

FSPCA 2020 VIRTUAL ANNUAL CONFERENCE

FSMA COMPLIANCE DURING THE PANDEMIC AND BEYOND

December 8-9, 2020 | Day 1



WELCOME

Robert Brackett

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

DAY 1 CONFERENCE AGENDA

MORNING SESSION			
START	END	SESSION	PRESENTERS
9:15 AM	11:00 AM	2020 FDA Update: Implementing FSMA Before and During COVID-19	Presenters: Glenn Bass, John Verbeten Moderator: Robert Brackett
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 2020 Perspectives	Expert: Glenn Bass 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	Keeping the Food Supply Chain Strong: Industry Insights and Impacts in 2020	Panel: Sally Klinect, Loralyn Ledenbach, Kelly Stevens Moderator: Juan Silva
1:30 PM	2:25 PM	The Pandemic's Impacts on Food Manufacturers: Food Safety and Beyond	Panel: Betsy Booren, Maile Hermida, Kevin Myers, Jenny Scott Moderator: Matt Botos

HOUSEKEEPING

- The WebEx link you received is good for the entire Conference and all Breakout Sessions. You have the ability to leave and rejoin the Main Conference and Breakout Sessions using that same link.
- All attendees are muted. Please submit questions via the Q&A Box. Questions will be relayed to the presenters by the moderator.
- This Conference is not being recorded. Approved presentations will be posted on the FSPCA Conference webpage after the Conference.

FSPCA UPDATE

Highlights

- Establishment of the Executive Advisory Board (EAB)
 - Provide strategic advice to move FSPCA forward
 - Made up of a diverse set of individuals with broad experience in food safety and training
- FSPCA Management
 - Responsible for day-to-day business of running of FSPCA



**MARTIN
BUCKNAVAGE**
Senior Food Safety
Extension
Associate,
Penn State
Department of
Food Science



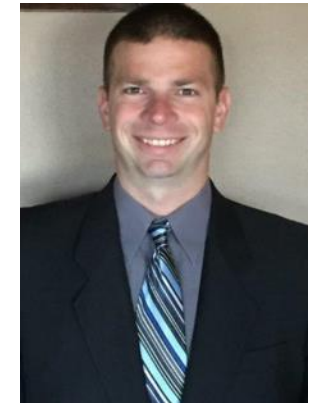
CLAUDIA COLES
President,
Seafood Products
Association (SPA)



DAVID FAIRFIELD
Senior Vice
President, Feed
Services,
National Grain
and Feed
Association
(NGFA)



**KATHY GOMBAS
(CHAIR)**
Food Safety
Consultant,
FSMA Solutions



CHRIS LINCECUM
Feed Safety
Director,
Cooperative
Farmers Elevator

FSPCA EXECUTIVE ADVISORY BOARD



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LIYOKHO**
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Quality
Manager/Director,
Coca Cola



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Agriculture: Food
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**DOUGLAS STEARN
(FDA EX OFFICIO
MEMBER)**
Deputy Director,
Center for Food
Safety and
Applied Nutrition,
FDA

FSPCA EXECUTIVE ADVISORY BOARD



ROBERT BRACKETT

Vice President
and Director,
Institute for Food
Safety and
Health, Illinois
Institute of
Technology



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MANDERNACH**

Executive
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Association of
Food and Drug
Officials (AFDO)



AKHILA VASAN

Food Safety
Manager,
Institute for Food
Safety and Health



JASON WAN

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



GERALD WOJTALA

Executive
Director,
International Food
Protection Training
Institute (IFPTI)

FSPCA MANAGEMENT

RESTRUCTURING OF COMMITTEE AND WORKING GROUPS

- As needed, we will be soliciting volunteers with food safety expertise to serve on both established and new Committees and Work Groups
- Hear about volunteer opportunities by signing up for FSPCA Updates



**WE WANT
YOU!!**

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.

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Email Lists
 FSPCA General Interest
 IFSH General Interest

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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!

Email Lists

- FSPCA General Interest
- IFSH General Interest

Security Check



PRESENTER

Glenn Bass
U.S. Food and Drug
Administration
(FDA)



PRESENTER

John Verbeten
U.S. Food and Drug
Administration
(FDA)



MODERATOR

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

2020 FDA UPDATE: IMPLEMENTING FSMA BEFORE AND DURING COVID-19

2020 FDA Update: Adapting to New Food Safety Paradigm

FSPCA 2020 Virtual Annual Conference

Glenn T. Bass, MS

Deputy, Human and Animal Food Program (HAF) - West

Office of Regulatory Affairs

U.S. Food & Drug Administration

December 8, 2020

Objectives

COVID-19 Pandemic Updates

Inspection Numbers: Domestic & Foreign

1. Human Food (HF)
2. Animal Food (AF)
3. Intentional Adulteration (IA)
4. Sanitary Transportation (ST)
 1. HF
 2. AF

Inspection Classifications: Domestic & Foreign

1. HF
2. AF

Objectives

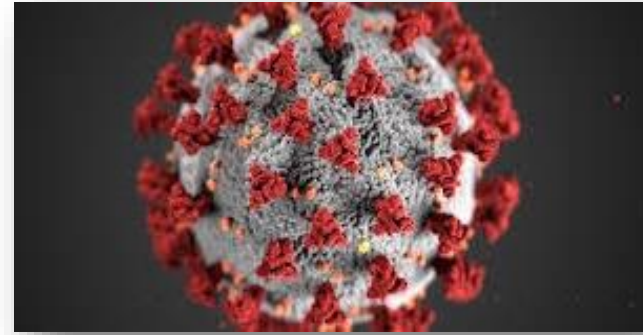
Frequent Cited Observations:

1. HF
2. AF

FSMA Implementation Updates

What's Next

Thank You for Your Resilience!



- We are all in this together!
- FDA's webpage [Food Safety and the Coronavirus Disease 2019](#)
- Some inspections are temporarily on hold, but the food industry is still required to meet food safety requirements – that has not changed.
- Mission Critical

FDA Inspection Timeline

March 10, 2020

- FDA postponed *foreign* inspections

March 18, 2020

- FDA postponed *domestic* inspections

July 10, 2020

- Resumption of inspections using risk assessment system (COVID-19 Advisory Tool)

FDA Activities

- Resuming inspections using an **Advisory Rating System**.
- **Pre-announcing** inspections using standardized script with assessment questions.
- Verifying the agency's Official Establishment Inventory.

COVID adjustments since March 2020

58K

OEI

211

On-Site
Mission Critical

98

Remote
Mission Critical

195

Surveillance

Mission Critical

(e.g. outbreaks of foodborne illness, Class 1 Recalls)

Outbreak Investigations by Year

2020

- *Salmonella*: Wood Ear Mushrooms - Dried Fungus (September 2020)
- *Salmonella*: Peaches (August 2020)
- *Cyclospora*: Bagged Salad (June 2020)
- *Salmonella*: Red Onions (July 2020)
- *Listeria monocytogenes*: Enoki Mushrooms (March 2020)
- *E. coli*: Clover Sprouts (February 2020)



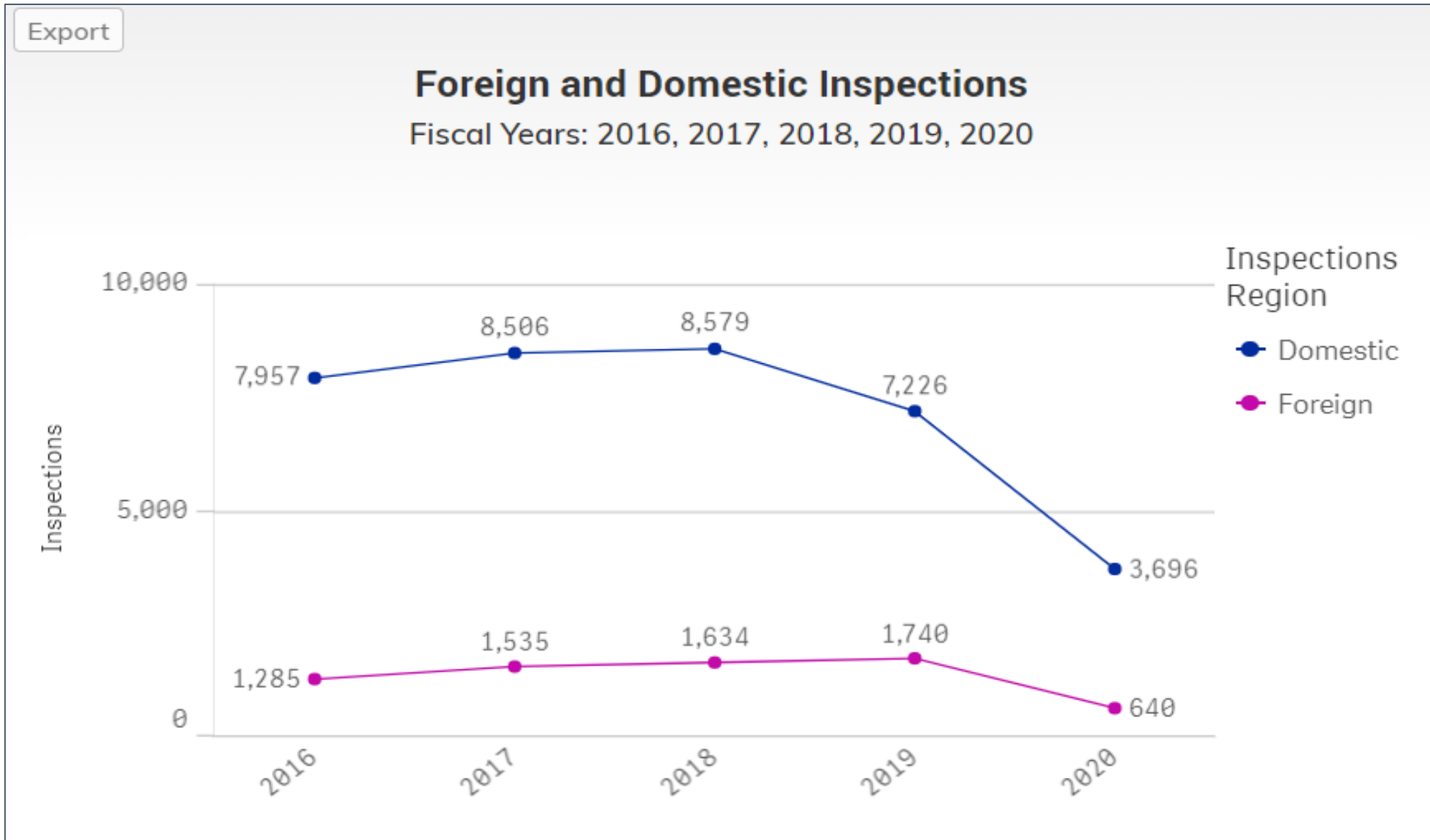
FDA Activities

Recall Events



The New Food Safety Paradigm





Human Food Inspections

	2018	2019	2020
Modernized GMPs- Human Food (HF): domestic	2786	3692	1964
Modernized GMPs- Human Food (HF): foreign	983	1273	549
Preventive Controls-Human Food (HF)-Full Scope: domestic	445	554	425
Preventive Controls-Human Food (HF)-Full Scope: foreign	151	212	98



Animal Food Inspections

	2018	2019	2020
cGMPs- Animal Foods (AF): domestic	322	288	91
cGMPs- Animal Foods (AF): foreign	4	23	2
Preventive Controls- Animal Food (PCAF): domestic	1	165	78
Preventive Controls- Animal Food (PCAF): foreign	0	13	10



Inspections

	2018	2019	2020			
Intentional Adulteration (IA)	0	0	1			
Sanitary Transportation (ST)						
Human Food (HF)	97	190	90			
Animal Food (AF)	27	95	30			

Inspection Classification

Definitions:

- No Action Indicated (NAI): No objectionable practices or conditions found during the inspection.
- Voluntary Action Indicated (VAI): Objectionable practices or conditions found during the inspection but not meeting the threshold for regulatory actions.
- Official Action Indicated (OAI): Objectionable practices or conditions found during the inspection that meet the threshold for a recommendation for regulatory actions

Inspection Classification

2018	NAI	VAI	OAI
CGMP-HF-domestic	2049	685	31
CGMP-HF-foreign	649	328	4
PCHF-domestic	245	178	14
PCHF-foreign	90	59	2
cGMP-AF-domestic	292	21	5
cGMP-AF-foreign	4	0	0
PCAF-domestic	0	1	0
PCAF-foreign	0	0	0

Inspection Classification

2019	NAI	VAI	OAI			
CGMP HF-domestic	2699	912	39			
CGMP HF-foreign	835	408	28			
PCHF-domestic	239	254	50			
PCHF-foreign	114	94	2			
cGMP-AF-domestic	253	24	6			
cGMP-AF-foreign	16	7	0			
PCAF-domestic	124	25	12			
PCAF-foreign	11	2	0			

Inspection Classification

2020	NAI	VAI	OAI			
CGMP-HF-domestic	1319	585	33			
CGMP-HF-foreign	317	215	16			
PCHF-domestic	194	197	22			
PCHF-foreign	40	56	2			
cGMP-AF-domestic	71	17	2			
cGMP-AF-foreign	2	0	0			
PCAF-domestic	59	15	3			
PCAF-foreign	5	5	0			

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

FSMA Implementation Updates

- Hired additional ORA Produce Safety Network Staff for farm investigations (24).
- Hired additional ORA National Expert- CVM
- Updated Compliance Program: [Preventive Controls and Sanitary Human Food Operations](#) (10/15/2020).
- Center for Veterinary Medicine: New Compliance Program
 - Comprehensive
- Continue to focus and conduct field activities (e.g. inspections & sampling):
 - Preventive Controls Rule (Human and Animal Food).
 - Sanitary Transportation Rule
 - Intentional Adulteration
 - Environmental Sampling

What's Next

- Reassess situation frequently.
- Discuss innovative ways to meet the mission of the Office of Regulatory Affairs.
- Continue to protect health, safety and well-being of our workforce, as well as the public.

FDA Resources

- FDA's webpage: [Food Safety and the Coronavirus Disease 2019 \(COVID-19\)](#)
- Have a Food Safety Modernization (FSMA) Question? [Technical Assistance Network](#).
- [Employee Health and Food Safety Checklist for Human Food Operations During the COVID-19 Pandemic \(recorded session\)](#)
- Questions may be submitted for food products to: [Food and Cosmetics Information Center](#)

Foreign Supplier Verification Programs (FSVP)

Human and Animal Food Inspections Update

Presenter:

John Verbeten, Acting OEIO Deputy Director



FY17 – FY21 FSVP Overview

- FSVP training and trained investigators
- FSVP inspection statistics
- Inspection classifications and top citations
- FY19 & FY20 DUNS trends
- Remote inspection positives, challenges, and barriers
- FDA and industry remote inspection feedback
- Transitioning from education to enforcement

FY17-21 FSVP Training

- FY17 → 3 courses = ~100 trained
- FY18 → 5 courses = ~200 trained
- FY19 → 4 courses = ~150 trained
- FY20 → 4 courses planned, 3 canceled due to pandemic = ~35 trained
- FY21 → 3 online courses planned = ~75 trained
- Anticipated total trained by end of FY21 = ~560

FY17-19 FSVP Inspection Summary

- FY17 → 280 FSVP inspections completed
 - OAI → 0; VAI → 170; NAI → 111
- FY18 → 785 FSVP inspections completed
 - OAI → 0; VAI → 505; NAI → 280
- FY19 → 870 FSVP inspections completed
 - OAI → 27; VAI → 518; NAI → 296



FY20 FSVP Inspection Statistics

- FY20 Work Plan Goal → 1400 FSVP Inspections
 - Human Food Goal: 1325
 - Animal Food Goal: 75

FY20 - 10/1/2019-9/30/2020:

- Completed Op12 FSVP Inspections → 1305 or 93% of goal completed
 - Human Food Completed: 1238 or 93%
 - Animal Food Completed: 67 or 89%

FY20 FSVP Inspection Classifications



- Human Food Inspection Classifications
 - OAI → 73 or 5.6%
 - VAI → 701 or 56.6%
 - NAI → 463 or 37.4%

- Animal Food Inspection Classification
 - OAI → 0
 - VAI → 36 or 53.7%
 - NAI → 31 or 46.3%

FY20 Top 5 Human Food Citations



Top 5 Human Food Inspection Citations FY20

The importer did not:

1. 1.502(a): Develop an FSVP - 485
2. 1.505(b): Document foreign supplier approval – 53
3. 1.504(a): Have a written hazard analysis – 47
4. 1.505(a)(2): Document evaluation conducted – 44
5. 1.506(b): Establish written procedures to ensure appropriate verification activities conducted – 39

FY20 Top 5 Animal Food Citations



Top 5 Animal Food Inspection Citations FY20

The importer did not:

1. 1.502(a): Develop an FSVP – 28
2. 1.512(b)(2)(4): Develop an FSVP (very small importer) – 4
3. 1.504(a): Have a written hazard analysis – 1
4. 1.504(c)(1): Include hazard evaluation in hazard analysis – 1
5. 1.505(a)(2): Document evaluation – 1



FY21 FSVP Inspection Statistics

FY21 Work Plan Goal → 1750 FSVP Inspections

- Human Food Goal: 1050 (Produce: 137; Dietary Supplements: 50)
- Animal Food Goal: 100
- Re-inspections: 600

FY21 - 10/1/2020-11/30/2020:

Completed Op12 FSVP Inspections → 83 or 4.7% of goal completed

- Human Food Completed: 80 or 7.6%
- Animal Food Completed: 3 or 3%

FY21 FSVP Inspection Classifications

- Human Food Inspection Classifications
 - OAI → 12 or 15.0%
 - VAI → 25 or 31.3%
 - NAI → 18 or 24.1%
 - Other → 25 or 31.3% (“null” or no final decision)
- Animal Food Inspection Classification
 - OAI → 0
 - VAI → 1 or 33.3%
 - NAI → 2 or 66.7%

FY21 Top 5 Human Food Citations



Top 5 Human Food Inspection Citations FY21

The importer did not:

1. 1.502(a): Did not develop an FSVP – 28
2. 1.506(a)(1): Establish written procedures to ensure use of approved foreign suppliers – 4
3. 1.504(b)(1): Include a known or reasonably foreseeable hazard in hazard analysis – 3
4. 1.505(a)(2): Document evaluation – 3
5. 1.504(a): Have a written hazard analysis - 2



FY21 Top Animal Food Citation

Top Animal Food Inspection Citation FY21

The importer did not:

1. 1.502(a): Develop an FSVP – 1

Remote FSVP Inspections

- April 3, 2020 – In response to COVID-19, FDA announced implementation of remote FSVP importer inspections
- Rare situations may warrant an onsite inspection (i.e., foodborne illness outbreak)
- If onsite inspection is warranted, investigator will:
 - Make appropriate arrangements with importer
 - Practice social distancing based on recommendations made by CDC



Remote FSVP Inspections: Overall, What is Going Well?

- Since implementation, FDA has conducted a total of 781 remote inspections
- Overall positive feedback received from both, FDA investigators and industry; examples include:
 - Convenient and efficient (i.e., elimination of travel, ability to conduct multiple inspections simultaneously)
 - Decrease in stress and intimidation factors
 - Reduces occurrence of potential technical issues

Remote FSVP Inspections: Challenges and Barriers



- Examples of challenges and barriers encountered since implementation of remote inspections:
 - Remote communication solely based on telephone calls and email; leading to unresponsive importers
 - FSVP records files are too large to send via email
 - Loss of face-to-face communication to build trust and rapport between investigator and importer

Transitioning from Educating to Enforcing



- Moving from “educate while we regulate” to enforcement action
- Educate while we regulate = softer approach, providing education, assisting to achieve compliance
- Primary focus → Helping importers understand requirements and take corrective actions
- Education will continue, but enforcement action has begun



Enforcement Action: Steps Taken

- FDA is initiating more “for cause” FSVP inspections
 - i.e., Food safety issues identified at time of entry or post entry
- FDA began conducting re-inspections in FY20
 - If observations were made during an initial inspection, FDA expects the importer have taken appropriate corrective actions prior to re-inspection

Enforcement Action: 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 – 36 Warning Letters issued
- FY21 – 8 Warning Letters issued

Enforcement Action: Import Alert 99-41



- FSVP Import Alert 99-41 published on July 31, 2019
- As of November 2020, ten importers (foods and foreign supplier) placed on IA 99-41
- 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



FSVP Inspections: On the Horizon

- Overall, a vast number of importers have a strong desire to comply with FSVP
- FDA will take compliance into consideration for entry screening and targeting
- Compliant importers benefit by decreasing problems with foods they import (i.e., recalls, refusals, withdrawals, and liability)
- FDA will continue efforts to provide outreach, education, and other communications to industry



EXPERT

Glenn Bass
U.S. Food and Drug
Administration
(FDA)



MODERATOR

Claudia Coles
Seafood Products
Association (SPA)



SCRIBE

Ron Tanner
Specialty Food
Association

BREAKOUT SESSION

Ask an Expert: FDA 2020 Perspectives | Summary: See slides 142-145



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 | Summary: See slides 146-150



PANELIST
Sally Klinect
Nestlé USA



PANELIST
Loralyn Ledenbach
Kraft Heinz
Company



PANELIST
Kelly Stevens
General Mills



MODERATOR
Juan Silva
Mississippi State
University

KEEPING THE FOOD SUPPLY CHAIN STRONG: INDUSTRY INSIGHTS AND IMPACTS IN 2020

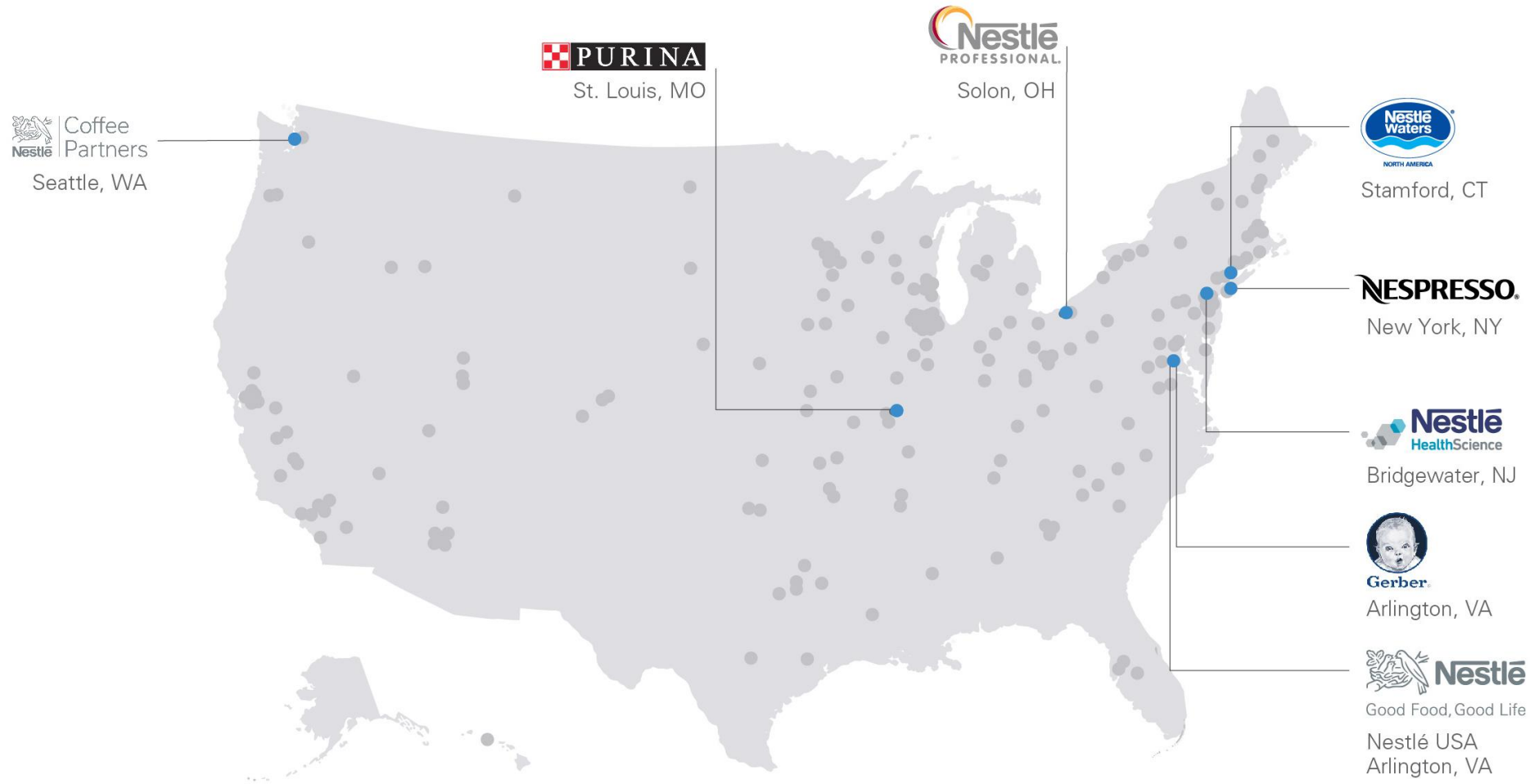
Panel Discussion

Keeping the Food Supply Chain Strong: Industry Insights and Impacts in 2020

Sally Klinect
Corporate Quality Manager, Food Safety

FSPCA Annual Conference
December 2020





Nestlé U.S. had

\$29B

in 2019 sales

NESTLÉ IN THE U.S.

- 7 operating companies
- 34 states
- 68 manufacturing facilities
- About 36,000 employees
- Largest market for Nestlé globally



NESTLÉ PROUDLY OFFERS STARBUCKS BRANDS



BLUE BOTTLE COFFEE



Nestlé's U.S. brands are in

97%

of households



We continue to evolve our incredible portfolio of brands to meet the expectations of our consumers



Baking



Beverages



Chilled and Frozen



Coffee



Pet Care



Gerber



Health Science



Water



Food Service



International

Diverse Portfolio

Across

10

Product Categories

Keeping the Food Supply Chain Strong: COVID-19 Response



Ensuring Supply



Meeting Demand



Operational Efficiency

Thank you



We make Nestlé trusted





THE KRAFT HEINZ COMPANY

Keeping the Food Supply Chain Strong: Industry Insights and Impacts in 2020

Loralyn Ledenbach
FSPCA Annual Conference 2020

About Kraft Heinz

A Global Food Powerhouse

- 3rd largest North American food and beverage company
- #1 Food Service company in North America



\$25
billion in
net sales
(2019)



5th largest
food
company in
the world



40+ countries
with dedicated
Kraft Heinz
employees

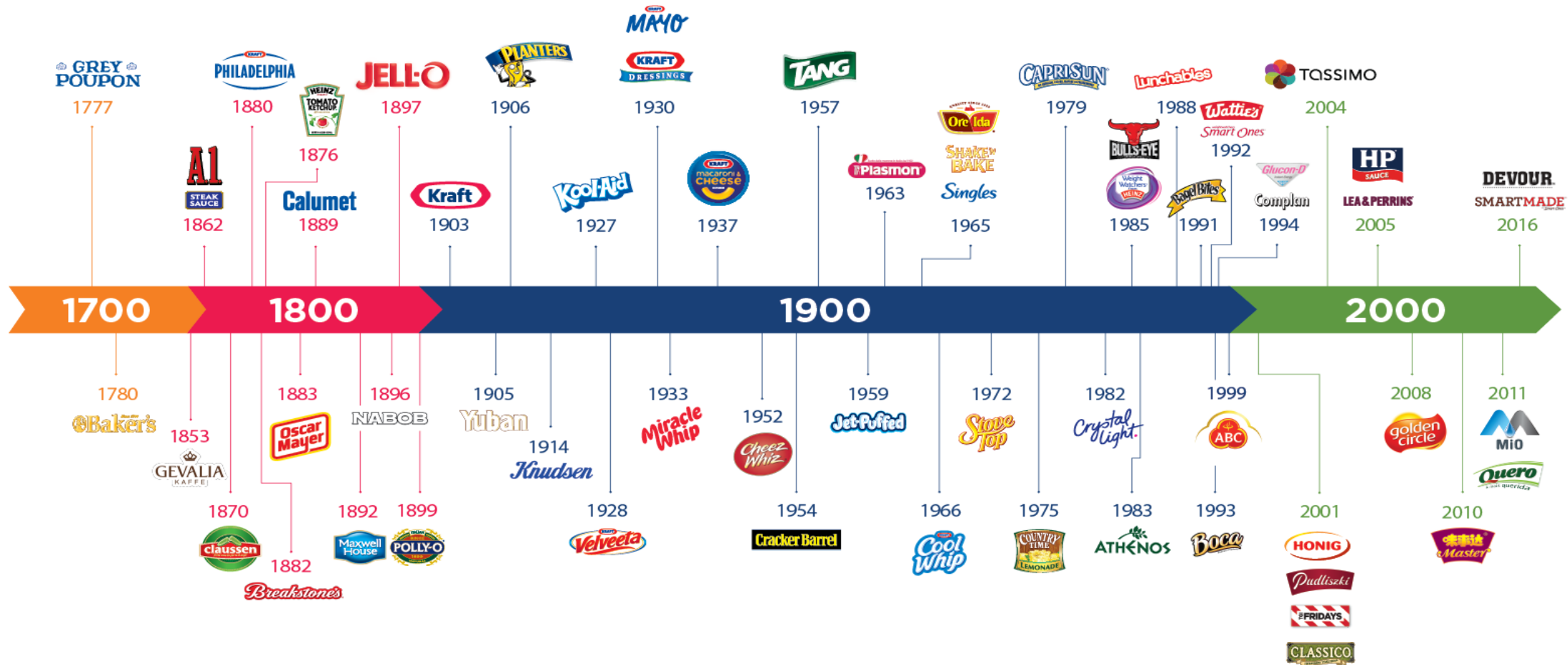


8 1-billion +
brands in
retail and
foodservice
sales



3.2 million meals
packaged by KHC
employees with our
partner Rise Against
Hunger (2019)

About Kraft Heinz



COVID-19 Response



Employee Health and Safety

- Pandemic had to be quickly addressed
- Across all manufacturing facilities, measures were implemented to require face masks and face shields (especially in closed spaces), do health check assessments, and temperature checks upon entry
- Production lines were altered as much as possible to maintain social distancing. Recently moved to maintaining 12 feet between employees wherever feasible.
- Performance monitoring on production floors is critical to maintain compliance with protective measures
- Digital signage installed across the facility to encourage social distancing
- Break rooms remodeled with plexiglass to assure social distancing. Break/lunch hours were staggered to minimize congregating inside the break areas.
- Newsletters were mailed to every employee's home in both English and Spanish to promote social distancing and wearing face masks outside of work to protect their communities and their families.
- Education coupled with contests and incentives increased compliance directly, but also gave another opportunity for employees to bring the messages home to other household members – constant vigilance needed as employees get fatigued on messaging
- Corporate offices were closed. R&D Center is only open with restricted access for critical product development work.

Production

- January-February:
 - Global leadership team pulled together the Crisis Management Team to prepare and proactively take social distancing measures at our plants
 - Majority of illnesses were related to transmissions between employees carpooling together or living together with people working at other companies
- Moving to March, we saw very significant impacts to retail and Foodservice businesses
 - 80% of foodservice business died immediately
 - Retail increased by about 20% on average
- In April-June:
 - Production facilities ramped up to make as much food as possible, retail continued to increase
 - Production prioritization was changed (i.e. cut out runs of low volume SKUs to expand capacity for popular items)
 - Outreach to communities and We Got You America message
 - Focus on reassuring public that food supply is safe
- Summer:
 - As we saw restrictions lifting, we saw demand in retail come down and saw a small increase in foodservice with an increased demand for single serve packages
- Fall-Winter:
 - Expect to see decreased demand for foodservice items again

Supply Chain Impacts

- Biggest supply chain impact was the immediate decrease in Foodservice production coupled with an immediate increase in Retail production
- Weekly spreadsheet created to track shortages, costs, and potential solutions
- Tracked by protective equipment, ingredients, packaging, co-manufacturers, etc.
- Obvious shortage: PPE, sanitizing solutions
- Surprising shortages
 - Packaging – bottles, jars, labels
 - Other companies' branded products that go into our meal kits
- Longer term had to move to Foodservice single serve vs. multiple use containers
 - Continuing to experience capacity issues for single serve items

We Got You America

KraftHeinz



Turning the (smartphone) cameras over to the factory workers, Kraft Heinz cooks up a new ad

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 is coordinated to allow for driving only

Lessons Learned

- Communication became absolutely key
 - Weekly town hall meetings with CEO and division presidents initially
 - Reduced frequency as less information was needed
- Mental health is key during this time
 - Did a number of things to engage employees
 - Webinars and Apps to help with mental health
- It is possible to keep a large multi-national company running from home offices
 - Shocking that we could do all of this from home
 - Sense of unity at company since pandemic began
- Continued need to ensure sufficient PPE available at all times
- Constant and continued vigilance for compliance at production facilities



PANELIST

Betsy Booren
Consumer Brands
Association



PANELIST

Maile Hermida
Hogan Lovells,
Washington, DC



PANELIST

Kevin Myers
Hormel Foods
Corporation



PANELIST

Jenny Scott
U.S. Food and Drug
Administration
(FDA)



MODERATOR

Matt Botos
ConnectFood

THE PANDEMIC'S IMPACTS ON FOOD MANUFACTURERS: FOOD SAFETY AND BEYOND

Panel Discussion



Jenny Scott
Senior Advisor
FDA CFSAN
Office of Food Safety

FDA's Message

- **COVID-19/SARS-CoV-2 is not a food safety issue**
- Changes to protect workers from COVID-19 could impact procedures, processes and practices related to food safety.
- [Employee Health and Food Safety Checklist for Human and Animal Food Operations During the COVID-19 Pandemic](#)

Personnel Changes

- Operating with reduced numbers of workers, workers may be assigned to different jobs to cover other employees
 - Changes to who performs key roles and responsibilities could impact control measures, monitoring, or verification procedures
 - Training?
- Need to reanalyze and revise the food safety plan?

Disruptions in Supply Chain

- Material shortages = new suppliers, ingredient substitutions could impact hazards and require changes in PCs (supplier controls)
- Travel restrictions impact supplier verification audits
 - still need to conduct verification activities to ensure incoming ingredients are safe. For audits related to FDA’s preventive controls requirements for human and animal food, see [Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency](#)



FDA

U.S. FOOD & DRUG

ADMINISTRATION

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

COVID-19: 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 capital improvements with production demands
- Remote supplier audits – the wave of the future?

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Kevin Myers

Hormel Foods





COVID Mitigation – ongoing efforts

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

CPG IN COVID-19:
HOW THE INDUSTRY
CHANGED
OVERNIGHT TO MEET
EXTRAORDINARY
DEMAND



COVID-19 is a Crisis

- **Lifted the membership requirements for all COVID-19 activities**
- **Developed COVID-19 specific member groups**
 - Regulatory Affairs
 - Supply Chain
- **Regulatory Affairs Team went into crisis mode**



Recognizing COVID-19 as a Crisis

- Worked to Keep the Industry Up and Running
- Protecting CPG Workers
- Helping Consumers

Where Do We Go Now?

Powering every day.



TEN POLICIES TO MAKE SMARTER REGULATORY POLICY PERMANENT

Transportation

1. Improve 'Hours of Service' Rules
2. Safely Modernize Truck Weight Limits

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

Pandemic Proves Smart, Nimble Regulatory Change Possible

CPG Industry Identifies Ten Regulatory Policies to Be Made Permanent



FSPCA 2020 VIRTUAL ANNUAL CONFERENCE

FSMA COMPLIANCE DURING THE PANDEMIC AND BEYOND

December 8-9, 2020 | Day 2

DAY 2 CONFERENCE AGENDA

MORNING SESSION			
START	END	SESSION	PRESENTERS
9:00 AM	10:30 AM	Applying Best Practices for Virtual Teaching to FSPCA Courses	Panel: Amanda Evans-Lara, Charles Kalish, Connie Landis Fisk Moderator: Kathy Gombas
10:30 AM	11:00 AM	FSMA's Intentional Adulteration Rule: An Update on Training and Implementation	Presenter: Jon Woody Moderator: Debra Freedman
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: Jon Woody, Colin Barthel Moderator: Debra Freedman Scribe: Caitlin Hickey
11:45 AM	12:30 PM	Influence FSPCA's Future – Listening Session for New Product and Services Ideas	Presenters: Kathy Gombas, Robert Brackett Moderator: Steven Mandernach Scribe: Claudia Coles
AFTERNOON SESSION			
12:30 PM	1:30 PM	FSPCA Preventive Controls for Human Food Survey for Curriculum Changes	Presenters: Martin Bucknavage, Katherine Simon Moderator: Jerry Wojtala
1:30 PM	2:30 PM	Breakout Session Summaries from Day 1 & 2	Presenters: Robert Brackett, Jason Wan Moderator: Matt Botos
2:30 PM	3:30 PM	Virtual Reception	All



PANELIST
Amanda Evans-Lara
HACCP Mentor



PANELIST
Charlie Kalish
Food Safety
Guides



PANELIST
Connie Landis Fisk
Produce Safety
Alliance



MODERATOR
Kathy Gombas
FSMA Solutions

APPLYING BEST PRACTICES FOR VIRTUAL TEACHING TO FSPCA COURSES

Panel Discussion

FSPCA VIRTUAL COURSE CRITERIA

1. Lead 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 **use of course materials verified**.
5. **Group work and exercises** must be conducted ensuring that all course content is delivered and there is interaction between participants and instructor.
6. **Contact hours** must meet FSPCA minimums. Contact Hours do not include breaks/lunch.
7. Administrative and/or electronic **monitoring tools** must be used to ensure participant activity during the course.
8. FSPCA has the right to **audit** a virtual course at their discretion.
9. A **course evaluation** completed by your course participants is required and retained by Lead Instructors for at least one year.

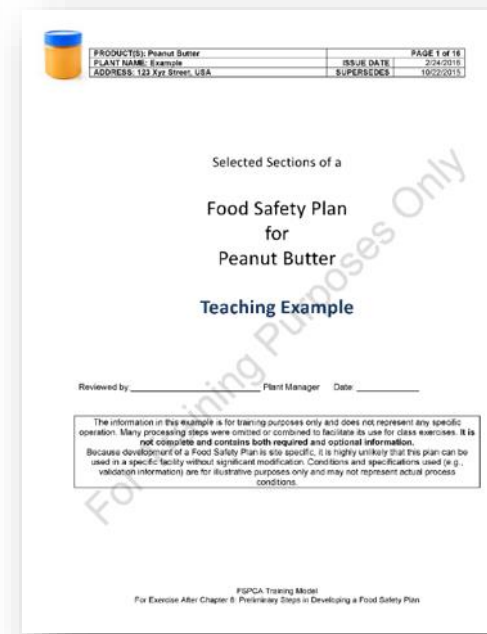
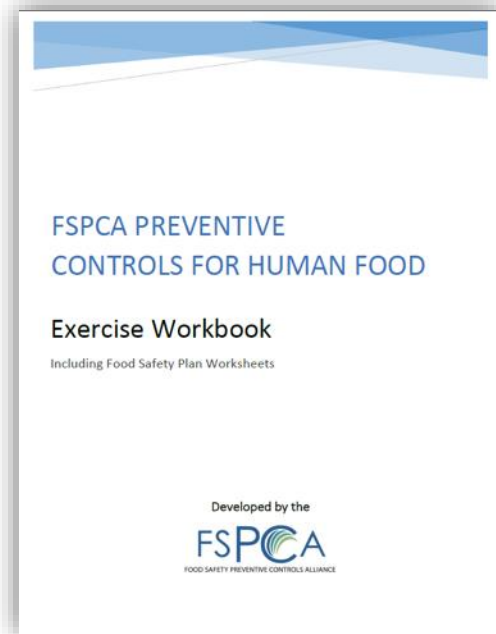
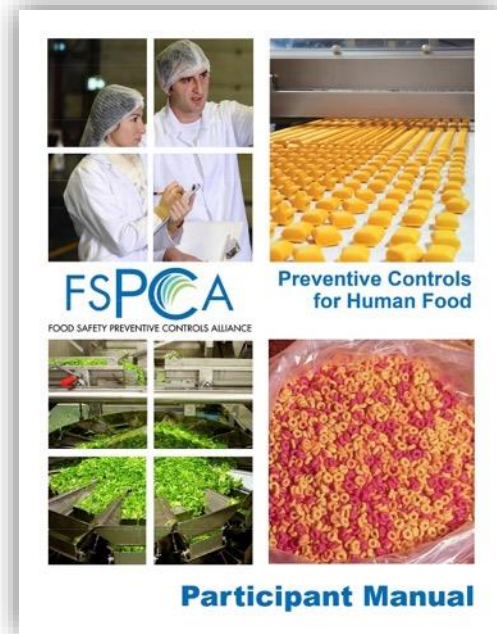
PANEL DISCUSSION

Q.1: Which FSPCA courses have you taught virtually? What platforms have you used?



PANEL DISCUSSION

Q.2: How do you provide training materials to your participants?



PANEL DISCUSSION

Q.3: How many participants can you comfortably handle? And do you use a course monitor to verify participant attendance and engagement?



PANEL DISCUSSION

Q.4: Which engagement tools do you use? What do you do if a participant doesn't engage or just isn't getting it?

Q.5: How do you do the exercises and assure participants are successful?

Q.6: Have any of your virtual courses been audited by the FSPCA?

PANEL DISCUSSION

Q.7: Do you offer a pre and post knowledge assessment for your virtual courses?

Q.8: How do you have your participants evaluate the course after delivery?

THANK YOU!





PRESENTER

CAPT Jon Woody
U.S. Food and
Drug
Administration
(FDA)



MODERATOR

Debra Freedman
Food Protection
and Defense
Institute

FSMA'S INTENTIONAL ADULTERATION RULE: AN UPDATE ON TRAINING AND IMPLEMENTATION

FSMA's Intentional Adulteration Rule: An Update on Training and Implementation

Who Is Covered by the IA Rule?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the Food, Drug, and Cosmetic Act (FD&C) Act
 - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply – see the IA Fact Sheet

What Is Required?

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

Compliance Dates

- Businesses that are not small or very small: July 26, 2019
- Small businesses (a business with fewer than 500 full-time equivalent employees): July 27, 2020
- Very small businesses (modified requirements): July 26, 2021

IA Rule Draft Guidance Update

GUIDANCE DOCUMENT

Supplemental Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration

FEBRUARY 2020

[Download the Draft Guidance Document](#)

[Read the Federal Register Notice](#)

Draft

Not for implementation. Contains non-binding recommendations.

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Docket Number: [FDA-2018-D-1398](#)

Issued by: Center for Food Safety and Applied Nutrition

The FDA Food Safety Modernization Act (FSMA) added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) several new sections that reference intentional adulteration. For example, section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food, and that are

Draft Guidance Overview

- **Introduction¹**
- **Ch 1 The Food Defense Plan¹**
- **Ch 2 Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps¹**
 - **Sections 2A-E, including background and Key Activity Types as a Method for Conducting a VAs ¹**
- **Ch 3 Mitigation Strategies for Actionable Process Steps¹**
- **Ch 4 Mitigation Strategies Management Components: Food Defense Monitoring¹**
- **Appendix 1. Food Defense Plan Worksheets¹**

1 = Installment 1

Draft Guidance Overview

- Introduction¹
- Ch 1 The Food Defense Plan¹
- Ch 2 Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps¹⁻²
 - Sections 2A-E, including background and Key Activity Types as a Method for Conducting a VAs¹
 - Sections 2F-H , including Evaluating the Three Fundamental Elements, Identifying Significant Vulnerabilities and Actionable Process Steps Using the Three Fundamental Elements, and Identifying Actionable Process Steps Using the Hybrid Approach²
- Ch 3 Mitigation Strategies for Actionable Process Steps¹
- Ch 4 Mitigation Strategies Management Components: Food Defense Monitoring¹
- Ch 8 Education, Training, or Experience²
- Appendix 1. Food Defense Plan Worksheets¹⁻²
- Appendix 4. Vulnerability Assessment Examples²

1 = Installment 1, 2 = Installment 2

Draft Guidance Overview



- Introduction¹
- Ch 1 The Food Defense Plan¹
- Ch 2 Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps¹⁻²
 - Sections 2A-E, including background and Key Activity Types as a Method for Conducting a VAs¹
 - Sections 2F-H, including Evaluating the Three Fundamental Elements, Identifying Significant Vulnerabilities and Actionable Process Steps Using the Three Fundamental Elements, and Identifying Actionable Process Steps Using the Hybrid Approach²
- Ch 3 Mitigation Strategies for Actionable Process Steps¹
- Ch 4 Mitigation Strategies Management Components: Food Defense Monitoring¹
- Ch 5 Mitigation Strategies Management Components: Food Defense Corrective Actions³
- Ch 6 Mitigation Strategies Management Components: Food Defense Verification³
- Ch 7 Reanalysis³
- Ch 8 Education, Training, or Experience²
- Ch 9 Records³
- Appendix 1. Food Defense Plan Worksheets¹⁻²
- Appendix 2. Mitigation Strategies in the Food Defense Mitigation Strategies Database³
- Appendix 3. Calculating Small Business and Very Small Businesses Sizes³
- Appendix 4. Vulnerability Assessment Examples²

1 = Installment 1, 2 = Installment 2, 3 = Installment 3

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, an employee of the establishment.

Guidance: Education, Training, or Experience





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

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)		<ul style="list-style-type: none"> • Conduct VAs using the KAT Method <u>only</u>
Conducting Vulnerability Assessments (IAVA)		<ul style="list-style-type: none"> • 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		<ul style="list-style-type: none"> • Identify Mitigation Strategies to implement at Actionable Process Steps
Food Defense Plan Preparation and Reanalysis		<ul style="list-style-type: none"> • Prepare the Food Defense Plan • Conduct Reanalysis activities

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

IA VA Virtual Delivery Pilot Purpose

- IAVA Virtual Pilot
 - Goal: evaluate the virtual IAVA course in a way that facilitates sharing of best practices and retains the integrity of the course

- Additional criteria for delivering the IAVA course virtually during the Pilot
 - Audits
 - Course Evaluation
 - Class size



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.*”

Inspection Strategies

Inspection Framework

- Two-level inspectional approach
 - Food defense plan Quick-Check inspection
 - Conducted on covered facilities during food safety inspections
 - High level review of Food Defense Plan (FDP)
 - Engage industry/educate while we regulate
 - Comprehensive food defense inspections
 - Conducted only at a limited number of prioritized facilities
 - Conducted by specially trained investigators
 - Critical evaluation of FDP, conclusions, rationale

Timing of Inspections

- Begin Quick Checks: March 2020 (**Covid-19 delay**)
 - Large firms (>500 FTE) currently subject to inspection

Inspections of Small Businesses under the FSMA Intentional Adulteration Rule to Begin March 2021

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Constituent Update

July 15, 2020

Today, the U.S. Food and Drug Administration announced that routine inspections of small businesses to verify compliance with the FDA Food Safety Modernization Act's (FSMA) [Intentional Adulteration \(IA\)](#) rule will begin in March 2021.



Version 2.0



www.fda.gov/fooddefense



EXPERT

CAPT Jon Woody
U.S. Food and Drug
Administration
(FDA)



EXPERT

Colin Barthel
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 | Summary: See slides 151-155



PRESENTER

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Institute for Food
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PRESENTER

Kathy Gombas
FSMA Solutions



MODERATOR

**Steven
Mandernach**
Association of
Food and Drug
Officials (AFDO)



SCRIBE

Claudia Coles
Seafood Products
Association (SPA)

LISTENING SESSION

For New Product and Services Ideas - Influence FSPCA's Future
Summary: See slides 156-160



PRESENTER
**Martin
Bucknavage**
Penn State



PRESENTER
Katherine Simon
Minnesota
Department of
Agriculture



MODERATOR
Gerald Wojtala
International Food
Protection Training
Institute (IFPTI)

FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD SURVEY FOR CURRICULUM CHANGES

OUTLINE

	Description:	Presenter(s):
1	Update Approach and Process	Katherine Simon
2	Survey Goals	Martin Bucknavage
3	Initial Survey Results	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

COMPLETED ACTIONS

- Existing Instructor Input Compiled
 - Lead Instructor Trainings
 - Feedback to FSPCA Admin
- Proposed Updates/Changes Reviewed by EAB
- Survey of Changes to Lead Instructors

- THANK YOU!

APPROACH TO UPDATES

- Technical updates
- Streamline and simplify
- Gain acceptance from third-party audit standard benchmarking groups, e.g. GFSI for HACCP training requirement

EXPECTED PROCESS

- Establish Full Work Group – in process
 - Content specific planning decisions
 - Detailed Survey Review
 - Identify interdependencies, additional support needs
 - Provide input and volunteer resources for specific chapter updates
 - Monitors progress of work plan
 - Updates provided to EAB and Related Committees
- **OUTPUT – Curriculum Update Workplan by Chapter**

EXPECTED PROCESS

- Chapter Lead
 - Implement Chapter Work Plan
 - Proposed changes drafted in PowerPoint content
 - Presented to Lead Instructor via webinar
 - Transparency, Awareness and Input
 - Text content updated based on PowerPoint
 - Errata tracking
 - Workgroup final review
- **OUTPUT – Content Update by Chapter**

CURRICULUM UPDATE – SURVEY OF LEAD INSTRUCTORS

Martin Bucknavage

Co- Chair, PCHF Curriculum Update Work Group

GOALS

- Necessary changes
- Reflect updated information, update references, e.g. RFR, CDC
- Address regulatory guidance documents
- Streamline sections, reduce redundancy
- Simplify concepts
- Gain acceptance from third-party organizations as approved HACCP-based curriculum
- Make more accessible for small and mid-sized producers

OVERALL RESULTS FROM SURVEY

- 127 respondents to survey
- There was a high levels of agreement (70%+) on many items
- Many excellent comments

INITIAL PROPOSALS

Preface

- Course management items, non-technical components
- Disclaimer
- Need for interaction
- What is FSPCA
- Introductions
 - What do participants want to get out of this course...where are they at on their food safety journey

INITIAL PROPOSALS

Introduction and Regulation

- With course management material being moved into preface, focus on an overview of the food safety plan
- HACCP-based with brief history
- Regulation (which may be covered as a chapter at the start)
- Components as required in the regulation
- How it fits into a company's overall food safety plan
- Added slides at end of chapter for International explanations

INITIAL PROPOSALS

GMPs and other Prerequisite Programs

- Discussion of components or rules of GMPs regulation
- More detailed discussion of other prerequisite programs
- How these programs control hazards with examples

INITIAL PROPOSALS

Hazards – Biological, Chemical, Physical

- Discussion of factors affecting growth
- Include additional bacterial hazards with controls
- Add additional information on chemical hazards beyond allergens
- Discuss specific controls for chemical and physical hazards
- Add resource information on Economically Motivated hazards

INITIAL PROPOSALS

Hazard Analysis

- Streamline hazard evaluation process
- Incorporate use of Hazard Guide and example
- To be decided - separate chapter for previewing Preventive Controls

INITIAL PROPOSALS

Process Preventive Controls

- Link to HACCP
- Move in discussion of verification and validation
- Move in discussion of record keeping

INITIAL PROPOSALS

Allergen Preventive Controls

- Discussion of interaction between control by prerequisite programs and control by an Allergen Preventive Control
- Add verification and record keeping

Sanitation Preventive Control

- Include discussion of allergen monitoring as a verification tool
- Add record keeping

INITIAL PROPOSALS

Supply Chain Preventive Control

- Streamline chapter
- Discussion of supplier approval and then supplier maintenance
- Discussion of COA, LOC, and LOG (one slide) including limitations

INITIAL PROPOSALS

Regulation

- Cover components of the entire FSMA regulation with emphasis of which sections may apply to food processors (IA for example)
- Discussion of regulatory oversight in the US

WHAT IS NEXT?

- Solicitation of Work Group Volunteers
- Work Group Meets
 - Workplan established per chapter
 - Based on Survey Responses
- Workplan implementation
 - **Chapter content webinars with Lead Instructors**
- Updates and coordination with other groups
 - International
 - Implementation
 - Translation



PRESENTER

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



PRESENTER

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



MODERATOR

Matt Botos
ConnectFood

BREAKOUT SESSION SUMMARIES FROM DAY 1 & 2

FDA 2020 PERSPECTIVES

1. Remote Regulatory Assessments (RRA):

- FDA is exploring the feasibility of RRA
- RRA would allow FDA to give credit to companies for the good they've done to implement corrective actions
- RRAs will be voluntary. FDA will reach out to companies to let them know an RRA is available.
- RRAs are not audits or inspections

FDA 2020 PERSPECTIVES

2. Regulator Training

- Regulator training is continuing during the COVID-19 pandemic. All regulator courses are being delivered virtually.

FDA 2020 PERSPECTIVES

3. FSVP Inspections

- The FSVP regulation was written to include the option for remote inspections since FSVP inspections are document review
- FDA expects to increase FSVP inspections in FY 2021

4. COVID Precautions

- FDA will only conduct domestic prioritized surveillance inspections in states in yellow and green zones, not red zones. All inspections are currently preannounced.
- Red zones - FDA will only conduct mission critical inspections (e.g., follow-up to Class 1 recalls, outbreak investigation, warning letter follow-up)
- FDA follows the CDC and White House guidance for COVID zones
- FDA investigators have a procedure that contains scripted language to be used when pre-announcing inspections; i.e., are facility employees infected with COVID, has there been an outbreak in the facility?

FDA 2020 PERSPECTIVES

5. New Administration

- There may be some delays in FDA regulations and guidances due to the administration change

ANIMAL FOOD

1. PCAF Curriculum

- Demonstrated where to submit suggested feedback and edits
- Explained the Livestock Food Safety Plan published in November
- Livestock food safety plan will be incorporated into the next curriculum update.
- Curricula update schedule has not been set at this time

ANIMAL FOOD

2. FDA's Comprehensive Animal Food Compliance Program Guidance Manual

- Expected to be issued in Jan 2021
- To include all animal food programs within one program

ANIMAL FOOD

3. The external FSMA Preventive Controls and Import Controls dashboards

- Demoed dashboard and provided links in the chat
- Feedback was requested on what additional measures would external stakeholders like to see be developed, and to email Dianne Milazzo
- The data on the FSMA dashboards uses inspections with a final decision for inspections where as the data presented yesterday morning may include inspections that may not have a finalized decision
- State inspections are also included in this dashboard

ANIMAL FOOD

4. Inspections conducted by the State that does not include the PC regulation

- This may be because the facility is located in a State that doesn't have any PC inspections in their contract
- It could be that this facility was not selected by the State for a PC inspection
- The State contract language lags behind our comprehensive approach
- The 2021-22 contract language is currently being edited to incorporate this comprehensive approach

ANIMAL FOOD

5. Remote regulatory assessments for animal food facilities

- More targeted and limited
- Voluntary
- Communications from the Office of Regulatory Affairs' Office of Human and Animal Foods Operations will publish in the new year

INTENTIONAL ADULTERATION

1. Food Defense Plan Quick-Check inspections

- These inspections are currently occurring at large facilities (started in March 2020, but Covid-19 is impacting FDA inspectional operations)
- Conducted on covered facilities during food safety inspections, not as a standalone inspection
- Includes a high level review of Food Defense Plan

INTENTIONAL ADULTERATION

2. **Comprehensive food defense inspections**

- Are not occurring now, and will not for another few years
- Conducted only at a limited number of prioritized facilities

INTENTIONAL ADULTERATION

3. Virtual IAVA courses

- FSPCA is currently piloting the virtual IAVA courses (at least through March 2021)
- The goal is to evaluate the virtual IAVA course in a way that facilitates sharing of best practices and retains the integrity of the course
- FSPCA has not made a decision on hosting virtual LI courses for IAVA or courses under other rules

INTENTIONAL ADULTERATION

4. Update on other food defense tools and guidance

- The second version of the Food Defense Plan Builder (version 2.0) published last year and aligns with the requirements in the IA rule
- The 3rd installment of IA rule guidance has published and includes the updated mitigation strategies from the Mitigation Strategies Database
- FDA would love feedback on the FDPB and comments on the draft guidance

INTENTIONAL ADULTERATION

5. IA rule exemptions

- Dietary supplements are not exempt from the IA rule
- Animal food facilities are exempt
- Facilities that hold food (except food in liquid storage tanks) are exempt
- Other exemptions apply

FSPCA NEW PRODUCT AND SERVICES IDEAS

1. Existing Products (primarily PCHF curriculum)

- Add example stories/ events and situations to go with the technical slides
- Add a scenario matrix type slide for Supplier Chain Controls
- Make the PCHF regulation overview video more useful
- Update the pictures of GMP failures
- Revise the case studies (teaching examples)
- Develop new models (teaching examples)
- Update PCAF materials

FSPCA NEW PRODUCT AND SERVICES IDEAS

2. New Products:

- Audit program to assess company compliance with FSMA rules
- HACCP training (or incorporate into PCQI training)
- Training focused on functional food ingredients and food supplement
- Manufacturing elements related to COVID
- A virtual PCQI LI course
- Food safety plans for the sanitary transportation rule

FSPCA NEW PRODUCT AND SERVICES IDEAS

2. New Products:

- Prerequisite course- GMPs, HACCP
- Refresher course for LIs who don't teach frequently
- Sanitary Transport
- Auditor Training, Root Cause Analysis
- Traceability / Recall Readiness
- Integrating Appendix A of Hazards guide into slides, Understanding the Guide, Using the guide (NOTE: FSPCA already created and posted in PCHF LI portal)

FSPCA NEW PRODUCT AND SERVICES IDEAS

3. Partnerships:

- Consumer Brands Association
- State Regulatory agency's as a partner.
- Partner with Frank Yiannas and the Food Policy and Response on traceability.



CLOSING REMARKS

Robert Brackett

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



THANK YOU!

Be well. Stay safe!