

# **U.S. FDA's Food Safety Modernization Act (FSMA)**

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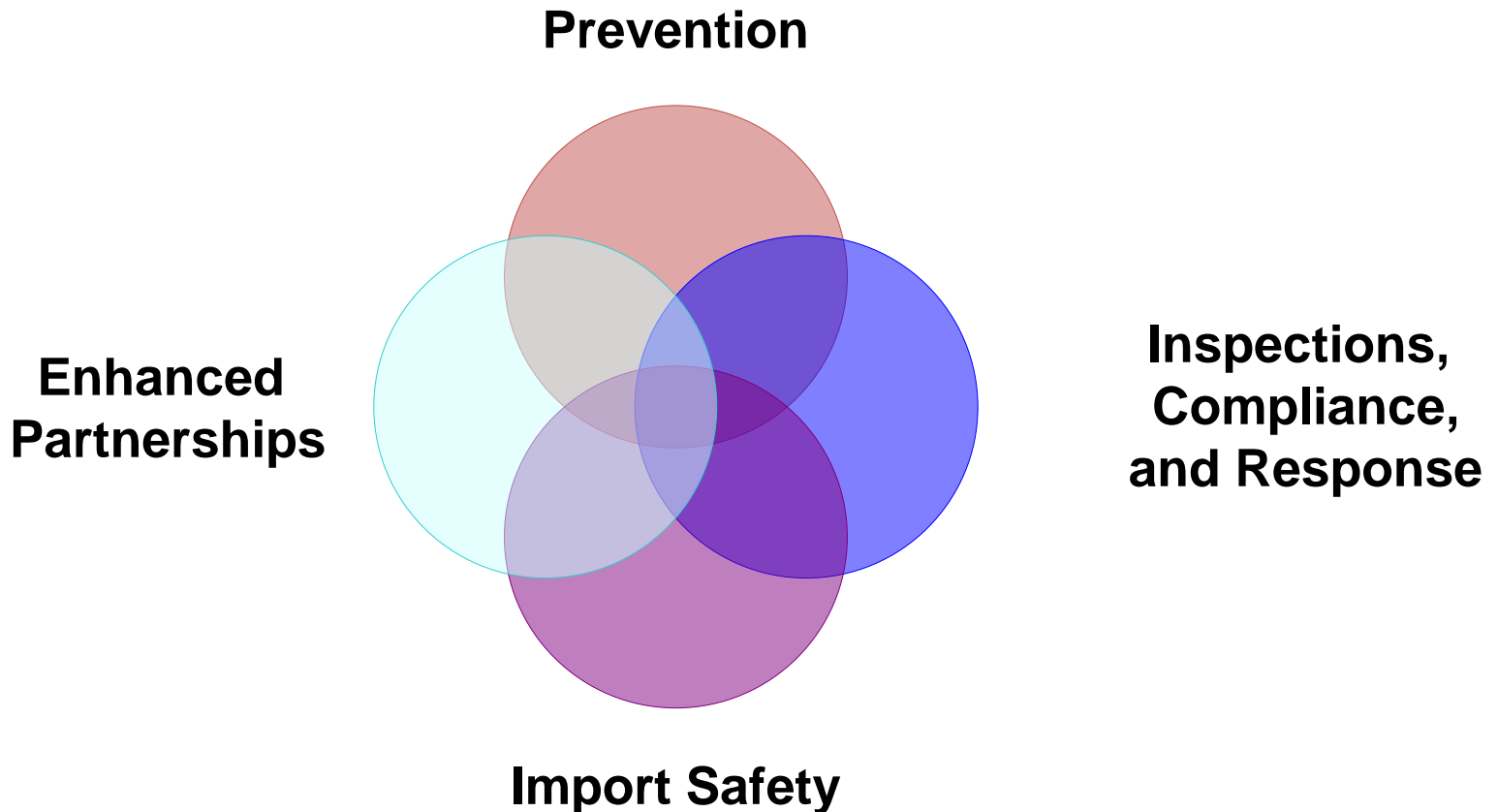
# Food Safety Modernization Act

1. Food Safety Modernization Act signed January 2011 by President Obama
2. Listening sessions
3. FDA drafted proposed rules based on the new law, as well as input from public meetings and listening sessions
4. FDA published proposed rules for comment
5. Comments were considered and changes integrated into proposed rules
6. Final Rules were published



# Food Safety Modernization Act

## FSMA's Main Themes





# Seven Foundational Final Rules

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Produce Safety
- Foreign Supplier Verification Program
- Accredited Third-Party Certification
- Sanitary Transportation
- Intentional Adulteration



# FSMA – Section 305

## “Building Capacity of Foreign Governments with Respect to Food Safety”

- **Directs FDA to:**  
...develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries, from which foods are exported to the United States.
- **FDA’s Capacity Building Plan – Element 4**  
Train foreign governments and food producers on US requirements for safe food



# International Communications and Engagement



- Key Implementation Principle: Facilitate industry compliance with prevention-oriented standards through guidance, developing tools/resources for education, outreach and technical assistance
  - Guidance Documents



# International Communications and Engagement



- Use of Regulatory Tools: Systems Recognition, bi/multilateral agreements, etc
- Partnerships: STDF, FAO, APEC, GFSP, WHO
- FSMA Outreach: FDA Outreach Meetings, Public Hearings, Presentations, and Webinars
- Interagency Collaboration: Food and Agriculture Sustainability Training (FAST), Food Safety Network
- Alliances: Food Safety Preventive Controls, Produce Safety, and Sprout Safety



# International Communications and



## Engagement: ALLIANCES

- Food Safety Preventive Controls Alliance (FSPCA)
  - Curricula to train those that manufacture, process, hold, and distribute human and animal food
  - Curriculum to train importers subject to the FSVP rule
  
- Produce Safety Alliance (PSA)
  - Curriculum to train the farming community
  
- Sprout Safety Alliance (SSA)
  - Curriculum to train sprout growers





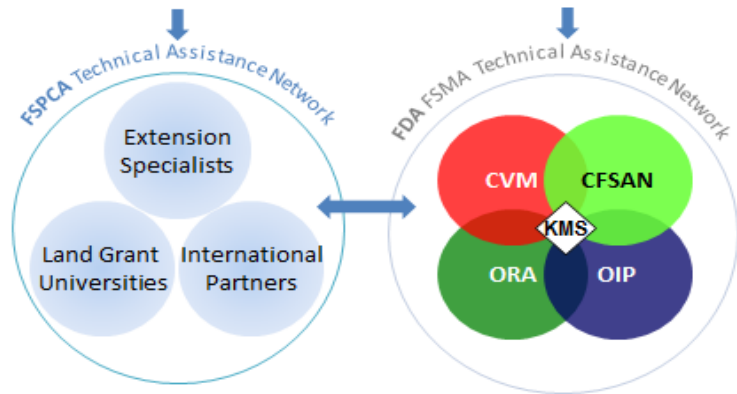
# FSMA Technical Assistance Networks

- To submit a FSMA regulatory interpretation question, visit [www.fda.gov/fsma](http://www.fda.gov/fsma)
- Scientific and technical questions can be submitted to the FSPCA TAN: [https://fspca.force.com/FSPCA/s/?language=en\\_US](https://fspca.force.com/FSPCA/s/?language=en_US)

## FSMA Technical Assistance Networks

Preventive Controls Scientific & Technical Questions from Industry – submit a web form at: [www.iit.edu/ifsh/alliance](http://www.iit.edu/ifsh/alliance)

FSMA Regulation & Policy Interpretation Questions – submit a web form at: [www.fda.gov/fsma](http://www.fda.gov/fsma)



The screenshot shows the FDA website's navigation bar with the U.S. Department of Health and Human Services logo and the FDA logo. Below the navigation bar, there are links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled 'Food' and includes a search bar and a 'Contact FDA About FSMA' section. This section features a 'Submit Inquiry' button and a list of links: 'The Law, Rules & Guidance', 'How to Comment on FSMA', 'Fact Sheets & Presentations', 'Frequently Asked Questions', 'FDA Actions to Date', 'FSMA Training', 'Contact FDA About FSMA', and 'Archive'. A sidebar on the right provides contact information for the Food and Drug Administration, including the address: 5100 Paint Branch Pkwy, Wilex Building, HFS-009, College Park, MD 20740.

# FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

## INTERNATIONAL SUBCOMMITTEE

Kathy Gombas, Food Safety Consultant  
kathy.Gombas@gmail.com



# Who is FSPCA?

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- **In 2011, the FDA helped to establish a public-private partnership called the Food Safety Preventive Controls Alliance (FSPCA), created to provide Food Safety Modernization Act (FSMA) technical assistance and training programs.**
  - The FSPCA is managed by the Illinois Institute of Technology (IIT). IIT partners with the International Food Protection Training Institute (IFPTI) and the Association for Food and Drug Officials (AFDO) for training implementation.



# Who is FSPCA?

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- **The FSPCA developed core curricula, training, and outreach programs to assist stakeholders to be prepared to adhere to the following FSMA final rules:**
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food;
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Animal Food;
  - Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals; and
  - Mitigation Strategies to Protect Food Against Intentional Adulteration for Human Food (in-progress)



# Who is FSPCA?

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- Food Safety Preventive Controls Alliance (FSPCA)
  - IIT Alliance homepage: [fspca.net](http://fspca.net)

# FSPCA Website: fspca.net

## Training

[List of FSPCA Participant Courses](#)  
[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)




[Supplier Evaluation Resources](#)  
[FDA Update! FDA Extends Certain FSMA Compliance Dates: Issues Draft Guidance](#)  
[FDA Food Safety Modernization Act Homepage](#)  
[FSMA Final Rule for Preventive Controls for Human Food](#)  
[FSMA Final Rule for Preventive Controls for Animal Food](#)  
[FSMA Final Rule on Foreign Supplier Verification Programs \(FSVP\) for Importers of Food for Humans and Animals](#)  
[FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration](#)

[Sign up for the FDA's e-mail updates](#)

## The Alliance

[Committees, Subcommittees, Work Groups](#)

## Quick Links

[Apply to Become a Lead Instructor](#)  
[FSPCA Advertising Recommendations for Lead Instructors \(Human Food\)](#)   
[FSPCA Advertising Recommendations for Lead Instructors \(Animal Food\)](#)   
[FSPCA Advertising Recommendations for Lead Instructors \(FSVP\)](#)   
[FSPCA Animal Food Bookstore](#)  
[FSPCA Community](#)  
[FSPCA FSVP Bookstore](#)  
[FSPCA Human Food Bookstore](#)  
[FSPCA Lead Instructor Listing](#)  
[FSPCA Materials](#)  
[FSPCA Metrics](#)  
[FSPCA Trainers of Trainers for Animal Food](#)  
[FSPCA Trainers of Trainers for Foreign Supplier Verification Programs \(FSVP\)](#)  
[FSPCA Trainers of Trainers for Human Food](#)  
[Register for a Course \(for Lead Instructors only\)](#)

## Stay Connected

[FSPCA Webinars](#)  
[FSPCA Presentations and Conferences](#)  
[Sign up for FSPCA Updates](#)  
[Contact Us](#)

## Sister Alliances

[Produce Safety Alliance](#)  
[Sprout Safety Alliance](#)



# Who is FSPCA?

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- Food Safety Preventive Controls Alliance (FSPCA)
  - FSPCA Community, an interactive portal where users can ask questions of Alliance Food Safety Experts (FSEs), find a list of Lead Instructor (LI) trainers, and locate technical resources:  
[https://fspca.force.com/FSPCA/s/?language=en\\_US](https://fspca.force.com/FSPCA/s/?language=en_US)





# FSPCA Community, an interactive portal

The header features the FSPCA logo on the left, a search bar with the text "Search for articles and discussions" and a "Search" button, and a "LOGIN" button on the right. Below the search bar is a navigation menu with the following items: HOME, TOPICS (with a dropdown arrow), COURSE LISTINGS, LEAD INSTRUCTORS, SPROUTS, PRODUCE, LEAD INSTRUCTOR INFO, and MORE (with a dropdown arrow). The background of the header is a photograph of a grocery store aisle with shelves of products.

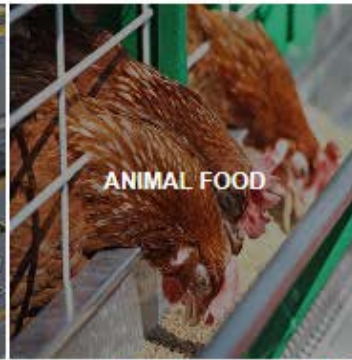
## WELCOME TO THE FSPCA TECHNICAL ASSISTANCE NETWORK

The Food Safety Preventive Controls Alliance is a place where you can find solutions and easily ask questions related to FSMA Implementation. The community is interactive and is here to provide guidance and technical assistance on FSMA related issues. Regulatory guidance is provided by FDA .

### PREVENTIVE CONTROLS QUESTION

#### FEATURED

#### DISCUSSIONS



#### TRENDING ARTICLES

- How will the existing GFSI certifications of companies be affected by preventive controls?
- How can I become a Food Safety Preventive Controls Alliance Lead Instructor?
- FSMA requirements and their relationship to Preventive Controls Qualified Individual (PCQI) Training Courses





# WHAT does the FSPCA do?

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Alliance outreach goals and objectives aim to:

- increase industry awareness about the education, outreach, and technical assistance programs;
- identify and develop relevant technical information and educational resources useful especially for the small food companies;
- establish a network of FSPCA FSEs that would be available to assist the industry with technical and scientific questions that they may have subsequent to the training; and
- ensure opportunities and educational materials are available to international audiences in a manner that is appropriate and sensitive to various cultures, religions, political situations, languages, and development levels.



# WHY seek this training?

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## **PCHF & PCAF -**

Require that certain activities must be completed by a “preventive controls qualified individual (PCQI).” The participant course, developed by FSPCA, is the “standardized curriculum” recognized by FDA; successfully completing this course is one way to meet the requirements for a “PCQI.” Individuals can also be qualified through job experience.

## **FSVP -**

In contrast to the PC rules for human or animal food, the FSVP rule does not require an FSVP “qualified individual” to attend a training program following a “standardized curriculum” recognized by FDA. Completing the FSVP participant course is not mandatory. Attending the FSVP course, however, will help course participants understand the FSVP requirements and how those requirements can be met in their circumstance.



# FSPCA Metrics

FSPCA Certificates Issued			
	Human Food	Animal Food	FSVP
Domestic			1,884
	15,233	240	
Total			

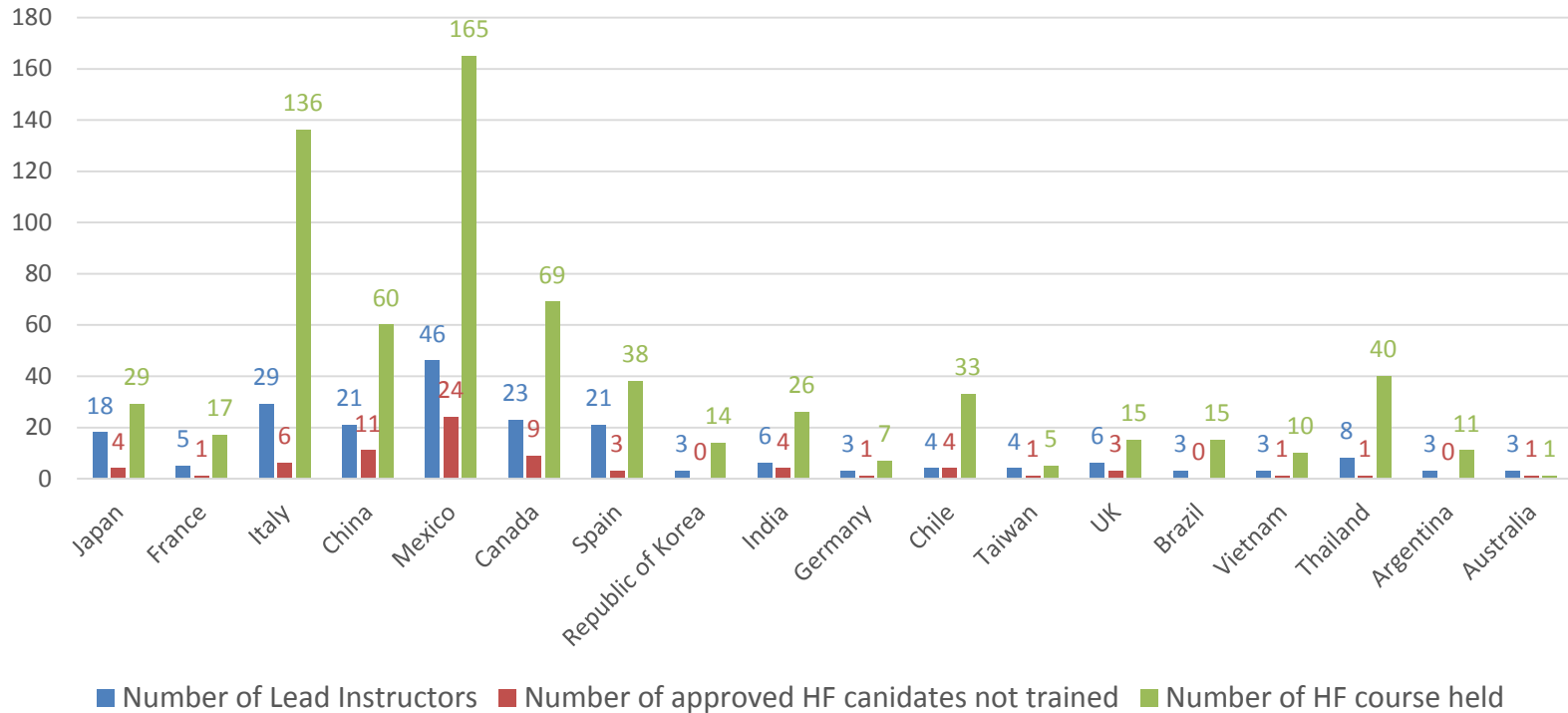
FSPCA Courses Registered			
	Human Food	Animal Food	FSVP
	3,872	311	230

*As of September 25, 2017*



# FSPCA Human Food International Information

FSPCA Human Food International Information  
As of 8-7-2017





# *WHERE, WHEN, & HOW* can the public access FSPCA training and resources?

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- How to find an FSPCA Participant Course:
  - [https://fspca.force.com/FSPCA/s/courselist?language=en\\_US](https://fspca.force.com/FSPCA/s/courselist?language=en_US)

# FSPCA Participant Courses:

COURSE TYPE: --Select--

- Human Food
- Animal Food
- Sprouts
- FSVP
- Human Food Part 2

 LEAD INSTRUCTOR: 
 Q START DATE: 
 COUNTRY: --Select--

COURSE TYPE	LEAD INSTRUCTOR	COURSE START	WEB ADDRESS TO REGISTER	COST	CONTACT EMAIL	ADDRESS	LANGUAGE	FORMAT
Human Food	Melissa Vaccaro	Sep 26, 2017	<a href="#">Register</a> USD 795	795	<a href="#">Contact</a>	Orlando Florida United States		
Human Food	Melissa Vaccaro	Nov 1, 2017	<a href="#">Register</a> USD 795	795	<a href="#">Contact</a>	King of Prussia Pa United States		
Human Food	Melissa Vaccaro	Nov 14, 2017	<a href="#">Register</a> USD 795	795	<a href="#">Contact</a>	Hershey PA United States		
Human Food	Franklin Guarisma	Oct 10, 2017	<a href="#">Register</a> MXN 10800	10,800	<a href="#">Contact</a>	Guadalajara Jalisco Mexico		
Human Food	Barbara Roman Rivera	Oct 16, 2017	<a href="#">Register</a> USD 850	850	<a href="#">Contact</a>	Research Triangle Park North Carolina United States		
Human Food	Mike Nolan	Nov 1, 2017	<a href="#">Register</a> USD 850	850	<a href="#">Contact</a>	Virtual Virtual Virtual		
Human Food	David Strait	Oct 16, 2017	<a href="#">Register</a> USD 850	850	<a href="#">Contact</a>	Rutherford New Jersey United States		



# FSPCA Metrics - Lead Instructors

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<b>Human Food LIs</b>	<b>1,333 (368 international)</b>
<b>Animal Food LIs</b>	<b>202 (15 international)</b>
<b>FSVP LIs</b>	<b>211 (31 international)</b>

*As of September 25, 2017*



# *WHERE, WHEN, & HOW* can the public access FSPCA training and resources?

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- How to become an FSPCA Lead Instructor:
  - [https://fspca.force.com/FSPCA/s/li-public-guidance?language=en\\_US](https://fspca.force.com/FSPCA/s/li-public-guidance?language=en_US)



# FSMA Technical Assistance Network

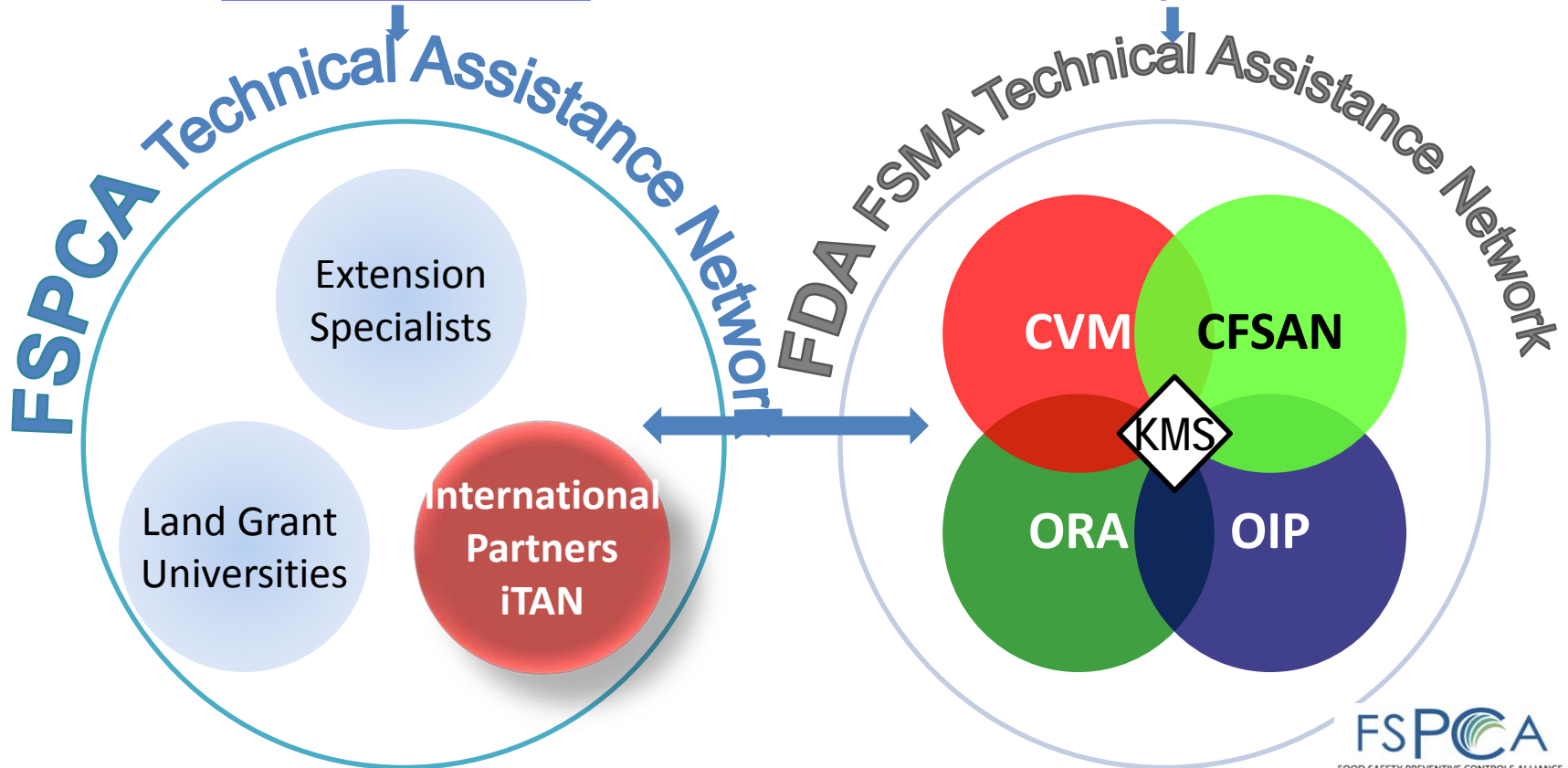
<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>

Preventive Controls **Scientific & Technical**  
Questions from Industry – a web form at:

[www.iit.edu/ifsh/alliance](http://www.iit.edu/ifsh/alliance)

FSMA **Regulation & Policy Interpretation**  
Questions – a web form at:

[www.fda.gov/fsma](http://www.fda.gov/fsma)





# FSPCA Community, an interactive portal



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### PREVENTIVE CONTROLS QUESTION

#### FEATURED

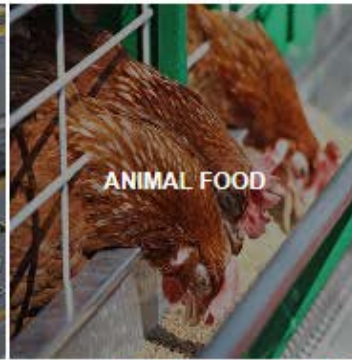
#### DISCUSSIONS



HUMAN FOOD



FOREIGN SUPPLIER VERIFICATION PROGRAM



ANIMAL FOOD

#### TRENDING ARTICLES

How will the existing GFSI certifications of companies be affected by preventive controls?

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FSMA requirements and their relationship to Preventive Controls Qualified Individual (PCQI) Training Courses

# FSPCA Technical Assistance Network



Submit Question to Sprouts

Submit Question to Produce

## SUBMIT YOUR QUESTION TO THE FSPCA

TYPE

--None--

CASE REASON\*

--None--

SUBJECT\*

DESCRIPTION\*

## NEED ANSWERS FAST?

Check out these articles...

How will the existing GFSI certifications o...  
Apr 15, 2016

How can I become a Food Safety Preven...  
Apr 15, 2016

FSMA requirements and their relationshi...  
Jun 21, 2016

FSPCA and Other Training FAQ  
Apr 19, 2016

Preventive Controls Qualified Individual  
May 5, 2016

# International Outreach Plan Implementation Update

Julia Bradsher, IFPTI

# Plan Elements

- Collateral Materials, Branding
- Presence at Meetings, Trade Shows, Speaking Engagements
- Work with FDA Office of International Programs
- E-mail “opt-in” through FDA outreach to registered food facilities

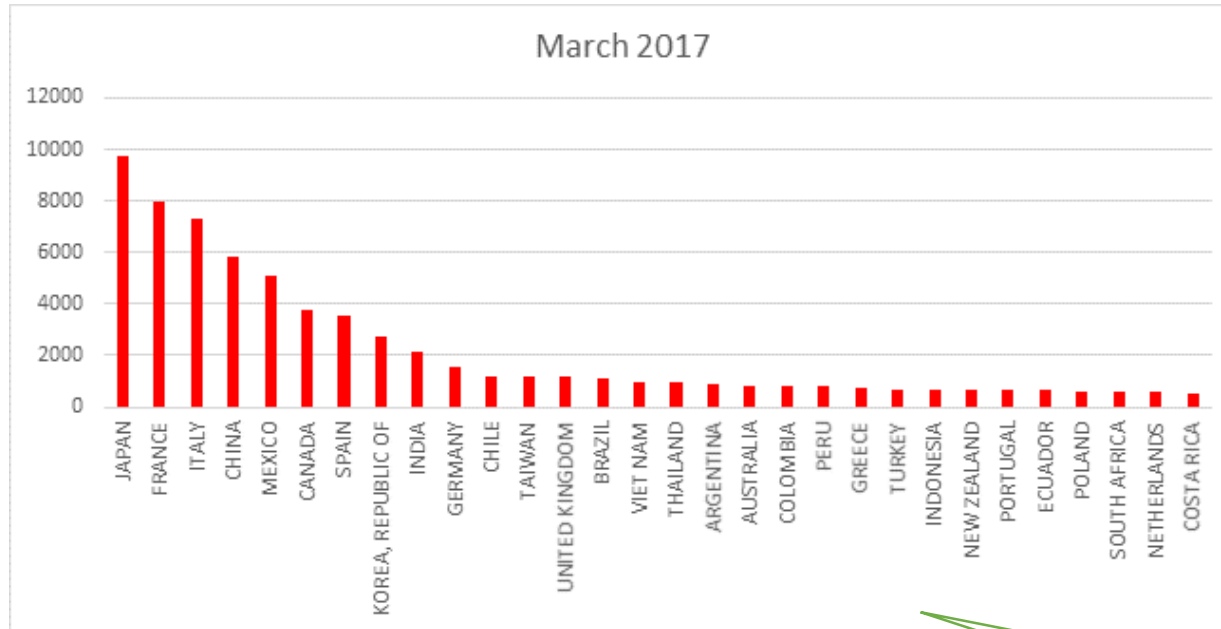
# Current Activities

- Collateral Materials
  - Compliance date handout
    - Currently in English and Spanish then Chinese and other languages as needed
  - FSPCA one-pager
  - Also utilizing FDA materials on FSMA that is already in multiple languages
  - Materials already used at international conferences in Mexico and Thailand.
- Trade Shows and Conferences
  - Booths at in US Food Safety Summit, IAFFP, IFT and Fancy Food Show
  - China Food Safety Conference in November, 2017
  - Germany in November, 2017, GFSI Tokyo in March, 2018
  - SIAL Paris in October 2018

# Current Activities, cont.

- Work with FDA
  - Meet with FDA's International Affairs Staff and Office of International Programs to coordinate the promotion of FSPCA awareness among FDA and USDA/FAS overseas staff.
    - FSMA and FSPCA awareness webinar (this call)
      - Follow up will include an FSPCA “packet” for them to utilize
    - Targeting based on numbers of registered food facilities
- Build Database of Registered Food Facilities through “opt-in” email plan
  - Working with FDA CFSAN Office of Compliance to send out communications to all registered food facilities; they will then opt-in to receive information from FSPCA

# Registered Food Facilities



Top 10 Countries:

- Japan
- France
- Italy
- China
- Mexico
- Canada
- Spain
- South Korea
- India
- Germany

Includes  
seafood,  
juice &  
LACF