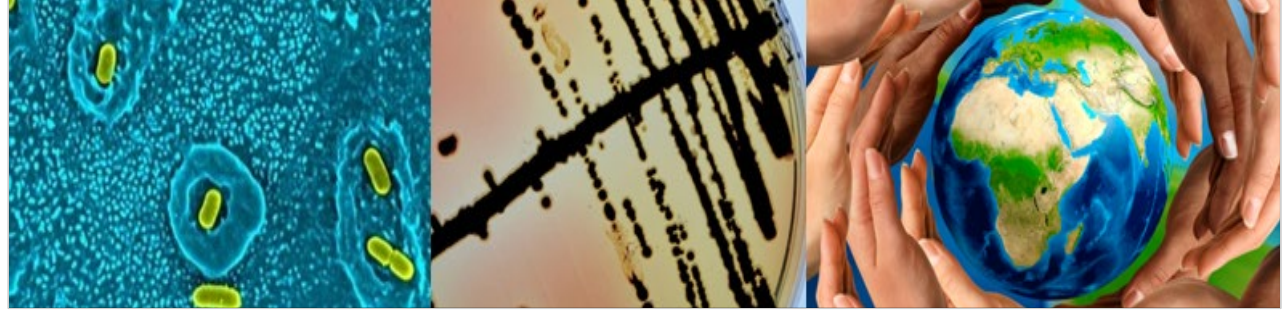


FSMA PC QI Workshop

Fall 2021



Aliyar Cyrus Fouladkhah
Public Health Microbiology Laboratory
Cooperative Extension Program
Tennessee State University



Food Safety Modernization Act (FSMA)

- Signed to law in January of 2011, FSMA is the largest expansion of U.S. food safety authorities since the 1930s.
- Many sectors of agriculture and manufacturing will undergo strict regulations for the **first time in the history of the country**.
- Shifting responses from food safety problems to **proactively prevent** the episodes
- FSMA, a large and comprehensive legislation **broaden FDA's ability** to:
 - **Mandatory recall** of contaminated food products
 - **Enhanced surveillance** to investigate foodborne illness outbreaks
 - Established **new preventive controls** and food safety plans at some food processing facilities and farms
 - Enhanced FDA's **traceability capacity**
 - **Increased inspection** frequencies of high-risk food facilities (both domestic and foreign facilities)
 - Expanded authority and oversight capabilities with regard to **foreign companies**

Regulatory Landscape of Food Industry Before FSMA

Very small companies:

Exemption from federal requirements, need to follow state policies

Restaurant operations:

Exemption from federal requirements, need to follow state policies (food code)

Food Safety Inspection Service (FSIS) of USDA:

Meat, Poultry and Egg products, HACCP requirements

Food and Drug Administration of DHHS:

High Risk Foods: Juices, seafood, and shell egg, HACCP requirements

Farmers and other food products:

No federal regulation



Mandated by FSMA

- Food manufacturing (processors)
- Farmers and growers (producers)
- Transportation, retailers
- Imported foods
- Third party laboratories
- Local, state, and federal agencies
- Foreign governments



Not mandated by FSMA

- FSMA does not directly address sectors under **pre-existing jurisdictions**. HACCP will remain the dominant regulation for:
- Meat, poultry, and egg products (USDA-FSIS)
- Juices, seafood, and shell eggs (DHHA-FDA)
- Very small producers and processors could receive exception from FSMA requirements (**cottage industry**).
- FSMA does not mandate **GM products, antibiotic resistant organisms, organic production, and pesticide and fertilizer use**.



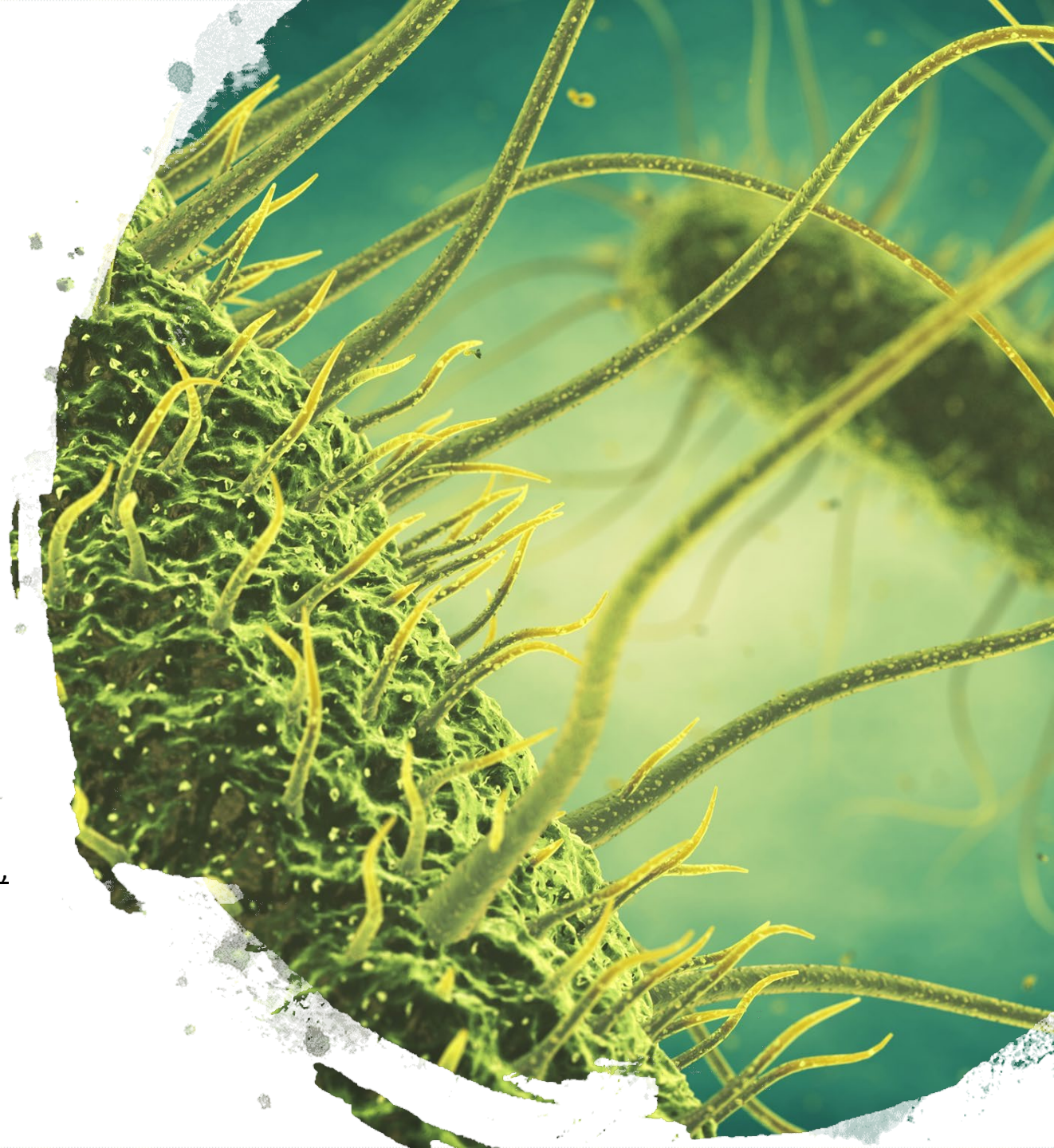
FSMA Implementation Schedule

FSMA was signed into law on **January, 2011**

Regulations were supposed to be finalized within one to two years of enactment (roughly **January 2012 and January 2013**)

Revised implementation dates: (all drafts are currently publically available)

- **Preventative controls:** FSMA §103(a) and(c): August 30, 2015
- **Foreign supplier verification program:** FSMA §301(a): October 31, 2015
- **Accreditation of third party auditors:** FSMA §307): October 31, 2015
- **Produce safety Rule:** FSMA §105(a): October 31, 2015 [Week 11+ Survey]
- **Sanitary transportation practices for food and feed:** FSMA §111: March 31, 2016
- **Intentional adulteration of food:** FSMA §106(b): May 31, 2016.



Produce and Preventive Rules and Land-grant Institutions

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (**Produce Rule**): **Producers**
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (**Preventive Rule**): **Processors**
- Large producers and processors
- Small and medium size producers and processors
- Very small (hobbyists) producers and processors (local and cottage industry)
- Many of small and medium size entrepreneur will require assistance from the nations 75 land-grant institution for **safe and economical access to market**.



Preventive Control for Human Food Rule: Overview (PC QI)

- Regulate “processors”
- Under the regulation all “facilities” have to be registered with FDA
- The rule has **two sections: Hazard Analysis (HARPC) and GMP**, facilities obligated to have one or both.
- **Exemptions:** Juice, seafood, and shell egg sectors and businesses that store agricultural commodities. (differs with preventive rule)

Modified Requirements:

- Three-year average sales less than \$500K, AND
 - Direct sales to restaurants and consumers within 275 mile radius, or
 - Within states sales in 275 mile radius.



Requirements of Preventive Rule *cGMP-Current Good Manufacturing Practices*

- Similar to prerequisite program in HACCP
- **Nearly all facilities are required** to follow this section of the rule

Exemption:

- (1) Businesses that store agricultural commodities
- (2) Businesses that selling directly to a manufacturing facility like canning operation (vertically integrated farms)

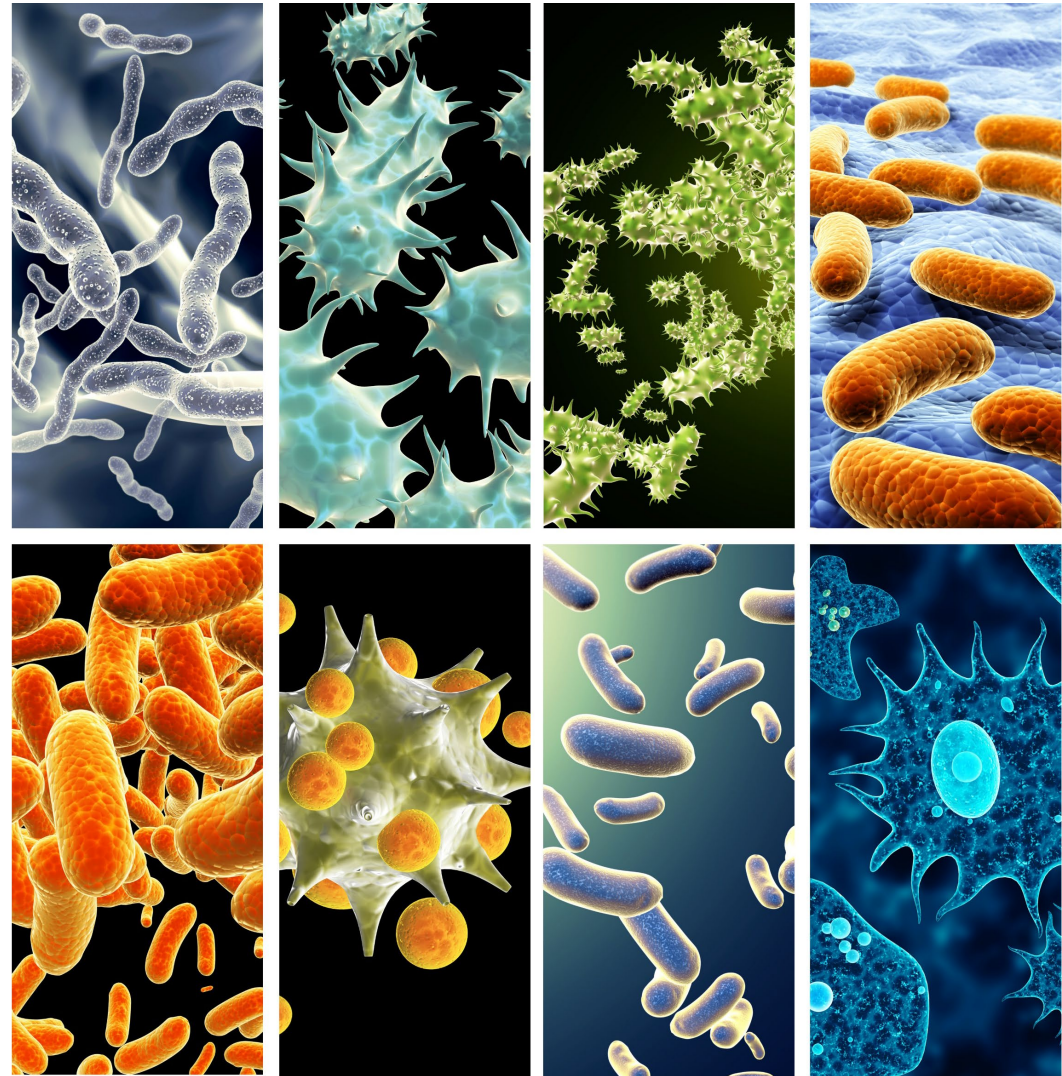
Main Principles:

- Sanitation
- Employee training
- Environmental control and training
- Recall contingency plan
- Allergen control
- Supplier verifications
- Sanitary transportation



Requirements of Preventive Rule *Hazard Analysis and Risk-Based Preventative Controls (HARPC)*

- Previous a 7-step plan for FSIS HACCP, 12-step plan for Codex HACCP, and currently 5-step plan for HARPC:
- **Hazard analysis**
- Identification and implementation **preventive controls**.
- **Monitoring** the performance of controls.
- Developing **corrective actions** for preventative deviation.
- **Verification and recordkeeping** of preventative controls effectiveness
- 2.5 day workshop Preventive Control Qualified Individuals (PC QI)



Preventive Rule: Implementation and compliance dates

- **Implementation date:** August 30, 2015
- **Compliance date:**
 - **Very small** facility (\$2.5*m and below): 3 year
 - **Small** facility (less than 500 employee and does not qualified for exception): 2 years
 - **“Other” facilities:** 1 years

Modified Requirements:

- Three-year average sales less than \$500K, AND
 - Direct sales to restaurants and consumers within 275 mile radius, or
 - Within states sales in 275-mile radius.

*Total annual sale; the categories differ in preventive and produce rules.

COURSE TYPE ↓	LEAD INSTRUCTOR ↓	COURSE START	WEB ADDRESS TO REGISTER	COST	CONTACT EMAIL	ADDRESS	LANGUAGE	FORMAT
Human Food	Esmeralda Paz Lemus	Dec 3, 2020	Register	USD 615	Contact	Alcaldía Cuauhtémoc Ciudad de México Mexico	Spanish	In Person - Live
Human Food	Derrick Payne	Dec 1, 2020	Register	USD 400	Contact	Decatur IL United States	English	Virtual - Online, Web Based Live
Human Food	Satoshi IMANARI	Oct 5, 2020	Register	JPY 108,000	Contact	Live-Virtual Live-Virtual Japan	Japanese	Virtual - Online, Web Based Live
Human Food	Donna F. Schaffner	Sep 30, 2020	Register	USD 645	Contact	Bridgeton NJ United States	English	Virtual - Online, Web Based Live
Human Food	Donna F. Schaffner	Dec 8, 2020	Register	USD 695	Contact	Bridgeton NJ United States	English	Virtual - Online, Web Based Live
Human Food	Sonia Akbarzadeh	Dec 16, 2020	Register	USD 695	Contact	Live-Virtual Interactive Live-Virtual Interactive United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Dec 2, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Nov 4, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Oct 7, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Bartosz Dobek	Nov 4, 2020	Register	USD 699	Contact	Naperville Illinois United States	English	Virtual - Online, Web Based Live
Human Food	Bartosz Dobek	Oct 14, 2020	Register	USD 699	Contact	Marietta Georgia United States	English	In Person - Live
Human Food	Bartosz Dobek	Sep 23, 2020	Register	USD 699	Contact	Naperville IL United States	English	In Person - Live

Preventive Control for Human Food: PC QI

- Our course 10-07-2021 to 10-28-2021
- THANK YOU NIFA and PHM Lab
- Animal Food PC QI:

https://fspca.force.com/FSPCA/s/courselist?language=en_US



United States Department of Agriculture
National Institute of Food and Agriculture

FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

Exercise Workbook

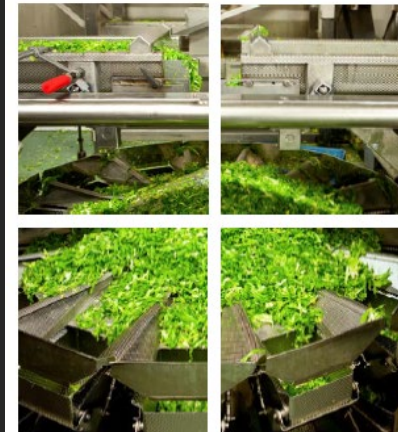
Including Food Safety Plan Worksheets

Developed by the
FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



**Preventive Controls
for Human Food**

First Edition - 2016



Participant Manual



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Preventive Controls for Animal Food

First Edition - 2016



Participant Manual

COURSE TYPE ↓	LEAD INSTRUCTOR ↓	COURSE START ↓	WEB ADDRESS TO REGISTER	COST	CONTACT EMAIL	ADDRESS	LANGUAGE	FORMAT
Animal Food	Kimberly Baker	Apr 13, 2021	Register	USD 495	Contact	Pendleton SC United States	English	In Person - Live
Animal Food	RACHEL MONTGOMERY	Dec 7, 2020	Register	USD 850	Contact	COST INCLUDES CERT., CONVENIENT PARTIAL DAYS NO TRAVEL, EARLY- BIRD & GROUP DISCOUNTS United States	English	Virtual - Online, Web Based Live
Animal Food	Dr. Jayne Stratton	May 24, 2021	Register	USD 599	Contact	Lincoln NE United States	English	Virtual - Online, Web Based Live
Animal Food	Bitu Saidi	Feb 16, 2021	Register	USD 695	Contact	Live-Virtual Interactive Live-Virtual Interactive Canada	English	Virtual - Online, Web Based Live
Animal Food	Dr. Tamla Blunt	Dec 16, 2020	Register	USD 795	Contact	Fresno CA United States	English	In Person - Live
Animal Food	RACHEL MONTGOMERY	Nov 2, 2020	Register	USD 850	Contact	COST INCLUDES CERT., CONVENIENT PARTIAL DAYS, NO TRAVEL, EARLY- BIRD & GROUP DISCOUNTS United States	English	Virtual - Online, Web Based Live
Animal Food	Bitu Saidi	Nov 18, 2020	Register	USD 695	Contact	Live-Virtual Interactive Live-Virtual Interactive Canada	English	Virtual - Online, Web Based Live
Animal Food	Charles Mike Nolan	Nov 4, 2020	Register	USD 850	Contact	Virtual Virtual Virtual	English	Virtual - Online, Web Based Live
Animal Food	Leslie Smith	Nov 16, 2020	Register	USD 600	Contact	Self-Study Flexible Schedule United States	English	Virtual - Online, Web Based Live

Animal Food PC QI:

https://fspca.force.com/FSPCA/s/courselist?language=en_US

Thank you!



Dear Dr. Aliyar,

Great talking to you this afternoon. Below is some preliminary information about the litigation we have:

We purchased an ingredient from [REDACTED] Corp, which was labeled as a Natural Flavor. It's use was as a natural preservative for a fresh cheese spread type of product.

This ingredient was successfully tested in our product and was used in the commercialization of our product which got sold to Cargill. After the product launched, Bavaria notified us of a potential allergen issue/update as a result of Lupin extract being present in their product which was deemed as an allergen. We had no problem with this, as we would handle it through a label update on our end and also at the customers end. However, during these conversations, we started suspecting that Bavaria was not being transparent as to the source of the lupin extract. After pushing them for full disclosure, they connected us with their supplier which told us in writing and via conference call, that the lupin extract sent to [REDACTED] from Portugal was only sent to them as an experimental sample, and that it had not received approval to be used as a food ingredient for consumption.

Additionally, [REDACTED] had not followed or complied with the foreign material verification process by FDA and therefore sold us a product containing an ingredient illegally imported into the US.

Once we learned about these details, we withdrew the product from Cargill causing us a 400k+ liability. We filed a law suit with [REDACTED] to recover these costs.

In summary, [REDACTED] sold an adulterated ingredient with an ingredient illegally imported, not GRAS listed, that contained an agricultural pesticide called BLAD that <https://www.cev.com.pt/en/blad-active-ingredient/> which was not sold to them, but rather sent to them by CEV as an experimental sample.

Let me know if with this information you feel that you could help us and I will be happy to connect you with our attorneys.

I really appreciate it and look forward to hearing your thoughts.

Regards,