Food Safety: Where Does 3-A Fit

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Milk Safety Team
Food Safety: Where Does 3-A Fit

I. FDA Food Safety Modernization Act

II. Where does 3-A Fit?
Focus on Prevention

I. FDA Food Safety Modernization Act
Agenda

- The public health imperative
- Why is the law needed?
- Provisions of the law, focus on prevention
- Implementation timeline and plans
Why is the law needed?

- Foodborne illness is a significant burden
  - About 48 million (1 in 6 Americans) get sick each year
  - 128,000 are hospitalized
  - 3,000 die
- Food supply more high-tech and complex
  - 15 percent of U.S. food supply is imported
  - More foods in the marketplace
  - New hazards in foods not previously seen
Main Themes of the Legislation

- Prevention Standards
- Enhanced Partnerships
- Inspections, Compliance, and Response
- Import Safety
Prevention: The cornerstone

- Comprehensive preventive controls for human and animal food facilities
- Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
- Strengthens accountability for prevention
- Produce safety standards
- Intentional adulteration standards
- Transportation
General Approach to Preventive Controls

1. Identify Hazard
2. Understand Cause
3. Implement Preventive Controls
4. Monitor Effectiveness
5. Review & Adjust
Prevention Standards Mandates

Sec. 103. Hazard analysis and risk-based preventive controls

Requires human and animal food facilities to:

- Evaluate hazards that could affect food safety;
- Identify and implement preventive controls to prevent hazards;
- Monitor controls and maintain monitoring records; and
- Conduct verification activities.

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov/fsma
Modified Requirements for Qualified Facilities (Section 103)

Facility is exempt if:

• Defined as very small business;

OR

• The facility has a limited annual monetary value of sales
Modified Requirements for Qualified Facilities (Section 103)

Limited annual monetary value of sales is defined as:

- During the last 3 years, sales were less than $500,000;

  **AND**

- Sales to "Qualified End Users" exceed sales to others
Examples of Compliance with Prevention Standards (Section 103)

- Sanitation procedures
- Training for supervisors and employees
- Environmental controls and monitoring
- Food allergen controls
- Recall plan
- Good Manufacturing Practices (GMPs)
- Supplier verification activities
Prevention Standards Mandates

Sec. 105. Standards for Produce Safety

- Establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables

- Applies to raw agricultural commodities for which FDA determines that such standards minimize the risk of serious adverse health consequences or death.
Exemption for Direct Farm Marketing (Sec. 105)

Farms exempt if:

• During the last 3 years, sales were less than $500,000 and

• Majority of product is distributed directly to consumers or farmers’ markets and restaurants either intrastate or within a 275-mile radius
Intentional Contamination

Sec. 106. Protection against Intentional Adulteration

• Issue final rule and guidance to protect against the intentional adulteration of food

• Conduct vulnerability assessments of the food supply and determine mitigation strategies

• Sec. 108. Prepare a National Agriculture and Food Defense Strategy with USDA, and DHS
Prevention Standards Mandates

Sec. 111. Sanitary Transportation of Food

• Addresses implementation of the Sanitary Food Transportation Act of 2005, which requires persons engaged in food transportation to use sanitary transportation practices to ensure that food is not transported under conditions that may render it adulterated.
Prevention in Imports

Sec. 301. Foreign Supplier Verification Program (FSVP)

- Requires importers to conduct risk-based foreign supplier verification activities to verify that food imported into the United States is not adulterated and that it was produced in compliance with FDA’s preventive controls requirements and produce safety standards.

Sec. 307. Third Party Auditor Accreditation

- Can be used by importers for supplier verification under FSVP.
Implementation Approach

• Items are prioritized based on public health protection

• Engage with stakeholders to help determine reasonable and practical ways to implement preventive control provisions

• Implementation progress at http://www.fda.gov/fsma
Prevention Projects Completed (as of October 2011)

- Public Meeting on Preventive Controls for Facilities (4/20/11)
- Preventive Controls for Registered Human Food and Animal Food/Feed Facilities Docket FDA-2011-N-0238 (5/23/11)
- Tours of farms and food / feed facilities
Outreach

- Recent farm tour at Milk Pail Farm
Outreach

- Upcoming public meetings on preventive controls and produce safety when proposals are issued
- Numerous listening sessions, meetings, presentations
- FSMA web page has subscription service for immediate updates
Rulemaking Process

• FDA proposes a regulation

• Draft rules are published on http://www.regulations.gov

• Time is allowed for public comment, and FDA is required to consider comments during the rulemaking process

• Regulation is revised and final rule is issued
Rulemaking Process

• After a final rule is published, it may have an effective date in the future

• FDA issues guidance documents

• Check http://www.fda.gov/fsma to find out what is open for comment
Snapshot of FSMA homepage elements at: http://www.fda.gov/fsma
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II. How Can 3-A Help?
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Get involved!
FDA encourages 3-A participants to use the resources provided in this presentation to become familiar with those parts of the FSMA that may effect them and to participate actively in the FSMA comment process.
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3-A Inc. Already Helps Support the FSMA in Several Important Ways.
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3-A Inc. develops widely accepted Sanitary Standards and Sanitary Practices that can be useful within a milk plant’s preventive Standards (Preventative Controls)
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3-A Certification of equipment is assured using an effective credentialed third party verification system
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3-A Inc. works with groups such as EHEDGE to promote harmonization of sanitary construction requirements for dairy and related equipment worldwide.
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3-A has a potential to aid those seeking to comply with FSMA through development of future Sanitary Standards and Sanitary Practices:

Example: Development of a sanitary practice for the credentialing and validation procedures for allergen washes
For more information

• Web site is at: http://www.fda.gov/fsma

• Subscription feature available

• Send questions to FSMA@fda.hhs.gov