



UPDATE - Food Safety Preventive Controls Alliance

**120th AFDO Educational Conference
Pittsburgh, PA
June 28, 2016**

Introduction

- Background
 - FDA recognized the need to assist the regulated industry to comply with FSMA
 - FSPCA public/ private partnership to achieve this goal

FSPCA – Public/Private Partnership



FSMA Rules and FSPCA Involvement

Regulation	Final Publication
Preventive Controls (Human Food)	Sept 17, 2015
Preventive Controls (Animal Food)	Sept 17, 2015
Produce Safety	Nov 27, 2015
Foreign Supplier Verification Program	Nov 27, 2015
Accredited Third Party Certification	Nov 27, 2015
Sanitary Transport	April 5, 2016
Intentional Adulteration	May 27, 2016

Organization and Governance

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

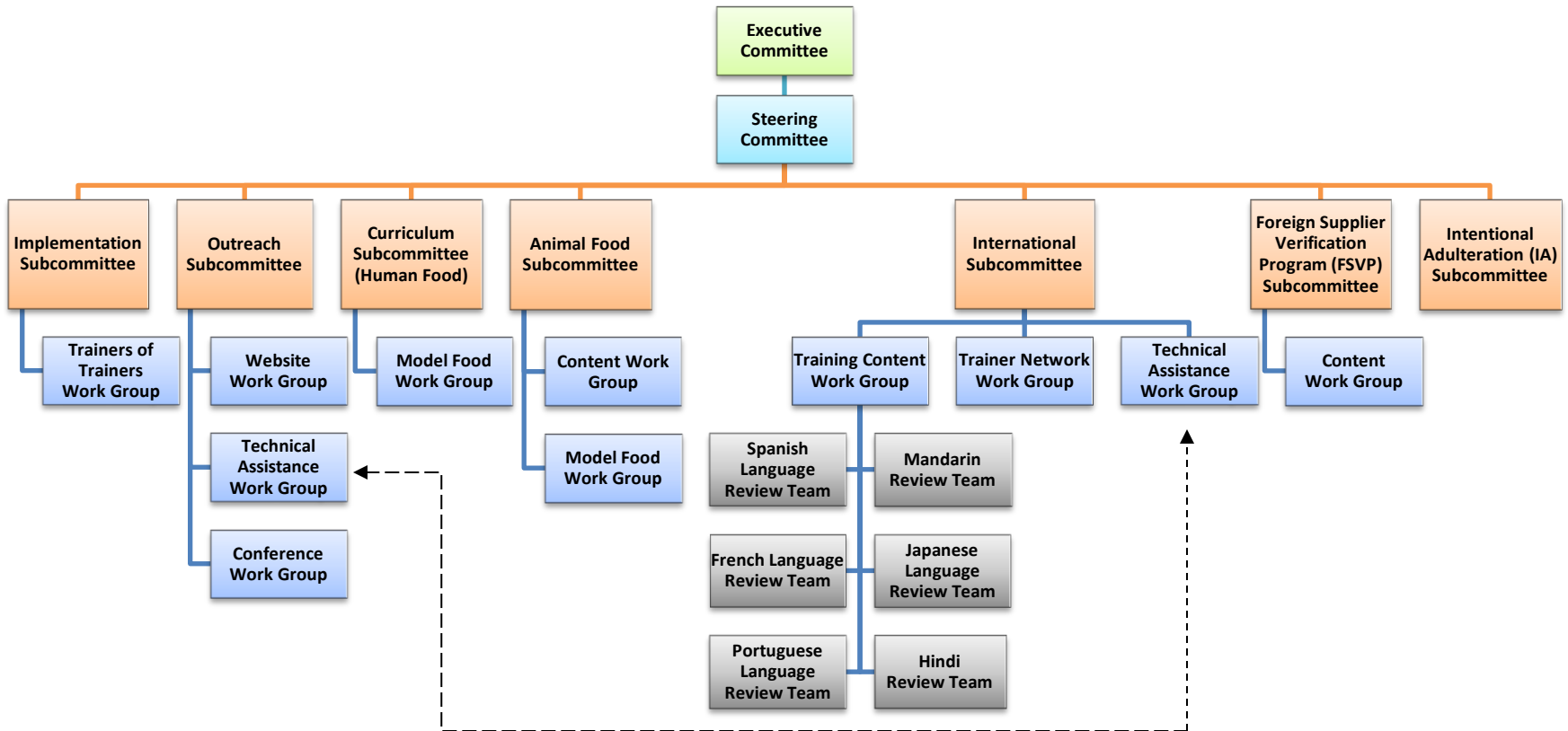
Training Materials, Course,
Models, Protocol

Certificates and Records

Association of Food and
Drug Officials and the
Association of American
Feed Control Officials

International Food
Protection Training
Institute

FSPCA Committees, Subcommittees, Work Groups



FSPCA Committee Tasks

Executive Committee

- Strategic direction of the Alliance

Steering Committee

- Alliance Business Function Decisions
- Legal
- Marketing
- Policies and Procedures
- Soliciting Funds/ Revenue Generation
- Budget Allocation
- Financial Reporting
- Prioritization/ Oversight Committee
- Partnerships
- Brand Guidelines

FSPCA Subcommittee Tasks

Implementation/ Operations Subcommittee (formerly Continuation):

- Metrics/ Data Collection/ Analysis
- Course Logistics
- Instructor Management
- Certificate Management
- Complaints/ Appeals/ Mediation
- Certificate/ Records
- Lead Instructor/ ToT Applicant Review and Approval/ Rejection

Outreach/Website Subcommittee:

- Create Website
- FSPCA Technical Assistance Network (TAN)
- TAN Conference
- FAQs, Social Media
- Posting of meeting minutes
- Presentations/ Proposals
- Outreach Materials
- Quarterly Update Webinars
- Web Portal
- Resources – Food Safety Information for FSPCA website
- Publications – Outreach (writing for Food Safety pubs)

International:

- Translations
- International Training Content
- International Trainer Network
- International Technical Assistance

FSVP Subcommittee

Curriculum Subcommittee (Human Food):

- Online Models
- Curriculum Updates and Dissemination
- Supplemental Materials (Models & Exercises)
- Online Modules
- Course Modification/ Review

Animal Food Subcommittee:

- Development of education materials that are specific to the animal food industry and its stakeholders

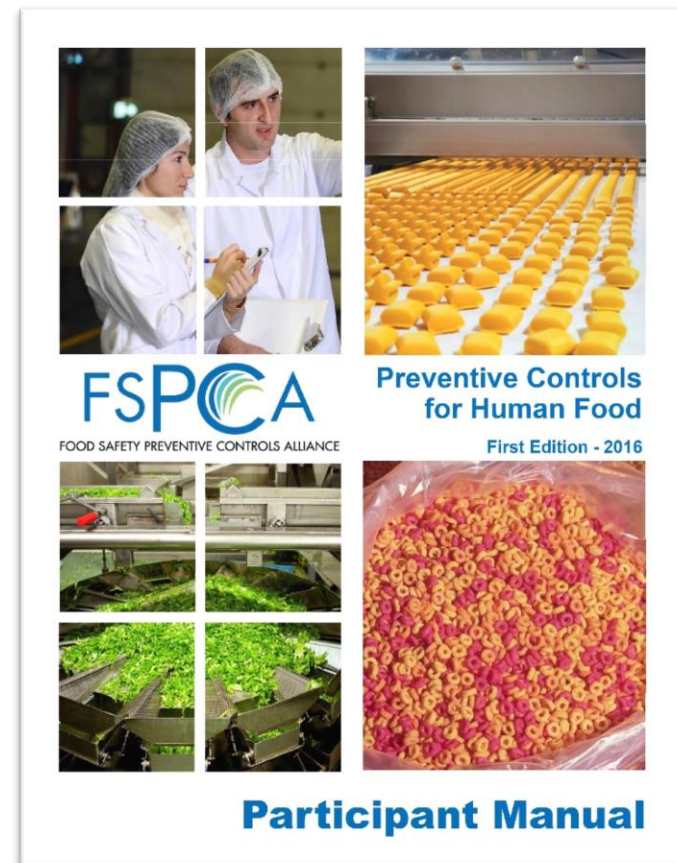
IA Subcommittee

Curriculum

Preventive Controls for Human Foods

FSPCA Preventive Controls for Human Food

- Version 1.2 released
- Changes address:
 - Technical amendments and corrections published by FDA
 - Editorial corrections
- Errata sheets for earlier versions on website



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

Human Food Blended Course Under Development



Part 1

- Online covering material in Participant Manual
- Self paced with learning checks

Two parts



Part 2

- One day **face-to-face**, Lead Instructor led
- Review material
- Exercises to reinforce learning using model foods
- Interaction with others is important for learning

Teaching Models Available

- Simple models with format consistent with curriculum
- Objective: Practice and reinforce concepts taught
- Currently available
 - Peanut butter
 - Cold pressed energy bar
 - Broccoli, carrot, pecan salad
 - Black pepper
 - Frozen ready-to-cook entrée
- Under review
 - Sliced tomatoes
 - Leafy greens salad
 - Pepper jack cheese
 - Other frozen foods

Lead Instructor Training Transition

- Phasing out 3-day Combo Course
 - Participant + Lead Instructor Training
- Implementing 2-day Lead Instructor Training
- Benefits
 - Enhanced learning of concepts in Participant Course
 - Blended or face-to-face
 - Emphasize how to teach “tricky” concepts in Lead Instructor course

Next Steps for Human Food Curriculum

- Develop and deploy Blended Course
- Add new exercise model foods
- Support:
 - Lead Instructor training
 - Animal Food curriculum development
 - Translation activities

Curriculum

Preventive Controls for Animal Foods

Animal Food Training Curriculum

- Preventive Controls and Lead Instructor courses have been created specifically for Animal Food
- The Animal Food courses have similar formats and learning materials as the Human Food courses, but with major content and layout changes to reflect the needs of the animal food industry

Animal Food Training Curriculum Status

- Preventive Controls course
 - The Preventive Controls participant course manual is finalized as of June 2016 and will be posted on the FSPCA website for public viewing soon

- Lead Instructor course
 - The Lead Instructor course manual is also finalized as of June 2016 and will be available to those who successfully complete a Lead Instructor course

Animal Food Training Curriculum Status

- Preventive Controls course
 - Drafts of the PowerPoint slides and training manual are completed for the upcoming pilot session
- Lead Instructor course
 - Course materials are under development
 - Will utilize Preventive Controls slides, but highlight key learning points

Animal Food Training Curriculum

- Current Preventive Controls Course Outline:
 - **Preface:** Introduction to the Course
 - **Chapter 1:** Regulatory Overview and Introduction to the Rule
 - **Chapter 2:** Current Good Manufacturing Practice
 - **Chapter 3:** Animal Food Safety Hazards
 - **Chapter 4:** Overview of the Food Safety Plan
 - **Chapter 5:** Hazard Analysis and Preventive Controls Determination
 - **Chapter 6:** Required Preventive Control Management Components
 - **Chapter 7:** Process Preventive Controls
 - **Chapter 8:** Sanitation Preventive Controls
 - **Chapter 9:** Supply-Chain-Applied Controls
 - **Chapter 10:** Recall Plan

Animal Food Training Schedule

- Combination courses are scheduled for July and August 2016
 - Invitation only to pilot participants and approved Animal Food Lead Instructors
 - There may be an additional combination course offered Fall 2016
- Preventive Controls courses are currently being scheduled starting end of June 2016
- Starting fall 2016, separate Lead Instructor courses will be offered

Animal Food on the FSPCA Website

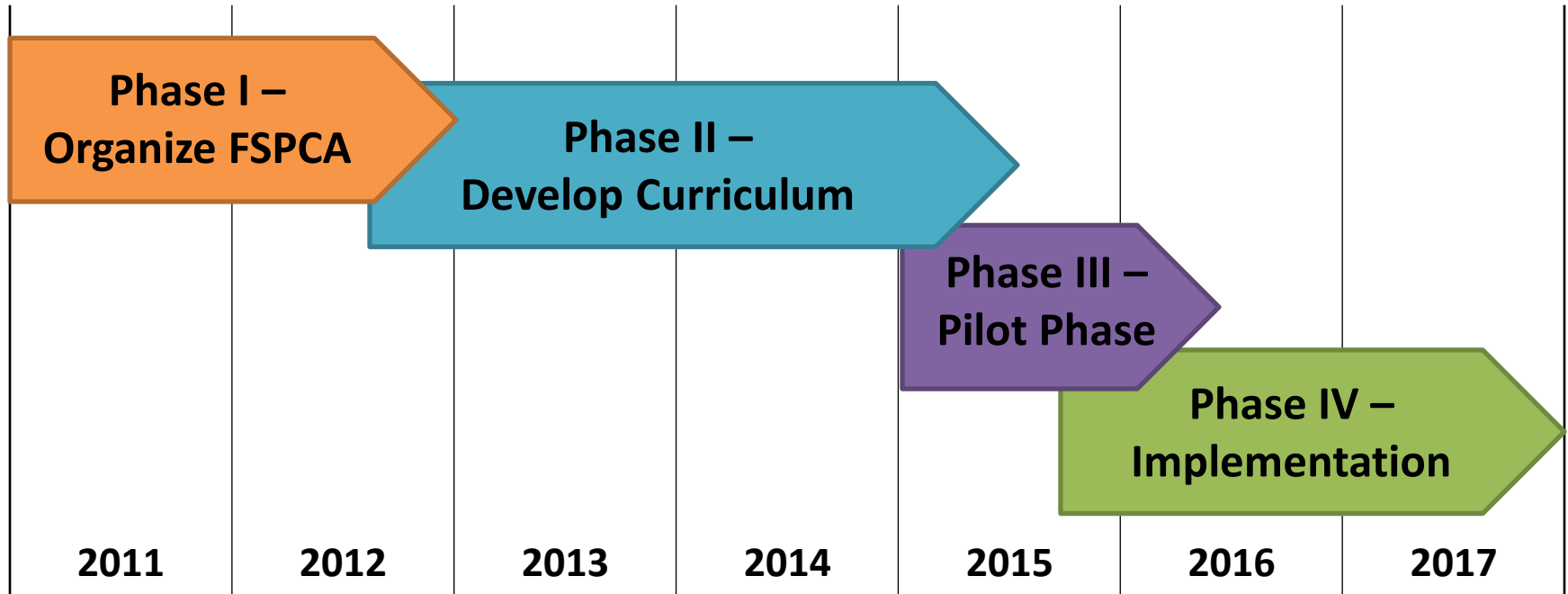
- Once courses are available, go to the FSPCA website for a link to course offerings
- Application to become a Lead Instructor for Animal Food is available on the FSPCA website
 - Human food and animal food applications are reviewed separately but follow the same process

Next Steps for Animal Food

- Evaluating the need for the number and location of future Combination/ Lead Instructor courses
- Beginning the development of a Blended course for Animal Food
- Reviewing additional example animal food safety plans for posting on the FSPCA website
- Building the animal food side of the FSPCA Technical Assistance Network (TAN)

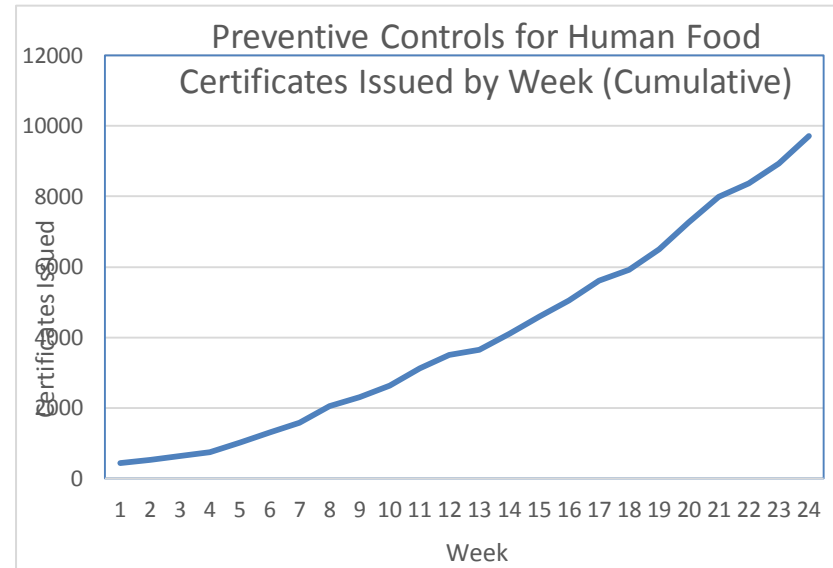
Implementation

Timeline



FSPCA Metrics

- ~10,000 Human Food course certificates issued (~1000 international)
- ~600 FSPCA Preventive Controls for Human Food courses conducted
- ~300 upcoming courses scheduled



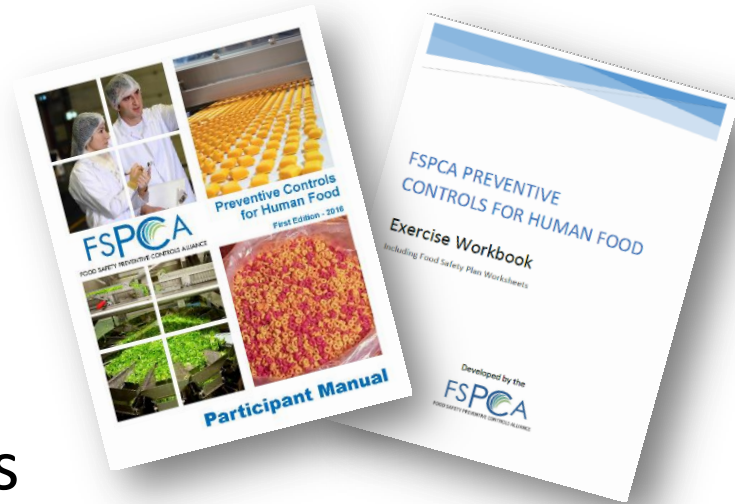
Lead Instructors

- 800 Lead Instructors
- 300 Candidates
- 26 Lead Instructor courses completed
- 10 courses currently scheduled
- 100 international Lead Instructors



FSPCA Bookstore

- Participant Manuals
- Workbooks
- Instructor Bundles
- Model Food Plans (5 pack)
- Coming soon: Spanish, Japanese, Chinese versions



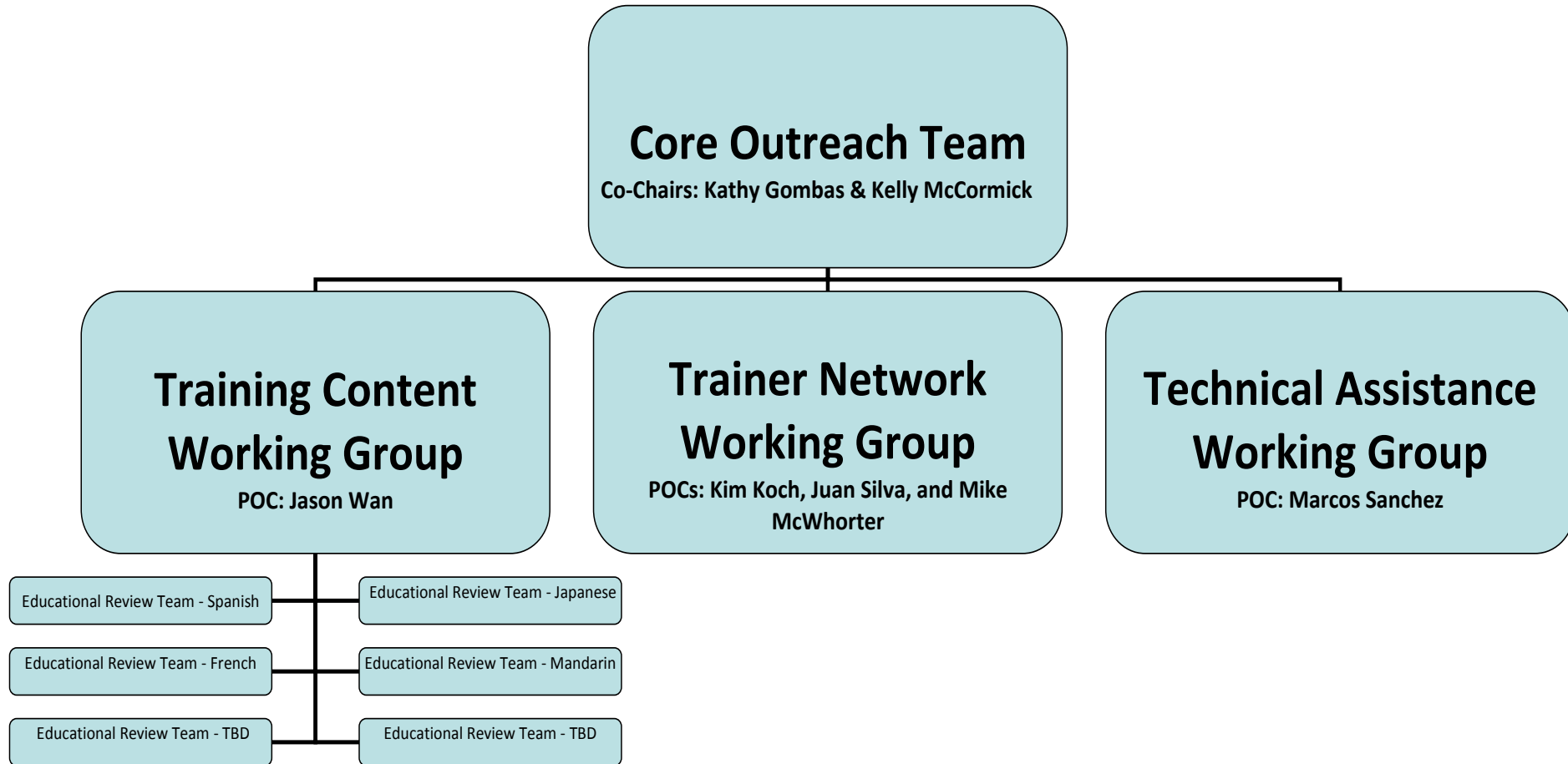
Public link (manual only): <http://bookstorefspca.ifpti.org/index.php/course-materials.html>

International Training

FSPCA International Subcommittee

- **LAUNCHED:** July 2015
- **CHARGE:**
 - Implement Outreach Strategy for Preventive Controls and Foreign Supplier Verification Program Rules
 - Develop and disseminate outreach, education, and technical materials
 - Establish training and technical assistance networks
 - Collaborate with Produce Safety Alliance on outreach efforts
- **IN A MANNER THAT IS:**
 - Consistent with domestic efforts, and
 - Considers cultural, political, religious, economic, technological, and language differences and needs

FSPCA International Subcommittee Structure



Trainer Network WG Charge

- Develop and execute a plan to employ the educational materials in capacity strengthening efforts and make them available to the international community, taking into consideration varied cultural, political, language, and technological needs and capacities.
- Responsible for coordinating with existing FSPCA domestic efforts

Trainer Network Concept

- Identify “Hubs” as points of contact for matters related to training and technical assistance with Preventive Control and related FSMA regulations.
- Consider existing centers, organizations, or groups that already provide food safety training to the industry
- Provide information on training and other relevant info to their industry/clients
- Provide FSPCA Preventive Controls Courses
- Assist with translation, interpretation, etc.

Training **Content** WG Charge

Educational Review Team

Training Content WG is charged with developing educational materials for an international audience that address the final rules and articulate the changes industry will need to make as a result of the rules' implementation, in a manner sensitive to varied cultural, political, trade, language, and technological needs and capacities.

Educational Review Team Objectives

- Establish selection criteria for Review Team Members to review translated materials
- Determine process and timeline for reviewing the translated materials
- Develop guidelines for review of translated materials
 - Review translated materials for vocabulary and language consistency
 - Review translated materials for cultural adaptability and sensitivity

Status of FSPCA PCHF Translations

- Spanish
 - In-progress: Manual V1.2, due to complete by end of Summer 2016
- Chinese
 - In-progress: Manual V1.2 translation – due to be completed by Fall 2016
- Japanese
 - In-progress: Manual V1.2 translation, projected by December 2016 or early 2017

Technical Assistance WG Charge

- Design and implement a plan to establish a international technical assistance network of experts
- Collaborate with existing domestic FSPCA Technical Assistance Network
- Address frequently asked questions and staff a communications platform (leveraging domestic FSPCA TAN resources and IT platform)

Technical Assistance

FSPCA Website: www.iit.edu/ifsh/alliance

- FAQs



The screenshot displays the website's header with the IFSH logo (Institute for Food Safety and Health) on the left and the FSPCA logo (Food Safety Preventive Controls Alliance) on the right. Below the header is a navigation menu with links for IFSH Home, FSPCA Home, The Alliance, About Us, Contact Us, FAQ, FSPCA Milestones, Upcoming Events, Committees, FAQ, and Resources. A 'SIGN UP FOR IIT IFSH FSPCA NEWS' button is located at the bottom of the menu. The main content area features the heading 'The Alliance / FAQ' and a sub-heading 'FAQ'. The first question is 'What is the Food Safety Preventive Controls Alliance (FSPCA)?' followed by a paragraph explaining the alliance's purpose. The second question is 'What prompted the creation of the FSPCA?' followed by a paragraph detailing the regulatory requirements. The third question is 'How was the FSPCA created?' followed by a paragraph describing the grant funding.

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

The Alliance / FAQ

FAQ

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). The

FSPCA Website

- FSMA Proposed, Supplemental, and Final 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@tda.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 **IAFP Annual Meeting** on July 27, 2015 from 5:15-6:00 pm Pacific. This IAFP 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)



ILLINOIS INSTITUTE OF TECHNOLOGY

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

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 FSPCA find benefit in having access to information that can help them comply with regulations and produce safe food. Market access is an added benefit. International public and private sector organizations are encouraged to participate in FSPCA 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.

Editorial Subcommittee	Animal Foods Subcommittee
Continuation Subcommittee	Working Groups
International Subcommittee	

Join the Technical Assistance Network: Resources (experts) available to industry (with an emphasis on small and mid-sized 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/fsh/alliance to view the current schedule.

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.it.edu/fsh/alliance and click on the "Apply to become an FSPCA Lead Instructor" button.

*Technical assistance is defined as resources (experts) available to industry (with an emphasis on small and mid-sized human food and animal food companies) to provide scientific and technical information on hazards associated with foods and preventive controls for those hazards.

FSPCA Website

2015 Webinars

- **March 12**
- **June 24**
- **September 3**
- **December 17**

FSPCA Update 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.

2016 Webinars

- **April 21**
- **July 21**
- **October 20**

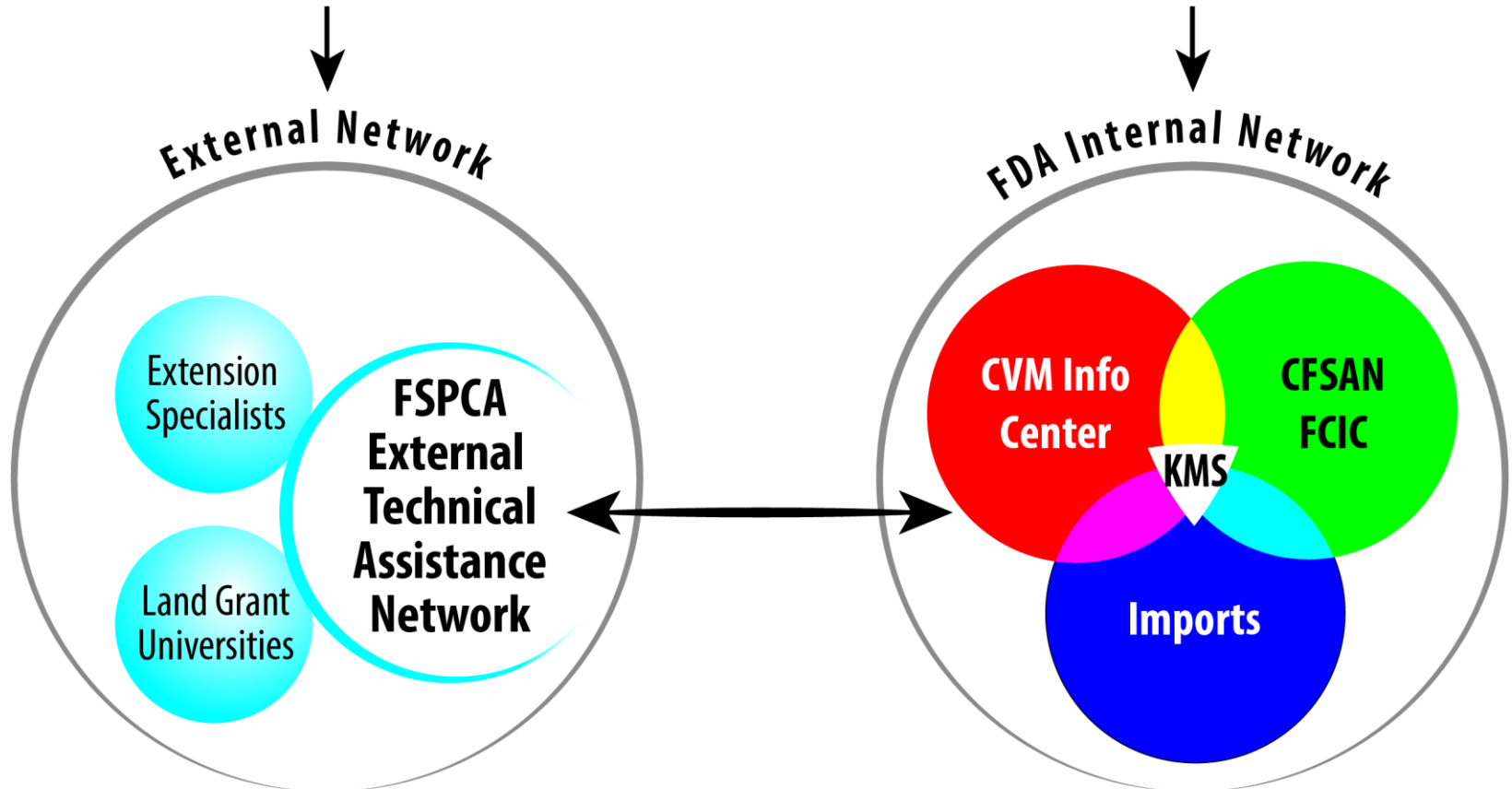
Update webinars are scheduled for April 21, July 21, October 20, 2016 and January 19, 2017.

* Go to “Upcoming Events on the FSPCA Website

FDA Food / Feed Internal and External Tech Assistance Networks

PC Scientific & Technical Questions from Industry

PC Regulation Interpretation Questions

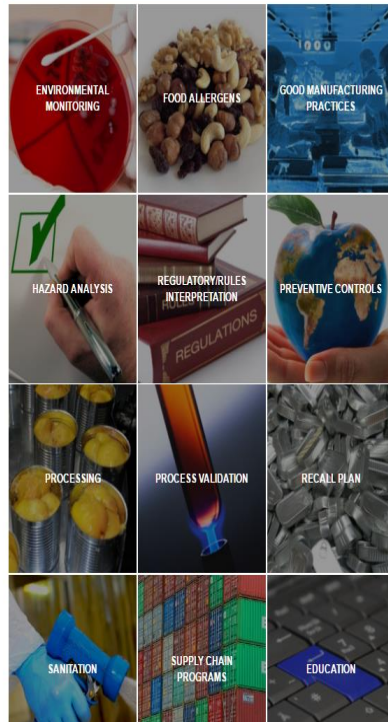


WELCOME TO THE FSPCA COMMUNITY

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

A list of FSPCA PCQI Classes can be found by searching "class" or going to the education section.

FEATURED DISCUSSIONS



SUBMIT ONLINE INQUIRY

TRENDING ARTICLES

How can I become a Food Safety Preventive Controls Alliance Lead Instructor?

Preventive Controls Qualified Individual

Completing a Lead Instructor Application Form

Current FSPCA Preventive Controls for Human Foods Class List 6-9-16

Animal Foods Participant Manual

TRENDING TOPICS

LJ APPLICATION

RISK ASSESSMENT

HAZARD ANALYSIS

TECHNICAL RESOURCE

ADDITIONAL DETAILS

LEADERBOARD

	mcarte111.45443 33355262996E12	79 Points
	JL824886	36 Points
	BJ008620	22

PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL

Explore other articles and discussions on this topic.

Preventive Controls Qualified Individual

What is a preventive controls qualified individual?

© May 5, 2016 - FSPCA

DETAILS

This is a new term in the final rule. A preventive controls qualified individual is someone who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system. The written food safety plan required of food facilities must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals. And the preventive controls qualified individual is charged with overseeing the validation that preventive controls are capable of controlling identified hazards and the records review.

View this page in Spanish

TRENDING ARTICLES

How can I become a Food Safety Preventive Controls Alliance Lead Instructor?

Preventive Controls Qualified Individual

Completing a Lead Instructor Application Form

Current FSPCA Preventive Controls for Human Foods Class List 6-9-16

Animal Foods Participant Manual

Don't see what you're looking for?

ASK A QUESTION

CONTACT SUPPORT

The Food Safety Preventive Controls Alliance (FSPCA)
 Institute for Food Safety and Health | Illinois Institute of Technology | Maffei Campus
 6502 South Archer Rd. Bedford Park, IL 60611-1667 | P: 708.903.1576

Coming Soon!

- Foreign Supplier Verification Training

The screenshot shows the website for the Foreign Supplier Verification Program (FSVPC) at the Illinois Institute of Technology (IIT). The page features a navigation menu on the left with links to IFSH Home, The Alliance, International, Intentional Adulteration, Foreign Supplier Verification, Upcoming Events, Committees, FAQ, and Resources. Below the menu are three buttons: 'TECHNICAL ASSISTANCE NETWORK INQUIRY FORM', 'SIGN UP FOR IIT IFSH FSPCA NEWS', and 'APPLY TO BECOME'. The main content area is titled 'Foreign Supplier Verification' and 'Foreign Supplier Verification Program'. It includes a section for 'FSVP Meeting Summaries' with a paragraph of text and a date 'July 1, 2015'. The text describes a pilot FSPCA Preventive Controls for Human Foods class and the development of an FSVP training program. A second date, 'July 29, 2015', is visible at the bottom of the content area.

ILLINOIS INSTITUTE OF TECHNOLOGY

Quick Links. Search Content

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Foreign Supplier Verification

Foreign Supplier Verification Program

FSVP Meeting Summaries

The following are summaries of the biweekly meetings held with the Illinois Institute of Technology/Institute for Food Safety and Health/Food Safety Preventive Controls Alliance (FSPCA), FDA, and the two IIT consultants responsible for development of the FSVP training program.

July 1, 2015

Bob Lake and Cathy Carnevale, the consultants to IIT who are developing FSVP training, had taken a pilot FSPCA Preventive Controls for Human Foods class and asked whether there was an expectation that they use the same format for creating a FSVP course. The PC courses are more technical, given that they are intended primarily for food manufacturers/processors, while the FSVP course is intended for importers, who could also be manufacturers, but may also be retailers and other business persons with little technical background. There was a conversation on the differences between the new supplemental FSVP proposal and the original FSVP proposal. Lake and Carnevale wanted to know more about how FDA planned to reach out to foreign food suppliers regarding the new PC and produce rule requirements – once those rules are finalized, the concern being that the foreign supplier should have awareness of these rules prior to importers contacting them about a requirements under the FSVP rule. The proposed roles of Qualified Individuals under PC and FSVP rules were also considered.

July 29, 2015

Coming Soon!

- Foreign Supplier Verification Training
- Intentional Adulteration Training



ILLINOIS INSTITUTE OF TECHNOLOGY

Quick Links. 

Search Content

IFSH
INSTITUTE FOR
FOOD SAFETY
AND HEALTH

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

IFSH Home

The Alliance

International

Intentional Adulteration

Foreign Supplier Verification

Upcoming Events

Committees

FAQ

Resources

Intentional Adulteration

Intentional Adulteration

FSMA Proposed Rule for Focused Mitigation Strategies to Protect Food Against Intentional Adulteration

FDA's proposed rule on food defense would require domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm. The proposed rule, which is required by the FDA Food Safety Modernization Act, would require the largest food businesses to have a written food defense plan that addresses significant vulnerabilities in a food operation.

The FDA is proposing that the requirements be effective 60 days after the final rule is published in the Federal Register. Recognizing that small and very small businesses may need more time to comply with the requirements, the FDA is proposing tiered compliance dates based on facility size.

For detailed information regarding Intentional Adulteration, [click here](#).

Outreach

- TAN Conference / Meeting
 - 3rd quarter of 2016
- FSPCA , FDA - (FSE's and SME's)
- Technical exchange to
 - Discuss TAN operation
 - Share best practices
 - Gain feedback to date
 - Plan next steps

FSPCA Website Format Conversion

- Basic Architecture complete for both IFSH and FSPCA sites
- IFSH site development in process (started mid January)
- 3 main areas of work , Links , Images , Database (Portal) in process to support changeover to Drupal
- All scheduled for completion in late June, 2016



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.