

Food Safety: Where Does 3-A Fit

**3-A Annual Meeting and Educational
Program Clarion Hotel and Conference
Center, Milwaukee, WI**

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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

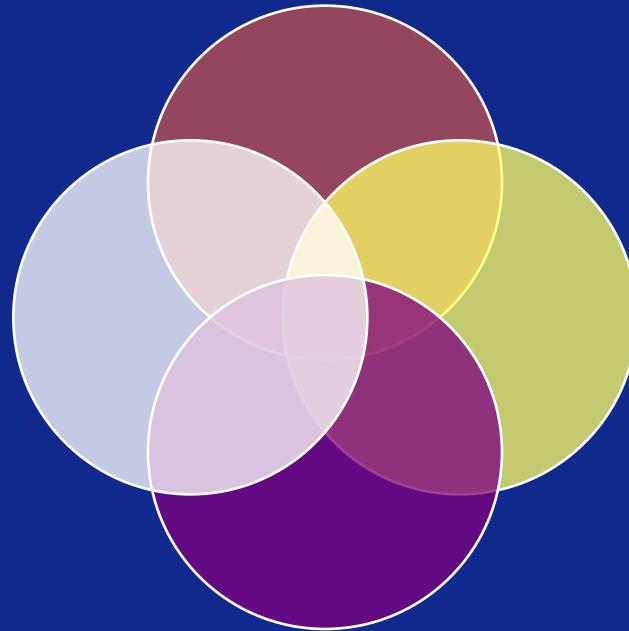
Why is the law needed?

- 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



U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov/fsma

**FDA FOOD SAFETY
MODERNIZATION ACT**



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



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.

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>

Implementation Executive Committee

Strategic Communications & Outreach Team – Sharon Natanblut

Prevention Standards
Don Kraemer

Inspection & Compliance
Barbara Cassens

Imports
David Elder

Federal/State Integration
Joe Reardon

Fees
Roxanne Schweitzer

Reports & Studies
David Dorsey

Produce Safety Regulation

Mandatory Recall/Recall Communications

Importer Verification & VQIP

Operational Partnership

Inspection & Auditor Fees

Reports to Congress/ Studies

Produce Safety Guidance

Administrative Enforcement Tools

Import Certification

Capacity Building

Preventive Controls Regulation

Registration

Accredited Third- Party Certification

Training

Preventive Controls Guidance

Frequency of Inspection

Lab Accreditation & Integrated Consortium / FERN

Safe Food Transport

Manner of Inspection / Food Safety Plan Review

International Capacity Building

Food Defense

Tracing

Comparability

Contaminants

RFR Improvements

Task A: Prior Notice

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>

The screenshot shows the FDA website with the following elements:

- Header: U.S. Department of Health & Human Services, www.hhs.gov, FDA U.S. Food and Drug Administration, A-Z Index, Search.
- Navigation: Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products.
- Section: Food, Home > Food > Food Safety > Food Safety Modernization Act (FSMA).
- Left Sidebar: Food Safety, Food Safety Modernization Act (FSMA), About FSMA, Full Text of the Law, Implementation and Progress, Drafts Open for Comment, Meetings, Hearings, and Workshops, Press Releases, Speeches and Statements, Videos, Webinars, and Interviews, Frequently Asked Questions, Translations of Key FSMA Resources.
- Main Content: The New FDA Food Safety Modernization Act (FSMA), The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4th, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it. Get FSMA Updates by E-mail, FDA Meeting National Food Safety Goals, View the Progress Report on Implementing the FDA Food Safety Modernization Act for more details on actions taken in the six months since President Obama signed the FSMA into law.
- Right Sidebar: FSMA Blog Posts, Consumer Corner.

FSMA Blog Posts

The US and Mexico Share Approaches on Food Safety
by Michael R. Taylor
Deputy Commissioner for Foods



*In June, I had the opportunity to lead a delegation of food safety officials from the Food and Drug Administration to meet with our Mexican counterparts. The trip was part of a larger, proactive strategy to reach out to stakeholders, both domestic and foreign, to explain the background and implementation strategies for the new Food Safety Modernization Act (FSMA) and importantly, to listen to issues raised by stakeholders. **MORE>***

For more blog postings, visit the FSMA Blog page.

Consumer Corner

Featured Item
Safer Fruits and Vegetables: FDA Aims to Set Production Standards



Recently Posted Consumer Updates
FDA Meeting FSMA Food Safety Goals
Fish Hazards and Controls
Food Bill Aims to Improve Safety

More Consumer Updates related to FSMA...

What's New

How to Participate

- Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredients, Dietary Supplements, and Related Issues
July 2011
- FDA Meeting FSMA Food Safety Goals
A Consumer Update on the implementation of FSMA in the first six months.
July 5, 2011
- FDA Progress Report on Implementing the Food Safety Modernization Act: May - July 2011
July 5, 2011
- Anti-Smuggled Food Strategy Fact Sheet
July 3, 2011

More on What's New...

Food Safety: Where Does 3-A Fit

II. How Can 3-A Help?

Food Safety: Where Does 3-A Fit

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.



Food Safety: Where Does 3-A Fit

**3-A Inc. Already Helps Support the
FSMA in Several Important Ways.**



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**FDA FOOD SAFETY
MODERNIZATION ACT**



Food Safety: Where Does 3-A Fit

**3-A Inc. develops widely accepted
Sanitary Standards and Sanitary
Practices that can be useful within
a milk plant's preventive
Standards (Preventative Controls)**



Food Safety: Where Does 3-A Fit

**3-A Certification of equipment
is assured using an effective
credentialed third party
verification system**

Food Safety: Where Does 3-A Fit

3-A Inc. works with groups such as EHEDGE to promote harmonization of sanitary construction requirements for dairy and related equipment world wide



Food Safety: Where Does 3-A Fit

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

FDA Consumer Health Information
www.fda.gov/consumer

The 'Teeth' of FDA's Food Safety Law


The Food Safety Modernization Act (FSMA), signed into law by President Obama in January, has been called "historic" because it puts the focus of the Food and Drug Administration (FDA) on prevention—working to ensure that unsafe foods are not distributed in the first place.

FDA Commissioner Margaret A. Hamburg says the law directs the agency to oversee food safety in a way that applies "the best available science and good common sense to prevent the problems that can make people sick."

What lends the new law additional importance is that it provides FDA with new enforcement and inspection authorities.

"These new authorities are critical for the law's success," said Michael B. Taylor, FDA's deputy commissioner for foods. "They give the food companies strong additional incentives for keeping their products safe, and that helps us achieve the new law's goal, which is to protect consumers from unsafe food."

Foodborne outbreaks are a significant public health burden that increases the cost of the nation's health care and, as Taylor has emphasized, many of them can be prevented. And keeping foodborne outbreaks from



FDA has new authorities to inspect food-producing facilities and enforce safeguards mandated by the Food Safety Modernization Act.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES | U.S. FOOD AND DRUG ADMINISTRATION

- Web site is at: <http://www.fda.gov/fsma>
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov