

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

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Regulatory Challenges in a Globalized World



- Greater volume of imported products
- Greater number of foreign facilities supplying the United States
- Increased complexity of products, manufacturing methods and supply chains
- Greater opportunities for economic fraud
- Data/information gaps
- Continued migration of research & development, clinical trials & manufacturing outside U.S. borders

Other Challenges in a Globalized World



- Strategic and efficient use of limited resources and better leveraging of external resources
- Creating harmonized standards
- Some regulatory counterparts have an economic promotion mission that may conflict with FDA's public health mission
- Cultural / linguistic / national differences

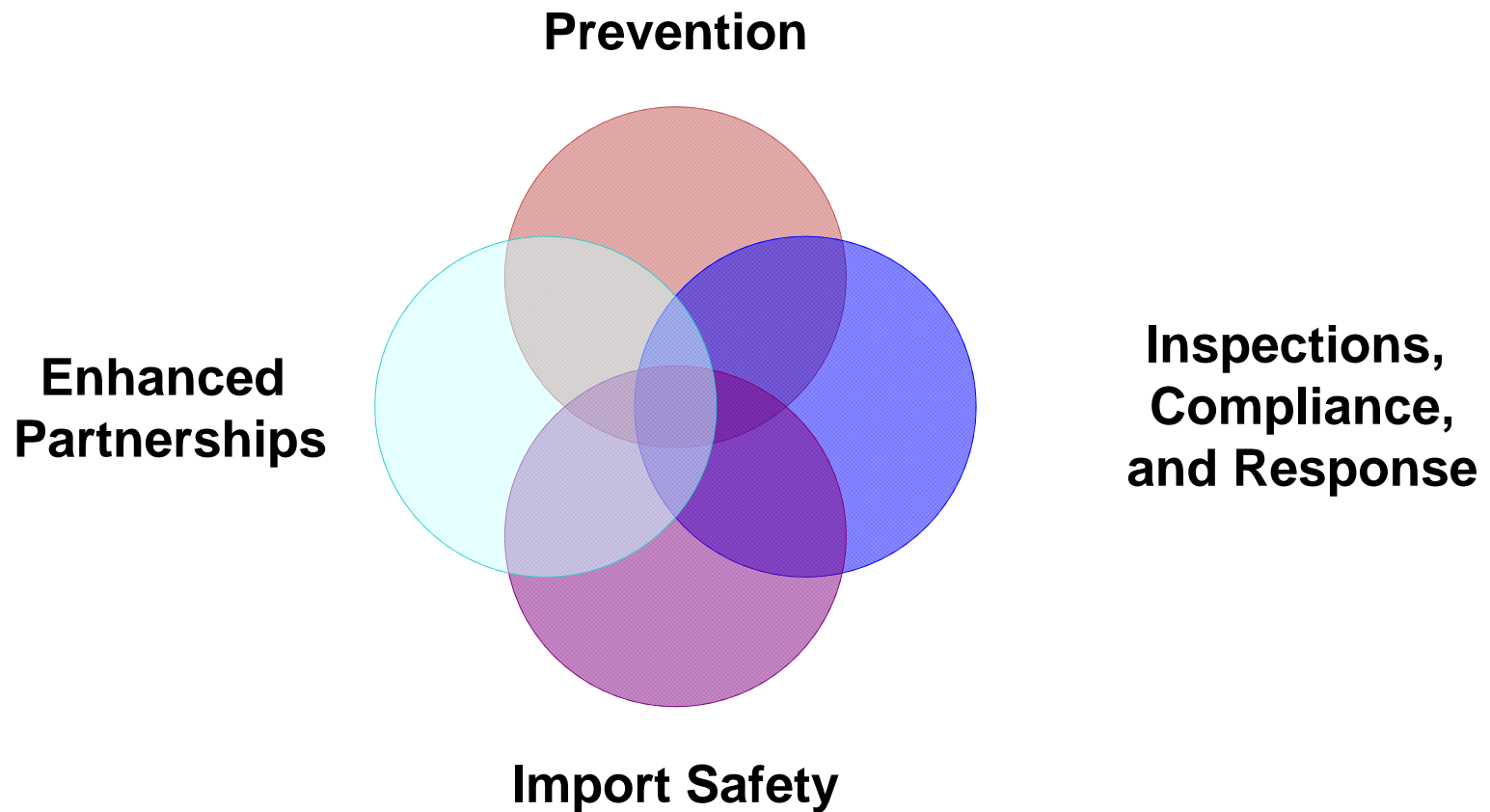


Food Safety Modernization Act

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

Food Safety Modernization Act

FSMA's Main Themes





Seven Foundational Final Rules

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

Compliance Dates



- Compliance arrived (large producers):
 - PC Human and modernized CGMPs – September 2016
 - PC Animal CGMPs – September 2016
 - Produce Safety: Sprouts – January 2017
 - Sanitary Transportation – April 2017
 - Foreign Supplier Verification – May 2017
- Compliance approaching:
 - PC Animal – September 2017
 - Produce Safety – January 2018

Inspections, Compliance, and Enforcement



- Key Principles:
 - Focus on gaining industry compliance and reducing the risk of foodborne illness
 - Not a “One Size Fits All” approach
 - Recognition that not all situations are equal relative to risk and potential for public health impact
 - Interactive, cooperative inspections
 - Encourage industry to comply and make corrections on its own
 - Regulatory strategy that is dynamic



Import Safety:

FSMA's most ground-breaking shift

- U.S. *importers* now responsible for ensuring that their *foreign suppliers* meet U.S. safety standards
- Can require mandatory certification for *in certain limited circumstances*
- Voluntary qualified importer program (*VQIP*)
 - expedited review
- Can deny entry if FDA *access for inspection* is denied
- *Requires food from abroad to be as safe as domestic*



FSMA – Section 305

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

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

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm301708.htm>

International Communications and Engagement



- Overarching Goal
 - Support high rates of compliance with new FSMA rules
- Purpose
 - Support the overarching goal by addressing a continuum of information needs of international stakeholders

International Communications and Engagement



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

International Communications and Engagement



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

International Communications and Engagement: ALLIANCES



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

International Communications and Engagement: FSPCA



- Food Safety Preventive Controls Alliance (FSPCA)
 - IIT Alliance homepage: fspca.net
 - FSPCA Community, an interactive portal where users can ask questions of Alliance Food Safety Experts (FSEs), find a list of Lead Instructor (LI) trainers, and locate technical resources:
https://fspca.force.com/FSPCA/s/?language=en_US
- Alliance outreach goals and objectives aim to:
 - increase industry awareness;
 - identify and develop relevant technical information and educational resources;
 - establish a network of FSPCA FSEs; and
 - ensure opportunities and educational materials are available.

International Communications and Engagement: FSPCA



- Why seek FSPCA training?
 - The two Preventive Controls rules require registered facilities that manufacture, process, pack or hold human or animal food have one or more “Preventive Controls Qualified Individuals(PCQI)”.
- How to find an FSPCA Participant Course:
 - https://fspca.force.com/FSPCA/s/courselist?language=en_US
- How to become an FSPCA Lead Instructor:
 - https://fspca.force.com/FSPCA/s/li-public-guidance?language=en_US



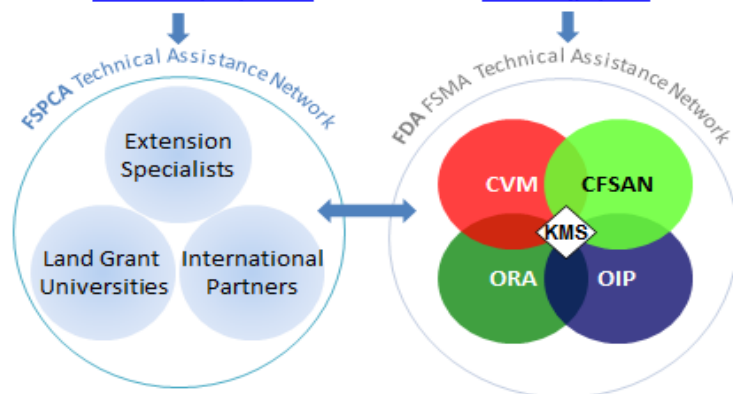
FSMA Technical Assistance Networks

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

FSMA Technical Assistance Networks

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

FSMA Regulation & Policy Interpretation Questions – submit a web form at: www.fda.gov/fsma



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The screenshot shows the FDA website's 'Food Safety Modernization Act (FSMA)' page. The header includes the FDA logo and the text 'U.S. Food and Drug Administration Protecting and Promoting Your Health'. A search bar is visible. The main navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The 'Food' section is selected, leading to a page titled 'Contact FDA About FSMA'. This page includes a 'Submit Inquiry' button and a list of links: 'The Law, Rules & Guidance', 'How to Comment on FSMA', 'Fact Sheets & Presentations', 'Frequently Asked Questions', 'FDA Actions to Date', 'FSMA Training', and 'Contact FDA About FSMA'. A sidebar on the right provides contact information for the Food and Drug Administration, including the address: 5100 Paint Branch Pkwy, Wiley Building, HFS-009, College Park, MD 20740.