post-process environment



Supplier Preventive Control

- Supplier control of ingredient where supplier controls the hazard

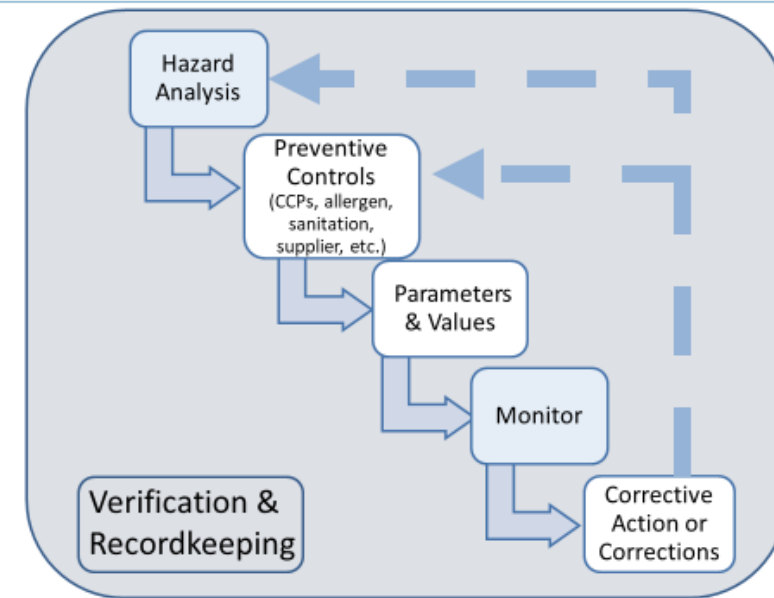
Process Preventive Control

- Cooking eliminates pathogens



CURRENT VERSION

Preventive Controls Include More Than HACCP



CHAPTERS ON HAZARDS

Chapter 3 – Biological Hazards

- Update RFR and CDC data
- Cover 5 biological hazards

Chapter 4 – Chemical, Physical and Economically Motivated

- Added additional information on chemicals with specific controls of each
- Heavy metals is one that got additional attention

CHAPTERS ON HAZARDS

Chapter 5 – Hazard Analysis (in progress)

- Combines elements of previous Chapter 7 (resources)
- Will incorporate 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

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 up to discuss after Critical Limits

Ch 9 – Monitoring and Corrective Action

- Added examples for both monitoring and corrective action

PROCESS PREVENTIVE CONTROLS

Chapters 8, 9 and 10

- **Ch. 10 - Verification and Record Keeping will be covered at this point**
 - Allows entire coverage for all elements
 - Allergen PC and Sanitation PC will have verification and record keeping elements as well without having to reintroduce overall concepts
 - PC Plan verification will be covered after the other Preventive Controls are discussed

PROGRESS

Pre.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	App.	WB
X	X	X	X	X		X	X	X	X									

Expected Timeline

- Goal completion of work group updates by December 2021

And then what?

KEY INTERDEPENDENCIES

Related Materials

- **Obtain formal FDA recognition**
- Update Online Course: “Part One”
- Update to “Part Two” materials
- Certificate, Bookstore product updates for printing
- Bookstore phase out/ phase in plan
- Establishing new book sales contracts
- Establish participant course evaluations
- Update current translation releases
- Complete new transitions

Lead Instructors

- Create and hold mandatory LI Refresher Course/Webinars
- Develop Plan to update ToTs on the new material
- Update Lead Instructor Course
- Create a new LI course Supplemental Instructor Guide
- Update Course Modification guidance
- Identify any changes needed to Admin slides

Communications

- Develop Transition Plan Marketing and Communications Plan
- FSPCA website updates
- Review TAN implications
- Determine international audience needs

BREAKOUT SESSION SUMMARIES FROM DAY 1 & 2



MODERATOR

Matt Botos

Connect Food



CLOSING REMARKS

Jason Wan

Interim Executive Director, FSPCA

Interim Director, Institute for Food Safety and Health (IFSH)

CERTIFICATE OF ATTENDANCE

- You will receive an email with a link to the post-conference survey
- A link to the survey will also be posted on the FSPCA website (under FSPCA Presentations and Conferences)
- The survey closes November 5th
- Certificates will be issued within 10 business days after the close of the survey, and no later than November 19th.



PRESENTATIONS

- Approved presentations will be posted on the FSPCA website shortly after the Conference
- This Conference was not recorded



THANK YOU!