FSMA Implementation: FDA Has a Plan; Do You?

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Preparing for FSMA Implementation

FDA has a FSMA Implementation plan; do you?

- Awareness
- Education & Understanding
- Planning
  - Procedures,
  - Policies,
  - Practices,
  - Training,
  - Recordkeeping
- Implementation
- Verification

Operational Strategy for Implementing The FDA Food Safety Modernization Act

www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm
**New FDA Authorities / Tools**

- Mandatory Recall Authority (Open Docket Comments Due 7/6)
- Administrative Detention
- Withdrawal of Facility Registration

### FSMA Proposed Rules

<table>
<thead>
<tr>
<th>Rule</th>
<th>Final Rule (anticipated)</th>
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<tbody>
<tr>
<td>Produce Rule</td>
<td>10/31/2015</td>
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<tr>
<td>Preventive Controls for Human Foods</td>
<td>8/30/2015</td>
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<tr>
<td>Preventive Controls for Animal Feed</td>
<td>8/30/2015</td>
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<tr>
<td>Foreign Supplier Verification Programs</td>
<td>10/31/2015</td>
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<tr>
<td>Sanitary Food Transportation</td>
<td>3/31/2016</td>
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<tr>
<td>VQIP DRAFT Guidance</td>
<td>8/4/2015 (Comments)</td>
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<tr>
<td>Traceability</td>
<td>Pending</td>
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FSMA Rules Coverage by Produce Supply Chain Segment

- **Grower (Domestic & International)**
  - Packing On-Farm
  - Packing Off-Farm
  - Fresh-cut Processor
  - Huller / Sheller

- **PC Rule**
- **SFTA Rule**
- **Food Defense**

- **Packing Off-Farm**
  - **PC Rule**
  - **SFTA Rule**
  - **Traceability**

- **Shipper**
  - **PC Rule**
  - **SFTA Rule**
  - **Traceability**

- **Importer**
  - **PC Rule**
  - **SFTA Rule**
  - **FSVP**
  - **Traceability**

- **Transporter**
  - **SFTA Rule**
  - **Traceability**

- **Wholesale Distributor**
  - **PC Rule**
  - **SFTA Rule**
  - **VQIP**
  - **Traceability**

- **Retailer / Foodservice**
  - **FSVP**

- * Regulatory Requirement for Training
- ** Import related rules

From: 16 April 2015 PMA FSMA Implementation Webinar
Food Safety Modernization Act

- **FSMA Final Rules**
  - Effective Dates vs Compliance Dates

- **FSMA Implementation**
  - How will FDA Implement FSMA?
    - FDA Public Meeting / Open Docket
  - Authorized vs Appropriated
FDA FY ’16 Proposed Budget
$109.5 M Increase
Budget Authority

www.fda.gov/Food/GuidanceRegulation/FSMA/ucm432576.htm

1. Inspection Modernization and Training - $25 million
3. Education and Technical Assistance for Industry - $11.5 million
4. Technical Staffing and Guidance Development at FDA - $4 million
5. New Import Safety Systems - $25.5 million
6. Risk Analytics and Evaluation - $4.5 million
7. FDA Infrastructure Improvements - $7 million
FDA FY ’16 Proposed Budget
$191.8 M in User fees

1) Food Imports,
2) Food Facility Registration,
3) Food Facility Inspection,
4) Food Contact Substance Notifications, and
5) International Couriers.

Note:
1) Authorization of user fees would require that Congress amend the Federal Food Drug and Cosmetic Act.
2) FDA re-inspection fees are authorized in FSMA already.
1) New FDA Inspection Model –
   • from evidence of violations / enforcement cases to assuring firms are implementing systems that effectively prevent food contamination,
   • specialized inspectors, supported by FDA technical experts, to assess the soundness and performance of a facility’s overall food safety system,
   • data to guide risk-based inspection priority, frequency, depth, and approach.

2) Training FDA Inspectors and Compliance Staff (≈2000)

3) IT systems
   • Identify & track risk,
   • Assess & track inspection efficiency and inspector competency.
National Integrated Food Safety System: $32M

1) Education and technical assistance to provide compliance support and oversight.
2) Build state partnerships and capacity to provide education and technical assistance to growers.
3) Inspection grants, contracts, and cooperative agreements,
4) Training State Inspectors and Compliance Staff (≈1000)
5) Assure nationwide quality, consistency and efficiency.
6) Investing in state laboratory accreditation and competency.
FSMA Implementation

Background:
- FSMA has proposed an integrated approach to FSMA implementation.
- Accessing local knowledge and expertise is essential.
- State-led models seem to work well CA & AZ LGMA, FL TGAPs, etc..
- Easier to teach an aggie food safety than teach a food safety professional everything there is to know about agricultural production and handling systems.
**Issue:** Market Access Audits vs Compliance Inspections

- How will states and FDA span the roles of educator, market access auditor and regulator?
- How can industry market access audit results be used to inform FDA/State work plans?
- USDA AMS and FDA are already working on harmonizing audit criteria and the FSMA Produce Rule requirements.
- How does one harmonize auditor/inspector competency and proficiency?
Education & Technical Industry Assistance: $11.5M
(Estimated ≈300,000 entities subject to the final FSMA rules)

1) Financial support to state agencies and public-private-academic collaborations:
   - Produce Safety Alliance
   - Sprout Safety Alliance
   - Food Safety Preventive Controls Alliance.

2) FDA Food Safety Technical Assistance Network

3) USDA NIFA FSMA - mandated compliance grants to provide technical assistance to small, sustainable, and organic farmers and processors.
FSMA Education Outreach by Supply Chain Sector

**Grower**
Domestic & International

**Packing**
On-Farm

**Packing**
Off-Farm

**Shipper**

**Importer**

**Transporter**

**Wholesale Distributor**

**Retailer / Foodservice**

**Fresh-cut Processor**

**Huller / Sheller**

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**Level I**
FSMA

Produce Safety Alliance (Cooperative Extension)
Food Safety Preventive Controls Alliance (Cooperative Extension)
State Departments of Agriculture
PMA Supporting Role (TBD)

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**Level II**
FSMA
B2B

Regional Trade Orgs, Commodity Boards, Marketing Agreements, Marketing Orders
Retailer (e.g. Wegmans) and Foodservice (Sysco)

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**Level III**
FSMA
B2B
Best of Class

Individual Consultations
FDA Technical Staffing & Guidance: $4M

1) Building FDA’s Cadre of Food Safety Experts:
   • 12 Preventive Controls SME’s
   • 8 Produce Safety SME’s
   • 60 Compliance Support Staff SME’s

2) FDA Food Safety Technical Assistance Network
   • technical assistance to industry,
   • technical support for FDA and state inspectors / compliance staff

3) Guidance Development
   • PC: Hazard Analysis, Allergen Controls, Environmental Monitoring
   • Produce: Packinghouse, Sprouts, Animal Intrusion, GAPs.
   • Small Entity Compliance Guides
FSMA Implementation

Issue: Harmonized Compliance Criteria

- 50,000 ft level - FSMA Statute
- 10,000 ft level - FSMA Regulations
- On the Ground - FSMA Compliance Policy Guides
  - Education outreach
  - Training
  - Harmonize compliance verification across agencies
  - International Stakeholders
**FSMA Implementation**

**Issue:** Harmonized Compliance Criteria

- The Conference for Food Protection Model?
- CFP: FDA Model Food Code provides continuity across multiple jurisdictions and agencies.
  - Consultative:
    - Academia,
    - Industry &
    - Government (Fed & State)
  - Deliberative
  - Harmonizing
  - Consensus Building
  - FDA has final editorial decision
New Import Safety Systems: $25.5M
12M line-entries to 88k consignees receiving food shipments
Imports: 50% of fruits, 20% of fresh vegetables,

1) Develop & Implement FSVP regulatory procedures & infrastructure.

2) FDA staffing & training including SME compliance support staff.

3) Guidance, outreach and technical assistance to industry
   • Hazard Analysis,
   • Risk Evaluation,
   • Appropriate selection of verification activities

GAO Survey Opportunity
Risk Analytics & Evaluation: $4.5M

1) Operations and Data Sharing (ERP)
   • System to link FDA-wide public health risk priorities to budgets, program performance, resource allocation data.

2) Data Structure & Gathering
   • Targeting data collection to make risk informed decisions and resource allocation

3) Data Analysis & Evaluation
   • Risk ranking, prioritization, and attribution tools
Group 1: FSMA and the National Integrated Food Safety System (Gorny)

- What roles should FDA, State Departments of Agriculture and State Departments of Public Health play regarding FSMA Implementation (Produce, PC and FSVP Rules) especially regarding education, compliance and enforcement:
  - Guidance Development
  - Education Outreach Re: FSMA Compliance
  - Routine Inspections
  - For-Cause Inspections
  - Produce Surveillance Sampling

- Would a non-regulatory pre-assessment of FSMA Compliance be of interest to the farming (Produce Rule), food facilities (PC rule) and Import (FSVP rule) regulated stakeholders?

- What resources and where should the resources come from to provide for successful FSMA implementation by industry and government?
Group 2: FSMA Guidance Development: Needs & Funding (Whitaker)

- What types of technical assistance & outreach will industry need for:
  - Farms? (Produce Rule)
  - Food facilities (packing houses & fresh-cut processors) (PC Rule)
  - Importers (FSVP)

- How can useful technical assistance and outreach be best provided?

- Is there particular information that needs to be provided?

- What kinds of guidance documents, or other technical assistance and outreach tools, would be most helpful in meeting the FSMA rule requirements?

- What resources and where should the resources come from to provide for successful FSMA implementation by industry and government?
Questions?

Thank You
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