

# Welcome

## OnTrak with FSMA: A Webinar Series

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*Today's Presentation:*

# FSMA Finalizes FSVP & 3rd Party Auditor Rules: What You'll Need



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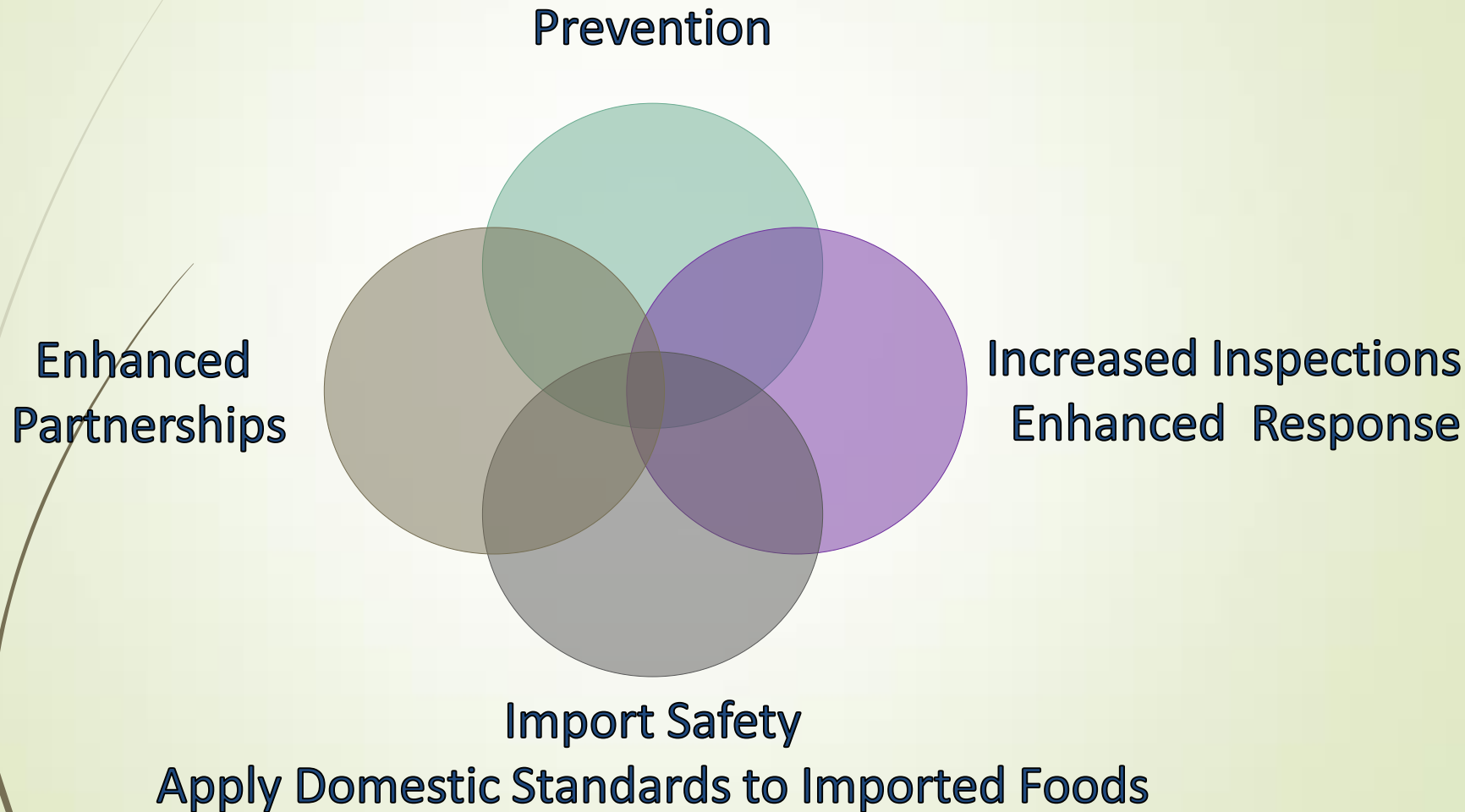
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# Overview



- FSMA Rules Review
- **Foreign Supplier Verification Program**
- Definition of an Importer
- Who has to comply with FSVP?
- Requirements and Implementation
- **Accredited Third Party Certification**
- When does this apply?
- Procedures and Records
- Summary

# Food Safety Modernization Act (FSMA)



# The Seven Pillars of Prevention

- Preventive controls for human food
- Preventive controls for animal food
- Produce safety
- Foreign supplier verification
- Third party auditor
- Intentional Adulteration
- Sanitary Transport



# FSMA Status Summary - “The 7 Pillars”

Proposed Rule	Final Deadline	Published
PC- Human Food-Final	September 17, 2015	✓
PC- Animal Food-Final	September 17, 2015	✓
Produce Safety	October 31, 2015	✓
FSVP	October 31, 2015	✓
Third Party Accreditation	October 31, 2015	✓
Sanitary Transport	March 31, 2016	
Food Defense	May 31, 2016	

## Foreign Supplier Verification Program

- ▶ Intent – Imported foods must be produced in compliance with the preventive controls and produce safety rules, not be adulterated or mislabeled
- ▶ Importers must develop, maintain and follow a FSVP
- ▶ Importer definition different than Customs and Border Patrol (CBP) importer definition



## Importer: Definition

- The US owner or consignee of an article of food that is being offered for import into the US. If there is no US owner or consignee of an article of food at the time of US entry, the importer is the US 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.





# Who has to comply with FSVP?

- All FDA regulated product with the exception of:
  - Seafood (due to seafood HACCP regs)
  - Juice (due to juice HACCP regs)
  - Foods for research or evaluation
  - Foods for personal consumption
  - Transshipped foods
  - USDA regulated foods
  - Small importers have modified requirements
    - \$1 million/year is the threshold



# Requirements

- Qualified Individual develops FSVP and performs FSVP activities
- Hazard Analysis
  - Known or reasonably foreseeable hazards in each food – biological, chemical and physical
- Evaluation of risk based on history and other factors
- Verification activities
  - Use of approved foreign suppliers – written procedures
  - Onsite audits
  - Food safety records
  - Sampling and testing



## What about GFSI?

“We agree that audits conducted to meet FSVP requirements should be held to the same standards as audits performed domestically for the purpose of supplier verification. To the extent that the results of GFSI, GAP, or any other audit schemes appropriately verify that the foreign supplier produces the food consistent with FDA food safety standards, importers may use audits conducted under those schemes to meet the requirements of the FSVP regulation.”

*Page 74288 FR Nov 27, 2015*



## Documentation

- Records can be original, copies or electronic
- Sign and date
- Available to FDA upon request
- May be in other languages but must be able to translate upon request
- Retain for 2 years



## FSVP Implementation

- 18 months after publication of the final rule
- For suppliers subject to preventive controls or produce safety, the compliance date is 6 months after the compliance date for the establishment to comply with the respective rule



# Accredited Third Party Certification

- Completely separate program from FSVP
  - Followed the same timeline
  - Very narrow coverage
- Congress gave FDA the authority to accredit auditors for foreign inspections in specific circumstances



# When does 3<sup>rd</sup> Party Certification Apply?

1. Food with a high risk profile
  - Mandatory Import Certification



2. Voluntary Qualified Importer Program



## 3<sup>rd</sup> Party Certification Program

- Establishes the legal authority, competency, capacity, conflict of interest safeguards, quality assurance and records procedures for the third party audit accreditation/certification program





## Who may seek accreditation from FDA?

- Foreign governments
- Agency of a foreign government
- Foreign cooperative
- Any other third party



# Audits

## ➤ Consultative Audit

- Preparation for an official audit

## ➤ Regulatory Audit

- Official audit by a certification body or an accredited auditor
  - Specific requirements for audits
  - ISO requirements for documentation, testing laboratories
  - Audits
    - Documentation conforming to ISO/IEC 17021:2011 or ISO/IEC 17065:2012
- Specific documentation and record keeping requirements are outlined in the rule



## Summary

- FSVP and Third Party Certification are separate programs
- FSVP is very broad and will impact many food companies who import
- Intent is to make sure imported foods meets the PC and produce safety rules
- Responsibility is on importer to verify
- Third party certification limited to mandatory import certification and VQIP, narrow in scope

# Thank You! - Questions??

*For more information...*

- <http://repositrak.com/>
- <http://achesongroup.com/>
- <http://www.fmi.org/>
- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>