



# **FOOD SAFETY MODERNIZATION ACT (FSMA) NEW FOOD SAFETY PERSPECTIVES !!**

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# Why FSMA?

- About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention.
- The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, enables FDA to better protect public health by strengthening the food safety system.
- It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur.
- The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur.

# *Important changes under FSMA:*

- **Prevention:** For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. This mandate includes:
  - **Mandatory preventive controls for food facilities**
  - **Mandatory produce safety standards**
  - **Authority to prevent intentional contamination**
  - **Inspection and Compliance** including:
    - **Mandated inspection frequency:** The FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately.
    - **Records access:** FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.
  - **Testing by accredited laboratories**



- **Mandatory recall:** The FSMA provides FDA with authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked to by FDA.
- **Expanded administrative detention:** The FSMA provides FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure FDA uses to keep suspect food from being moved).
- **Suspension of registration:** FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death.
- **Additional Recordkeeping for High Risk Foods**
- **Importer accountability:** For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.
- **Third Party Certification:** The FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports.

# HACCP Vs. HARPC

## HACCP

- Worldwide standard
- Applies to a wide variety of food products
- Focus on control steps
- Requires qualified team

## HARPC

- US standard
- Applies to FDA regulated products
- Preventive programs
- Needs qualified individual

# HACCP Vs. HARPC Compliance

## HACCP

- Voluntary across most food industry
- Mandatory for certain foods like seafood, juice, meat and poultry

## HARPC

- Mandatory for all facilities requiring FDA registration
- Exemptions for FDA mandatory HACCP programs

# Implementation Executive Committee

Strategic  
Communications  
& Outreach Team –  
*Sharon Notofblut*

**Prevention Standards**  
*Don Kraemer*

Produce Safety Regulation

Produce Safety Guidance

Preventive Controls Regulation

Preventive Controls Guidance

Safe Food Transport

Food Defense

Contaminants

**Inspection & Compliance**  
*Barbara Cassens*

Mandatory Recall / Recall Communications

Administrative Enforcement Tools

Registration

Frequency of Inspection

Manner of Inspection / Food Safety Plan Review

Tracing

RFR Improvements

**Imports**  
*Roberta Wagner*

Importer Verification & VQIP

Import Certification

Accredited Third-Party Certification

Lab Accreditation & Integrated Consortium / FERN

International Capacity Building

Comparability

Task A: Prior Notice

**Federal/State Integration**  
*Joe Reardon*

Operational Partnership

Capacity Building

Training

**Fees**  
*Roxanne Schweitzer*

Inspection & Auditor Fees

**Reports & Studies**  
*David Dorsey*

Reports to Congress / Studies

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