



# Food Safety Modernization Act (FSMA): Industry perspective

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# Agenda

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- Company Overview
- Food Safety Modernization Act (FSMA) overview
- Major elements of the law
- Preventive Controls
- Inspection and Compliance
- Imported Food Safety
- Implementation Activity
- Key Focus Areas
- Questions

# Abbott at a Glance

Market Leading  
PHARMACEUTICALS

Advanced  
MEDICAL PRODUCTS

Trusted  
NUTRITIONAL PRODUCTS



# Nutrition is our *Expertise...*and our *Business*

- Pediatric nutrition
- Performance nutrition & nutritious snacks
- Therapeutic nutrition



# Global reach

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- 100+ facilities
- 130+ countries
- 83,000 employees
- Headquarters: North Suburban Chicago, Illinois, U.S.A.



# Food Safety Modernization Act Overview

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## What is it?

- The FDA Food Safety Modernization Act (FSMA) is a U.S. federal statute signed into law by President Obama on January 4, 2011.
- It is the most significant update of American food safety laws since the Federal Food, Drug and Cosmetic Act of 1938.

### Old Law

- Reactive
- U.S.-centric
- Focused toward on-market products

### New Law

- Proactive
- Global Implications
- More **PROCESS/PREVENTION** oriented
  - Early identification of risk
  - Supplier emphasis
  - Increased communication

# FSMA overview

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**“...requires the agency to build a new food safety system. This new system will better leverage the resources of federal agencies and it will make industry a major partner in safeguarding the health of U.S. consumers.”**

**Michael R. Taylor**  
**FDA Deputy Commissioner for Foods**

# FSMA overview

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**“The future ain't what it used to be.”**

**Yogi Berra**  
**Baseball Hall of Famer**

# 5 Major elements of the law

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## Preventive controls

- For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply.

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## Inspection and Compliance

- The legislation recognizes that inspection is an important means of holding industry accountable for its responsibility to produce safe food.

## 5 Major elements of the law

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### Imported Food Safety

- FDA has new tools to ensure that those imported foods meet US standards and are safe for our consumers.
- Importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety.
- FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards.

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### Response

- FDA will have mandatory recall authority for all food products.
- FDA expects that it will only need to invoke this authority infrequently since the food industry largely honors our requests for voluntary recalls.

# 5 Major elements of the law

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## Enhanced Partnerships

- The legislation recognizes the importance of strengthening existing collaboration among all food safety agencies: U.S. federal, state, local, territorial, tribal and foreign..

# Preventive Controls

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## Food Safety Plans

- Each registered facility is required to conduct a hazard analysis then implement and maintain a preventative control plan.
- Identify the hazards, identify and implement preventive controls; and then monitor to make certain that the controls work.

# Preventive Controls

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## Preventive Controls...

- ...shall identify and implement controls, including critical control points
- ...assure that hazards identified will be significantly minimized or prevented
- ...risk-based, appropriate procedures, practices and processes that are employed to significantly minimize or prevent hazards identified and that are consistent with current scientific understanding of safe food manufacturing, processing, packing or holding at the time of analysis
- ...***assure that food will not be adulterated***

# Preventive Controls

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Preventive Controls includes:

- Sanitation
- Training
- Environmental Monitoring
- Food Allergen Controls
- Recall Plan
- GMPs
- Supplier Verification

# Preventive Controls

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## Requirement to Reanalyze and Revise Plan

- Must conduct a plan reanalysis whenever a significant change in activity occurs
- Required to Reanalyze **Not less frequently** than once every 3 years

# Inspection and Compliance

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- **Suspension of Facility Registration:** If there is a “reasonable probability of causing serious adverse health consequences or death”
- **Mandatory Recall:** Same standard as for registration suspension
- **Administrative Detention:** ....“reason to believe” that a product is adulterated or misbranded
- **Record Access:** Expands accessibility to virtually all records related to the quality system and production of product

# Inspection and Compliance

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- **New Fees:** Re-inspection costs, mandatory recalls
- **Facility Registration:** Biennial process but no registration fees
- **Inspection Frequency:** Expected to increase among the food industry
- **Sanitary Transportation Practices:** Requires FDA to issue regulations for previously existing statutory provisions
- **Improving the Reportable Food Registry (RFR):** Adding specific product information to registry and potential posting of information

# Imported Food Safety

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## Imports

- Import certificates: FDA may require import certificates as a condition of granting admission
- Foreign Supplier Verification Program: importers must ensure product complies with US requirements, such as food safety preventative control plans

## Laboratory Accreditation

- FDA to develop model standards for accreditation and criteria for recognition of accreditation bodies; certain tests will need to be conducted by accredited labs

**U.S. consumers enjoy the benefit of imported foods from more than 150 countries.**

# Imported Food Safety

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## **Third Party Certification:**

- Development of model standards and recognition of accreditation bodies

## **Voluntary Qualified Importer Program (VQIP)**

- The new law directs FDA to issue guidance on participation in and compliance with VQIP.

**FDA now has the authority to refuse entry into the US of a food that has refused U.S. inspection.**

# Implementation Activity

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## **Cross functional group assessing impact and driving implementation**

- Quality, Regulatory, R&D, Manufacturing, Legal, and Government Affairs

## **Plant teams established**

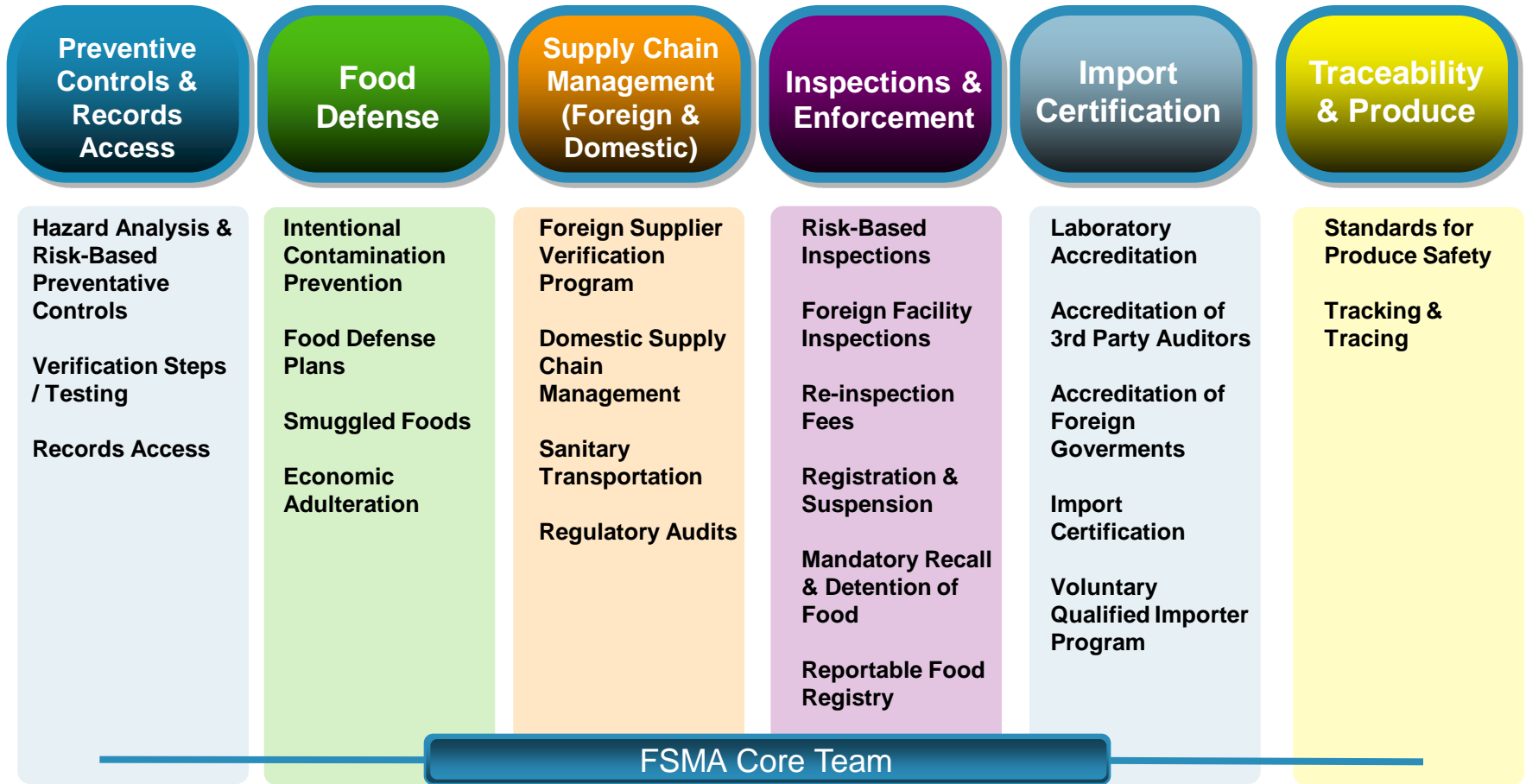
- Cross functional, multi-shift

## **Monitoring and engaged in rule making process**

- Directly with FDA as necessary
- Through Non Government Organizations (NGO) and trade associations

# Implementation Activity

## Food Safety Modernization Activity



# Implementation Activity

## Integrated Food Safety Program

HACCP  
and SQF

Design  
for Safety

Food  
Defense

Cleaning &  
Sanitation

Pest  
Control

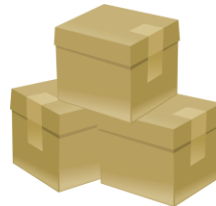
RFR

Micro

Allergens

Map Division SOPs to:

- Sites
- Warehouses
- TPMs



# Key Focus Areas

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Two categories within the Act where focused work is critical:

- Development of comprehensive **Food Safety Plans** at each registered facility
  - Sanitation
  - Training
  - Environmental Monitoring
  - Food Allergen Controls
  - Recall Plan
  - GMPs
  - Supplier Verification
- Robust **Supplier Verification Program**
  - Assure suppliers meet U.S. food safety law
  - Allows for risk-based approach

# Questions?

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# Thank You!

