

The Food Safety Modernization Act and the Food Safety Preventive Controls Alliance Robert E. Brackett, Ph.D. Illinois Institute of Technology





#### Background: The U.S. Food Safety System





### Agencies involved in Food Safety

- U.S. Food and Drug Administration (FDA)
- USDA/Food Safety and Inspection Service (FSIS)
- Environmental Protection Agency (EPA)
- National Oceanic and Atmospheric Agency (NOAA)
  - National Marine Fisheries Service
- Center for Disease Control and Prevention (CDC)
- States
  - State food safety agencies
  - "Cooperative Programs" with FDA (e.g. Interstate Shellfish Sanitation Program)





- Two Main Federal Food Safety Regulatory Agencies
  - USDA/FSIS
    - Cattle, Sheep, Goats, Horses, Mules, Egg products, catfish
  - FDA
    - All foods NOT covered by USDA
      - Dairy, Produce, Bakery, Dietary Supplements, Seafood, Ingredients, Game Meats
  - Environmental Protection Agency
    Sanitizers





### Food Groups Under FDA Authority

- Dairy Products
  - Milk
  - Cheese
  - Butter
- Plant products
  - Vegetables
  - Fruits
  - Nuts
  - Juices
- Spices

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Dietary Supplements



- Finfish
- Shellfish
- Crustaceans
- Surimi based
- Grain-based
  - Bread
  - Cereals
  - Flour
- Bottled water
- Cosmetics



- Two Main Federal Food Safety Regulatory Agencies -Why Does it Matter?
  - Statutory authority
    - Continuous Inspection (USDA) vs. Periodic (FDA)
    - On-farm authority (FDA)





- Two Main Federal Food Safety Regulatory Agencies -Why Does it Matter?
  - Statutory authority
    - o Continuous Inspection (USDA) vs. Periodic (FDA)
    - o On-farm authority (FDA)
  - Inspectional capacity
    - USDA 7800 inspectors for 6800 facilities
    - FDA 2000 inspectors for 130,000+ facilities





- Two Main Federal Food Safety Regulatory Agencies -Why Does it Matter?
  - Statutory authority
    - o Continuous Inspection (USDA) vs. Periodic (FDA)
    - o On-farm authority (FDA)
  - Inspectional capacity
  - Analytical Methodology
    - o USDA similar food matrices
      - Efficient throughput
    - FDA very **diverse** matrices
      - Laboratories also responsible for non-food products











#### **Statutory Authority**

- The Federal Food and Drugs Act of 1906
- The Federal Meat Inspection Act of 1906
- The Federal Import Milk Act (1927)
- The Federal Food, Drug, and Cosmetic Act of 1938, as amended
- The Public Health Service Act (1944)
- The Poultry Products Inspection Act of 1957
- The Fair Packaging and Labeling Act (1966)





#### **Statutory Authority**

- The Infant Formula Act of 1980, as amended
- The Nutrition Labeling and Education Act of 1990
- The Dietary Supplement Health and Education Act of 1994
- The Bioterrorism Act of 2002
- Food Allergen Labeling and Consumer Protection Act of 2004
- FDA Food Safety Modernization Act of 2011





### THE PREVENTIVE CONTROLS RULES AND THE FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE





#### Food Safety Modernization Act

# "...the most sweeping reform of our food safety laws in more than 70 years..."

- FDA





### FSMA is historical...

- Involves creation of a new food safety system
- Broad prevention mandate and accountability
- New system of import oversight
- Emphasizes partnerships
- Emphasizes farm-to-table responsibility
- Developed through broad coalition





#### **FSMA Rules**

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)	January 16, 2013	August 30, 2015*
Preventive Controls (Animal Food)	October 29, 2013	August 30, 2015*
Produce Safety**	January 16, 2013	October 31, 2015
Foreign Supplier Verification Program**	July 29, 2013	October 31, 2015
Third Party Accreditation	July 29, 2013	October 31, 2015
Sanitary Transport	February 5, 2014	March 31, 2016
Intentional Adulteration	December 24, 2013	May 31, 2016

\*Final submitted on August 31, 2015, made public on September 10, 2015 \*\*Supplemental proposals published September 2014







#### Preventive Controls Human and Animal Food Regulations Implementation Timeline





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### Preventive Controls for Human Foods

- Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food
  - Subpart A--General Provisions
  - Subpart B--Current Good Manufacturing Practice
  - Subpart C--Hazard Analysis and Risk-Based Preventive Controls
  - Subpart D--Modified Requirements
  - Subpart E--Withdrawal of a Qualified Facility Exemption
  - Subpart F--Requirements Applying to Records That Must Be Established and Maintained
  - Subpart G--Supply-Chain Program





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# **Food Safety Plan**





- A written *food safety plan*;
  - Hazard analysis;
  - Preventive controls;
    - Monitoring;
    - Corrective actions and corrections;
    - Verification;
  - Supply-chain program;
  - Recall plan; and
  - Associated records.





- A written *food safety plan*;
  - Hazard analysis
    - $\,\circ\,$  Identify and evaluate reasonably for eseeable hazards
      - Source
        - » Experience
        - » Illness data
        - » Scientific reports
        - » Other





- A written *food safety plan*;
  - Hazard analysis
    - Identify and evaluate reasonably foreseeable hazards
      - Source
      - Туре
        - » Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
        - » Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
        - » Physical hazards





- A written *food safety plan*;
  - Hazard analysis
    - $\,\circ\,$  Identify and evaluate reasonably for eseeable hazards
      - Source
      - Туре
      - Food Matrix
        - » Formulation
        - » Source of ingredients
        - » Storage and transportation
        - » Etc.





- A written *food safety plan*;
  - Hazard analysis
  - Preventive Controls
    - MUST be written
    - Process controls
    - Food allergen controls
    - Sanitation controls
    - Supply-chain controls
    - Other controls (eg. hygiene training)
    - Verification and validation, monitoring, corrective actions





- A written *food safety plan*;
  - Hazard analysis
  - Preventive Controls
  - Supply-chain program\*
    - MUST be written
    - Using approved suppliers
    - Appropriate supplier verification activities
      - Onsight audits
      - Sampling and testing
      - Review of Suppliers records

\*Described in Part 117 Subpart G





- A written *food safety plan*;
  - Hazard analysis
  - Preventive Controls
  - Supply-chain program
    - MUST be written
    - Using approved suppliers
    - Appropriate supplier verification activities
    - Documenting supplier verification





- A written *food safety plan*;
  - Hazard analysis
  - Preventive Controls
  - Supply-chain program
  - Recall Plan
    - o MUST be written
    - Procedures
    - Notifications (consignees and public)
    - Effectiveness checks
    - Disposal procedures





#### • A written *food safety plan*;

- Hazard analysis
- Preventive Controls
- Supply-chain program
- Recall Plan
- Associated records
  - Rationale for NOT using preventive controls
  - Monitoring
  - Corrective actions
  - Validation, verification, calibration, etc.
  - Product testing





# Why the Food Safety Preventive Controls Alliance?





#### Introduction

- Background
  - FDA recognized the need to assist the regulated industry to comply with FSMA
  - Decision was made to follow the Seafood HACCP Alliance model
  - FSPCA followed similar format, but with different structure to account to various commodities included in FSMA





#### FSPCA - Public-Private Partnership



# Organization and Governance





#### FSPCA Committees, Subcommittees, Work Groups







### Curriculum

### Preventive Controls for Human Foods





#### Benefits of FSPCA Preventive Controls Course

- The FSPCA Preventive Controls for Human Food course is the "standardized curriculum" recognized by FDA
- Training will be one means to become "Preventive Controls Qualified Individual" required by PC Rules
- Lead Instructors have access to:
  - "Instructor Notes" to assist with delivery and interpretation
  - Exercise guides and instructions to reinforce key learning objectives
  - Simplified model foods for exercises that are consistent with regulatory requirements
  - Access to all current resources and information that the Alliance provides




# Standardized Curriculum Goals

- Facilitate understanding of FDA expectations
- Provide training leading to "Preventive Controls Qualified Individual"
- Understanding of "Food Safety Plan"





# **Risk-based Preventive Controls**

- Focus on what matters most for food safety
- Preventive, not reactive
- Work in conjunction with and supported by other programs like Good Manufacturing Practices
- Designed to minimize the risk of food safety hazards





### Other Risk-based Food Safety Programs







### Historically HACCP Focuses on the Process



### **Preventive Controls Enhance HACCP**



### Preventive Food Safety Systems



# Food Safety Plan vs. HACCP Plan

Food Safety Plan	HACCP Plan
Hazard analysis	Hazard analysis
Preventive controls (PCs)	CCPs to control food hazards
Process controls*	Critical limits
Monitoring**	Monitoring
Corrective actions**	Corrective actions
Verification**	Verification
Records	Records





### What's New in a Food Safety Plan

Element	HACCP Plan	Added in Food Safety Plan
Hazard analysis	Biological, chemical, physical	Chemical hazards to include radiological; consider econ. motivated adulteration
Preventive controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs
Parameters and values	Critical limits	Parameters and minimum/maximum values (= Critical limits for process controls)
Monitoring	Required for CCPs	Required as appropriate for preventive controls
Corrective actions or Corrections	Corrective actions	Corrective actions or corrections, as appropriate
Verification	For process controls	As appropriate for all preventive controls; supplier verification required when supplier controls a hazard
Records	For process controls	As appropriate for all preventive controls
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified

### **FSPCA Delivery Model**

Trainers-of-Trainers(ToTs) train Lead Instructors



Lead Instructors train Participants

**Participants** meet training requirements for PC Qualified Individual







# **Curriculum Support Materials**

### **For Students**

- Participants Manual (Open access)
  - Slide images, supporting text, example forms, Food Safety Plan example, references
- Exercise Workbook



### For FSPCA Lead Instructors

- Instructors Manual
  - Annotated Participant's Manual
- Slide set
- Instructor's Exercise Guide
  - Model foods teaching examples
- Adult learning and administration procedures



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## OUTREACH

# www.iit.edu/ifsh/fspca





#### Illinois Institute of Technology





Menu 🔻

### **FSPCA Home**

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of key industry, academic and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training and outreach programs to assist companies producing human and animal food in complying with the preventive controls regulations that will be part of the Food Safety Modernization Act (FSMA).

#### Training

FSPCA Preventive Controls for Human Food FSPCA Preventive Controls for Animal Food Foreign Supplier Verification Programs (FSVP) Intentional Adulteration

#### Technical Assistance Networks FSPCA Technical Assistance Network

FDA FSMA Technical Assistance Network

Food Safety Modernization Act (FSMA)

#### CIFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

#### The Alliance

Committees, Subcommittees, Work Groups

#### Quick Links FSPCA Trainers of Trainers for Human Food FSPCA Trainers of Trainers for Animal Food Apply to Become a Lead Instructor FSPCA Lead Instructor Listing FSPCA Advertising Recommendations for Lead Instructors FSPCA Human Food Bookstore FSPCA Animal Food Bookstore



# **FSPCA Flyers**

- Domestic
- International
  - Multiple languages

FSPCA Domestic One Page Flyer (pdf)

FSPCA International One Page Flyer (pdf)

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#### About the FSPCA

The Food Safety Preventive Controls Alliance (FSPCA) is a public-private partnership created by the U. S. Food and Drug Administration (FDA), and the Illinois Institute of Technology's Institute for Food Safety and Health (IFSH).

The main mission of the FSPCA is to support safe food production by developing and delivering a core curriculum, conducting training, and supporting a technical assistance\* network and outreach programs that will help the human food and animal food industry comply with Preventive Controls regulations.

#### International Partnerships

The public and private stakeholders that collaborate within FIPCA find benefit in having access to information that can help them comply with regulations and produce sate food, Market access is an added benefit.

International public and private sector organizations are encouraged to participate in RSPCA in order to provide assistance and training to companies in their regions. FSPCA strives to support international centers who provide training and technical assistance.

#### Get Involved

The FSPCA is engaged in efforts to provide resources for stakeholders to use in meeting both the Human and Animal Food Preventive Controls rules requirements under FSMA.

Participate: Join one of the FSPCA subcommittees or Working Groups that interest you.



Become an FSPCA Lead Instructor, FSPCA provides train-the-trainer courses for independent instructors to gain the skills necessary to deliver the standardized training. Apply online at www.lit.edu/fsh/alliance and click on the "Apply to become an FSPCA Lead instructor" button. Join the Technical Assistance Network: Resources (expects) available to industry (with an emphasis on small and mid-sited human food and animal food companies) to provide scientific and technical information on hazards associated with foods and preventive controls for those hazards, Experts can participate in information portals, conduct research, share models, and communicate directly with small businesses. Network participants come together with industry and regulators for an annual technical conference.

Take a Course: Attend a Food Safety Preventive Controls course for human food or animal food. The FSPCA Certificate of Course Completion provides evidence of training against the standardized curriculum.

Stay informed: FSPCA will continue to provide information and resources through its website, conferences, working groups, and webinars for the whole community interested in food safety preventive controls.

FSPCA Update Webinars are scheduled quarterly. Go to www.it.edu/itsh/aliance to view the current schedule.

\*Technical assistance is defined as resources (expend) available to instantly (with an empirical on small and mid-dised human food and animal food companies) to provide scientific and technical information on hazards associated with foods and preventive controls for those hazards.







#### Menu 🔻

### **FSPCA** Webinars

The Food Safety Preventive Controls Alliance (FSPCA), in collaboration with the Food and Drug Administration (FDA), hosts quarterly webinars to update stakeholders on the progress of the Alliance. Update webinars will be held on April 21, July 21, October 20, 2016 and January 2017

#### Register

#### **PREVIOUS WEBINARS:**

#### 2016

July 21, 2016 April 21, 2016

#### 2015

March 12, 2015 June 24, 2015 September 3, 2015 December 17, 2015



### **« FSPCA HOME**

- + THE ALLIANCE
- + COURSES
- LEAD INSTRUCTOR
- TECHNICAL ASSISTANCE NETWORK (TAN) DATABASE
- + RESOURCES
- + FAQ
- INTERNATIONAL
- INTENTIONAL ADULTERATION
- + COMMITTEES
- + NEWS
- RETURN TO IFSH



# **FSPCA Community**

- Web Community and Technical Assistance
- Supports Industry, Food Safety Experts , Lead Instructors
- Project Completed May 12, 2016
- User Acceptance Testing April 26
- Launch May 11-13





# **Community Overview**

- Interactive Community
- Technical Assistance
- Resources
- Lead Instructor Support
- Phase 2 Upgrades September 2016

### https://fspca.force.com/FSPCA/s/







#### WELCOME TO THE FSPCA COMMUNITY

The Food Safety Preventive Controls Alternoe is a prace where you can find solutions and easily ask questions related to FSMA implementation.

A list of FSPCA PC0I Human Food Classes (7/14/16) can be found at this link https://hpca.force.com/FSPCA/s/question/0053800000HExD0CAL?t=1468889007919



SUBMIT ONLINE INQUIRY

TRENDING ARTICLES
How can I become a Food Safety
Preventive Controls Allance Lead
Instructor?

Proventive Controls Qualified Instructual
Completing a Lead Instructor Application
Form

How to check the status of a lead instructor
application in the FSFCA Control by Human
Foods Clauses as of 7-14-16

#### LEADERBOARD

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### Outcomes

- Training Metrics
- Research Needs and Questions
  - Validation of both existing and new technologies
  - Evaluation of training and messaging





### **FSPCA Metrics**

FSPCA Preventive Controls Certificates Issued			
	Human Food	Animal Food	
Domestic	23,711	2160	
International	7,383	14	
Total	31,094	2,174	

As of February 10, 2017







### **FSPCA** Metrics



Preventive Controls for Human Food Certificates Issued by Week (Cumulative)

As of February 10, 2017





### **FSPCA Preventive Controls Courses**

	Animal Food	Human Food
Total Courses Registered	135	2,400
<b>Courses Completed</b>	70	2,025



### **International Courses Conducted**

57







### Lead Instructors

Human Food Lis	1,095
Animal Food LIs	196
Human Food Candidates	572
Animal Food Candidates	336
Human Food LI Courses Completed	40
Animal Food LI Courses Completed	3

In 2017, see the FSPCA website for upcoming LI courses



As of February 10, 2017



# **FSPCA International Action Plan**







# **Technical Assistance**





### FSPCA Website: https://www.ifsh.iit.edu/fspca







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#### **Technical Assistance Networks**

ESPCA Technical Assistance Network FDA F5MA Technical Association Network

#### Food Safety Modernization Act (FSMA)

Supplier Evaluation Resources FDA Updatel FDA Extends Certain FSMA Compliance Dates: Husses Draft Guadance FBA Food Safety Modernization Act Homepage FSMA Final Rule for Preventive Controls for Human Food FSMA Final Ilula for Preventive Controls for Animal Flood FSMA Final Role on Family's Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals PSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration

Sign up for the FDV's e-mail updates

#### The Alliance

Committees, Subcommittees, Work Snoops

#### Quick Links

Apply to Become a Lead Instructor FSPCA Advertising Recommendations for Lead Instructors G FSPEA Animal Food Bookstone **PSPCA Community** FIPCA FIVP Bookstore **PSPCA Human Food Bookstore FSPCA Lead Instructur Listing PSPCA Mahirials FSPCA Metrics FSPCA Trainers of Trainers for Animal Food** FSPCA Trainers of Trainers for Foreign Supplier Verification Programs (FSVP) ESPCA Trainers of Trainers for Human Food.

#### Stay Connected

FSPCA Webmars **PSPCA Presentations and Conferences** Sign up for FSPCA Updates Contact Lhs

#### Sister Alliances

Produce Safety Albance Sproot Safety Alliance



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### FDA Food / Feed Internal and External Tech Assistance Networks







# **FSPCA** Community







### FSPCA Preventive Controls for Human Food Lead Instructor Training – Milan, Italy

Date: March 21-23, 2017
Time: 9:00 AM – 6:00 PM
Location: Hotel Des Etrangers \*\*\* Space Supranational Hotels Via Sirte, 9 – 20146

- Prerequisites:
  - 1. Successful completion of the FSPCA Preventive Controls for Human Food Course
  - 2. Must be an approved FSPCA Lead Instructor candidate to register

Information on how to apply to become a Lead Instructor can be found at fspca.net

- Course Description: This 2.5-day course provides the participant the knowledge and tools needed to perform the duties of a Lead Instructor for the standardized training curriculum that FDA considers adequate in meeting the requirements for training of a "Preventive Controls Qualified individual" under FDA's Preventive Controls for Human Food rule.
- (<u>https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food#LICS</u>)





# Why the Institute for Food Safety and Health?





# IFSH – At a Glance

- Four research centers with primary focus:
  - Food processing safety
  - Nutrition research
  - National security related to food
- Holds consortium between IIT/FDA/Industry (68 Members)
  - Location for FDA's Division of Food Processing Science & Technology
- 100+ Scientists 50/50 IIT/FDA
  - 137 IIT Graduate Students
    - Masters and Professional Certificates in FST and FPE
    - Students gain valuable research experience with FDA on research projects



IIT Main Campus, State Street, Chicago, IL



IIT Moffett Campus, Bedford Park, IL





# **IFSH Centers**









### Department of Food Science and Nutrition (FdSN) Current enrollment ~137 students

### **Thesis Degrees**

- Master of Science in Food Safety and Technology
- Master of Science in Food Process Engineering
- Ph.D. in Food Science and Nutrition

### **Non-Thesis Degrees**

- Master of Food Safety and Technology
- Master of Food Safety and Technology with Specialization in Business
- Master of Food Safety and Technology with Specialization in Industrial Technology Management
- Master of Food Process Engineering

### Certificate

- Food Safety and Technology
- Food Safety and Industrial Management
- Food Process Engineering
- Food Processing Specialist









# **THANK YOU!**



Robert E. Brackett, Ph.D. IIT Vice President and Director Institute for Food Safety and Health Illinois Institute of Technology


## Questions

If you have any questions, please contact the FSPCA at fspca@iit.edu or or visit the FSPCA website at http://www.iit.edu/ifsh/alliance for resources on preventive controls, lead instructor application, and details of other FSPCA activities.



