

# FSMA Update

## Where We've Been, Where We're Going ?

Lydia Johnson 4/2/15

# FSMA

- From the State perspective this is some of the information being shared with the States.

# FMISA

## TOPICS

- **Guiding FSMA Implementation**
  - Program Alignment Initiative
  - FSMA Operational Strategy
- **FSMA Implementation in Phases**
- **Stakeholder Engagement Remains a Priority**
- **President's FY2016 Budget Proposal for FSMA Implementation**

# FSMA

- **Program Alignment Initiative Announced in February 2014 Memo from the Commissioner**
  - **Vertically Integrated, Commodity Specific Programs**
  - **Specialization of Inspection/Compliance Staff, Regulatory Labs**
  - **Clear, Current, Consistently Applied Technical/Operational Policy**
  - **Clear Roles, Responsibilities, Streamlined Decision Making**
  - **Risk Based Allocation of Program Resources**
  - **Agreed Upon Performance/Public Health Metrics**

# FSMA

**Program Alignment will set the Agency  
up for Successful FSMA Implementation**

# FSMA

## FSMA Implementation is a Continuum

# FSMA

## **Phase 1: Set standards**

**Develop regulations, guidance, protocols for new administrative enforcement tools**

## **Phase 2: Implement standards**

**Design strategies to implement standards  
Fully develop and implement the standards**

## **Phase 3: Monitor, evaluate, refresh**

# FSMA

## Phase 1: Standard Setting



# FSMA

<b>Regulation</b>	<b>Proposal</b>	<b>Final (consent decree)</b>
• <b>Preventive Controls (Human Food)*</b>	<b>Jan 16, 2013</b>	<b>Aug 30, 2015</b>
• <b>Preventive Controls (Animal Food)*</b>	<b>Oct 29, 2013</b>	<b>Aug 30, 2015</b>
• <b>Produce Safety*</b>	<b>Jan 16, 2013</b>	<b>Oct 31, 2015</b>
• <b>Foreign Supplier Verification Program*</b>	<b>Jul 29, 2013</b>	<b>Oct 31, 2015</b>
• <b>Third Party Accreditation</b>	<b>Jul 29, 2013</b>	<b>Oct 31, 2015</b>
• <b>Sanitary Transport</b>	<b>Feb 5, 2014</b>	<b>Mar 31, 2016</b>

# FSMA

## Phase 2: Workgroups Charge

# FSMA

- **Develop a framework and multi-year implementation plan for ensuring compliance with regulations:**
  - **Education, outreach and technical assistance for industry**
    - **Alliances**
  - **Training for regulators**
  - **Data collection, analysis, updated IT**
  - **Performance goals and metrics**
  - **Inspections, compliance and enforcement**

# FSMA

- **FDA will speak with one voice**
- **Inspection, compliance functions specialized**
- *Investigators and subject matter experts work together to drive correction of problems*
- *Invest in regulator training to promote consistent inspections, decision making*

# FSMA

- **FY2015 PC Rule Readiness Training**
- **PC Rule Readiness FSMA Chats**
  - Typically Third Thursday of the Month
  - **Speakers: Academia, Industry and Government**
  - **State Participation; Webinars Limited to 1000 Lines**
  - **Recordings of FSMA Chats posted on Food Shield & FDA Intranet**
- **Tentative Schedule**
  - **March 19:** Food Safety Culture Series (5 Webinars)
  - **May 21:** Environmental Monitoring: Industry Best Practices
  - **June 18:** Supply Chain Management: Industry Best Practices
  - **July 16:** Minimizing Allergen Risks: Industry Best Practices

# FSMA

- **FY2015 PC Rules Regulator Training**

**FY2015:** Develop PC Rule Regulatory Curriculum Centrally  
State Involvement; PFP to Provide State Representatives

**FY2015 – FY2016:** Complete Pre-requisite Training/FSPCA  
Industry Training

**FY2016:** Deliver PC Rule Regulatory Training/Training Hubs

**What:** Human Food: GMPs/PC; Animal Food: GMPs Followed by  
PC?

**How:** TTT/Training Cadre; Criteria for Inclusion; Pre-requisite  
Training; Periodic “Evaluation” of Trainers

**Who:** Federal/State Investigators/Inspectors/Food Safety Staff  
Performing Food Inspections in FDA/States Under Contract

**Where:** Nationwide Based on Location of Large Firms

# FSMA

## How FDA Will Operate Differently:

- **Robust data integration, analysis and information sharing**
- **Public health metrics**
- **Work closely with government counterparts and other food safety system stakeholders**

## Educate Before regulate:

- **Facilitate industry implementation of modern, preventive practices through:**
  - **Commodity and sector-specific guidance**
  - **Education, outreach and technical assistance**
  - **Regulatory incentives for compliance**

# FSMA

- **PC Inspection Program “Must Haves”**
  - **Federal/State Food Safety Staff Train Together**
  - **Multi-Year Work Planning Prioritization/Planning**
  - **Integrated Strategy for Federal/State Inspections**
  - **Integrated Data Collection Strategy/Structured Data**
  - **Explicit Compliance Strategy; Agreement on Critical/Non-Critical Deviations**
- **Dynamic” Inspection Approach**
  - **Timely Follow Up to Critical Deviations**
- **Tiered PC Inspections for Large Facilities**
  - **Not One Size Fits All**
  - **Adequacy of Food Safety Plan; Implementation of Plan**
  - **Review of Corporate Programs; Implementation at Facility Level**
- **Focus on Gaining Industry Compliance**
  - **“Incentives” for Compliance**
  - **Better Tracking/Reporting of Corrective Actions**
  - **Investigators Kept Abreast of Industry Best Practices**



# FSMA

## FSMA Integrated Master Schedule

- Is a living document and is regularly updated and maintained
- Provides an integrated view to support effective planning, monitoring, and control of implementation progress
- Identifies key milestones, deliverables, and dependencies
- Helps connect tasks to activities to costs and enables data-driven trade-off decisions
- Consists of data consolidated from supporting schedules
- Enables FDA to organize and manage plans and schedules comprehensively and consistently across FSMA
- Identifies issues and risks
- Is a communications tool
- Integrated with FSMA Decision Tracker and Work Group Milestone Timelines
- Posted on FDA's FSMA Program Management SharePoint Site

# FSMA

## *Approach to Operational Activities*

- **Targeted, risk-based inspection models**
- **Wider range of inspection, sampling, testing and data collection activities**
- **Improved risk-based work planning through targeted data collection and more timely data analysis and program evaluation**

# FSMA

- **Why Sample/Test Food Under FSMA**

# FSMA

- **Surveillance**
  - ✓ Risk based targeting of operational resources
  - ✓ Emerging issues
  - ✓ Baseline/prevalence data for risk analysis/policy decisions
- **Verification (Emphasis Under FSMA)**
  - Environmental sampling programs are robust
  - Preventive controls/mitigation strategies/corrective actions effective
  - Import controls are effective: FSVP, Third Party Accreditation, VQIP, Import Certification, Systems Recognition
- **Compliance (Public Health Focus Under FSMA)**
  - Support removal of adulterated/misbranded foods from market
  - Environmental assessments / root cause(s) of contamination events/foodborne outbreaks
  - Enforcement actions, including import actions

# FSMA

- **Transparency Remains a Priority**
- **Next Phase: Inclusive/Coalition Approach**
  - **Engage FDA employees, key partners, and the public to help determine ways to implement provisions and concepts before rules become final.**
- **Future: Partnerships/Collaboration Key**
  - **Establish mechanisms, including working with multiple partners, to foster industry understanding of final rules/guidance and encourage firms to comply and initiate any corrections on their own.**

# FSMA

- **President's FY2016 Budget Proposal**
- **An increase of 109.5 million requested in the President's budget for FSMA implementation**
- **FDA plans to continue to make improvements in the following areas:**
  - **Inspection Modernization and Training 25 million**
  - **National Integrated Food Safety System 32 million**
  - **Industry Education and Technical Assistance 11.5 million**
  - **Technical Staffing and Guidance Development at FDA 4 million**
  - **Modernized Import Safety Programs/System 25.5 million**
  - **Risk Analytics and Evaluation 4.5 million**

***And \*\* 7 million for necessary infrastructure costs***

# FSMA

- The State will continue to monitor the “roll out” of the Rules.
- The state will attend any training offered.
- We will be speaking with FDA about contracts, co-operative programs or other means to complete inspections.
- We will continue to communicate with industry

# FSMA

Questions?