FSMA Standardized Curricula Update

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Illinois Institute of Technology

International Citrus & Beverage Conference

Clearwater Beach, FL

September 22, 2016

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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

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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?

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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

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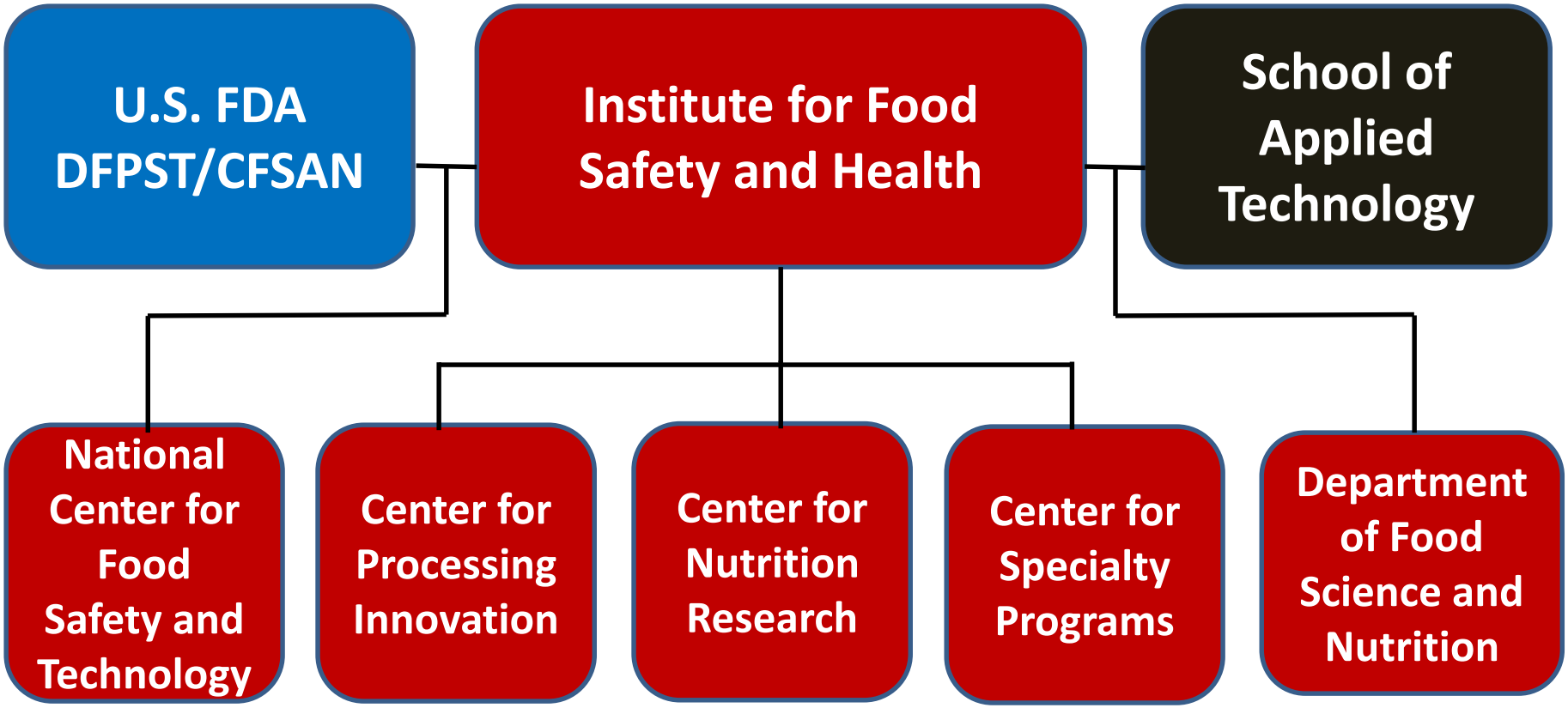
IFSH Centers



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IFSH & Industry Collaboration

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

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

FSMA Rules and FSPCA Involvement

Regulation	Final Publication
Preventive Controls (Human Food)	Sept 17, 2015
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Produce Safety	Nov 27, 2015
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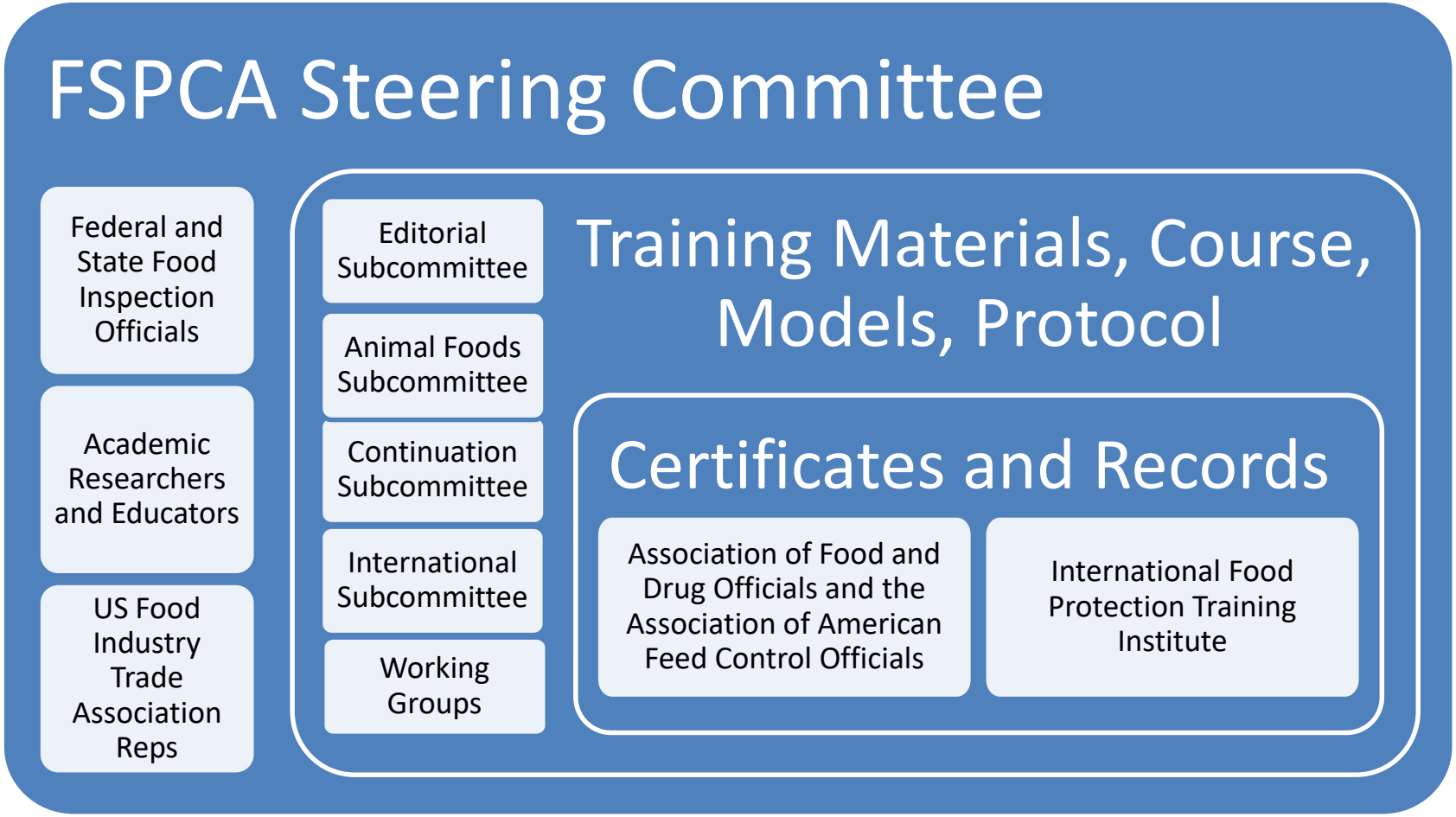
Organization and Governance

FSPCA Structure (old)



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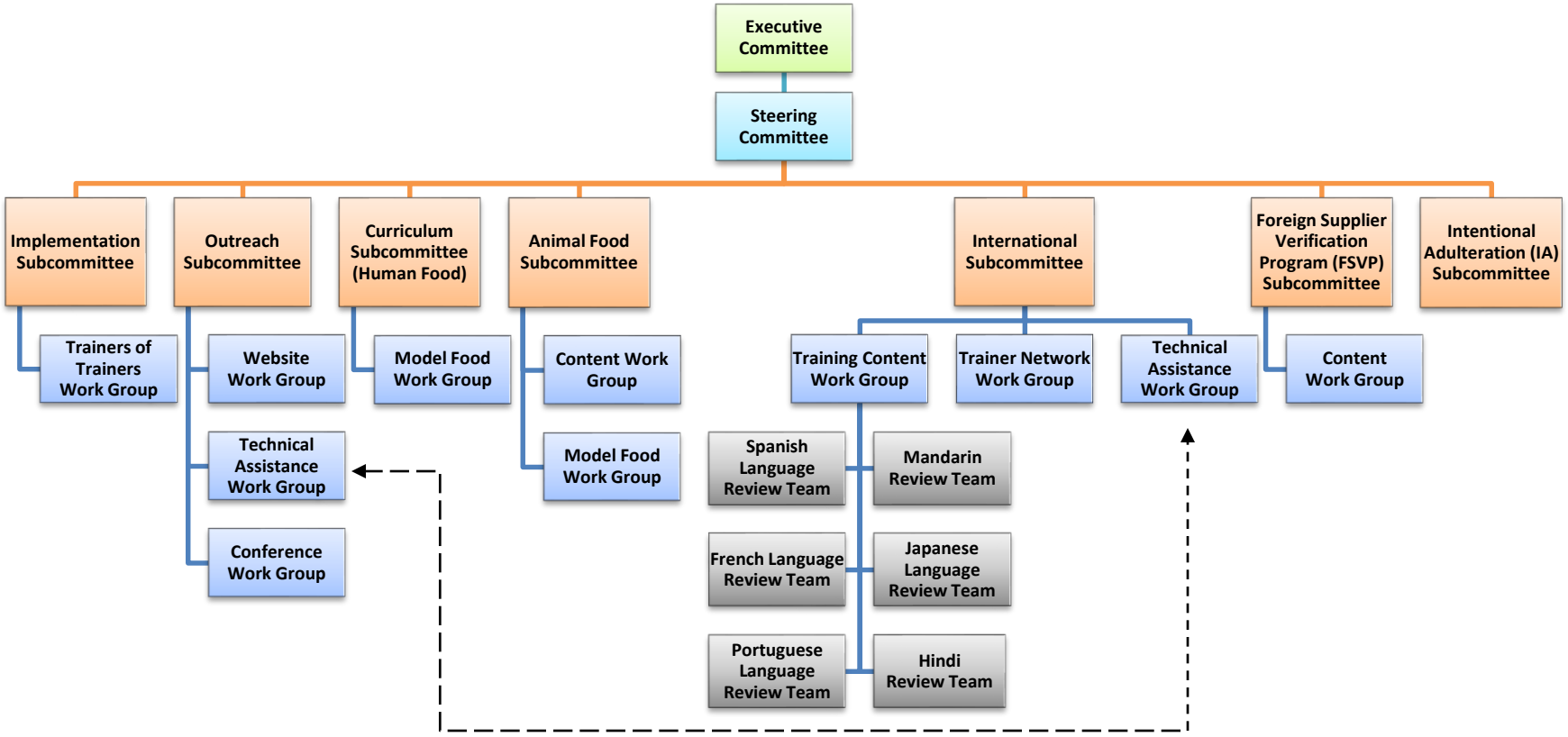
FSPCA Committees, Subcommittees, Work Groups



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

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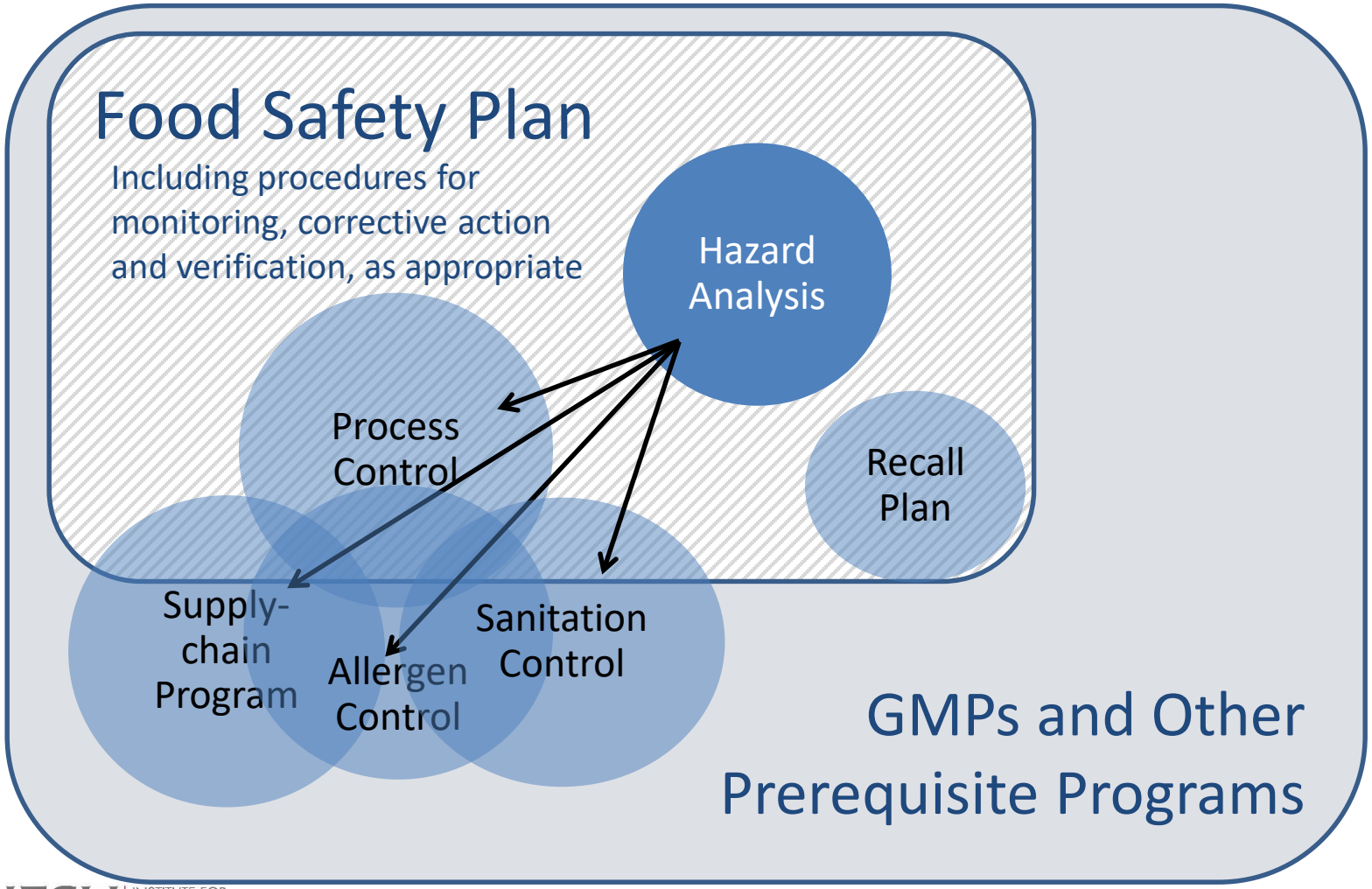
Hazard Analysis and Risk-Based Preventive Controls

Preventive Food Safety Systems



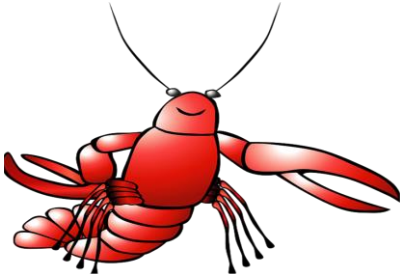
Risk-based Preventive Controls

- 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

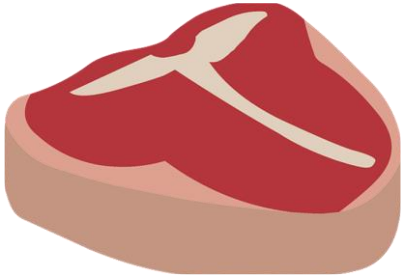
US Space program

Low-acid canned food regs



FDA Seafood HACCP regs

FDA Juice HACCP regs



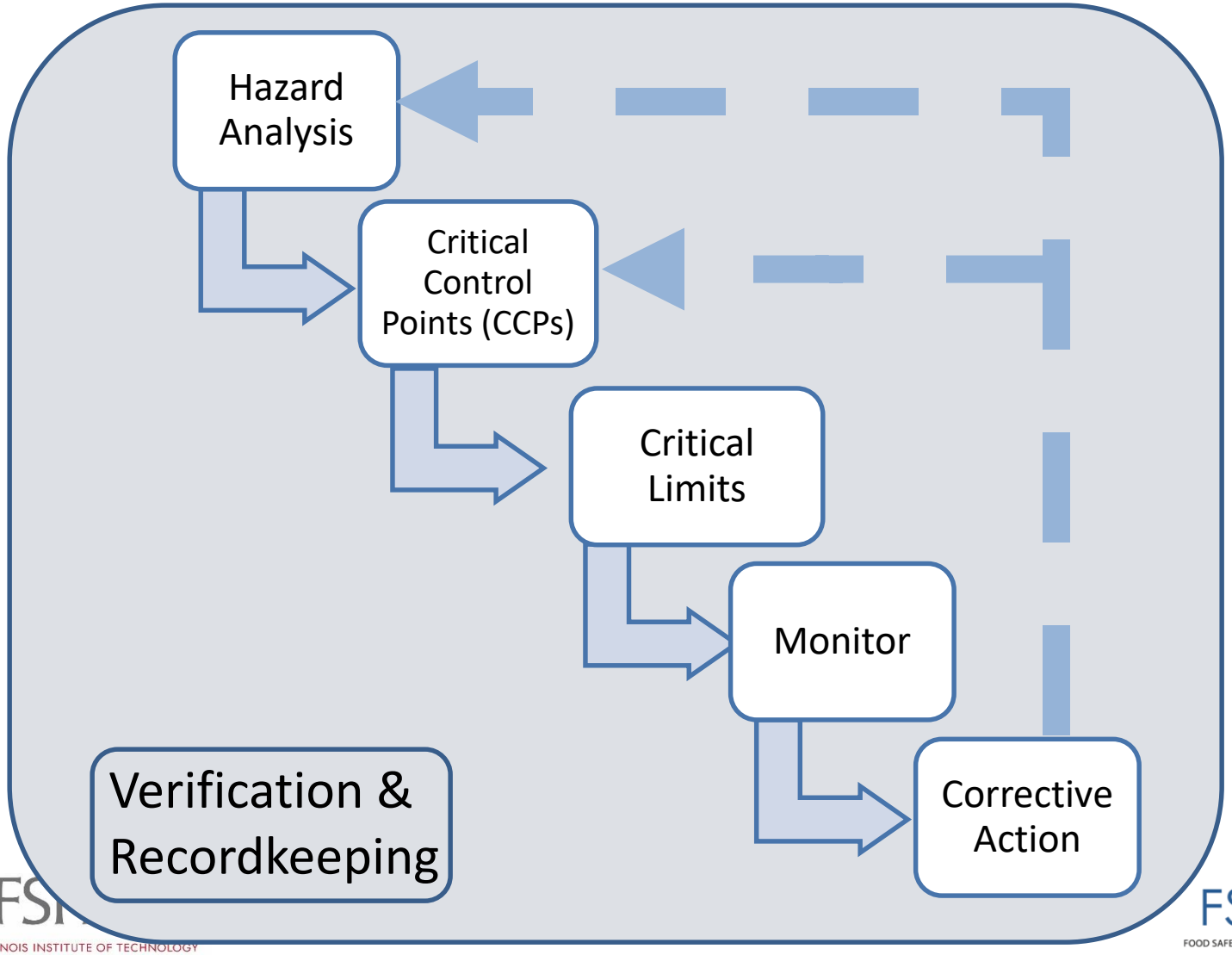
USDA HACCP regs

Codex HACCP Annex

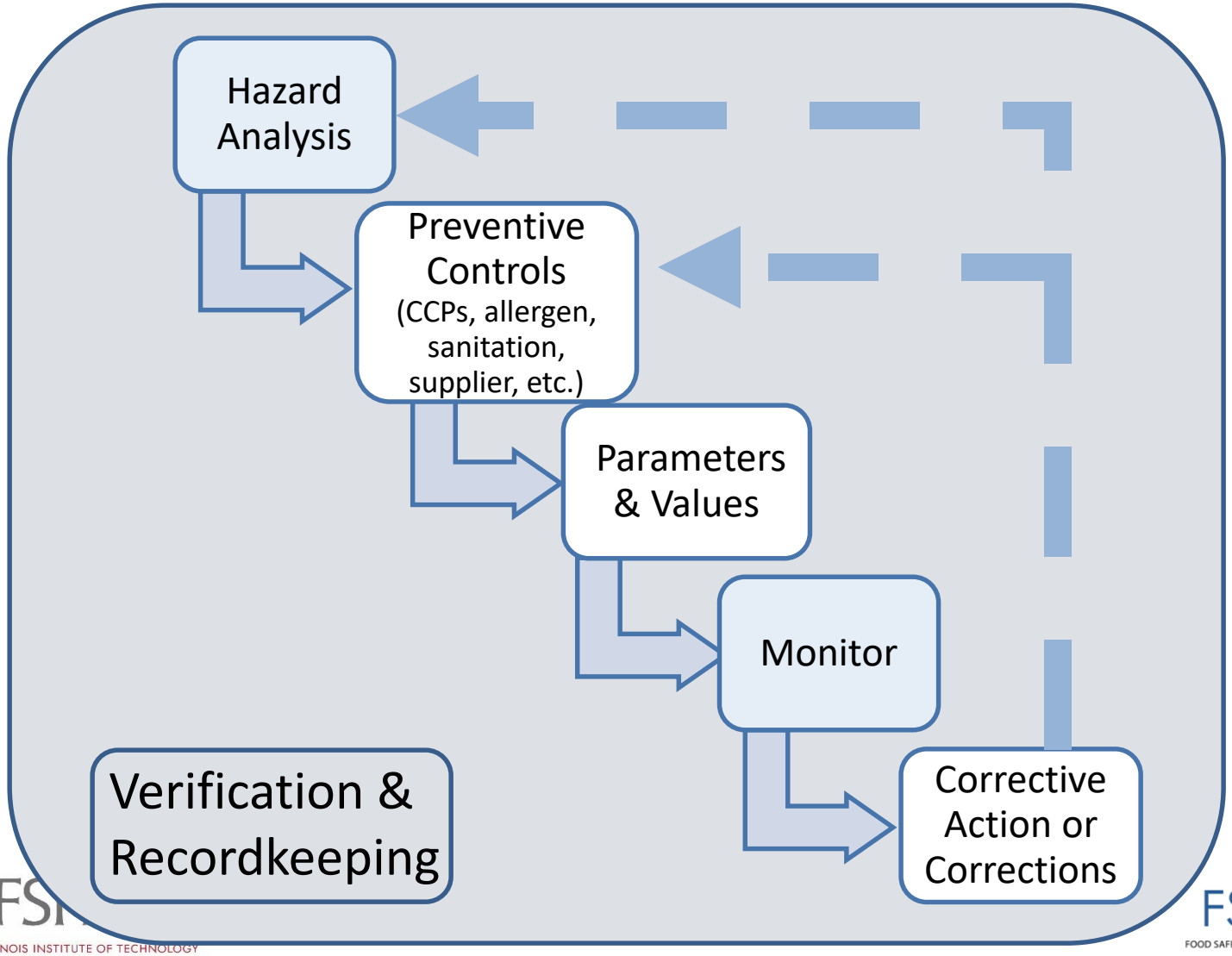
NCIMS Dairy HACCP

Image source: Microsoft clip art

Historically HACCP Focuses on the Process



Preventive Controls Include More Than HACCP

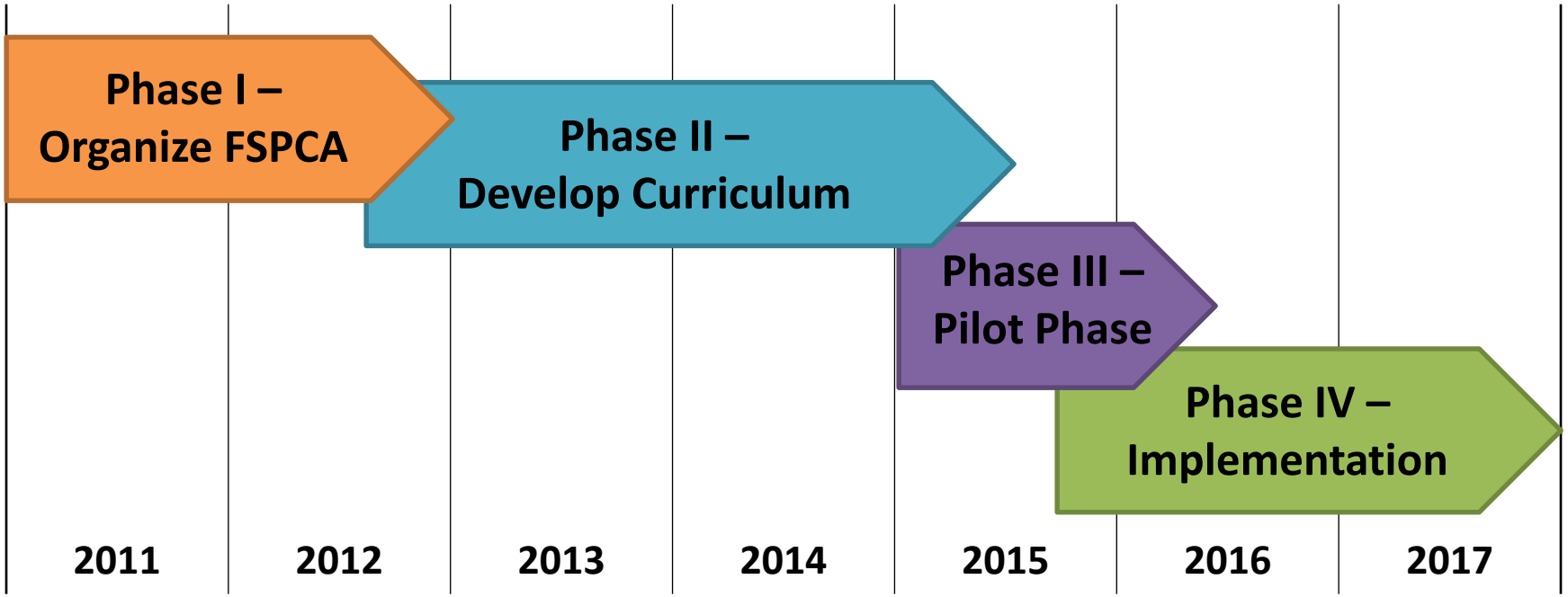


What's New in a Food Safety Plan

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

Implementation

Timeline



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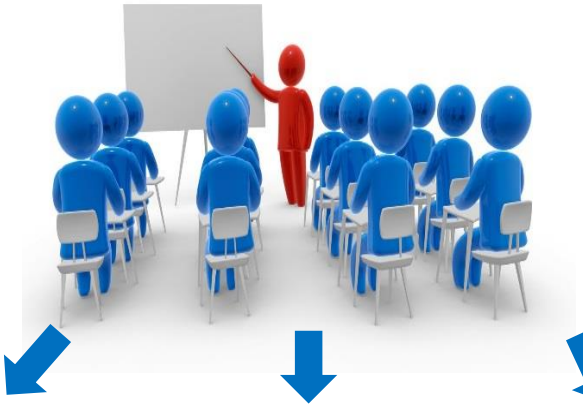
How are we doing?

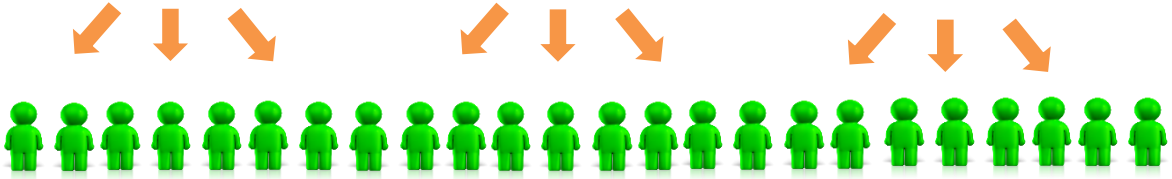
FSPCA Delivery Model

Trainers-of-Trainers (ToTs) train Lead Instructors



Lead Instructors train Participants

Participants meet training requirements for PC Qualified Individual



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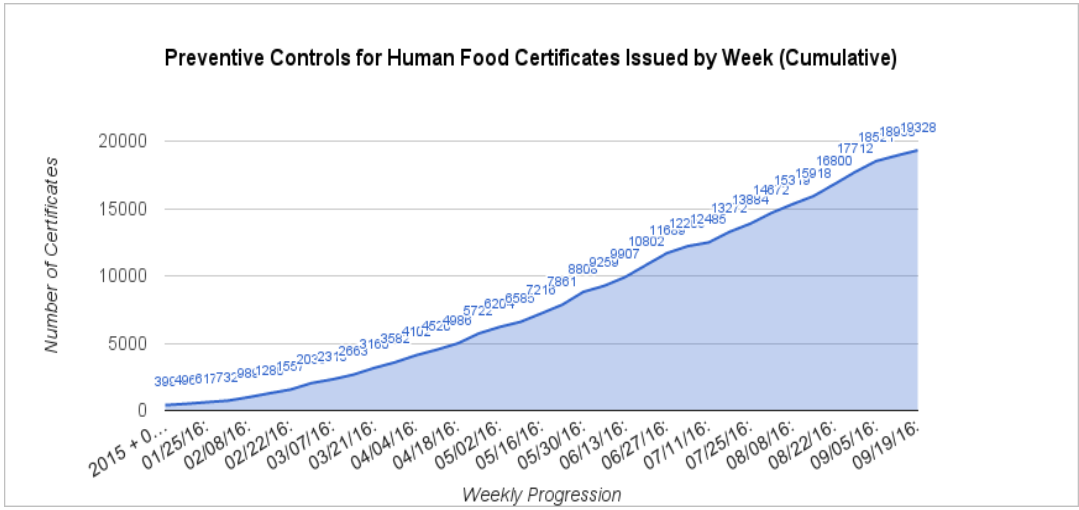
FSPCA Metrics (Human Foods)*

- ~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

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CERTIFICATE OF TRAINING

is awarded to

Jenifer Kane

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Lead Instructor Training for FSPCA Preventive Controls for Human Food

delivered by Lead Instructor,
Kathy Gombas
completed on,
01/14/2016

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

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INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

Certificate # d6920c04-8465-4646-9e3c-27acb0f272c3

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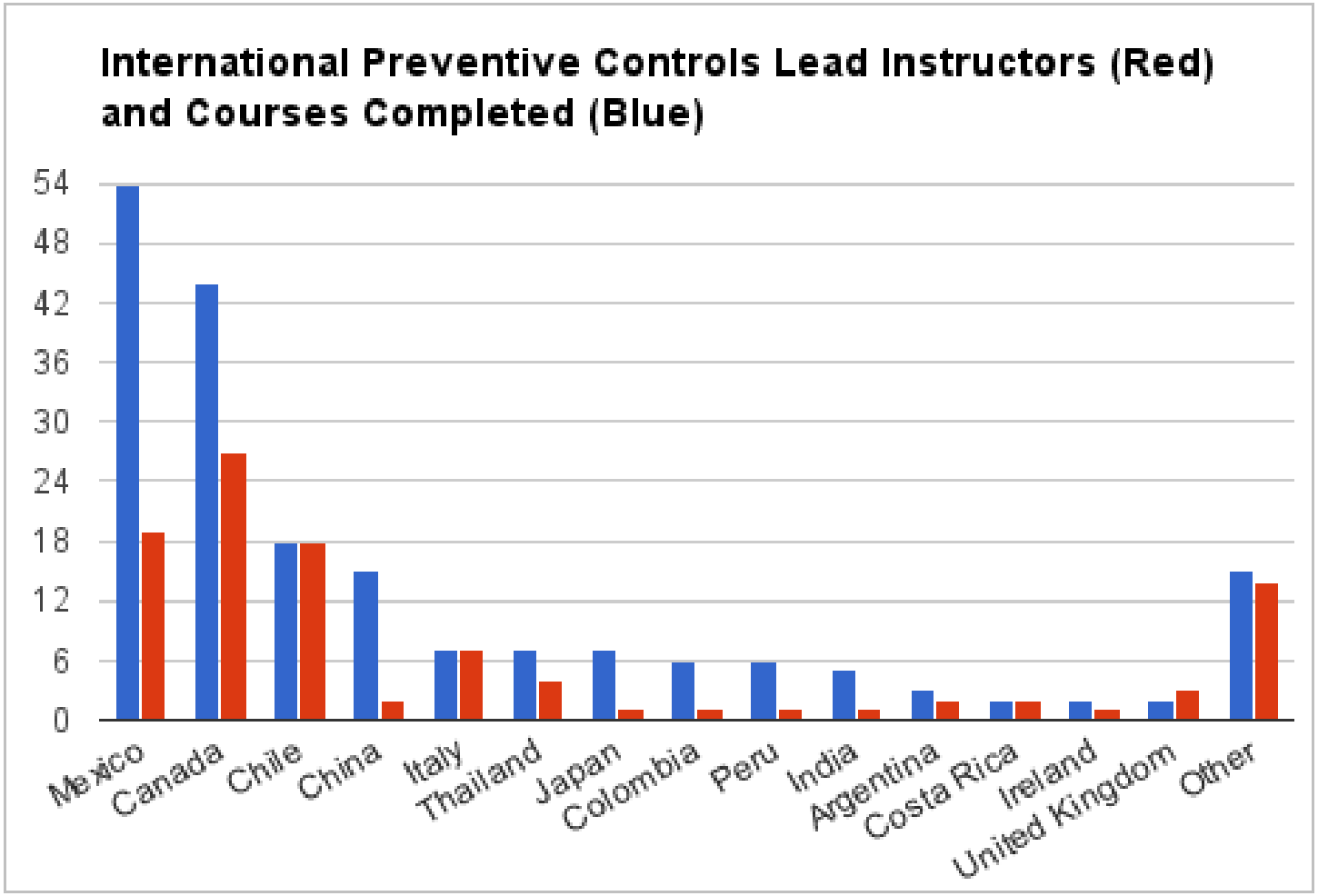
FSPCA Metrics (Human Foods)



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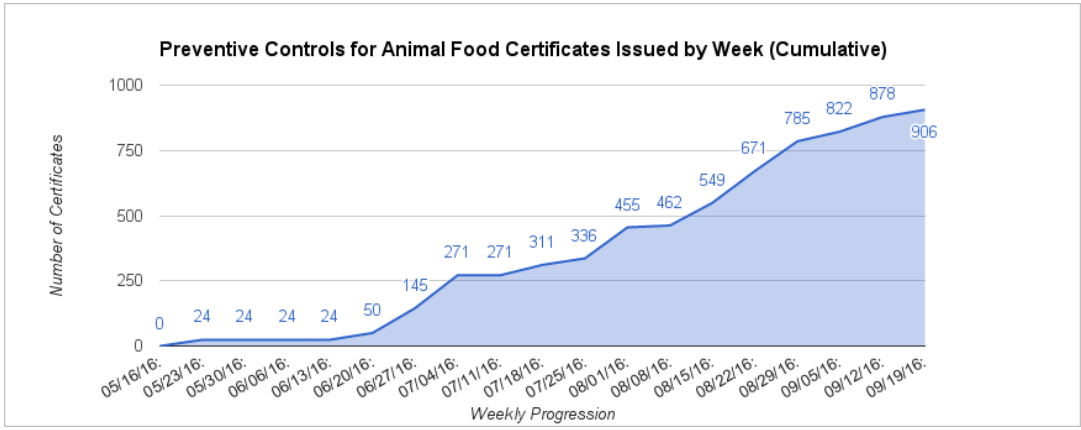
FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FSPCA Metrics (Animal Foods)*

- ~906 Animal Food course certificates issued

  (~18 international)
- ~33 FSPCA Preventive Controls for Animal Food courses conducted
- ~32 upcoming courses scheduled



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FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Lead Instructors (Animal Foods)

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

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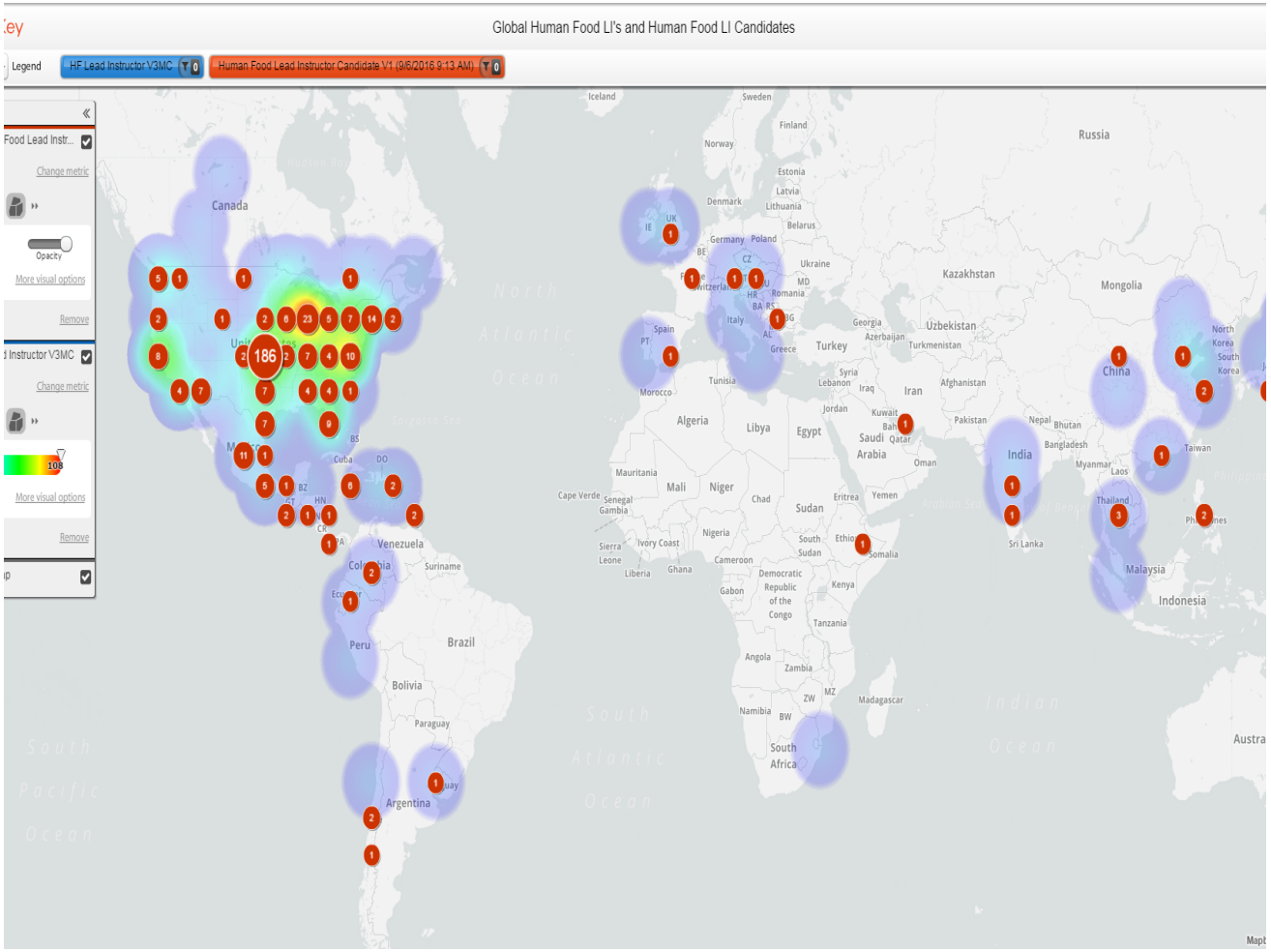


Instructor and Candidates Distribution – Example

Example of GeoMap for Lead Instructors and Lead Instructor Candidates

LI Candidates are red LI's are represented by heat circles

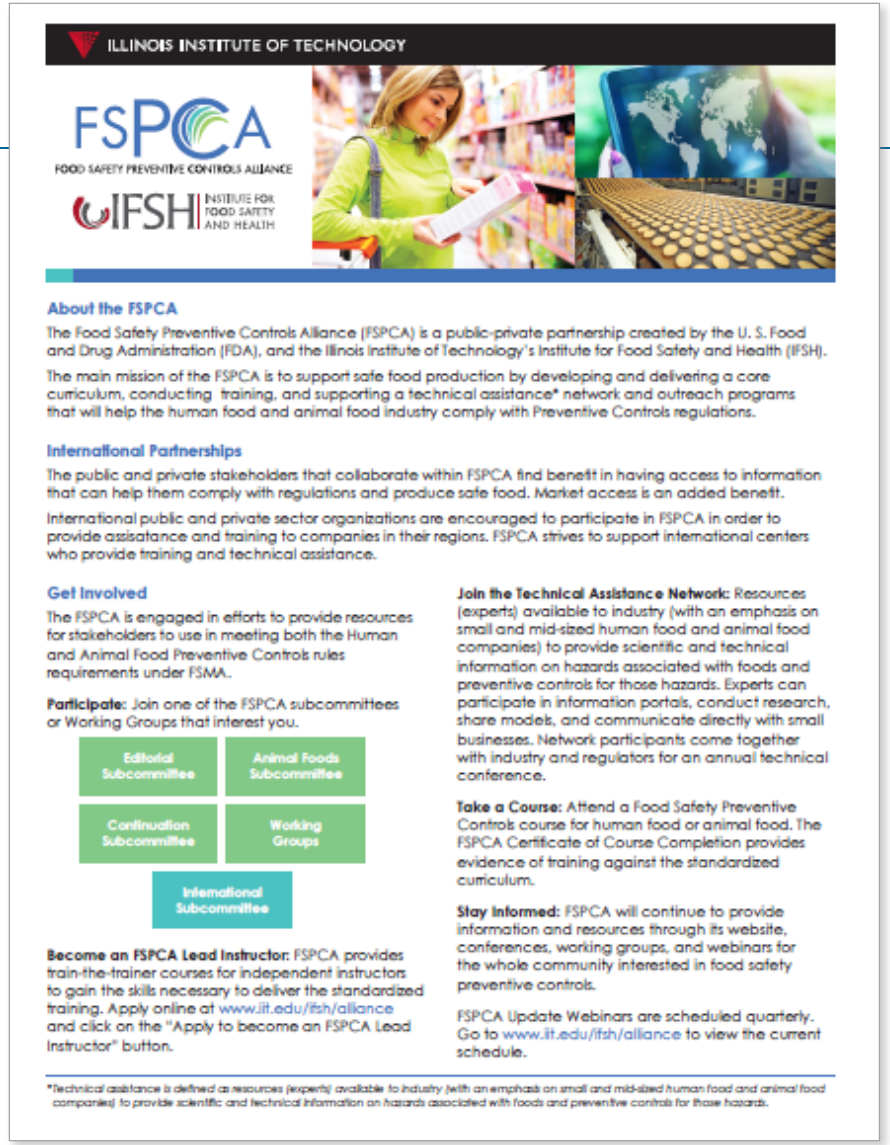
Technical Assistance

FSPCA Flyers

- Domestic
- International
  - Multiple languages

FSPCA Domestic One Page Flyer (pdf)

FSPCA International One Page Flyer (pdf)



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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 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

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

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.iit.edu/ifsh/alliance to view the current schedule.

*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.

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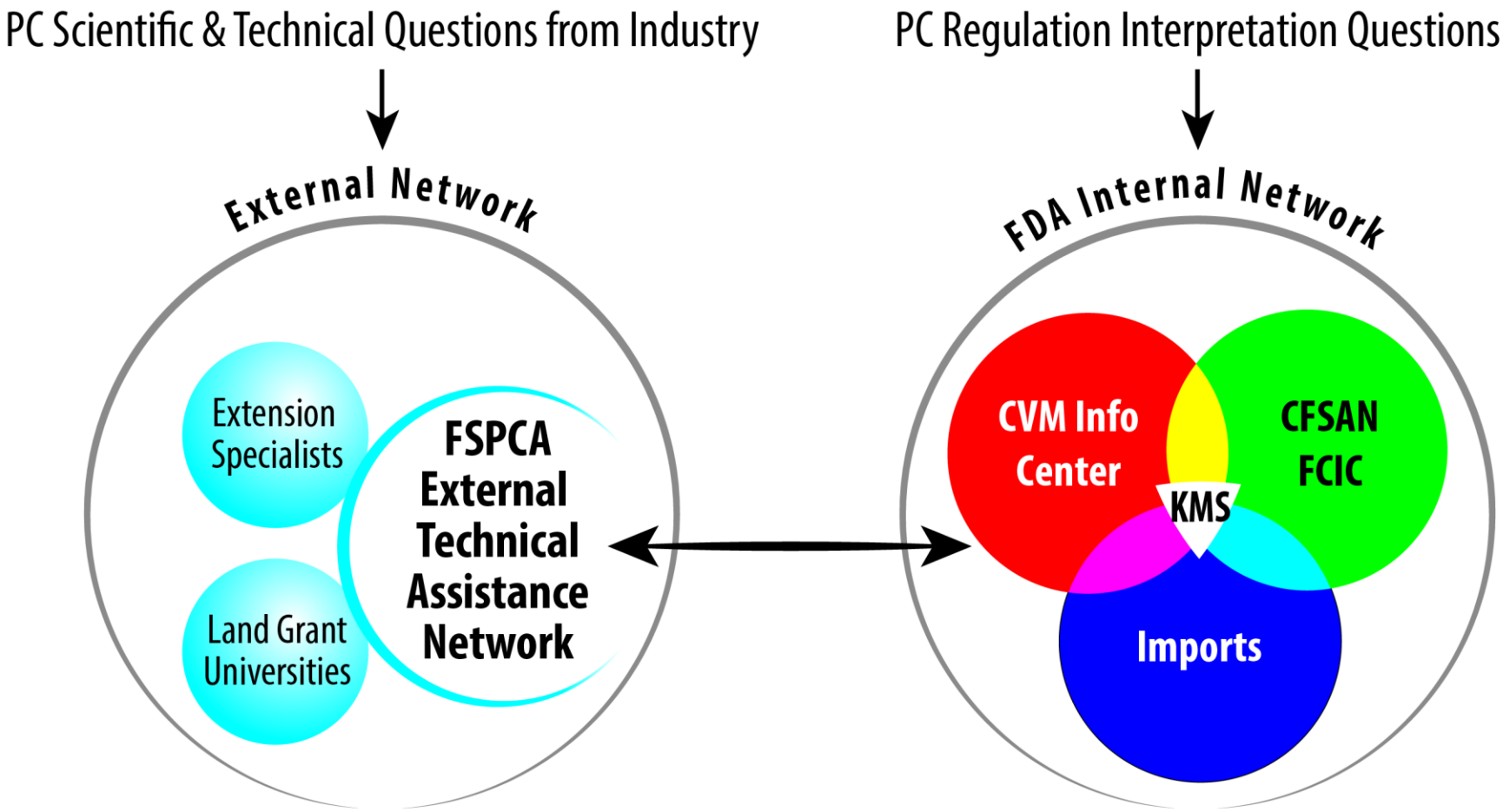
FDA Food / Feed Internal and External Tech Assistance Networks



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FSPCA Community

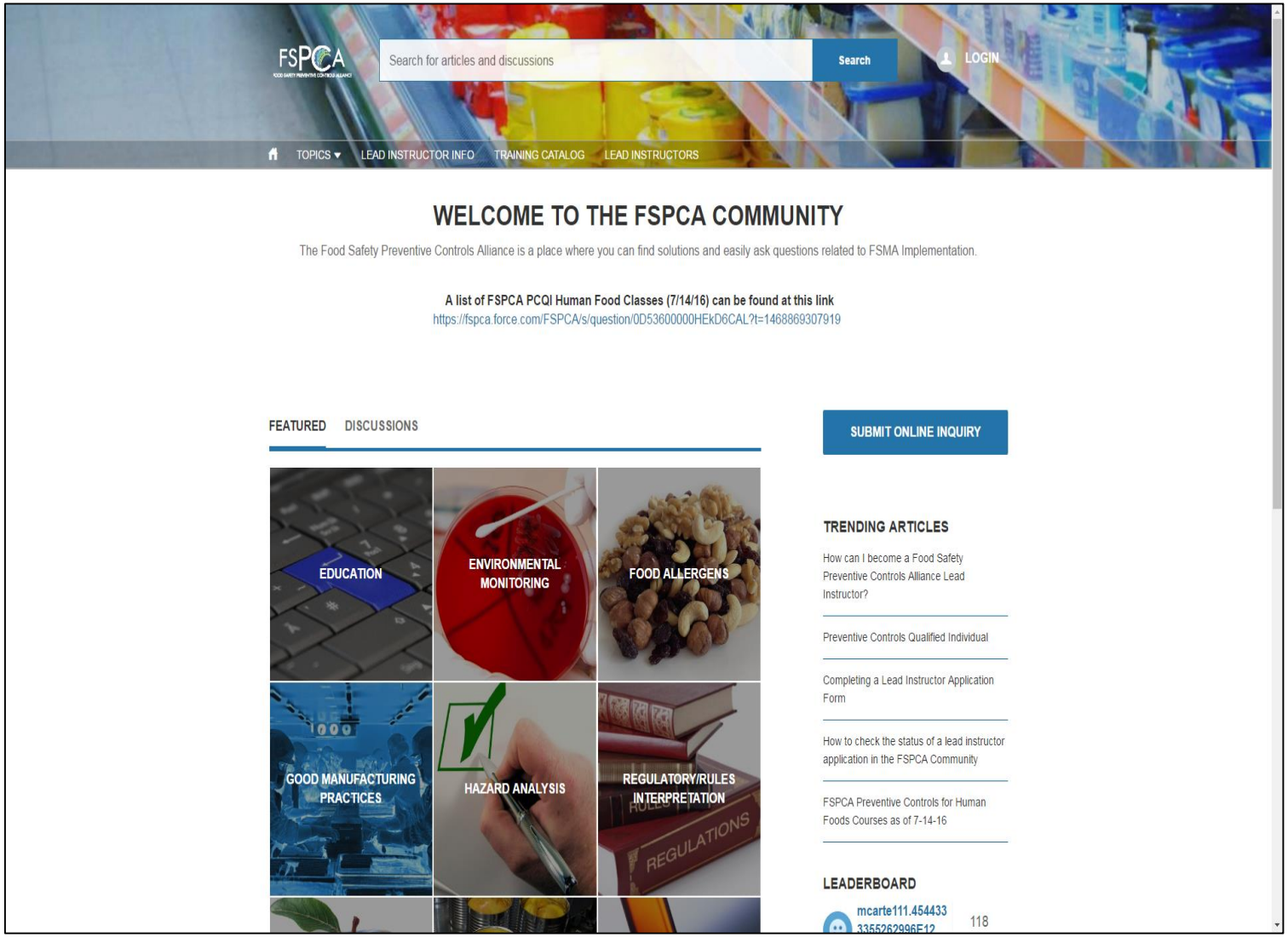
- Web Community and Technical Assistance
- Supports Industry, Food Safety Experts , Lead Instructors
- Project Completed – May 12, 2016

- 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/



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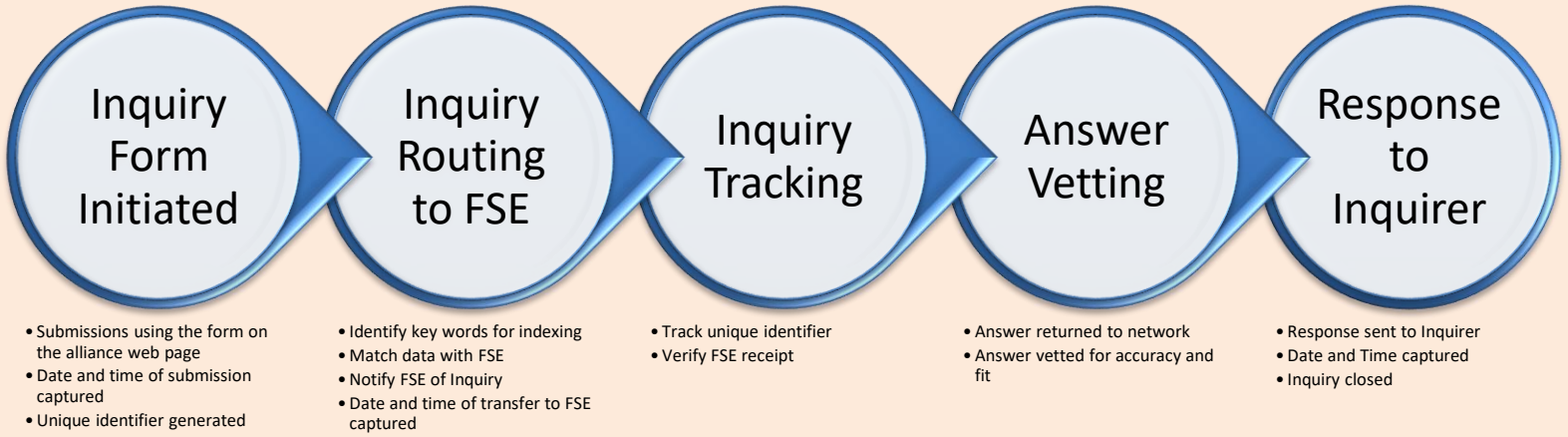
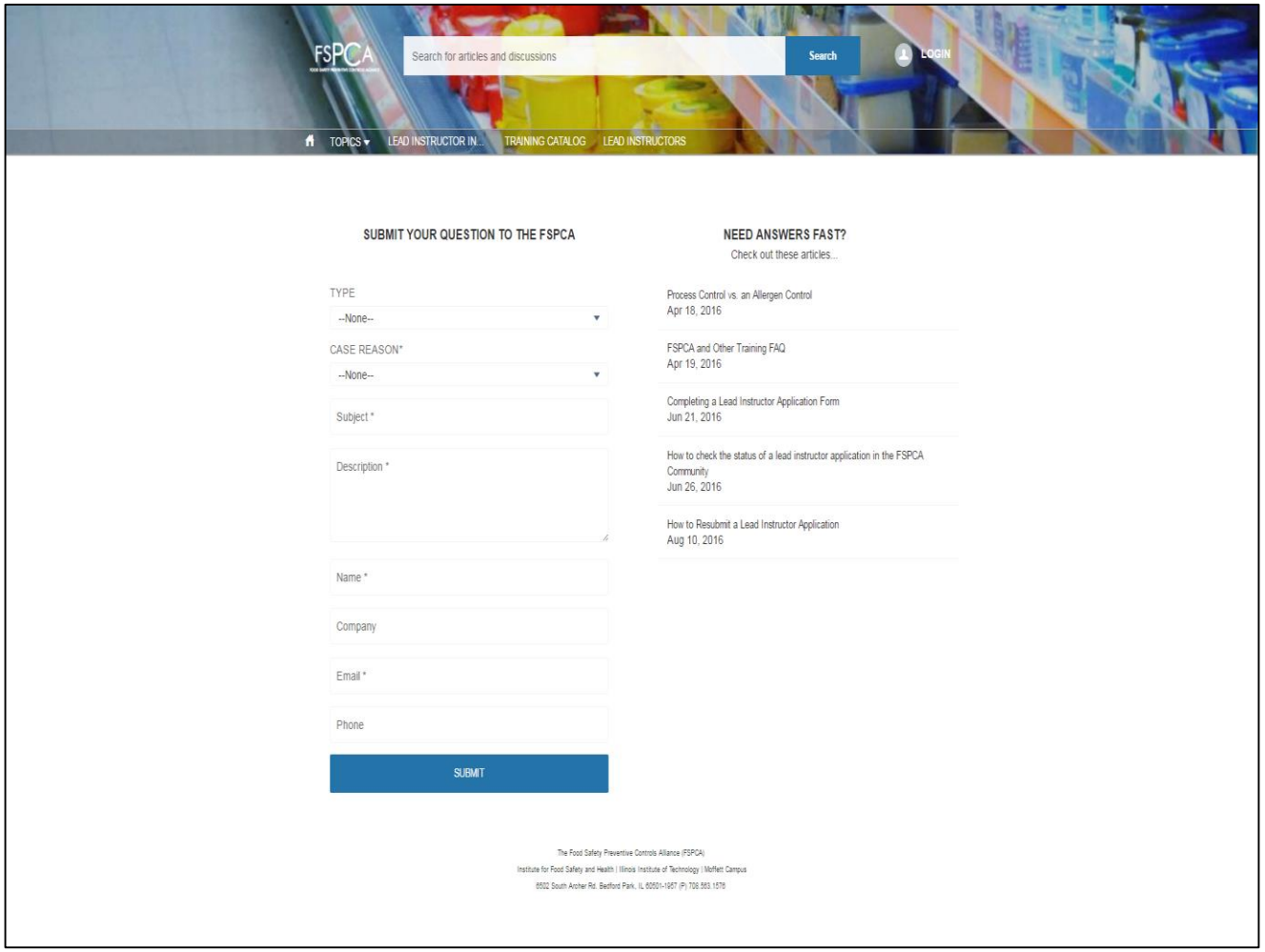
FSPCA Technical Assistance Network –Inquiry Routing Process



- 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 Questoins 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**

2017 Webinars

- **January 19**
- Spring TBD
- Summer TBD
- Fall TBD

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.

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

* Go to "Upcoming Events on the FSPCA Website

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Coming Soon!

- Foreign Supplier Verification Training

FSPCA

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Menu

Foreign Supplier Verification Program (FSVP)

FSVP CURRICULUM AND TRAINING

The FSVP course is in development. In late September 2016, a "walkthrough" will take place with FDA reviewers and content experts. In late October/early November 2016, a face-to-face pilot of the course will be conducted. After the pilot, the face-to-face (instructor-led) course will be offered, targeted to begin in late November 2016. FSPCA is evaluating mechanisms for current Preventive Controls Lead Instructors to add the FSVP course to their portfolio.

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.

« FSPCA HOME

+ THE ALLIANCE
– COURSES
  - **FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)**
  - INTENTIONAL ADULTERATION
  - FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD
  - FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD
- LEAD INSTRUCTOR
- TECHNICAL ASSISTANCE NETWORK (TAN) DATABASE
+ RESOURCES
+ FAQ
- INTERNATIONAL
- INTENTIONAL ADULTERATION
+ COMMITTEES
+ NEWS
- RETURN TO IFSH

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Coming Soon!

- Foreign Supplier Verification Training
- Intentional Adulteration Training

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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

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THANK YOU!

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

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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.