THE PREVENTIVE CONTROLS RULES AND THE FSPCA

Dr. Robert Brackett, Illinois Institute of Technology

International Citrus & Beverage Conference

Clearwater Beach, FL
September 17, 2015
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

<table>
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<th>Regulation</th>
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**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
Preventive Controls for Human Foods

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Hazard Analysis and Risk-Based Preventive Controls

Food Safety Plan
Hazard Analysis and Risk-Based Preventive Controls

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

• A written *food safety plan*;
  ▪ Hazard analysis
    o Identify and evaluate reasonably foreseeable hazards
      - Source
        » Experience
        » Illness data
        » Scientific reports
        » Other
Hazard Analysis and Risk-Based Preventive Controls

• A written *food safety plan*;
  ▪ Hazard analysis
    o Identify and evaluate reasonably foreseeable hazards
      – Source
      – Type
        » 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
Hazard Analysis and Risk-Based Preventive Controls

• A written *food safety plan*;
  
  ▪ Hazard analysis
    
    ○ Identify and evaluate reasonably foreseeable hazards
      
      – Source
      
      – Type
      
      – Food Matrix
        
        » Formulation
        
        » Source of ingredients
        
        » Storage and transportation
        
        » Etc.
Hazard Analysis and Risk-Based Preventive Controls

• 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
Hazard Analysis and Risk-Based Preventive Controls

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

*Described in Part 117 Subpart G
Hazard Analysis and Risk-Based Preventive Controls

• 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
Hazard Analysis and Risk-Based Preventive Controls

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

• 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 Structure

FSPCA Steering Committee

- Federal and State Food Inspection Officials
- Academic Researchers and Educators
- US Food Industry Trade Association Reps
- Editorial Subcommittee
- Animal Foods Subcommittee
- Continuation Subcommittee
- International Subcommittee
- Working Groups

Training Materials, Course, Models, Protocol

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

Institute for Food Safety and Health
Illinois Institute of Technology
Coming Up Next

FSPCA Editorial Subcommittee
FSPCA Curriculum Pilots

• Pilot objectives:
  ▪ Solicit feedback on content, organization, exercises, slides, etc.
  ▪ Estimate timing

• Invitees:
  ▪ Experienced trainers from academia, government and industry

• Sessions:
  ✓ 3 course pilots – Rockville, MD; Vancouver, WA; Chicago, IL
  ✓ Train-the-trainer walkthrough – Chicago IL
  ▪ August 2015 (St. Paul, MN) – Small processor Focus Group
HACCP Focuses on the Process

- Hazard Analysis
- CCPs
- Critical Limits
- Monitor
- Corrective Action

Verification & Recordkeeping
Preventive Controls Enhance HACCP

- Hazard Analysis
- Preventive Controls (CCPs & others)
- Parameters & Values
- Monitor
- Verification & Recordkeeping
- Corrections / Corrective Action
Food Safety Plan Includes More Than HACCP

- Hazard Analysis
- Process Control
- Sanitation Control
- Allergen Control
- Recall Plan
- Supplier Programs

GMPs and Other Prerequisite Programs
<table>
<thead>
<tr>
<th>Introduction to Course</th>
<th>Process Preventive Controls</th>
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<tbody>
<tr>
<td>Food Safety Plan Overview</td>
<td>Food Allergen Preventive Controls</td>
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<td>GMPs and Prerequisite Programs</td>
<td>Sanitation Preventive Controls</td>
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<tr>
<td>Biological Food Safety Hazards</td>
<td>Supplier Preventive Controls</td>
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<tr>
<td>Chemical, Physical and Economically Motivated Food Safety Hazards</td>
<td>Verification and Validation Procedures</td>
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<tr>
<td>Preliminary Steps</td>
<td>Record-keeping Procedures</td>
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<td>Resources for Preparing a Food Safety Plan</td>
<td>Recall Plan</td>
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<td>Hazard Analysis and Preventive Control Determination</td>
<td>Regulation Overview</td>
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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
Animal Food Curriculum

• Follows the Human Food structure for the training curriculum, fees, outreach and course translation

• AAFCO will provide administrative support for the animal food training course
Animal Foods Training Curriculum

• Using the Human Food training curriculum as a starting point
• Altering it to make it applicable to the animal food industry, e.g.
  ▪ Added emphasis on cGMPs
  ▪ Removal of allergen chapter
  ▪ Addition of nutrient toxicity and deficiency information
  ▪ Removal of hazards not applicable to animal food
Animal Food Training Curriculum Status

- Currently editing all chapters
- Next steps:
  - Peer review the edited chapters
  - Work on the classroom exercises and examples
- Plan to finalize and pilot after the final rule is published
FSPCA Curriculum Summary

• Three pilots of a draft curriculum for *Preventive Controls for Human Food* have been conducted
  ▪ Focus group with small processors scheduled
  ▪ Materials being updated

• *Preventive Controls for Animal Food* curriculum is in progress

• FSPCA curricula *will not be finalized* until after the final rule is published
Coming Up Next

FSPCA Continuation Subcommittee
Goals and Objectives

• To increase industry awareness about the FSPCA education, outreach, and technical assistance programs

• To develop a comprehensive network of lead instructors interested in participating in the FSPCA training program

• To identify and develop relevant technical information and educational resources useful especially for small food businesses

• To establish a food safety technical assistance network for industry
Continuation Subcommittee Activity

- Recruit and Select FSPCA Lead Instructors
  - Apply Now!
  - Review & Selection Protocol
Lead Instructor Recruitment

- State Regulators
- University & Extension Specialists
- Contract Laboratories
- Third Party Audit Companies
- International Partners
- Associations
- Others
Technical Assistance Network - Domestic

Establish a network of University and Extension food safety experts that would be available to assist the industry with technical questions:

- Publish University and Extension specialists names on FSPCA’s webpage
- Experts answer scientific and technical questions using publically available materials including scientific literature
  - Establish repository of technical resources
- Refer preventive controls regulation interpretation questions to FDA’s experts
FDA Food / Feed Internal and External Tech Assistance Networks

PC Scientific & Technical Questions from Industry

External Network

- Extension Specialists
- Land Grant Universities
- FSPCA External Technical Assistance Network

FDA Internal Network

- CVM Info Center
- CFSAN FCIC
- KMS
- Imports

PC Regulation Interpretation Questions
OUTREACH

www.iit.edu/ifsh/alliance
FAQs

What is the Food Safety Preventive Controls Alliance (FSPCA)?

The Food Safety Preventive Controls Alliance (FSPCA) is a public-private partnership of key stakeholders from the food industry, academia and government. The Alliance seeks to develop an industry-oriented food safety training program to help firms producing human and animal food for the U.S. market to comply with preventive controls regulations required by the Food Safety Modernization Act (FSMA).

What prompted the creation of the FSPCA?

The food safety preventive controls regulations that will be issued by the U.S. Food and Drug Administration (FDA) will require facilities that manufacture, process, pack or hold food for humans and animals put measures in place to help prevent foodborne illness by implementing preventive controls for hazards. The FDA funded FSPCA to develop training that will help industry, particularly small- and medium-sized companies, to comply with the new preventive controls rules.

How was the FSPCA created?

FSPCA was created from a one-year, $1 million partnership grant funded by the FDA Office of Foods to the Illinois Institute of Technology’s Institute for Food Safety and Health (IIT IFSH).
FSPCA Website: www.iit.edu/ifsh/alliance

• FSPCA Task Timeline
• Draft Training Curriculum – Human Food

**New! FSPCA Downloads**

- FSPCA Task Timeline (pdf)
- FSPCA Hazard Analysis and Preventive Controls for Human Food - Draft Training Curriculum Outline (pdf)
FSPCA Website

• FSMA Proposed & Supplemental Rules

Supplemental Rules
Redline versions of the codified text of the four recently released proposed supplemental rules are now available. The redline versions allow you to see how the proposed codified text has been modified from the original proposal.

Proposed Supplemental Rule for Preventive Controls for Human Food

Proposed Supplemental Rule for Preventive Controls for Animal Food

Translations of the fact sheets of the four proposed supplemental rules are now available.

Proposed Supplemental Rule for Preventive Controls for Human Food

Proposed Supplemental Rule for Preventive Controls for Animal Food

Proposed Rules

FSMA Proposed Rules, Fact Sheets and Summaries

The Proposed Rule for Preventive Controls for Food for Animals was released on October 25, 2013 and the comment period ended March 31, 2014. For more information, email animalpc@fda.hhs.gov.
FSPCA Website

- Pilot Sessions
- FSPCA Presentations

FSPCA Pilot Sessions
Guests from academia, state and federal government, industry and industry associations attended FSPCA Pilot sessions held in Maryland, Washington State and Chicago. Overall, the course was deemed well organized and the content clear. Based on Pilot feedback, the materials will be adjusted in preparation for publication of the final rule expected in August 2015.

FSPCA Presentations
July 12, 2015
A 15 minute overview of "FSMA and FSPCA Education and Outreach" will be presented during the Council of Food Science Administrators Luncheon Meeting at the IFT Annual Meeting in Chicago. The CFSA lunch is a ticketed event and is scheduled on Sunday, July 12, 2015 from 12:00 pm – 1:30 pm CDST.

July 27, 2015
Join the FSPCA for an informative session at the IAFF Annual Meeting on July 27, 2015 from 5:15-6:00 pm Pacific. This IAFF session will provide an update on the FSPCA activities and inform participants how to take advantage of preventive controls resources. A Q&A session is included.

For past presentations, click here.
FSPCA Flyers

- Domestic
- International
  - Multiple languages

FSPCA Domestic One Page Flyer (pdf)
FSPCA International One Page Flyer (pdf)
FSPCA Website

2015 Webinars

• March 12
• June 24
• September 3
• December 17

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. 2015 webinars are scheduled for March 12, June 24, September 3 and December 17. Click here to register.

June 24, 2015

With publication of the final rules expected this August, the FSPCA Quarterly Update Webinars are filling up quickly. Early registration is encouraged. If you were unable to register for the June 24th webinar, you can download the recording here.

Download past webinar recordings:
August 24, 2014 | May 12, 2014 | March 12, 2015
FSPCA Website

• Committees, Subcommittees & Working Groups

• NEW! International Subcommittee

FSPCA Committees, Subcommittees and Working Groups

Executive Committee
The Executive Committee met April 21, 2015. Meeting summaries.

Steering Committee
The Steering Committee met June 10, 2015. Meeting summaries.

Editorial Subcommittee
The Editorial Subcommittee met April 2, 2015. Meeting summaries.

Continuation Subcommittee

Animal Foods Subcommittee
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.