FSMA Standardized Curricula Update

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International Citrus & Beverage Conference
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Background
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
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 to achieve this goal
  - Based at IIT Institute for Food Safety and Health
Why the Institute for Food Safety and Health?
Why IFSH?

• Largest and oldest of FDA/CFSAN’s Centers of Excellence
  ▪ Founded in 1988 as National Center for Food Safety and Technology
  ▪ Reorganized as IFSH in 2011

• Long-standing Public/Private Partnership

• Expertise in food safety and food processing
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

U.S. FDA DFPST/CFSAN

Institute for Food Safety and Health

School of Applied Technology

National Center for Food Safety and Technology

Center for Processing Innovation

Center for Nutrition Research

Center for Specialty Programs

Department of Food Science and Nutrition
FSPCA Public/Private Partnership
FSPCA – Public/Private Partnership
FSPCA Management Entity Partners

• Institute for Food Safety and Health (IFSH)
  ▪ Hosts the website for Lead Instructors to get resources and information.
  ▪ Manages FSPCA interactions with FDA

• International Food Protection Training Institute (IFPTI)
  ▪ Hosts the website for online course enrollment, recordkeeping, and certificates.
  ▪ Manages fees for the FSPCA.

• Association of Food and Drug Officials (AFDO)
  ▪ Works with Lead Instructors on registering courses.
# FSMA Rules

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# FSMA Rules and FSPCA Involvement

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Organization and Governance
FSPCA Structure (old)

FSPCA Steering Committee

- Federal and State Food Inspection Officials
- Academic Researchers and Educators
- US Food Industry Trade Association Reps

Training Materials, Course, Models, Protocol

- Editorial Subcommittee
- Animal Foods Subcommittee
- Continuation Subcommittee
- International Subcommittee
- Working Groups

Certificates and Records

- Association of Food and Drug Officials and the Association of American Feed Control Officials
- International Food Protection Training Institute

[Images and logos]
Curriculum

Preventive Controls for Human Foods
FSPCA Preventive Controls Course

• The *FSPCA Preventive Controls for Human Food* course is the “standardized curriculum” recognized by FDA
• Training is 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”
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
Hazard Analysis and Risk-Based Preventive Controls

Food Safety Plan
Preventive Food Safety Systems

Food Safety Plan
Including procedures for monitoring, corrective action and verification, as appropriate

- Hazard Analysis
- Process Control
- Recall Plan
- Supply chain Program
- Allergen Control
- Sanitation Control

GMPs and Other Prerequisite Programs
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

- US Space program
- Low-acid canned food regs
- FDA Seafood HACCP regs
- FDA Juice HACCP regs
- USDA HACCP regs
- Codex HACCP Annex
- NCIMS Dairy HACCP

Image source: Microsoft clip art
Historically HACCP Focuses on the Process

1. Hazard Analysis
2. Critical Control Points (CCPs)
3. Critical Limits
4. Monitor
5. Corrective Action
6. Verification & Recordkeeping
Preventive Controls Include More Than HACCP

Hazard Analysis

Preventive Controls (CCPs, allergen, sanitation, supplier, etc.)

Parameters & Values

Monitor

Corrective Action or Corrections

Verification & Recordkeeping
## What’s New in a Food Safety Plan

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

- **Phase I** – Organize FSPCA (2011)
- **Phase II** – Develop Curriculum (2012-2013)
- **Phase III** – Pilot Phase (2014)
- **Phase IV** – Implementation (2015-2017)
How are we doing?
FSPCA Delivery Model

Trainers-of-Trainers (ToTs) train Lead Instructors

Lead Instructors train Participants

Participants meet training requirements for PC Qualified Individual
FSPCA Metrics (Human Foods)*

• ~19,500 Human Food course certificates issued (~3,100 international)
• ~1,300 FSPCA Preventive Controls for Human Food courses conducted
• ~270 upcoming courses scheduled

*As of 9/9/16
Lead Instructors (Human Foods)

- 877 Lead Instructors
- 542 Candidates
- 36 Lead Instructor courses completed
- 8 courses currently scheduled
- 103 international Lead Instructors
FSPCA Metrics (Human Foods)
• ~906 Animal Food course certificates issued (~18 international)
• ~33 FSPCA Preventive Controls for Animal Food courses conducted
• ~32 upcoming courses scheduled

*As of 9/9/16
Lead Instructors (Animal Foods)

- 159 Lead Instructors
- 322 Candidates
- 3 Lead Instructor courses completed
- 0 courses currently scheduled

*As of 9/9/16
Instructor and Candidates Distribution – Example

Example of GeoMap for Lead Instructors and Lead Instructor Candidates

LI Candidates are red       LI’s are represented by heat circles
Technical Assistance
FSPCA Flyers

• Domestic
• International
  ▪ Multiple languages

FSPCA Domestic One Page Flyer (pdf)

FSPCA International One Page Flyer (pdf)
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 – Target Completion – September 2016

https://fspca.force.com/FSPCA/s/
FSPCA Technical Assistance Network – Inquiry Routing Process

- **Inquiry Form Initiated**
  - Submissions using the form on the alliance web page
  - Date and time of submission captured
  - Unique identifier generated

- **Inquiry Routing to FSE**
  - Identify key words for indexing
  - Match data with FSE
  - Notify FSE of Inquiry
  - Date and time of transfer to FSE captured

- **Inquiry Tracking**
  - Track unique identifier
  - Verify FSE receipt

- **Answer Vetting**
  - Answer returned to network
  - Answer vetted for accuracy and fit

- **Response to Inquirer**
  - Response sent to Inquirer
  - Date and Time captured
  - Inquiry closed

- **Response fields for every question are fully searchable**
- **Usage statistics and demographics are available in real time**
Technical Assistance Network

Page to submit a question to the FSPCA Technical Assistance Network

Frequently Asked Questions and Topics are on the side
Outreach

- TAN Conference / Meeting - 2017
- Structural Changes
- FSPCA, FDA - (FSE’s and SME’s)
- Technical exchange to
  - Discuss TAN operation
  - Share best practices
  - Gain feedback to date
  - Plan next steps
FSPCA Webinars

2016 Webinars

• April 21
• July 21
• October 20

FSPCA Update Webinars*

2017 Webinars

• January 19
• Spring TBD
• Summer TBD
• Fall TBD

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 scheduled for April 21, July 21, October 20, 2016 and January 19, 2017.

* Go to “Upcoming Events on the FSPCA Website
Coming Soon!

- Foreign Supplier Verification Training
Coming Soon!

- Foreign Supplier Verification Training
- Intentional Adulteration Training
Coming Soon!

- Foreign Supplier Verification Training
- Intentional Adulteration Training
- “Blended Course”
Human Food “Blended Course”

**Part 1 – Online, self-paced**
- Covers material in Version 1.2
- Knowledge checks to engage learner
- Anticipate to go “live” late fall of 2016

**Part 2 – Lead Instructor led**
- Slide set for review of learning objectives
- Exercise Workbook used to reinforce learning using model foods
THANK YOU!

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