



**Asia-Pacific  
Economic Cooperation**

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## **Development and Implementation of Food Safety Modernization Act**

Submitted by: United States



**Second Expert Meeting on Trade  
Facilitation Through an APEC Framework  
on Food Safety Modernisation  
Port Moresby, Papua New Guinea  
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# Development and Implementation of Food Safety Modernization Act (FSMA)



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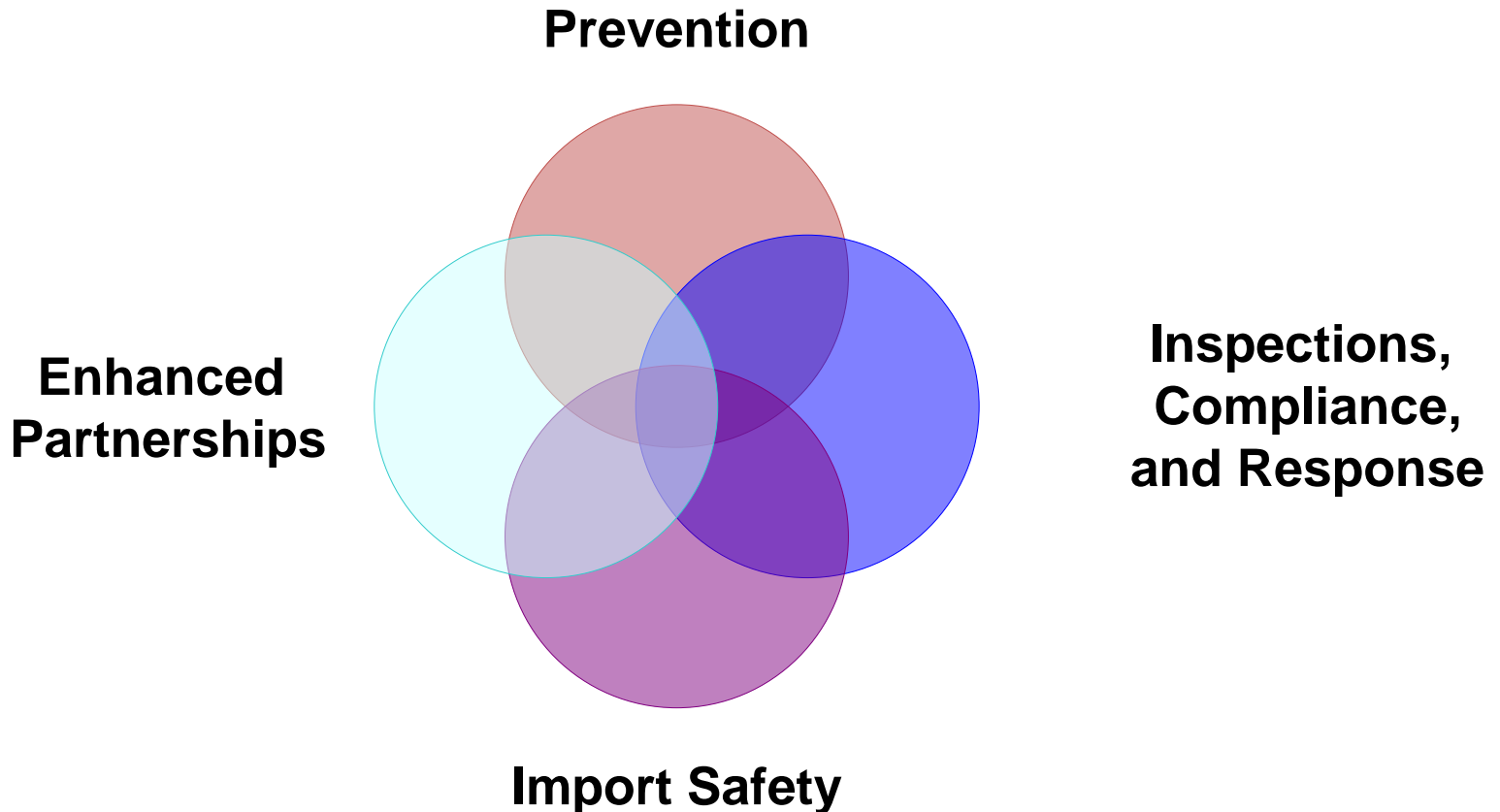
# Food Safety Modernization Act

- **In our increasingly globalized world, we face a host of regulatory challenges.**
- **The FDA Food Safety Modernization Act (FSMA) was drafted, and became law in 2011.**
  - Most sweeping reform of FDA's food safety authority in more than 70 years.

# Food Safety Modernization Act



## FSMA's Main Themes



# Import Safety:



- U.S. *importers* now responsible for ensuring that their *foreign suppliers* meet U.S. safety standards
- **FSMA DOES NOT MANDATE CERTIFICATION FOR IMPORTED FOODS**
- 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*

# 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



<u>Rule</u>	<u>Effective Date</u>
1. Preventive Controls for Human Food	2016 – Sept.
2. Preventive Controls for Animal Food	2016 – Sept.
3. Produce Safety	2018 – Jan.
4. Foreign Supplier Verification Program	2017 – May
5. Accredited Third-Party Certification	N/A
6. Sanitary Transportation	2017 – April
7. Intentional Adulteration (Human Food)	2019 – July

\* *Compliance deadlines for businesses with more than 500 full-time equivalent (FTE) employees.*

# Compliance Tool:

## FDA Issues Guidance to Assist Industry

- Guidance documents represent FDA's current thinking on a topic.
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- They do not create or confer any legally enforceable rights or responsibilities and do not legally bind FDA or the public.
- These documents often discuss issues that relate to the design, production, labeling, promotion, manufacturing, and testing of regulated products.



# FSMA – Section 305

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

- **Directs FDA to:**

...develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries, from which foods are exported to the United States.

- **FDA’s Capacity Building Plan – Element 4**

Train foreign governments and food producers on US requirements for safe food.

# International Communications and Engagement



- **Use of Regulatory Tools:** Bilateral and multilateral agreements
- **Partnerships:** STDF, FAO, APEC, GFSP, WHO, Academia
- **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

## Engagement: ALLIANCES

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



# FSMA Technical Assistance Networks

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

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## WELCOME TO THE FSPCA TECHNICAL ASSISTANCE NETWORK

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

### PREVENTIVE CONTROLS QUESTION

FEATURED DISCUSSIONS

HUMAN FOOD FOREIGN SUPPLIER VERIFICATION PROGRAM ANIMAL FOOD

#### TRENDING ARTICLES

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

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### Food Safety Modernization Act (FSMA)

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### Contact FDA About FSMA

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You may contact FDA about FSMA by submitting an inquiry form.

The modified form is designed to facilitate questions that are specific to FSMA and its implementation. Your use of the form will provide the FSMA Technical Assistance Network with the information needed to give accurate and timely responses and to improve our customer service. We hope you find our online form useful in identifying the specific nature of your inquiry and we remain open to suggestions about improving the form to meet your needs.

**Submit Inquiry**

You may also mail your question to the address below:

Food and Drug Administration  
5100 Paint Branch Pkwy  
Wiley Building, HFS-009  
Attn: FSMA Outreach  
College Park, MD 20740

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**We welcome your questions!**

**Please encourage your agencies,  
companies, associations and  
consumers to send their questions to  
one of the Technical Assistance  
Networks**

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# Implementation Principles/Continual learning

- Performance monitoring to measure effectiveness/course correct as needed
- Foodborne disease surveillance and laboratory capacity informs activities priorities (e.g., foods intended to be cooked but eaten raw/cookie dough, STEC in cookie dough, listeria in ice cream)
- Proactive Initiatives (e.g., contaminants)
- Forecasting: How we use “big data”
- Educate while we regulate

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THANK YOU!

