US FOOD SAFETY MODERNIZATION ACT (FSMA) – IMPACTS ON GLOBAL FOOD TRADE, CAPACITY BUILDING AND TRAINING

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Discussion Topics

1. Food Safety Modernization Act (FSMA) overview
2. FSMA regulations impacting imports
3. Impact on global trade
4. Where to go for help
Food Safety Modernization Act (FSMA)

“...the most sweeping reform of our food safety laws in more than 70 years...”

- FDA
Main Themes of the FSMA

- Prevention
- Inspections, Compliance, and Response
- Import Safety
- Enhanced Partnerships
FMSA Regulations Intended to Work as One

Preventive Controls
For Human Foods

Foreign Supplier
Verification

Intentional
Adulteration

Preventive Controls
For Animal Foods

Produce
Safety
Preventive Controls Rules

• **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**
  - “Preventive Controls for **Human Food**”

• **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Animal Food**
  - “Preventive Controls for **Animal Food**”
Key Requirements of Preventive Controls Rules

• A written **food safety plan**
  ▪ Hazard analysis
  ▪ Preventive controls
    o Monitoring
    o Corrective actions and corrections
    o Verification
  ▪ Supply-chain program
  ▪ Recall plan
  ▪ Associated records for all of the above, as appropriate
Who is Covered by the *Preventive Controls for Human Food Regulation*?

- Facilities that manufacture, process, pack or hold human food (§ 117.1)
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
  - Not farms or retail food establishments
- Applies to *domestic and imported* food
- Some exemptions and modified requirements apply
Produce Safety Rule - Key Requirements

• Minimum standards and testing protocols for agricultural water
• Standards for using raw manure or compost as soil amendments
• Requirements for sprouts production
• Address domesticated and wild animals in growing areas
• Worker training, health and hygiene
• Standards related to equipment, tools and buildings
Produce Safety Rule – Who is Covered?

- Farms* that grow, harvest, pack, or hold fresh produce (§ 112.3(c)), with exceptions
  - ≤ $25,000 annual produce sales
  - Commodities rarely eaten raw
  - Personal or on-farm use
  - Qualified end user
Intentional Adulteration Rule

• Establishes requirements to prevent or significantly minimize acts intended to cause wide-scale public health harm

• Uses a HACCP-type approach, with important differences from the Preventive Controls for Human Food rule
  ▪ Requires food defense plan and training

• Is risk-based and flexible
Intentional Adulteration – Who Is Covered?

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FSMA Import Structure
Programs Under Import Safety Phase 2 Workgroup

VQIP
Sec. 302: Allows for expedited review and entry; facility certification required (Sec. 806 of FD&C Act)

Accredited Third Party
Sec. 307: Accreditation of Third-Party Auditors / Certification Bodies to conduct food safety audits and to issue certifications (Sec. 808 of FD&C Act)

Import Certification
Sec. 303: Certification for high-risk food imports (Sec. 801(q) of FD&C Act)

Lab Accreditation
Sec. 202: Provides for recognition of laboratory accreditation bodies (Sec. 422 of FD&C Act)

FSVP
Sec. 301: Requires importers to develop, maintain and follow an FSVP for each food imported, unless an exemption applies (Sec. 805 of FD&C Act)

*Systems Recognition

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

Illinois Institute of Technology

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
Foreign Supplier Verification Program (FSVP) – Purpose

• To provide adequate assurances that:
  ▪ Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety provisions
  ▪ Food is not adulterated or misbranded (as it relates to allergen labeling)
Foreign Supplier Verification Program – Principles

• Requires **importers** to share responsibility for ensuring safety of imported food

• Risk-based (according to types of hazards, importers, and suppliers)

• Flexibility in meeting requirements (assessing activities conducted by others)

• Alignment with preventive controls supply-chain provisions
FSVP – Who Must Comply?

- “Importer” is U.S. owner or consignee of a food at time of U.S. entry.
- If no U.S. owner or consignee at entry, importer is U.S. agent or representative of the foreign owner or consignee, as confirmed in signed statement of consent.
FSMA Impact on Global Food Trade

• International food trade more complex
  ▪ Stricter record-keeping, verification/validation, recall coordination

• Likely to influence:
  ▪ Regulatory policy of U.S. trading partners
  ▪ CODEX decisions/standards

• Will drive increased compliance by suppliers

• Could drive more vertical integration among food companies

• Could negatively impact small entities that are unable to comply with foundational rules
Where to Go for Help

FSPCA Website: https://www.ifsh.iit.edu/fspca
Why FSPCA?

- The *FSPCA Preventive Controls for Human Food* course is the “standardized curriculum” recognized by FDA
- Training is one means to become “Preventive Controls Qualified Individual” required by PC Rules
- Training conducted in the U.S. and Internationally
FSPCA Delivery Model

Trainers-of-Trainers (ToTs) train Lead Instructors

Lead Instructors train Participants

Participants meet training requirements for PC Qualified Individual
FSPCA Training Metrics*

<table>
<thead>
<tr>
<th></th>
<th>Human Food</th>
<th>Animal Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certificates issued</td>
<td>~19,500</td>
<td>~906</td>
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<tr>
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<td>3100</td>
<td>18</td>
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<tr>
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<td>~33</td>
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<td>Upcoming courses scheduled</td>
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*As of 9/9/16
FSPCA Metrics (Human Foods)
Instructor and Candidates Distribution – Example

Example of GeoMap for Lead Instructors and Lead Instructor Candidates

LI Candidates are red  LI’s are represented by heat circles
FSPCA Flyers

- Domestic
- International
  - Multiple languages

FSPCA Domestic One Page Flyer (pdf)
FSPCA International One Page Flyer (pdf)
FSPCA Community Overview

- Interactive web community
- Technical Assistance
- Resources
- Lead Instructor Support

https://fspca.force.com/FSPCA/s/
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
FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

Featured Announcements

What to Expect Now that the First Big FSMA Compliance Dates Are Here
September 19, 2016

FDA Provides $21.8 Million to States for Produce Safety
September 9, 2016

FSPCA Home

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of key industry, academic and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training and outreach programs to assist companies producing human and animal food in complying with the preventive controls regulations that will be part of the Food Safety Modernization Act (FSMA).

Training
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)
https://www.ifsh.iit.edu/fspca Evaluation Resources

The Alliance
Committees, Subcommittees, Working Groups

Quick Links
FSPCA Trainers of Trainers for Human Food
FSPCA Trainers of Trainers for Animal Food
Apply to Become a Lead Instructor
FSPCA Lead Instructor Listing
FSPCA Advertising Recommendations for Lead Instructors
FSPCA Human Food Bookstore
FSPCA Animal Food Bookstore
FSPCA Materials

Questions

If you have any questions, please contact the FSPCA at

fspca@iit.edu

or or visit the FSPCA website at

http://www.iit.edu/ifsh/alliance

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

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THANK YOU!

Robert E. Brackett, Ph.D.
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