WELCOME!

FSPCA Annual Conference
Tampa, FL
July 13-14, 2017
WELCOME AND OPENING REMARKS

Donna Garren
FSPCA Co-chair Executive Committee
STATE OF FSMA IMPLEMENTATION

Sharon Lindan Mayl
Senior Advisor for Policy, OFVM

Glen Bass
Human and Animal Food Program, Deputy, ORA

Wanda Honeyblue
Special Advisor, CFSAN
FSMA Implementation: “A Continuum”

- **Phase 1: Set Standards**
  - Develop regulations, guidance, policy

- **Phase 2: Design Strategies to Promote and Oversee Industry Compliance**
## Phase 1: Standard Setting

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Proposal</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive Controls (Human Food)*</td>
<td>Jan 16, 2013</td>
<td>Sept 17, 2015⁰</td>
</tr>
<tr>
<td>Preventive Controls (Animal Food)*</td>
<td>Oct 29, 2013</td>
<td>Sept 17, 2015⁰</td>
</tr>
<tr>
<td>Produce Safety*</td>
<td>Jan 16, 2013</td>
<td>Nov 27, 2015⁰</td>
</tr>
<tr>
<td>Foreign Supplier Verification Program*</td>
<td>Jul 29, 2013</td>
<td>Nov 27, 2015⁰</td>
</tr>
<tr>
<td>Third Party Accreditation</td>
<td>Jul 29, 2013</td>
<td>Nov 27, 2015⁰</td>
</tr>
<tr>
<td>Sanitary Transport</td>
<td>Feb 5, 2014</td>
<td>April 6, 2016⁰</td>
</tr>
<tr>
<td>Intentional Adulteration</td>
<td>Dec 24, 2013</td>
<td>May 31, 2016⁰</td>
</tr>
</tbody>
</table>
Phase 2:

• Established internal Phase 2 structure to operationalize each new rule:
  - Rules/Programs Workgroups (e.g., Preventive Controls, Produce, Import Controls)
  - Cross Cutting Workgroups (e.g., IT, Metrics, Training)
• Charge: Develop a framework and multi-year implementation plan for ensuring compliance with regulations:
  - Education, outreach, and technical assistance for industry
  - Training/technical assistance for regulators
  - Inspections, compliance and enforcement
  - Data collection, analysis, updated IT
  - Performance goals and metrics
Phase 2: Key Implementation Principles

• Goal of FSMA is to move food safety system from a reactive to a preventive mode.
• FSMA’s success depends on bringing about high rates of compliance.
• FDA is committed to educating before and while we regulate.
• FDA will engage and communicate to international community that is consistent with domestic efforts.
Education, Outreach, and Technical Assistance for Industry

- Facilitate industry compliance with prevention oriented standards through guidance, developing tools/resources for education, outreach and technical assistance
  - Website
  - Guidance Documents
  - Alliances
  - Technical Assistance Networks
Guidance Documents

• Preventive Controls Human Food:
  ▪ Hazard Analysis and Preventive Controls: Draft Published 8/16
  ▪ Listeria in RTE Food: Draft Published 1/17
  ▪ Classification of Activities for Farms and Facilities: Draft published 8/16
  ▪ Small Entity Compliance Guide: Published 10/16
  ▪ Planned Guidances include: Supplier Controls, Validation of Process controls, Food Allergens
Guidance Documents (cont.)

• Preventive Controls Animal Food:
  - CGMP: Draft published 8/16
  - Human Food By-Products for Use as Animal: Draft published 8/16
  - Small Entity Compliance Guide: Published 10/16
  - Planned guidances include: Hazard Analysis and Preventive Controls, Supplier Controls
Guidance Documents (cont.)

• Produce:
  ▪ Sprouts: Draft published 1/17
  ▪ Planned guidances include: Updated GAPs, Compliance Guide, Small Entity Compliance Guide
  ▪ FSVP, Intentional Adulteration, Sanitary Transport
  ▪ FSVP: Guidances regarding DUNS/entry data
  ▪ Planned guidances include: Compliance Guides, Small Entity Compliance Guides
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
- **International Subcommittee**
• Established an FDA FSMA Technical Assistance Network (TAN) to provide central, consistent, sources of outreach and technical assistance
  ▪ Part 1: FSMA Rule Interpretation Questions for External Stakeholders
  ▪ Part 2: Food Safety Regulatory Community Questions Before, During, and After Inspections
Technical Assistance Network

• Launched FDA’s FSMA TAN on September 10, 2015
  ▪ Provide technical assistance to industry, academia, and consumers regarding FSMA
  ▪ Address questions related to FSMA rules, programs, and implementation
  ▪ Submit inquiries via the web form or by mail
  ▪ To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us
Contact FDA About FSMA

The FDA Food Safety Modernization Act (FSMA) Technical Assistance Network (TAN) is now operational and providing technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation.

The TAN will address questions related to the FSMA rules, FSMA programs, and implementation strategies after the rules are final.

Note: For Food Safety Preventive Controls Alliance (FSPCA) training and scientific/technical questions, please contact the FSPCA Technical Assistance Network using their web form at http://www.iit.edu/fsa/ alliance.

Submit Inquiry

Mail an Inquiry
Inquiries may also be submitted by mail if the Internet is not available at the following address:
Food and Drug Administration
5100 Paint Branch Pkwy
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740
Regulator Training

• FDA Food Safety Staff are expected to participate in:
  ▪ FSMA Rule Readiness Webinar Series and FSMA Chats
  ▪ Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls Course with industry and state counterparts
  ▪ PC Regulator Training Curriculum for Human and Animal Food
    o Modernized GMP webinar (all)
    o On-the-Job Experience (OJE) for cadre
  ▪ Focus on “Systems Thinking”
Inspections/Compliance

• **Not** a “One Size Fits All Approach”
• Gain Industry Compliance, Reduce the Risk of Foodborne Illness
• **Systems-Based Inspections**, Not “Observation Focused”
• How industry is working to comply with the new food-safety **standards and protect** consumers from unsafe food.
## FDA Inspections

<table>
<thead>
<tr>
<th></th>
<th>Planned</th>
<th>Accomplished</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Food modernized GMP</td>
<td>450</td>
<td>307</td>
</tr>
<tr>
<td>Full PC</td>
<td>240 (domestic)</td>
<td>45* (OJE)</td>
</tr>
<tr>
<td></td>
<td>60 (foreign)</td>
<td>5</td>
</tr>
<tr>
<td>6-OAI:</td>
<td></td>
<td>6/19/17-9/30/17</td>
</tr>
<tr>
<td>Animal Food cGMP</td>
<td>250</td>
<td>47</td>
</tr>
<tr>
<td>FSVP</td>
<td>325</td>
<td>6/19/17-9/30/17</td>
</tr>
<tr>
<td>Sprout Facilities</td>
<td>30</td>
<td>5/19/17-9/30/17</td>
</tr>
</tbody>
</table>

*Conducted by cadre; includes On-the-Job Experience*
What’s Next?

• **FDA will continue** to:
  - Focus on **education, training, and technical assistance** to help companies comply with the new requirements.
  - **Collaborate** with regulated industry to ensure everyone understands and engages their respective roles in food safety.
  - Focus our inspections on **assessing the progress** a company has made towards compliance and whether it is taking appropriate steps necessary to **protect public health**.
  - **Work** with the food industry to **create a culture** of food safety, with procedures, processes, and practices that we know will achieve **high rates of compliance** with the rule and minimize the risk of foodborne illness.
In Summary

• Purpose of new law to create a system that is self-sustaining and encourages the prevention of food safety problems throughout the supply chain.
• New requirements fulfill the paradigm shift toward prevention intended to protect consumers.
• Working together, learning together.
Systems Thinking:
A Brief Overview
The FSMA Context

- Technical Knowledge & Skills
- Inspectional Knowledge & Skills
- Behavior & Systems Thinking

Systems Thinking
Habits of Systems Thinking
The Guiding Principles
# Key Habits for a Systems Thinking Mindset

| **Looking at the Big Picture** | stepping back to examine the dynamics of a system and the interrelationships among its parts.  
- Systems Thinker balances their focus between the forest and the details of any tree.  
- Question: “When we look at the firm, what does the big picture (the larger context) look like and how do the parts (other systems) fit together?” |
|-----------------------------|-------------------------------------------------|
| **Recognizing Interdependencies** | recognizing the cause and effect relationships from the parts of the system.  
- Systems Thinker sees the interdependencies in a system and uncovers the connections.  
- Question: “How do the parts affect one another, and depend on one another?” |
| **Making Connections** | connect new information to what has already been observed by adding, modifying, transferring, and synthesizing the information  
- Systems Thinker sees how concepts, facts, and ideas link together, which can lead to new learning, discoveries and innovations.  
- Question: “How does this new information change/affect my understanding? Should I re-think my next steps?” |
| **Considering Assumptions and Internal Representations** | thinking through how past experiences influence the development of personal theories, views, filters, biases and mental models (pictures in the mind)  
- A systems thinker is aware of how their beliefs and attitudes, and personal mental pictures influence perspectives and actions  
- Question: “What are my biases, assumptions, expectations, past experiences and mental pictures about the firm, and how can I get think differently?” |
| **Assessing from Many Perspectives** | considering the system from a variety of different angles and from differing points of view, in collaboration with others  
- A systems thinker increases understanding by changing the ways he or she looks at the system.  
- Question: “Am/are I/we open to other points of view?” |
| **Seeing Issues Fully** | be patient and resist the urge to come to a quick conclusion  
- A Systems Thinker takes time to understand the system’s structure and its behaviors before making judgement while a deeper understanding of the system is developed  
- Question: “What questions could I ask to deepen my understanding of the issues before I take action?” |
Guiding Principles of a Systems-Based Food Safety Regulatory Program

- Build trust and accountability
- Promote open communication to enhance mutual understanding of food safety systems
- Utilize all tools to achieve compliance with relevant regulations
- Accomplish a common goal—produce safe food products and protect public health
Soft Skills

• Along with systems thinking, the course will integrate behaviors and skills needed to effectively:
  ▪ build rapport
  ▪ get information from others
  ▪ develop good working relationships
  ▪ diffuse difficult situations

• These soft skills are very important to your success as an investigator to conduct an effective inspection.
Summary of Systems Thinking Approach

• Effective use of soft skills can make all of the difference.

• The PC rule, in particular, is amenable to systems thinking because it is SO FLEXIBLE. Systems thinking habits accentuate your adoption of a more FLEXIBLE approach.
STATE OF FSPCA IMPLEMENTATION

Gerald Wojtala
Executive Director, IFPTI and Implementation Subcommittee Chair

Kathy Gombas
FSPCA International Subcommittee Co-Chair
FSPCA Implementation Timeline

- **Phase I – Organize FSPCA**
- **Phase II – Develop Curriculum**
- **Phase III – Pilot Phase**
- **Phase IV – Implementation**

- **2011**
- **2012**
- **2013**
- **2014**
- **2015**
- **2016**
- **2017**
Course Implementation Timeline

- Human Food
- Animal Food
- Foreign Supplier
- Blended Courses
- Intentional Adulteration
- Lead Instructor Courses

2016 2017 2018
## FSPCA Metrics

<table>
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<tr>
<th>FSPCA Preventive Controls Certificates Issued</th>
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<tbody>
<tr>
<td><strong>Human Food</strong></td>
<td><strong>Animal Food</strong></td>
<td><strong>FSVP</strong></td>
<td></td>
</tr>
<tr>
<td>Domestic</td>
<td>30,599</td>
<td>3,616</td>
<td>1,395</td>
</tr>
<tr>
<td>International</td>
<td>11,587</td>
<td>241</td>
<td>81</td>
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<tr>
<td><strong>Total</strong></td>
<td>42,186</td>
<td>3,857</td>
<td>1,476</td>
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<table>
<thead>
<tr>
<th>FSPCA Preventive Controls Courses Registered</th>
<th></th>
<th></th>
<th></th>
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<tbody>
<tr>
<td><strong>Human Food</strong></td>
<td><strong>Animal Food</strong></td>
<td><strong>FSVP</strong></td>
<td></td>
</tr>
<tr>
<td>3,364</td>
<td>270</td>
<td>155</td>
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*Note: All numbers represent counts of certificates or courses registered.*
Linear Regression
of Human Food Certificates Issued

\[ y = 119.75 \ln(x) + 172.84 \]
\[ R^2 = 0.2278 \]

\[ y = 3.3405x + 448.01 \]
\[ R^2 = 0.0729 \]

Weeks
## Human Food Blended Course

<table>
<thead>
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<th>HUMAN FOOD BLENDED</th>
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<tbody>
<tr>
<td>Total Enrollments</td>
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<tr>
<td>Completed Part 1</td>
</tr>
<tr>
<td>Completed Part 2</td>
</tr>
<tr>
<td>Part 2 Courses Registered</td>
</tr>
<tr>
<td>Part 2 Courses Completed</td>
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</table>
# Lead Instructors

<p>| | | |</p>
<table>
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<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Human Food LIs</strong></td>
<td>1,237 (287 international)</td>
<td></td>
</tr>
<tr>
<td><strong>Human Food Candidates</strong></td>
<td>731</td>
<td></td>
</tr>
<tr>
<td><strong>Human Food LI Courses Completed</strong></td>
<td>48</td>
<td></td>
</tr>
<tr>
<td><strong>Animal Food LIs</strong></td>
<td>202 (15 international)</td>
<td></td>
</tr>
<tr>
<td><strong>Animal Food Candidates</strong></td>
<td>370</td>
<td></td>
</tr>
<tr>
<td><strong>Animal Food LI Courses Completed</strong></td>
<td>5</td>
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</tr>
<tr>
<td><strong>FSVP LIs</strong></td>
<td>176 (28 international)</td>
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<tr>
<td><strong>FSVP Candidates</strong></td>
<td>200</td>
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<tr>
<td><strong>FSVP LI Courses Completed</strong></td>
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*As of April 19, 2017*
# 2017 FSPCA Lead Instructor Training

## HUMAN FOOD

<table>
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<tr>
<th>Location</th>
<th>Dates</th>
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<tbody>
<tr>
<td>Arlington, VA</td>
<td>Mar 28-30</td>
</tr>
<tr>
<td>Long Beach, CA</td>
<td>Apr 19-21</td>
</tr>
<tr>
<td>Kingston, RI</td>
<td>Jun 7-9</td>
</tr>
<tr>
<td>ST. Paul, MN</td>
<td>Jul 25-27</td>
</tr>
<tr>
<td>Denver, CO</td>
<td>Sep 19-21</td>
</tr>
<tr>
<td>Dallas, TX</td>
<td>Dec 5-7</td>
</tr>
</tbody>
</table>

## ANIMAL FOOD

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacramento, CA</td>
<td>Mar 22-24</td>
</tr>
<tr>
<td>Beijing, China</td>
<td>Apr 10-14</td>
</tr>
<tr>
<td>Kansas City, MO</td>
<td>June 13-15</td>
</tr>
<tr>
<td>Arlington, VA</td>
<td>Nov 7-9</td>
</tr>
<tr>
<td><strong>As needed – potentially in Midwest towards the end of the year</strong></td>
<td></td>
</tr>
</tbody>
</table>
# 2017 FSPCA Lead Instructor Training

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
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<tbody>
<tr>
<td>Houston, TX</td>
<td>Feb 26-27</td>
</tr>
<tr>
<td>Dallas, TX</td>
<td>Apr 11-13</td>
</tr>
<tr>
<td>Anaheim, CA</td>
<td>May 23-25</td>
</tr>
<tr>
<td>West Palm Beach, FL</td>
<td>May 30-Jun 1</td>
</tr>
<tr>
<td>Bedford Park, IL</td>
<td>Jun 6-8</td>
</tr>
<tr>
<td><strong>Deerfield Beach, FL</strong></td>
<td><strong>Jul 25-27</strong></td>
</tr>
<tr>
<td>NJ/NY</td>
<td>TBD</td>
</tr>
<tr>
<td>CA</td>
<td>TBD</td>
</tr>
<tr>
<td>FL</td>
<td>TBD</td>
</tr>
<tr>
<td>IL</td>
<td>TBD</td>
</tr>
</tbody>
</table>
Lead Instructor Course Survey

• Scheduling a set number of Lead Instructor courses
• Surveyed ~200 approved Lead Instructor candidates:
  – where/when will you attend a course

https://www.surveymonkey.com/r/9FH7Q9V
Current FSPCA Development Projects

1. Animal Food version 1.2
2. Animal Food Blended course

Moving to 2.5 day LI courses
Current FSPCA Development Projects

3. FSVP version 1.1
4. FSVP modules for insertion into PC and PS courses
Current FSPCA Development Projects

5. Human Food Spanish Version 2
6. Human Food Blended Spanish
Current FSPCA Development Projects

7. Intentional Adulteration online and Instructor-Led

8. Sprout online course
Quality Improvement

- Focus will be on developing mechanisms to improve Lead Instructor effectiveness:
  - Participant surveys about instructors
  - LI webinars
  - LI newsletter
  - Instructor Portal resources
  - Audits
  - Remediation
Monitoring and Evaluation Work Group

- Addressing advertising issues
- Course modification review & criteria
- Equivalency requests
- Lead Instructor Audit/Evaluation Process
IMPLEMENTATION SUBCOMMITTEE
ToT WORKGROUP

Kathy Gombas
FSPCA Trainer-of-Trainers Work Group, Co-Chair
FSPCA Trainer-of-Trainers Work Group
PCHF and FSVP

• Co-chairs: Hilary Thesmar; Claudia Coles; Kathy Gombas

• Members: Lauri Yarger; Suzanne Kidder; Dawn Johnson; Michelle Haynes
FSPCA Trainer-of-Trainers
Work Group Charges

• Develop policies and procedures
• Determine and coordinate Lead Instructor courses worldwide
• Coordinate Trainers of Trainers and Lead Instructor communications, e.g. Newsletters, Webinars.
FSPCA Policies/Procedures

Existing Policies

• Process for Selecting Trainers of Trainers for Human Food
• Roles and Responsibilities of Trainer of Trainers and Trainer of Trainer Candidates
• Trainer of Trainers Candidate Training Evaluation Form

New Policies

• LI candidate application approval process
• LI candidate approval and remediation process
• FSPCA LI course scheduling and delivery process
FSPCA Training Delivery Model

- **Trainers**
  - Train **Lead Instructors**
  - Lead Instructors train **Participants**

- **Participants**
  - Domestic & International Stakeholders
# FSPCA Trainer of Trainers
## PC Human Food

<table>
<thead>
<tr>
<th>U.S. (32)</th>
<th>International</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gary Acuff</td>
<td>Adriana Camacho (Mexico)</td>
</tr>
<tr>
<td>David Gombas</td>
<td>Miguel Angel De los Santos (Mexico)</td>
</tr>
<tr>
<td>Jenny Scott</td>
<td>Marco Antonio León Félix (Mexico)</td>
</tr>
<tr>
<td>Matthew Botos</td>
<td>Claudio Gallottini (Italy)</td>
</tr>
<tr>
<td>Kathy Gombas</td>
<td>Tania Martinez (Spain)</td>
</tr>
<tr>
<td>Juan Silva</td>
<td>Virachnee Lohachoompol (Thailand)</td>
</tr>
<tr>
<td>Robert Brackett</td>
<td>Ai Kataoka (Japan)</td>
</tr>
<tr>
<td>Linda Harris</td>
<td>Qi Neng Lu (China)</td>
</tr>
<tr>
<td>Manpreet Singh</td>
<td></td>
</tr>
<tr>
<td>Claudia Coles</td>
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<tr>
<td>Tim Jackson</td>
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<tr>
<td>Katherine Simon</td>
<td></td>
</tr>
<tr>
<td>Faith Critzer</td>
<td></td>
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<tr>
<td>Lynette Johnston</td>
<td></td>
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<tr>
<td>Kelly Stevens</td>
<td></td>
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<tr>
<td>Michelle Danyluk</td>
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<td>Jenifer Kane</td>
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<tr>
<td>Warren Stone</td>
<td></td>
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<tr>
<td>Debra DeVlieger</td>
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<tr>
<td>Kim Koch</td>
<td></td>
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<tr>
<td>Katherine Swanson</td>
<td></td>
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<td>James Dickson</td>
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<tr>
<td>Loralyn Ledenbach</td>
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<tr>
<td>Purnendu Vasavada</td>
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<tr>
<td>Nancy Doyle</td>
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<td>Eduardo Rodrique</td>
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<tr>
<td>Jason Wan</td>
<td></td>
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<tr>
<td>Girish Ganjyal</td>
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<tr>
<td>Marcos Sanchez</td>
<td></td>
</tr>
<tr>
<td>Edith Wilkin</td>
<td></td>
</tr>
<tr>
<td>Donna Garren</td>
<td></td>
</tr>
<tr>
<td>Donna Schaffner</td>
<td></td>
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</table>

1 ToT Candidate pending approval  
3 ToT Candidates awaiting instruction
<table>
<thead>
<tr>
<th>Name</th>
<th>First Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adam</td>
<td>Fahrenholz</td>
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<tr>
<td>Cassie</td>
<td>Jones</td>
</tr>
<tr>
<td>Kim</td>
<td>Koch</td>
</tr>
<tr>
<td>Brandi</td>
<td>Miller</td>
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<tr>
<td>Charles</td>
<td>Stark</td>
</tr>
<tr>
<td>Sonya</td>
<td>Lambkin</td>
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<tr>
<td>Dianne</td>
<td>Milazzo</td>
</tr>
<tr>
<td>Jenny</td>
<td>Murphy</td>
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<tr>
<td>David</td>
<td>Fairfield</td>
</tr>
<tr>
<td>Matt</td>
<td>Frederking</td>
</tr>
<tr>
<td>David</td>
<td>Meeker</td>
</tr>
<tr>
<td>Pat</td>
<td>Tovey</td>
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## FSPCA Trainer of Trainers
### FSVP (25)

<table>
<thead>
<tr>
<th>Name</th>
<th>Last Name</th>
<th>First Name</th>
<th>Last Name</th>
<th>First Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gary</td>
<td>Acuff</td>
<td>Marco Antonio</td>
<td>Leon Felix</td>
<td></td>
</tr>
<tr>
<td>Bob</td>
<td>Bauer</td>
<td>Erik</td>
<td>Lieberman</td>
<td></td>
</tr>
<tr>
<td>Cathy</td>
<td>Carnevale</td>
<td>Sharon</td>
<td>Mayl</td>
<td></td>
</tr>
<tr>
<td>Claudia</td>
<td>Coles</td>
<td>Brian</td>
<td>Ravitch</td>
<td></td>
</tr>
<tr>
<td>Miguel Angel de los Santos</td>
<td>Marcos</td>
<td>Sanchez-Plata</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Girish</td>
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<td>Juan L.</td>
<td>Silva</td>
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<td>David</td>
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<td>Manpreet</td>
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<td>Jenifer</td>
<td>Kane</td>
<td>Jason</td>
<td>Wan</td>
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</tr>
<tr>
<td>Bob</td>
<td>Lake</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
2017 Communications: ToT and Lead Instructor Webinar

• **Monthly Trainer of Trainers Webinars**
• **Quarterly Lead Instructor Webinars**
  - Opportunity for Lead Instructors to hear about course material updates, tips to register and advertise courses, new resource materials, frequently asked questions, international efforts
  - PCHF: February 9, May 18, August 24, November 16
  - PCAF: TBD
  - FSVP: TBD
  - Recordings and slide presentations are posted on the FSPCA Community site
• **Newsletters**
Lead Instructor Private Chatter Group

• Forum for Lead Instructors to interact, get updates and exchange information.

• Once a Lead Instructor certificate number is confirmed, they will receive notification of acceptance into the private group.

• **How to join:**
  1. Log into the FSPCA Community at [https://fspca.force.com/FSPCA/s/](https://fspca.force.com/FSPCA/s/)
  2. Enter your email and password for the FSPCA Community
  3. Click on "More" in the horizontal bar and choose "Groups" from the drop-down menu
  4. Choose the Lead Instructor Group(s) you wish to join from the list displayed. *We have both Human Food and Animal Food Lead Instructor Groups.*
  5. Click on the "Request Membership" button
Lead Instructors – Heads Up

- Update Profiles (add country where you primarily work)
- Encourage Lead Instructors to offer courses
- Instructor Portal Updates
  - Current version of the Instructor Manual
  - FDA Guidance Documents
  - New Human Food Teaching Examples for
    - Leafy greens salads
    - Fresh Blueberries
    - Mature Green Round Tomatoes
INTERNATIONAL SUBCOMMITTEE

Kathy Gombas
FSPCA International Subcommittee Co-Chair
FSPCA International Subcommittee Structure

Core Outreach Team
Co-Chairs: Kathy Gombas & Kelly McCormick

Training Content Work Group
POC: Jason Wan

- Spanish Review Team
- French Review Team
- Japanese Review Team
- Mandarin Review Team
- Portuguese Review Team
- Hindi Review Team

Trainer Network Work Group
POCs: Kim Koch, Juan Silva & Mike McWhorter

Technical Assistance Work Group
POC: Marcos Sanchez
Translation Update – Human Food

- Translating Version 1.2 manuals & teaching examples
- Translations under development
  - **Spanish**
    - Piloted in Guadalajara & Lima Lead Instructor courses (S1)
    - Version S1 is available on the Lead Instructor Resource Portal
    - Version S2 coming August 2017
  - **Japanese**
    - Piloted in February during Lead Instructor course
  - **Chinese**
    - Piloted in March during Lead Instructor course
- Post Translations in the Instructor Portal when available
International Trainer Network

Identify resources to provide FSPCA training:

- Increase number of PCQI courses offered worldwide
- Build capacity of international Lead Instructors
- Use data to guide Lead Instructor course planning
FSPCA Human Food Lead Instructor International Courses
2017 -2018 Planning

# of HF Lead Instructors
Approved Lead Instructor HF Candidates (Awaiting Training)
PCQI HF Courses Being Held in Country
## 2017 International Human Food Lead Instructor Courses

<table>
<thead>
<tr>
<th>Country</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campden, England</td>
<td>Jan 23-26</td>
</tr>
<tr>
<td>Shibuya-ku, Japan</td>
<td>Feb 6-10</td>
</tr>
<tr>
<td>Kuala Lumpur, Malaysia</td>
<td>Feb 22-24</td>
</tr>
<tr>
<td>Milan, Italy</td>
<td>Mar 21-23</td>
</tr>
<tr>
<td>Queretaro, Mexico*</td>
<td>Mar 22-24</td>
</tr>
<tr>
<td>Beijing, China</td>
<td>Mar 29-31</td>
</tr>
<tr>
<td>Madrid, Spain*</td>
<td>Apr 26-28</td>
</tr>
</tbody>
</table>

Others being reviewed by ISC Trainer Network Work Group
- Beijing, China (target Nov 2017)
- Paris, France (target Nov 2017)
- Tokyo, Japan (target Mar, 2018)
  - Korea (2018)
  - Munich, Germany (2018)

*courses instructed in Spanish
Food Safety and Agricultural Sustainability Training (FAST)
FAST GOALS

• Phase 1
  • Strengthen the knowledge of FSMA with a diagnostic tool for evaluating the levels of preparedness.
  • Identify intermediary candidates to train as local lead instructors.
  • Concluded on Aug 2015

• Phase 2
  • Building technical assistance activities tailored to country specific needs with FSPCA Train-the-Trainer.
  • Begin PCQI/LI courses for local Lead Instructors.
## 2017 FAST Human Food
### FSPCA Lead Instructor Courses

<table>
<thead>
<tr>
<th>Country</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>El Salvador</td>
<td>Jan 10-13</td>
</tr>
<tr>
<td>Guatemala City</td>
<td>Feb 21-24</td>
</tr>
<tr>
<td>Santo Domingo, Dominican Republic</td>
<td>Mar 7-10</td>
</tr>
<tr>
<td>Bogotá, Columbia</td>
<td>Apr 18-21</td>
</tr>
<tr>
<td>Lima, Peru</td>
<td>May 16-19</td>
</tr>
<tr>
<td>Asuncion, Paraguay</td>
<td>May 30 - June 2</td>
</tr>
</tbody>
</table>

Courses instructed in Spanish
FSMA Technical Assistance Networks

Preventive Controls Scientific & Technical Questions from Industry – a Web form at: www.iit.edu/ifsh/alliance

FSMA Regulation & Policy Interpretation Questions – a Web form at: www.fda.gov/FSMA
Enhance Existing FSPCA TAN

• Add international Food Safety Experts (FSEs)
• Develop and translate knowledge articles and outreach documents
• Expand chat groups in the FSPCA community
  ▪ Country leads
  ▪ Language leads
Enhance Existing FSPCA TAN

- Add international Food Safety Experts (FSEs)
- Develop and translate knowledge articles and outreach documents
- Expand chat groups in the FSPCA community
  - Country leads
  - Language leads
Implementation Timeline

What Comes Next?

2018  2019  2020  2021
PANEL: WHAT INDUSTRY WANTS; WHAT INDUSTRY NEEDS

Sally Klinect
Nestle

Steve Gendel
IEH Laboratory and Consulting Group

Derrick King
Urban Accents

Donna Lynn Browne
Naturipe Farms

Moderator: Julia Bradsher, IFPTI
FSPCA TOWN HALL DISCUSSION

Allow Stakeholders to ask the FSPCA experts questions regarding: FSMA outreach, training, and technical assistance

Moderators:
Gerald Wojtala
Executive Director, International Food Protection Training Institute (IFPTI)
Kathy Gombas
FSPCA International Subcommittee Co-Chair
FSPCA COMMUNITY PORTAL

Jason Wan, Ph.D.,
IFSH Associate Director
David Griesemer | Mark Carter (until May 2017)
WELCOME TO THE FSPCA COMMUNITY

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Please Login with your FSPCA Credentials to the FSPCA Community to access features. The LMS login will not work.
FSPCA Community Portal Functions

- FSPCA TAN
- Lead Instruction Applications and Profiles
- Course Registration and Listing
- LI Group Discussions
- Interactions with LMS
FSPCA

TECHNICAL ASSISTANCE NETWORK (TAN)
FSMA Technical Assistance Network

Preventive Controls Scientific & Technical Questions from Industry – a web form at:
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FSMA Regulation & Policy Interpretation Questions – a web form at:
www.fda.gov/fsma

Extension Specialists
Land Grant Universities
International Partners ITAN

CVM
CFSAN
ORA
OIP

IFSH
INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

77
How to Submit a TAN Question to FSPCA?
FSPCA TAN Question Statistics by Case Reasons (5/1/16 to 7/07/17)

- Training / FSPCA Courses 31.00%
- Lead Instructor Application 26.00%
- Preventive Controls 13.00%
- Foreign Supplier Verification Program 6.00%
- Regulatory / Rules Interpretation 5.00%
- Other 5.00%
- Hazard Analysis 4.00%
- Good Manufacturing Practices 3.00
- Food Allergens 2.00%
- Supply Chain Programs 2.00%
- Environmental Monitoring 1.00%
- Process Validation 1.00%
- Processing 1.00%

*Note: The “Other” category includes Intentional Adulteration, Recall Plan, Sanitation, and Non-specified questions with the Intentional Adulteration, Recall Plan, and Sanitation categories each being less than .20%.*
Allergen Controls FAQ

WHAT ARE SOME DRY-AREA CLEANING TECHNIQUES FOR HUMAN FOOD ALLERGEN CONTROL?
Dry cleaning techniques may include vacuuming, scraping and wiping with dry cloths. Dry cleaning techniques may be product specific.

Food Safety Systems FAQ

HOW WILL THE EXISTING GFSI CERTIFICATIONS OF COMPANIES BE AFFECTED BY PREVENTIVE CONTROLS?
Firms that have received GFSI recognized certifications will need to comply with FDA’s Preventive Controls regulation (unless they are subject to one of the exemptions) regardless of their certification. Third party audits and certifications will not be accepted in lieu of an FDA inspection; however, private audit certifications may be considered by FDA as they assess a firm’s performance history for work planning purposes. GFSI audits may also be useful with respect to supplier verification.

CAN I USE MY EXISTING HACCP PLAN AND JUST ADD THE THINGS REQUIRED FOR PREVENTIVE CONTROLS?
Yes, your HACCP plan includes controls such as process controls applied at CCPs. Other controls such as sanitation controls may apply to your products, but you do not need to rewrite your HACCP plan to include these. In fact, you may already have programs in place in addition to your HACCP plan that address the Preventive Controls rule requirements. As long as these programs meet the requirements of the rule, you can use them and the existing records. You can also supplement your HACCP plan with other things required by the rule, such as a recall plan.
FSPCA TAN – Future Development

• Scope
   PCHF
   PCAF
   Produce
   Sprout
   FSVP
   IA

• Serving Industries
  • Domestic and International

• Food Safety Experts
  • Domestic and International
FSPCA LEAD INSTRUCTOR APPLICATIONS & PROFILES
WELCOME TO THE FSPCA COMMUNITY

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FSPCA Lead Instructor Application

• Selection Criteria
  • Education
  • Work Experience
  • Food Safety Training Experience

• Create a Login/password in the FSPCA Community

• LI Application for
  • PCHF/PCAF/SSA/FSVP/IA

• Knowledge Article and Video tutorial available
  https://www.youtube.com/watch?v=obURa5281d8
This is a growing list of lead instructors. **Lead Instructors are being added to the list.** If you are looking to engage a Lead Instructor to teach a course, please select the course type and location in order to filter the list. Please continue to check the list for updates.

<table>
<thead>
<tr>
<th>Relevant Experience</th>
<th>North American Travel Range</th>
<th>International Travel Regions</th>
<th>Location</th>
<th>Specialty</th>
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<td>Food Processing</td>
<td>All 50 US States</td>
<td>Africa</td>
<td>State</td>
<td>Asia</td>
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<tr>
<td>Food Safety</td>
<td>All US &amp; Canada</td>
<td>Asia</td>
<td>Specialty</td>
<td></td>
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<td>Alaska</td>
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<td>Jason Wan</td>
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<td>Europe</td>
</tr>
<tr>
<td>Mark Carter</td>
<td>MC Squared</td>
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<td>Preventive Controls</td>
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<td>Food Processing</td>
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<td>Dr. Atcharaporn</td>
<td>TUV Nord (Thailand) Ltd.</td>
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<td>Food Processing, Food Safety, Sanitation, Auditing, Safe Quality Foods, HACCP, Good Manufacturing Processes, Preventive Controls</td>
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<td></td>
<td>Middle East</td>
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FSPCA COURSE REGISTRATION AND LISTING
High-Level Overview of Course Delivery Steps

Lead Instructor decides to host a course

Lead Instructor completes online course registration form

AFDO reviews registration form

AFDO sends questionable forms to Course Review Committee for rejection or acceptance
WELCOME TO THE FSPCA COMMUNITY

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## COURSE REGISTRATIONS

**Upcoming Courses**

50+ items • Sorted by City • Filtered by Approval Status, Course Start Date, This course is • Updated a few seconds ago

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<tr>
<th>COURSE...</th>
<th>LEAD I...</th>
<th>COUR...</th>
<th>WEB A...</th>
<th>COST...</th>
<th>CURRE...</th>
<th>CONTA...</th>
<th>CITY</th>
<th>STATE</th>
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<td>cpisi@fr...</td>
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<td>IA</td>
<td>USA</td>
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<td>USD</td>
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<td>GA</td>
<td>USA</td>
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<td>USD</td>
<td>richard@...</td>
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<td>TX</td>
<td>USA</td>
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<td>7 Human F... Brent Heldt 7/25/201... <a href="https://ac...control-for-human-food-in-person-course/">https://ac...control-for-human-food-in-person-course/</a></td>
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<td>USD</td>
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<td>United St...</td>
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<td>USA</td>
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</table>
How to Register an FSPCA Course

• Video tutorial available

https://www.youtube.com/watch?v=mdHpJNs8Ahg
<table>
<thead>
<tr>
<th>GROUP NAME</th>
<th>LAST ACTIVITY</th>
<th>MEMBERS</th>
<th>OWNER</th>
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<tr>
<td>Human Food Lead Instructors (Private)</td>
<td>7/4/2017 1:18 PM</td>
<td>254 Members</td>
<td>Mark Carter</td>
</tr>
<tr>
<td>FSVP Lead Instructors (Private)</td>
<td>6/26/2017 3:10 PM</td>
<td>46 Members</td>
<td>Dawn Johnson</td>
</tr>
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<td>FAST Lead Instructors Guatemala (Private)</td>
<td>6/20/2017 9:01 PM</td>
<td>48 Members</td>
<td>Marcos Sanchez</td>
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<tr>
<td>FAST Project Peru (Private)</td>
<td>5/21/2017 8:08 PM</td>
<td>41 Members</td>
<td>Marcos Sanchez</td>
</tr>
<tr>
<td>Animal Food Lead Instructors (Private)</td>
<td>5/18/2017 11:20 AM</td>
<td>34 Members</td>
<td>Mark Carter</td>
</tr>
</tbody>
</table>
PROCESS CONTROL VS. AN ALLERGEN CONTROL

Explore other articles and discussions on this topic.

Process Control vs. an Allergen Control

Is there a right way to use a Process Control vs. an Allergen Control or can I decide which one to use?

Apr 18, 2016 · FSPCA

DETAILS

There is flexibility provided to apply preventive controls as appropriate to the food, the facility and the nature of the preventive control and its role in the facility’s food safety system. It does not matter what you call a preventive control.
PANEL: STATE OF FOREIGN SUPPLIER VERIFICATION PROGRAMS TRAINING

Catherine Carnevale
FDA, Retired

Robert Lake
FDA, Retired

Sharon Mayl
FDA

Moderator: Kirk Sundling, IFPTI
FSVP Curriculum

• Current Version is 1.0
• Next Version 1.1 due after August 2017
  ▪ An errata will be published for version 1.0
  ▪ Currently available at the FSPCA online bookstore.
    http://bookstorefspca.ifpti.org/index.php/fsvp.html
FSVP Instructor Resource Portal

• One stop to find all resources to teach the Participant course.
FSVP Instructor Resource Portal—Resources
Evaluation Results—FSVP as of 07/05/17

- 46 total FSVP participants responded
- Average rating 4.6 out of 5

<table>
<thead>
<tr>
<th>Question</th>
<th>Average Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional behavior of instructors.</td>
<td>4.85</td>
</tr>
<tr>
<td>Instructors' abilities to interact with participants during this class.</td>
<td>4.82</td>
</tr>
<tr>
<td>Instructor(s) was/were prepared to teach this course.</td>
<td>4.78</td>
</tr>
<tr>
<td>Instructors' knowledge of the content.</td>
<td>4.74</td>
</tr>
<tr>
<td>Course materials will be useful to me.</td>
<td>4.74</td>
</tr>
<tr>
<td>Instructors' abilities to present the material clearly and at a reasonable pace.</td>
<td>4.69</td>
</tr>
<tr>
<td>Ease in following FSPCA’s Administration process in accessing certificates.</td>
<td>4.65</td>
</tr>
<tr>
<td>I will be able to apply the knowledge and skills learned in this course to develop foreign supplier verification programs.</td>
<td>4.64</td>
</tr>
<tr>
<td>Overall quality of classroom instruction.</td>
<td>4.63</td>
</tr>
<tr>
<td>Course length.</td>
<td>4.63</td>
</tr>
<tr>
<td>Use of classroom equipment (e.g., projectors, computers) by the instructors.</td>
<td>4.59</td>
</tr>
<tr>
<td>My expectations were met.</td>
<td>4.53</td>
</tr>
<tr>
<td>Use of training aids (e.g., slides, handouts) provided by the instructors.</td>
<td>4.52</td>
</tr>
<tr>
<td>Usefulness of classroom exercises.</td>
<td>4.44</td>
</tr>
</tbody>
</table>
Certificate Metrics—FSVP as of 07/03/17

• FSPCA FSVP certificates issued to date:
  - Total: 1391
  - Domestic: 1310
  - International: 81

• FSPCA FSVP Lead Instructor certificates to date:
  - Total: 176
  - Domestic: 148
  - International: 28
Panel Q & A—FSVP

• Now, I will ask the panel to introduce themselves and their relation to FSVP.
• After the panel has addressed the questions, there may be time for the audience to ask questions.
FDA Guidance on Complying with the Unique Facility Identifier (UFI) Requirement at Entry

- When a food product under FDA oversight is offered for entry into the U.S., the Customs and Border Protection (CBP) Automated Commercial Environment (ACE) system will prompt the filer to transmit one of the following codes:
  - An entity role code “FSV” – signals to ACE system that entry line subject to FSVP rule;
    - ACE will request FSVP importer’s name, email address, and DUNS number
  - An Affirmation of Compliance code “FSX” – entry line is exempt from or not yet subject to FSVP;
  - An Affirmation of Compliance code “RNE” – entry line is exempt from FSVP as food is being imported for research or evaluation.

- If one of these codes is not transmitted, the filer will receive an error message.

- The filer can make the appropriate adjustments to the entry submission and retransmit the entry line.
In March 2017, FDA published guidance recognizing the DUNS number as an acceptable UFI for the FSVP regulation available at: https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM549647.pdf

In May 2017, FDA issued additional guidance describing how the U.S. CBP Automated Commercial Environment (ACE) system will operate in practice to handle the FSVP importer data available at: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm
• If FSVP importers are temporarily unable to obtain a DUNS number, FDA will allow filers to transmit the value “UNK” (to represent “unknown”) in the UFI field.

• FDA will contact FSVP importers for whom “UNK” was transmitted to ensure that they understand this FSVP regulation requirement and take steps to obtain a UFI.
PANEL: CHALLENGES IN BECOMING FSVP COMPLIANT

Jennifer McEntire
United Fresh

Michael Roberson
Publix

Maile Hermida
Hogan Lovells

Samantha Cooper
Grocery Manufacturers Association

Moderator: Ron Tanner, Specialty Food Association
PANEL: SUPPLY CHAIN PROGRAMS—SOLVING THE PUZZLES

Maile Hermida
Hogan Lovells
Sally Klinect
Nestle

Moderator: Robert Brackett
1. What’s the relationship between FSVP and supplier verification under PC?

§ 1.502:

(c) Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act. You are deemed to be in compliance with the requirements of this subpart for a food you import, except for the requirements in § 1.509, if you are a receiving facility as defined in § 117.3 or § 507.3 of this chapter and you are in compliance with the following requirements of part 117 or part 507 of this chapter, as applicable:

(1) You implement preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34 of this chapter;

(2) You are not required to implement a preventive control under § 117.136 or § 507.36 of this chapter with respect to the food; or

(3) You have established and implemented a risk-based supply-chain program in compliance with subpart G of part 117 or subpart E of part 507 of this chapter with respect to the food.
Top 10 Puzzles: A Lawyer’s Perspective

2. Who bears the responsibility for conducting supplier verification?
   • PC: Receiving facility
   • FSVP: Importer (NOT the “Importer of Record”!)

*Receiving facility means a facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.*

*Importer means the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.*

*U.S. owner or consignee means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.*
Top 10 Puzzles: A Lawyer’s Perspective

3. If I require annual audits of all suppliers, is that enough to be compliant?

4. Will GFSI audits suffice?
5. When does packaging need to be verified under the FSMA supplier verification rules?
   - PC v. FSVP

6. What if my supplier’s supplier controls the hazard?
   - § 117.410(a)(5)
Top 10 Puzzles: A Lawyer’s Perspective

7. Can corporate handle all of the supplier verification work on behalf of the company’s facilities?

8. Can you conduct supplier verification for your contract manufacturers?

• § 117.415(a)(3)

(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity’s applicable documentation, and documents that review and assessment:
   (i) Establish written procedures for receiving raw materials and other ingredients by the entity;
   (ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and
   (iii) Determine, conduct, or both determine and conduct the appropriate supplier verification activities, with appropriate documentation.
Top 10 Issues: A Lawyer’s Perspective

9. Where do things stand on the disclosure statement and written assurance requirements (e.g., 21 CFR § 117.136)?

10. What’s my compliance date?
Top Tips

• Be sure you understand the regulations
  ▪ The FSPCA’s FSVP training is beneficial for both FSVP and facilities that are only under the Preventive Controls/Subpart G requirements
  ▪ Make sure you’re working with legal counsel and that they really understand FSMA – FSPCA lead instructors are not your legal counsel!

• Read before you sign
  ▪ There are lots of confused FSMA communications and contracts being passed throughout the supply chain

• Don’t panic!
ORIENTATION TO FDA’S FSMA GUIDANCE DOCUMENTS AND FDA/ FSPCA WEBSITE RESOURCES

Lillian Hsu
FDA

Kathy Gombas
FSPCA International Subcommittee Co-Chair
Orientation to FDA’s FSMA Guidance
Documents and Resources

Lillian Hsu
July 14, 2017 | FSPCA Annual Meeting
Introduction to FDA’s FSMA website

- Hyperlink: [www.fda.gov/fsma](https://www.fda.gov/fsma)
- [https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm)
The Law, Rules & Guidance

View the full text of the Food Safety Modernization Act (FSMA) as well as a list of rules and guidance for industry associated with the law.

- Full Text of the Law
- Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)
- Rules & Guidance for Industry Related to the Law
- General Information
  - Background on the FDA Food Safety Modernization Act (PDF, 51KB)
FSMA Rules & Guidance for Industry

Rules and Guidance for Industry related to the FDA Food Safety Modernization Act (FSMA).

- **Rules**
  - **Guidance for Industry & Others**

**Rules**

- Final Rule: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules
  - August 2016

- Final Rule: Amendments to Registration of Food Facilities
  - Docket Number: FDA-2002-N-0323
  - July 2016

- Final Rule: Mitigation Strategies to Protect Food Against Intentional Adulteration
  - Docket Number: FDA-2013-N-1425
  - May 2016

- Final Rule: Sanitary Transportation of Human and Animal Food
  - Docket Number: FDA-2013-N-0013
  - April 2016

- Final Rule: Accredited Third-Party Certification
  - Docket Number: FDA-2011-N-0146
  - November 2015

- Final Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
FDA Guidance

**Guidance for Industry & Others**

- Guidance for Industry: [Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation](#)
  Docket Number: FDA-2011-N-0143
  May 2017

- Guidance for Industry: [Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation](#)
  Docket Number: FDA-2011-N-0143
  March 2017

- Draft Guidance for Industry: [Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations](#)
  Docket Number: FDA-2017-D-0175
  January 2017

- Draft Guidance for Industry: [Control of *Listeria monocytogenes* in Ready-To-Eat Foods](#)
  Docket Number: FDA-2008-D-0096
  January 2017
Hazard Analysis and Risk-based Preventive Controls for Human Food

Individual Chapter Downloads

- Introduction and Purpose (PDF: 68KB)
- Chapter 1: The Food Safety Plan (PDF: 99KB)
- Chapter 2: Conducting a Hazard Analysis (PDF: 201KB)
- Chapter 3: Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food (PDF: 488KB)
- Chapter 4: Preventive Controls (PDF: 499KB)
- Chapter 5: Application of Preventive Controls and Preventive Control Management Components (PDF: 146KB)
- Chapter Six - Use of Heat Treatments as a Process Control (coming soon)

• Guidance Documents & Regulatory Information by Topic > Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food
Docket Number: FDA-2016-D-2343  (August 2016)
Control of *Listeria monocytogenes* in Ready-to-Eat Foods

Contains Nonbinding Recommendations

**Control of *Listeria monocytogenes* in Ready-to-Eat Foods: Guidance for Industry**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting the form available at [http://www.fda.gov/Food/GuidanceRegulation/PSMA/ucm459719.htm](http://www.fda.gov/Food/GuidanceRegulation/PSMA/ucm459719.htm).

I. Introduction

This guidance is intended for those persons ("you") who are subject to our regulation, in 21 CFR part 117 (part 117), entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" and who manufacture, process, pack, or hold ready-to-eat (RTE) foods. This guidance is intended for you regardless of whether you are only subject to the current good manufacturing practice requirements for human food of part 117 (CGMP requirements), the requirements for hazard analysis and risk-based preventive controls for human food in part 117 (PCHF), or both the CGMP requirements and the PCHF requirements. See section II.A of this guidance for additional information about the CGMP and PCHF requirements. This guidance is intended to help you comply with the CGMP and PCHF requirements of part 117 with respect to measures that can significantly minimize or prevent the contamination of RTE food with *L. monocytogenes* whenever a RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to *L. monocytogenes*) that would significantly minimize *L. monocytogenes*.

This guidance is not directed to processors of RTE foods that receive a listerical control measure applied to the food in the final package, or applied to the food just prior to packaging in a system that adequately shields the product and food contact surfaces of the packaging from contamination from the food processing environment.

- [https://www.fda.gov/ Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/ucm073110.htm](https://www.fda.gov/ Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/ucm073110.htm)
- Docket Number: **FDA-2008-D-0096**  
  January 2017
Human Food By-Products for Use as Animal Food

Contains Nonbinding Recommendations
Draft – Not for Implementation

Draft Guidance for Industry

Human Food By-Products For Use As Animal Food

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended for domestic and foreign facilities that are required to register under section 415 the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and its implementing regulations because they manufacture, process, pack, or hold human food for consumption in the United States and their human food production also provides by-products for use as animal food in the US. This guidance contains information for these facilities to determine what requirements to follow for their human food by-products for use as animal food. The regulations applicable to human food by-product for use as animal food were established in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule published on September 17, 2015 (the final rule). (80 FR 56170).

This guidance applies only to by-products of human food processing and not to by-products from other types of processing. Examples of by-products of other types of processing that are sometimes used for animal food include spent grains from fuel ethanol production, glycerin from biodiesel production, lignin sulfonate and Kraft lignin from wood pulp production or paper-making, or hemicellulose extracted from wood. Facilities that are not producing human food but are producing by-products for use as animal food are required to register and comply with all of 21 CFR part 507, unless they meet the criteria for an exemption. Resources on whether a facility is required to register and how to complete the registration process can be found online at:


• [Link](https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf)

• Docket Number: [FDA-2016-D-1220](https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf) (August 2016)
Small Entity Compliance Guide: CGMP & PC for Human Food rule

Download the Guidance (PDF: 332KB)

Individual Chapter Downloads

- **Chapter 1: Introduction**
- **Chapter 2: Who Must Comply with the Rule**
- **Chapter 3: Key Terms Used in Part 117**
- **Chapter 4: Who is Exempt from the Requirements for Hazard Analyses or Subject to Modified Requirements?**
- **Chapter 5: What Foods are Covered by this Regulation?**
- **Chapter 6: When do I have to Comply with the Rule?**
- **Chapter 7: Hazard Analysis**
- **Chapter 8: Preventive Controls**

- [https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm525201.htm](https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm525201.htm)
- Docket Number: FDA-2011-N-0920 (October 2016)
Current Good Manufacturing Practice
Requirements for Food for Animals

I. INTRODUCTION

This guidance is intended for domestic and foreign facilities that are required to register as food facilities under the Federal Food, Drug and Cosmetic Act (the FDCA or Act) because they manufacture, process, pack, or hold animal food for consumption in the U.S. This guidance contains information to help these facilities determine whether they need to comply with the current good manufacturing practice (CGMP) requirements for animal food established in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule published on September 17, 2015 (80 FR 56170) (the final rule). This guidance also provides additional information and recommendations for compliance with the CGMP requirements for animal food, as well as compliance with related requirements such as training and recordkeeping. The CGMP requirements are codified in 21 CFR part 507, subpart B (subpart B), and some related requirements are codified in 21 CFR part 507, subpart A (subpart A).

In general, FDA’s (hereinafter also referred to as “Agency”, “we”, or “our”) guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353). This law enables FDA to better protect public health by helping to ensure the safety and security of the animal food supply by focusing on prevention of food safety problems rather than reacting to problems after they occur. As part of our implementation of

- Docket Number: FDA-2016-D-1229 (August 2016)
Small Entity Compliance Guide: PC for Animal Food rule

Guidance for Industry

Small Entity Compliance Guide

What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR Part 507)

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The Food Safety Modernization Act of 2011 (FSMA) directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety. On September 17, 2015, FDA published the final rule Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (PCAF or the rule) (80 FR 56173). FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. Law 104-121). The intent of this guide is to inform domestic and foreign animal food facilities about the PCAF regulations and enable them to better understand the requirements of the rule. It contains important information that may affect your facility.

The regulation creates new current good manufacturing practice (CGMP) requirements for animal food facilities. In addition, it creates new requirements for certain animal food facilities to establish and implement risk-based preventive controls. The regulations are found at Title 21 of the Code of Federal Regulations part 507 (21 CFR part 507). The rule became effective on November 16, 2015, but compliance dates are staggered – see section II. E “When Do I Have to Comply with the Rule?”

- Docket Number: FDA-2011-N-0922 (October 2016)
Describing a Hazard that Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA

I. Introduction

This guidance concerns four of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–155). Table 1 lists these four rules.

Table 1. Four Foundational Rules Providing the Framework for Implementing FSMA

<table>
<thead>
<tr>
<th>Title</th>
<th>Regulatory Codification</th>
<th>Abbreviation for the Purpose of This Guidance</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food</td>
<td>21 CFR part 117</td>
<td>Part 117</td>
<td>80 FR 55908, September 17, 2015</td>
</tr>
<tr>
<td>Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals</td>
<td>21 CFR part 507</td>
<td>Part 507</td>
<td>80 FR 56170, September 17, 2015</td>
</tr>
<tr>
<td>Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals</td>
<td>21 CFR part 1, subpart L</td>
<td>FSVP regulation</td>
<td>80 FR 74226, November 27, 2015</td>
</tr>
</tbody>
</table>

Recognition of Acceptable Unique Facility Identifier for the FSVP reg

- [https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm](https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm)
- Docket Number: FDA-2011-N-0143
  March 2017
Compliance with Providing an Acceptable UFI for the FSVP reg

https://www.fda.gov/Food/GuidanceRegulation/FSM/ucm556661.htm

Docket Number: FDA-2011-N-0143
May 2017
Other resources

- FDA Fact sheets
  https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm

**Final Rule Fact Sheets**

- Accredited Third-Party Certification Final Rule (PDF: 109KB)
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals Final Rule (PDF: 265KB)
- Mitigation Strategies to Protect Food Against Intentional Adulteration Final Rule (PDF: 252KB)
- Preventive Controls for Food for Animals Final Rule (PDF: 144KB)
- Preventive Controls for Human Food Final Rule (PDF: 156KB)
- Sanitary Transportation of Human and Animal Food Final Rule (PDF: 113KB)
- Standards for Produce Safety Final Rule (PDF: 405KB)
Other resources: FDA Fact sheet – Preventive Controls for Human Food

Other resources: FDA Fact sheet – FSVP rule


KEY REQUIREMENTS: Final Rule on Foreign Supplier Verification Programs

The FDA is committed to helping ensure that importers can meet the FSVP requirements. In order to facilitate compliance, FDA will provide guidance, outreach, and training.

1. SCOPE

• Who is covered by the rule?
  • For the purposes of FSVP, an importer is the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee, the importer is the U.S. agency or representative of the foreign owner of consignee at the time of entry, as confirmed in a signed statement of consent. See Am I Subject to FSVP? (PDF: 69KB) for more information.
  • There are exemptions discussed below.
The following compliance dates are grouped according to the category of FSVP importer. This list does not include importers that are themselves a manufacturer or processor subject to the supply chain program provisions in the PC rules. If importers are subject to the supply chain program requirements in those rules, the compliance date for FSVP is the later of the applicable date in the below list or the date by which the importer is required to comply with the PC supply chain program provisions.

1. FSVP importer whose foreign supplier is not subject to the PC or produce safety rules: May 30, 2017

2. FSVP importer whose foreign supplier is required to comply with the PC rule for human food. Compliance dates when foreign suppliers are in these categories:
   - Small businesses as defined in 21 CFR 117.3: March 19, 2018
   - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 117.3: March 18, 2019
   - Suppliers subject to the Pasteurized Milk Ordinance: March 18, 2019
   - “All Other” Businesses Suppliers: May 30, 2017

3. FSVP importer of animal food whose foreign supplier is subject to the current good manufacturing practices (“CGMP”) requirements in subpart B of 21 CFR part 507 in the PC rule for animal food. Compliance dates when foreign suppliers are in these categories:
   - Small Businesses as defined in 21 CFR 507.3: March 19, 2018
   - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: March 18, 2019
   - “All Other” Businesses: May 30, 2017

4. FSVP importer whose foreign supplier is required to comply with the animal food preventive controls requirements in subpart C of part 507 of the PC rule for animal food, but that is not required to comply with the CGMP requirements in subpart B of 21 CFR part 507. Compliance dates when foreign suppliers are in these categories:
   - Small Businesses as defined in 21 CFR 507: March 18, 2019
   - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: March 17, 2020
   - “All Other” Businesses: March 19, 2018

5. FSVP importer whose foreign supplier is required to comply with the produce safety rule, except for the requirements applicable to sprouts in subpart M of 21 CFR part 112. Compliance dates when foreign suppliers

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https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm
Other resources: Decision trees

- Decision trees:
  - FSVP rule: [link](https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf)
  - Produce Safety rule: [link](https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf)
  - Intentional Adulteration rule: [link](https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM502602.pdf)
Other resources: What to do if you are subject to the CGMP & PC rule and FSVP rule

Foreign Supplier Verification Programs

*What Do Manufacturers/Processors Covered by the PC Supply-Chain Program Need to know about FSVP?*

A manufacturer/processor subject to the preventive controls (PC) requirements that uses imported raw materials or other ingredients may also be an importer covered by the Foreign Supplier Verification Programs (FSVP) rule. It’s important for these manufacturers/processors to know that

- they can be deemed in compliance with most of the FSVP requirements for foods they import if they implement preventive controls for the hazards in the food in accordance with applicable requirements or comply with the PC supply-chain program requirements, and

- they will still need to provide certain identification information when importing the food, as required in the FSVP rule. For example, they will need to provide a unique facility identifier (UFI) recognized as acceptable by the FDA for each line entry of food product offered for importation into the United States.

The first major compliance date for FSVP is May 30, 2017. Compliance dates for both FSVP and the PC supply-chain requirements are staggered, based on the size of the supplier.

- For more information on PC compliance dates
  Human Food: [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm)
  Animal Food: [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm)

- For more information on FSVP compliance dates
  [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm)

Other resources: Supplier evaluation

• [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm)

• “One-stop shop” of resources to assist with complying with the requirement that importers and facilities evaluate the applicable food safety regulations and information relevant to the supplier’s compliance with those regulations, including whether or not the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action.
Other resources: Supplier evaluation

Supplier Evaluation Resources

Three FDA FSMA rules (Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals) require that importers and facilities perform certain risk-based activities to verify that their suppliers are meeting applicable U.S. food safety standards. Under these rules, you must evaluate, among other things, the applicable FDA food safety regulations and information relevant to the supplier’s compliance with those regulations, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation.

Below is a list of publically available resources that can be used to meet the requirement set out in these regulations as well as information on their use:

- Warning Letters
- Import Alerts
- Recalls
- Import Refusals
- Inspection Classifications
- Other Compliance Resources
Other resources: FSMA Inflation Adjusted Cutoffs

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm
Other resources: Information for Qualified facilities

Qualified Facility Attestation

https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm

A business that meets the definition of a “qualified facility” is subject to modified requirements of the preventive controls rules. These modified requirements can be met by submitting a form to FDA, attesting to the business’s status as a qualified facility and attesting that the facility is implementing preventive controls to address hazards associated with its food or is in compliance with non-Federal food safety laws and regulations.

The draft guidance, “Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food),” explains how to determine whether a business meets the definition of “qualified facility” and how to submit the FDA form attesting to its status as a qualified facility. The two draft forms, FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food), once finalized, should be used to submit attestations.

Draft Materials:

- Draft Guidance for Industry: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)

- Draft Instructions for Submitting Your Attestation: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)

- Draft Form FDA 3942a Note: This is a draft form for commenting only and should not be submitted until after the draft form has been finalized.

- Draft Form FDA 3942b Note: This is a draft form for commenting only and should not be submitted until after the draft form has been finalized.
Other resources: FSMA Frequently Asked Questions

Frequently Asked Questions on FSMA

Questions & Answers on the Food Safety Modernization Act

- Preventive Controls Rules: Human Food and Animal Food
- Final Rule for Preventive Controls for Human Food as it Relates to Dairy Products Produced under the Pasteurized Milk Ordinance (PMO)
- Dietary Supplements
- Produce Safety Rule
- Enforcement
- FSVP Rule
- Accredited Third-Party Certification
- Voluntary Qualified Importer Program
- Sanitary Transportation of Human and Animal Food
- Intentional Adulteration
- Recalls
- Administrative Detention
- Records and Records Access
- Registration

Additional Resources

- Common Technical Assistance Network (TAN) Questions (PDF: 146KB)
- Contact TAN for Assistance

https://www.fda.gov/food/guidance/regulation/fsma/ucm247559.htm
How to contact FDA

FSMA Technical Assistance Network (TAN)

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Have a FSMA Question? Start Here.

The Technical Assistance Network staff has compiled answers to common FSMA TAN questions. In addition, the complete set of frequently asked questions on FSMA contains answers to questions on specific provisions of the rule.

Submit Your Question

Didn't find your question above? Please submit your question to TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:
Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: For Food Safety Preventive Controls Alliance (FSPCA) training and scientific/technical questions, please contact the FSPCA Technical Assistance Network using their web form at http://www.iit.edu/ffsh/alliance.

- www.fda.gov/FSMA
- Go to Contact Us and How to Contact FDA on FSMA
- FSMA TAN Popular Topics posted April 2017
- Inquiries may be submitted by mail, if internet is not available
FDA’s Technical Assistance Network

TAN Process – CFSAN
Stakeholder Inquiries (Phone or Web Form)

CFSAN FCIC

FCIC

Too Complex - Escalate

Office of Chief Counsel Clearance

Provide Response/Close

Administrators

OC

OFS

OAO

Too Complex - Escalate

OC SMEs

OFS SMEs

OAO SMEs

All SME responses go to the Administrator who will provide final response and close case.
**FDA FSMA Technical Assistance Network**  
**Sept 10, 2015 – June 30, 2017**

**Case Count by FSMA Topic**

<table>
<thead>
<tr>
<th>FSMA Topics</th>
<th>Inquiry Count</th>
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<tbody>
<tr>
<td>Preventive Controls-Human Food</td>
<td>2,029</td>
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<tr>
<td>Foreign Supplier Verification Program (FSVP)</td>
<td>1,084</td>
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<td>Sanitary Transportation for Human and Animal Food</td>
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<td>Produce Safety</td>
<td>591</td>
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<tr>
<td>Preventive Controls-Animal Food</td>
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<tr>
<td>Other</td>
<td>417</td>
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<tr>
<td>Accredited Third-Party Certification (3rd Party)</td>
<td>193</td>
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<tr>
<td>Food Facility Registration</td>
<td>121</td>
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<tr>
<td>Intentional Adulteration</td>
<td>63</td>
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<tr>
<td>Voluntary Qualified Importer Program (VQIP)</td>
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</tr>
<tr>
<td>Lab Accreditation</td>
<td>13</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
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### International/Domestic Inquiry Count

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<tr>
<td>International</td>
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- **Domestic** 81.17%
- **International** 18.83%

### Top International Case Count by Country

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<tr>
<td>Italy</td>
<td>111</td>
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<tr>
<td>Mexico</td>
<td>74</td>
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<tr>
<td>Spain</td>
<td>62</td>
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<tr>
<td>China</td>
<td>47</td>
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<tr>
<td>Chile</td>
<td>45</td>
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<tr>
<td>India</td>
<td>37</td>
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<td>Japan</td>
<td>24</td>
</tr>
<tr>
<td>Brazil</td>
<td>23</td>
</tr>
<tr>
<td>Korea, South</td>
<td>23</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>23</td>
</tr>
</tbody>
</table>
ORIENTATION TO FSPCA WEBSITE RESOURCES

Kathy Gombas
July 14, 2017
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
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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
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
PCHF Training

FSPCA Preventive Controls for Human Food

Training

FSPCA Preventive Controls for Human Food Course
FSPCA Preventive Controls for Human Food Blended Course
FSPCA Preventive Controls for Human Food Lead Instructor Training
Selection Criteria for Lead Instructor
Lead Instructor Course Schedule

RESOURCES

- FSPCA Preventive Controls for Human Food Participant Manual (English)
- Errata Sheet for Preventive Controls For Human Food: Versions 1.0 & 1.1
- FSPCA Errata Sheet for Version 1.2 Instructor
- FSPCA Preventive Controls for Human Food Courses
- FSPCA Human Food Bookstore
PCHF Blended Course

FSPCA Preventive Controls for Human Food

Training

NEW! FSPCA Preventive Controls for Human Food Blended Course

This Food Safety Preventive Controls Alliance (FSPCA) Blended Training course was developed to provide an alternative for individuals to complete the FSPCA Preventive Controls for Human Food course. The Blended course consists of 2 parts. Part 1 is online and Part 2 is instructor-led. Both parts must be completed in order to obtain the certificate. Any Lead Instructor can provide a one-day Part 2: Instructor-Led course, and you can search for upcoming courses and Lead Instructors on the FSPCA Community website.

IMPORTANT

Once you begin the process, you have up to six months to complete the Part 1: Online course. Upon completion, you have six months to complete a Part 2: Instructor-Led course. We recommend you have a Part 2: Instructor-Led course identified before enrolling in Part 1: Online.

Before you enroll for Part 1: Online course, please read the background information to help you understand how the course is structured and what options will work best for you.
PCHF Lead Instructor Course Schedule

FSPCA Preventive Controls for Human Food

Training

<table>
<thead>
<tr>
<th>Year</th>
<th>Location</th>
<th>Course Type</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul. 25 - 27</td>
<td>St. Paul, MN</td>
<td>2.5-Day LI</td>
<td>Delivered in English with English course materials</td>
</tr>
<tr>
<td>Sep. 19 - 21</td>
<td>Denver, CO</td>
<td>2.5-Day LI</td>
<td>Delivered in English with English course materials</td>
</tr>
<tr>
<td>Dec. 5 - 7</td>
<td>Dallas, TX</td>
<td>2.5-Day LI</td>
<td>Delivered in English with English course materials</td>
</tr>
</tbody>
</table>
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
PCAF Training Materials

FSPCA Preventive Controls for Animal Food Training

FSPCA Preventive Controls for Animal Food Course
FSPCA Preventive Controls for Animal Food Lead Instructor Training
FSPCA Preventive Controls for Animal Food Course AND Lead Instructor Training
Selection Criteria for Lead Instructor
Animal Food Lead Instructor Course Schedule

RESOURCES
FSPCA Preventive Controls for Animal Food Participant Manual (English)
FSPCA Preventive Controls for Animal Food Courses
FSPCA Animal Food Bookstore
## FSPCA Preventive Controls for Animal Food

### Training

<table>
<thead>
<tr>
<th>2017</th>
<th>Location</th>
<th>Course Type</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov. 7 - 9</td>
<td>Arlington, VA</td>
<td>2.5 Day LI</td>
<td>English</td>
</tr>
</tbody>
</table>
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
FSVP Training Materials

Foreign Supplier Verification Programs (FSVP)

FSVP CURRICULUM AND TRAINING

FSPCA has completed the process of piloting the New Foreign Supplier Verification Programs (FSVP) course and is now accepting applications for FSVP Lead Instructors and planning FSVP courses.

FSPCA Foreign Supplier Verification Programs (FSVP) Courses

FSPCA FSVP Bookstore

FSPCA FSVP Course Participant Manual_v1.0
### FSVP Lead Instructor Course Schedule

<table>
<thead>
<tr>
<th>2017</th>
<th>Location</th>
<th>Course Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 25 – 27</td>
<td>Deerfield Beach, FL</td>
<td>COMBINATION COURSE</td>
</tr>
</tbody>
</table>

*Considering Combo Courses in CA, FL, and IL*
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

FSPCA Website: fspca.net
Intentional Adulteration

New FSPCA Webinar Series on the FSMA IA Rule

The Food Safety Preventive Controls Alliance (FSPCA), in collaboration with the Food and Drug Administration (FDA), will host a series of new webinars specific to the FSMA Final Rule - Mitigation Strategies to Protect Food against Intentional Adulteration (IA Rule). These webinars will provide stakeholders with more information about the IA Rule and assist food facilities that are required to comply with the IA rule to have a more in-depth understanding of those requirements.

The webinars will be 1 hour in length which includes a short Q&A session. For more information or to watch a video overview presentation of the IA Rule, please visit [www.fda.gov/fooddefense](http://www.fda.gov/fooddefense).

Please register for FSPCA Webinar Series on the FSMA IA Rule by clicking the links below. After registering, you will receive a confirmation email containing information about joining the webinar.

Jun 20, 2017 11:00 AM CDT [Recording](http://example.com) | [Presentation](http://example.com)
Aug 22, 2017 11:00 AM CDT
Oct 24, 2017 11:00 AM CDT

Intentional Adulteration Curriculum and Training

The FSPCA IA Subcommittee held their kickoff meeting on September 21, 2016. A combination of online and face-to-face standardized training to support the IA final rule is being planned. The training development process is underway and is being done in concert with guideline development. Each component of the training package is being developed to meet the specific needs of the learner.
FSPCA Technical Assistance Networks

CONTACT FSPCA ABOUT FSMA

The FSPCA Technical Assistance Network (TAN) is now operational and providing technical assistance to industry, academia and others regarding training and scientific/technical questions related to FDA's Preventive Controls human food and animal food regulations. For more information, download

FSPCA TAN At-a-Glance

Submit an Inquiry Online

Mail an Inquiry: Inquiries may also be submitted by mail at the following address: FSPCA TAN, 6502 South Archer Road, Bedford Park, IL 60501

For questions related to the FSMA rules, FSMA programs, and implementation strategies, please submit your questions electronically to FDA's FSMA Technical Assistance Network at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm
FDA Technical Assistance Networks

Technical Assistance Networks
FSPCA Technical Assistance Network
FDA FSMA Technical Assistance Network

FSMA Technical Assistance Network (TAN)

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FSMA Resources / Regulations

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

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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

Supplier Evaluation Resources

Below is a list of publicly available resources that can be used to meet the requirement set out in these regulations as well as information on their use:

- Warning Letters
- Import Alerts
- Recalls
- Import Refusals
- Inspection Classifications
- Other Compliance Resources
FSPCA Committees

For Committee Rosters and More Information, Please Click on the Links Below:

- Executive Committee
- Steering Committee
- Implementation Subcommittee
  - Trainers-of Trainers Work Group
  - Monitoring and Evaluation Work Group
- Outreach Subcommittee
  - Website Work Group
  - Technical Assistance Work Group
  - Conference Work Group
  - Marketing and Promotions Work Group
  - Resource Community Content Development Work Group
- Curriculum Subcommittee (Human Food)
  - Food Safety Plan Teaching Examples Work Group
- Animal Food Subcommittee
- International Subcommittee
  - Training Content Work Group
  - Trainer Network Work Group
  - Technical Assistance Work Group
- Foreign Supplier Verification Programs (FSVP) Subcommittee
- Intentional Adulteration (IA) Subcommittee
- Work Groups
Food Safety Plan Teaching Examples

MISSION

The mission of the Food Safety Plan Teaching Examples Work Group is to develop guidelines for FSPCA acceptance of industry-specific food safety plan teaching examples submitted for use during FSPCA Preventive Controls for Human Food courses.

RESOURCES

- FSPCA Guidelines for Industry-specific Food Safety Plan Teaching Examples for FSPCA Human Food Training
- FSPCA Food Safety Plan Template

WORK GROUP MEETINGS

2016 Meetings
September 15
September 30
FSPCA Course Advertising Do’s and Don’ts

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
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for Importers of Food for Humans and Animals
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Intentional Adulteration

Sign up for the FDA’s e-mail updates

The Alliance
Committees, Subcommittees, Work Groups

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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)
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FSPCA Presentations and Conferences
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Produce Safety Alliance
Sprout Safety Alliance
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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)
FSPCA Materials / Resources

FSPCA Materials

Check this page often for updated materials issued by the Food Safety Preventive Controls Alliance.

Download a PDF of the FSPCA Preventive Controls for Human Food Participant Manual.

FSPCA Bookstore


FSPCA Food Safety Plan Template.

Recall Plan: This Recall Plan template is based on the template in the FSPCA curriculum. It must be modified by a company to develop an individualized Recall Plan.

FSPCA Task Timeline.

FSPCA ONE PAGE FLYERS

Domestic
International

Translations
English
French
Hindi
Mandarin
Portuguese
Spanish

IFSH Institute for Food Safety and Health

167
FSPCA Materials / Resources

Resources

FSPCA is dedicated to collecting and making available a variety of resources to assist the human and animal food industry in complying with upcoming Food Safety Modernization Act (FSMA)-related preventive control regulations.

- Resources by Chapter: Preventive Controls for Human Foods Curriculum
- FSMA Public Meeting: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards
- Validation and Verification White Paper
- USDA/ARS Pathogen Modeling Program
- FDA Food Code
- Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables
- Guidance for Commercial Processors of Acidified & Low-Acid Canned Foods
- Food Processing & HACCP Guidance Documents & Regulatory information
- Small Businesses / Small Entity Compliance Guides
- Evaluation & Definition of Potentially Hazardous Foods
- COMBASE – Combined Database for Predictive Microbiology
- Cornell’s GMP Internet Training Course
- North Carolina State University’s on demand short course – Sanitation Control Procedures for Food
- Voices of FSMA: The Road to Implementation

Please check these pages frequently for updated resource materials. If you experience any difficulties downloading materials or discover broken links, please contact us via e-mail.

GUIDANCE FOR INDUSTRY

- Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation
- Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation
- Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods
- Guidance for Industry: What You Need to Know About the FDA Regulation: Current Good Manufacturing
FSPCA Metrics

Quick Links
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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)
### FSPCA Weekly Metrics

**June 26, 2017**

#### Human Food Certificates

**FSPCA Preventive Controls certificates issued to date:**

<table>
<thead>
<tr>
<th></th>
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**FSPCA Lead Instructor certificates to date:**

<table>
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<td>950</td>
<td>287</td>
</tr>
</tbody>
</table>
FSPCA Quarterly Webinars

Stay Connected
FSPCA Webinars
FSPCA Presentations and Conferences
Sign up for FSPCA Updates
Contact Us

FSPCA Webinars

New FSPCA Webinar Series on the FSMA Intentional Adulteration (IA) Rule
Visit the FSPCA IA webpage for details

FSPCA QUARTERLY 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. 2017 Update Webinars will be held on January 19, April 20, July 20 and October 19.

Recording | Presentation

2017
January 19, 2017
April 20, 2017

PREVIOUS WEBINARS

2016
October 20, 2016
July 21, 2016
April 21, 2016
FSPCA TECHNICAL ASSISTANCE NETWORK OVERVIEW

Marcos Sanchez-Plata
FSPCA International Subcommittee Technical Assistance Work Group
The International Subcommittee will work through the FSPC Alliance to develop and implement a FSMA Outreach Strategy for the Human and Animal Food Preventive Controls rule and FSVP regulation, consistent with basic principles and methodology of the FSMA Communications and Engagement Framework for International Stakeholders. This strategy aims to support high rates of FSMA rule compliance by addressing a continuum of information needs of international stakeholders.

To do so, the Alliance’s International Subcommittee will follow the four-stage approach of the Framework, and will work in concert with the international efforts of the Produce Safety Alliance.
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
International Subcommittee Charge

- The **fourth and final stage** of the Framework focuses on the establishment of a **technical assistance network** which will include **the identification of resources (experts)** available to industry (with an emphasis on small and mid-sized human food and animal food companies including importers) **to provide scientific and technical information**.

- Once the training network is established, the Technical Assistance Working Group will develop a plan establishing this network of experts.

- This effort will include offering access to a communications platform, where information can be shared amongst experts and with the Alliances and FDA.

- The Technical Assistance Working Group will also address and publish Q&As.
FSPCA International Subcommittee

Technical Assistance Working Group: TA-WG

• Design and implement a plan to establish a network of experts
• Address frequently asked questions and staff a communications platform
• Facilitate stakeholder information-sharing and provision of specific technical expertise
• Responsible for coordinating with existing FSPCA domestic efforts.
Action Plan

• Recruitment of members
• Regional coordination
• Food Safety Experts
• International TAN
• Coordination with domestic TAN
• Review of responses
• Cataloguing responses
FSPCA Technical Assistance Network

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
FSMA Technical Assistance Network

Preventive Controls Scientific & Technical Questions from Industry – a web form at: www.iit.edu/ifsh/alliance

FSMA Regulation & Policy Interpretation Questions – a web form at: www.fda.gov/fsma
FSPCA Technical Assistance Network

Statistics 5/1/16 to 07/07/17

TAN Portal Users: 2992 in 50 Countries

TAN User Logins: 26,504

TAN Questions Submitted to TAN: 993

TAN Approved Human Food Lead Instructors: 906

TAN Approved Animal Food Lead Instructors: 154

TAN Course Registrations: 2407
 iTAN
Based on the domestic FSPCA TAN
Accessible through the FSPCA Community link
Question submitted by user
System selects a pool of 3 Food Safety Experts (FSEs)
Email discussion between FSEs to develop a response
Response submitted by one of the FSEs
Responses revised by FSPCA
Anonymous response received by inquirer
Strategy to establish the iTAN of Food Safety Experts

**Nomination**
- Lead Instructor Requirement, as per F2F 2016 meeting.
- Invitation sent 1/4/2017, Field in Profile page.
- Self-nomination, Peer Recommendation
- FSPCA affiliated recommendation.

**Screening Process**
- Review by PoC of ISC-TA-WG.
- Review of selected candidates by TA-WG members.
- Submission of revised applications for approval.

**Approval Process**
- Receipt of screened nominations from TA-WG.
- Revision by International Subcommittee Core Group.
- Final approval List send to IFPTI and Certificates emitted.
- Responsibilities.

---

**Lead Instructor Approved Profile**
- Experience in Food Safety
- Training Experience
- Technical Assistance Record
- Affiliation to a Center
- Publications
- Extension services
- Government and regulatory experience
- Private certifications, credentials
- English proficiency
- PC Certificate
- Other qualifications
Dear FSPCA Lead Instructor for Human and Animal Foods

The Food Safety Preventive Controls Alliance’s (FSPCA) International Subcommittee is currently the establishing an International Technical Assistance Network (ITAN), and will identify international experts in food safety and the Food Safety Modernization Act (FSMA) related subjects. The Food Safety Experts (FSEs) will be responsible for providing technical assistance by addressing scientific and technical questions from the public through the FSPCA Community Portal. The FSEs will not answer regulatory interpretation questions as these types of questions will continue to be handled by the FDA FSMA Technical Assistance Network.

The ITAN will be staffed by a number of volunteer FSEs. Please consider this letter to be an invitation to consider applying to become a FSE for the ITAN.

FSEs are individuals involved in training, education, technical assistance or related activities with significant expertise in food safety and related fields, as well as the regulatory framework and the FSMA regulations. In order to be considered for membership, interested candidates must be approved FSPCA Lead Instructors.

The main duty of approved candidates for the ITAN is to address questions from the public, create FAQs and support the FSPCA Community Portal at the global, regional and country level in a manner that is sensitive to varied cultural, political, trade, language, and technological needs and capacities.

The selection process for ITAN FSE candidates takes advantage of the current FSPCA Lead Instructor Profile, already available through your FSPCA Community Portal Login.

A new FSE field will be available in your profile through the following link:

http://xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Please select if you want to be considered for ITAN membership and Food Safety Expert activities for the FSPCA.

Each FSE applicant’s information will be reviewed and approved by the Technical Assistance Working Group of the International Subcommittee at the FSPCA. The FSEs are selected on the basis of their expertise and geographical location.

Approved candidates will receive official notification from the FSPCA and will be included in the pool of International Food Safety Experts for three years to periodically receive and answer
Updating Your Lead Instructor Profile
iTAN Food Safety Expert Nomination

Nomination

- Lead Instructor Requirement
- Invitation
- Self-nomination, Peer Recommendation
- FSPCA affiliated recommendation
iTAN Interest by Country
International FSE Candidates

FSE Candidates

- Mexico: 23
- Canada: 10
- Italy: 9
- Chile: 5
- Costa Rica: 5
- China: 4
- Peru: 4
- Spain: 4
- Honduras: 3
- India: 3
- Japan: 3
- Thailand: 3
- Colombia: 2
- Ecuador: 2
- France: 2
- Guatemala: 2
- Argentina: 2
- Australia: 1
- Ireland: 1
- Korean Republic of: 1
- Malaysia: 1
- Mauritius: 1
- Poland: 1
- Qatar: 1
- Trinidad and Tobago: 1
- United Kingdom: 1
- Vietnam: 1
FDA Facility Registration Data (Human Food)

March 2017

Countries with the highest number of registered facilities:
1. Japan
2. France
3. Italy
4. China
5. Mexico
6. Canada
7. Spain
8. India
9. Germany
10. Chile
11. Taiwan
12. Brazil
13. Vietnam
14. Thailand
15. Argentina
16. Australia
17. Colombia
18. Peru
19. Greece
20. Turkey
21. Indonesia
22. New Zealand
23. Portugal
24. Ecuador
25. Poland
26. South Africa
27. Netherlands
28. Costa Rica
Strategy to establish the iTAN of Food Safety Experts

Screening Process

• Review by PoC of ISC-TA-WG.
• Review of selected candidates by TA-WG members.
• Submission of revised applications for approval.
“Soft Launch” of iTAN Pilot

Approval Process

- Receipt of screened nominations from TA-WG
- Revision by International Subcommittee Core Group
- Final approval List send to IFPTI and Certificates issued
- Responsibilities communicated
“Soft Launch” of iTAN Pilot - Launching Options

• How many preliminary approvals?
• Trial group?
• Approval of all applicants?
• Webinar with approved FSEs for instructions
• Trial question period (1 month)
• Current FSEs will mentor the Pilot FSEs
• Others
INTERNATIONAL TECHNICAL ASSISTANCE NETWORK (iTAN)
Food Safety Expert (FSE) Approval Notification

Congratulations!

Your application for consideration to become a volunteer FSPCA Food Safety Expert (FSE) for the International Technical Assistance Network (iTAN) has been approved. Please find attached an iTAN FSE Certificate recognizing this distinction and a document briefly describing the iTAN activities in support of FSPCA efforts. Your certificate will be due for renewal on a bi-annual basis. Renewal eligibility is determined based on your active involvement with the iTAN and other FSPCA training and technical assistance activities.

Questions received by the FSPCA iTAN from international stakeholders will be screened and shared with up to three iTAN FSE’s, including experts from countries or regions from where the inquiries originate.

The responsibilities of the FSPCA iTAN FSEs include addressing questions from the public, develop FAQs, and support the FSPCA Community Portal.

**Note:** rule interpretation and policy questions are to be referred to FDA’s FSMA Technical Assistance Network via a web form.

A directory of the iTAN FSEs will be listed on the FSPCA webpage with each FSEs permission. FSEs in the FSPCA International Technical Assistance Network will be invited to participate in periodic conference calls to discuss trends and technical issues as well as share information with regulators, industry and consumers.

You will be invited to participate in a Webinar to discuss the launching of the Pilot iTAN in the next few days. Participation in this webinar is required for FSE approval.

If you have any questions, please contact Marcos Sanchez-Plata, marcos.x.sanchez@ttu.edu.

Sincerely:

**Robert E. Brackett, PhD**
Illinois Institute of Technology (IIT) Vice President,
Director, Institute for Food Safety and Health (IFSH)
and FSPCA Coordinator
“Soft Launch” of iTAN Pilot – FSE Pools and Algorithm

• Keep 3 members per question
• Include an experienced FSE
• Include a “volunteer” administrator to delegate questions to FSEs
• Food theme
• Regional
• Country
iTAN Operational Strategy Flowchart

1. Question submitted by international inquirer

2. Country field indicates the country-source of the question

3. System generates a pool of 3 FSE’s to participate in the response:
   - Mentor FSE 1
   - Mentor FSE 2
   - iTAN FSE from country or region where question originated

4. Email sent to FSE pool

5. Discussion of response between mentor FSE’s and iTAN FSE

6. Consensus answer developed and send by iTAN FSE to the system
“Soft Launch” of iTAN Pilot

- A total of 28 International FSEs are expected
- Utilize “volunteer” administrator until FTE can be hired for full implementation
- A “Trial question period” (1 month) could be used to get FSEs familiar with the system
- Practice rounds to be organized with 9 domestic FSEs (mentors)
- 3 FSE members per question
- Questions sorted by “Country of Origin”
- Send “Congratulation letters” including webinar invitation to selected FSEs and “Thank you letters” to other applicants
- Potential launching of the International FSE, Pilot Mode: August, 2017
Potential New Activities for iTAN FSEs

• Team-Translations of knowledge articles and FSPCA documents

• Regional chat groups in the community
  ▪ Country leads
  ▪ Language leads

• Notifications to FSPCA

• Others
If you have any questions, please contact the FSPCA at

fspca@iit.edu

or or visit the FSPCA website at

fspca.net

for resources on preventive controls, lead instructor application, and details of other FSPCA activities.
THANK YOU!