FSMA Implementation
“A Continuum”

• **Phase 1:** Set Standards
  – Develop regulations, guidance, policy

• **Phase 2:** Design Strategies to Promote and Oversee Industry Compliance
  – Identify performance metrics to measure success

• **Phase 3:** Implement, Monitor, Evaluate, Refresh
  – Transition strategies and performance metrics from design to operational, evaluate success
## Phase 1: Standard Setting

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Supplemental proposals published September 2014

Final rule publication date
Phase 2: Design Strategies to Promote and Oversee Industry Compliance

Develop a framework and multi-year implementation plan for ensuring compliance with regulations:

– Education, outreach and technical assistance for industry
  • Alliances
– Training/technical assistance for regulators
– Data collection, analysis, updated IT
– Performance goals and metrics
– Inspections, compliance and enforcement
Phase 3
Key Implementation Principles

Regulatory Strategy

• Gain high rates of industry compliance, reduce the risk of foodborne illness
• Encourage industry to voluntarily comply and make corrections on its own
• Regulatory strategy that is dynamic
• Not a “one size fits all” approach
Key Implementation Principles

Regulatory Strategy

• Develop/implement explicit inspection and enforcement strategies that facilitate *consistent* decision-making by regulators
• Systems-based inspections, not “observation focused”
• Recognition that not all observations are equal relative to risk and potential for Public Health Impact
• Rank violations according to Public Health Impact
  – Minor, major, critical to inform the classification (NAI, VAI, OAI), follow-up verification activities and timing for these activities, work planning
• Interactive, cooperative inspections
Compliance dates by business size

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Produce Safety Rule
Education, Technical Assistance and Training

• Objectives
  – Facilitate compliance through standardized, education-focused regulatory inspections using farm inspection reports that include guidance and educational references
    • Educate before and while we regulate
  – Collect and evaluate inspection data to identify regional trends for targeted outreach, education, research, and work plan prioritization
  – Develop relationships between produce farmers and local FDA Produce Safety Network staff & regulatory partners
  – Initiate legal action as needed to protect public health
Produce Safety Rule

Inspections

• Collaborating with NASDA to develop a consistent and flexible approach that can be implemented by State regulators and FDA
  – Routine on-farm inspections will be conducted by State regulators, as funding permits
  – Leverage with private-public third party audit system, where possible
  – FDA may do inspections in States that choose not to conduct produce inspections; FDA Specialized Produce Safety Cadre would conduct such domestic inspections and foreign inspections
Produce Safety Regulation Compliance Dates

**Publication of Final Rule**
- Nov 27, 2015
- Effective Jan 26, 2016

**Sprouts - All Others**
- All Provisions
- Jan 26, 2017

**Sprouts - Very Small**
- All Provisions
- Jan 26, 2019

**Farms - Small**
- Except Water *
- Jan 26, 2021

**Farms - Small**
- All Provisions
- Jan 26, 2022

**Full Implementation & Transition to Operational Mode**
- 2022

**Sprouts - Small**
- All Provisions
- Jan 26, 2018

**Farms - Very Small**
- Except Water *
- Jan 26, 2020

**Farms - All Others**
- Except Water *
- Jan 26, 2022

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* Only applies to certain water requirements
Small Businesses – average produce sales over 3 years > $250,000 and ≤ $500,000
Very Small Businesses – average produce sales over 3 years > $25,000 and ≤ $250,000
≤ $25,000 in average produce sales over 3 years is not a covered farm
FDA’s Produce Safety Network

Roles and Responsibilities

• Technical assistance
• Outreach and training
• Work planning
• Outbreak investigations
• Inspections (*particularly foreign*)
• Enforcement
Preventive Controls: Human and Animal Food

- Covered facilities must establish and implement a food safety system that includes analysis of hazards and risk-based preventive controls
- Covered facilities must establish a recall plan
- Clarifies definition of a farm
- Supply-chain program
- Current Good Manufacturing Practices (CGMPs) are updated and clarified for human food
- CGMPs established for animal food production
Import Provisions

**VQIP**
Sec. 302: Allows for expedited review and entry; facility certification required (Sec. 806 of FD&C Act)

**Accredited Third Party**
Sec. 307: Accreditation of Third-Party Auditors / Certification Bodies to conduct food safety audits and to issue certifications (Sec. 808 of FD&C Act)

**Import Certification**
Sec. 303: Certification for high-risk food imports (Sec. 801(q) of FD&C Act)

**Lab Accreditation**
Sec. 202: Provides for recognition of laboratory accreditation bodies (Sec. 422 of FD&C Act)

**FSVP**
Sec. 301: Requires importers to develop, maintain and follow an FSVP for each food imported, unless an exemption applies (Sec. 805 of FD&C Act)

***Systems Recognition**
Intentional Adulteration

- Update and add to existing intentional adulteration guidance and technical assistance documents already available
- Recognize the need to establish training programs for both regulators and industry
- Inspection must be tailored to the unique challenges of food defense
- Establish an efficient and effective system, potentially leveraging resources being used to conduct food safety inspections
Sanitary Transportation

Shippers, carriers by motor vehicle and rail vehicle, loaders and receivers engaged in the transportation of covered food, including food for animals, must use sanitary transportation practices to ensure the safety of the food they transport.

• Principal types of foods covered:
  • Foods transported in bulk, e.g., animal feed
  • Packaged foods not fully enclosed by a container, e.g., fresh produce
  • Foods that require temperature control for safety

• Compliance dates:
  • April 2018 for small businesses, April 2017 for all other businesses
FDA FSMA Technical Assistance Network

• Recent Process Improvements:
  – Administrators have system licenses
  – Summary TAN reports posted on web
  – Auto-responses after 30/60 days
  – Internal access database for all cleared TAN responses
Integrated Food Safety System (IFSS)

• Partnership for Food Protection (PFP)
• FDA Office of Partnerships funding of States
• MFRPS (Manufactured Food Regulatory Program Standards)
• AFRPS (Animal Feed Regulatory Program Standards)
• Voluntary Retail Food Regulatory Program Standards
• Laboratories
• NASDA
  – Produce Model Implementation Framework
IFSS Success

• Updated food safety laws (FSMA)
• Standardized regulatory programs
• Increased resources
• Strategic plan developed
• Coordination of operations and activities
• Updates to data systems to allow sharing
• New disclosure mechanisms for sharing data and information
Questions?