

Overview

FDA Food Safety Modernization Act

The Dairy Practices Council Conference

November 3, 2011



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



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Food Safety Modernization Act

“I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action.”

Margaret A. Hamburg, M.D.,

Commissioner of Food and Drugs

*Signed into law Jan 4, 2011



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**FDA FOOD SAFETY
MODERNIZATION ACT**

Agenda

- The public health imperative
- Why is the law needed?
- Provisions of the law and their significance
- Implementation



The Public Health Imperative

- Foodborne illness is a significant burden
 - About 48 million (1 in 6 Americans) get sick each year
 - 128,000 are hospitalized
 - 3,000 die
- Immune-compromised individuals more susceptible
 - Infants and children, pregnant women, older individuals, those on chemotherapy
- Foodborne illness is not just a stomach ache—it can cause life-long chronic disease
 - Arthritis, kidney failure

Why is the law needed?

- Globalization
 - 15 percent of U.S. food supply is imported
- Food supply more high-tech and complex
 - More foods in the marketplace
 - New hazards in foods not previously seen
- Shifting demographics
 - Growing population (about 30%) of individuals are especially “at risk” for foodborne illness



What's so historic about the law?

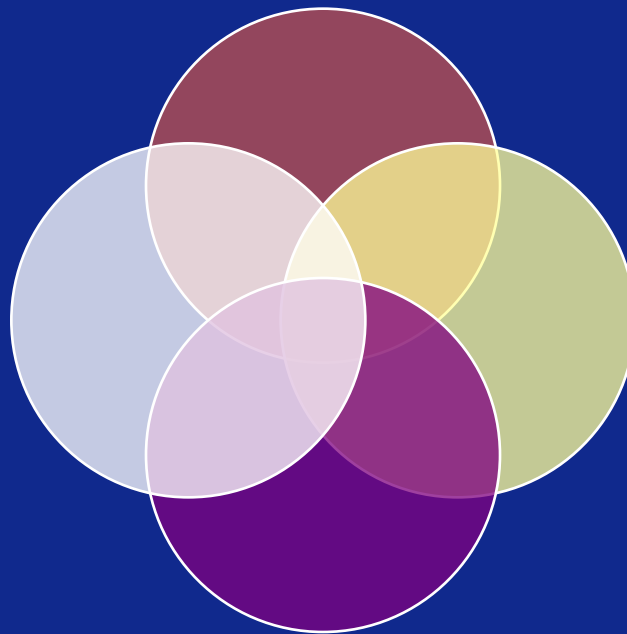
- Involves creation of a new food safety system
- Broad prevention mandate and accountability
- New system of import oversight
- Emphasizes partnerships
- Emphasizes farm-to-table responsibility
- Developed through broad coalition



Main Themes of the Legislation

Prevention Standards

**Enhanced
Partnerships**



**Inspections,
Compliance,
and Response**

Import Safety



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Prevention: The cornerstone

- Comprehensive preventive controls for food and feed 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



Inspection, Compliance, and Response

- Mandated inspection frequency
 - More inspections, but with preventive controls in place, we can consider new ways to inspect
- New tools
 - Mandatory recall
 - Expanded records access
 - Expanded administrative detention
 - Suspension of registration



Import Safety: Most groundbreaking shift

- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements
- Can require mandatory certification for high-risk foods
- Voluntary qualified importer program--expedited review
- Can deny entry if FDA access for inspection is denied
- Requires food from abroad to be as safe as domestic

Enhanced Partnerships: Vital to Success

- Reliance on inspections by other agencies that meet standards
- State/local and international capacity building
- Improve foodborne illness surveillance
- National agriculture and food defense strategy
- Consortium of laboratory networks
- Easier for consumers to find recall information



Implementation Approach

- Implementation already underway
- Coalition needed
- Transparency a priority
- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to implement provisions



Implementation Executive Committee

**Strategic Communications
& Outreach Team –**
Sharon Natanblut

Prevention Standards

Don Kraemer

**Produce Safety
Regulation**

**Produce Safety
Guidance**

**Preventive
Controls
Regulation**

**Preventive
Controls
Guidance**

**Safe Food
Transport**

Food Defense

Contaminants

Inspection & Compliance

Barbara Cassens

**Mandatory
Recall / Recall
Communications**

**Administrative
Enforcement
Tools**

Registration

**Frequency of
Inspection**

**Manner of
Inspection /
Food Safety
Plan Review**

Tracing

**RFR
Improvements**

Imports

David Elder

**Importer
Verification &
VQIP**

**Import
Certification**

**Accredited
Third- Party
Certification**

**Lab
Accreditation &
Integrated
Consortium /
FERN**

**International
Capacity
Building**

Comparability

**Task A:
Prior Notice**

Federal/State Integration

Joe Reardon

**Operational
Partnership**

**Capacity
Building**

Training

Fees

David Wardrop

**Inspection &
Auditor
Fees**

Reports & Studies

David Dorsey

**Reports to
Congress/
Studies**

But, many challenges

- Enormous workload
 - 50 new rules, guidance documents, reports in 3 years
- Tight deadlines
- Changes won't appear overnight
 - Building new system will be a long-range process
- Resources



Rulemaking Process

- Rulemaking is open and public.
- Draft rules are published on www.regulations.gov.
- Time is allowed for public comment, and FDA is required to consider significant comments during the rulemaking process.
- Check www.fda.gov/fsma to find out what is open for comment.



Snapshot of FSMA homepage elements at: <http://www.fda.gov/fsma>

What's New

- Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications 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...


How to Participate

Main Topics

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...

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Food

Home > Food > Food Safety > Food Safety Modernization Act (FSMA)

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Food Safety

- Food Safety Modernization Act (FSMA)
- About FSMA
- Full Text of the Law
- Implementation and Progress
- Dockets Open for Comment
- Meetings, Hearings, and Workshops
- Press Releases
- Speeches and Statements
- Videos, Webinars, and Interviews
- Frequently Asked Questions
- Translations of Key FSMA Resources

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.

Anti-Smuggling Strategy

A joint anti-smuggling strategy developed with the Department of Health and Human Services and the Department of Homeland Security is released. [More >](#)



2 of 3



For more information



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

Food Defense Tools and Resources

Industry Guidance Self Assessment Checklist



Training Programs

ALERT and
Employees FIRST

In today's world it is important to be ALERT to protect your business.

- A** How do you **ASSURE** that the supplies and ingredients you use are from safe and secure sources?
- L** How do you **LOOK** after the security of the products and ingredients in your facility?
- E** What do you know about your **EMPLOYEES** and people coming in and out of your facility?
- R** Could you provide **REPORTS** about the security of your products while under your control?
- T** What do you do and who do you notify if you have a **THREAT** or issue at your facility?



**EMPLOYEES
are the
FIRST
Line of Food Defense**

Follow company food defense plan and procedures.

Inspect your work area and surrounding areas.

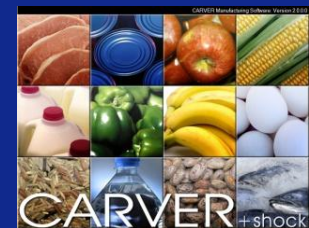
Recognize anything out of the ordinary.

Secure all ingredients, supplies, and finished product.

Tell management if you notice anything unusual or suspicious.

CARVER+Shock

Vulnerability
Assessment
Software 2.0



Mitigations Strategies Database

‘Searchable’ Preventative
Measures, based on user
Selections to categories
and nodes

Coming Soon!

**FDOT tools and
resources webinar
with the NCFPD –
9/9/11**

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Three (3) FDA based scenarios

Two (2) USDA based scenarios



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Overview of the FREE-B

5 scenarios, available online – FREE of charge!

www.FDA.gov/FoodDefense

Each scenario contains a lead planner's guide, situation manual and facilitator's guide

- Guides are presented in an easy to follow approach, from establishment of the exercise planning committee to the distribution of certificates of participation - we've left no stone unturned!!



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Overview of the FREE-B

This set is designed to provide jurisdictions with a variety of options to test and improve their capabilities to respond to human or animal health emergencies.

The five exercises in the set are designed so that jurisdictions can conduct them right out of the box with a minimal amount of effort and editing.

Each exercise is stand-alone. Collaboration and partnering with several jurisdictions and stakeholders may be needed to ensure a successful exercise.

FREE-B has been developed to be consistent with the Homeland Security Exercise and Evaluation Program (HSEEP) doctrine.



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A decorative white line with a slight curve, positioned below the FDA Food Safety Modernization Act text.

Scenario Descriptions



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How Sweet It Is(n't)

This scenario focuses attention on the regulatory traceback investigation that occurs after standard product testing shows that a food product contains excessive levels of a contaminant, as well as a recall of contaminated food.



Stealthy Situation

This exercise is a comprehensive scenario and highlights nuances encountered when a cluster of illness is associated with a foodservice establishment. The scenario includes the epidemiological investigation, identification of affected product through traceback procedures, implementation of a recall, and the role of regulatory agencies.



Wilted Woes

This scenario begins at the outset of early signal detection with clinical illness reports, and focuses on the epidemiological investigation process to identify the food vehicle when there is a human health emergency caused by an unintentional contamination of produce with *E. coli* O157:H7.



Highplains Harbinger

- This scenario focuses on the investigation of animal disease caused by intentional infection of cattle with Foot and Mouth Disease (FMD) virus, highlighting the various animal agriculture agencies (Federal, state, local, territorial, and tribal) and their roles and responsibilities, as well as introducing the roles and responsibilities of law enforcement agencies during an animal health emergency.



Insider Addition

This scenario focuses attention on the intentional aspect of contamination of a raw meat product at the processor with a chemical agent. Various nontraditional organizations and expertise needed to investigate intentional contaminations and the establishment of collaborative processes and roles and responsibilities with the traditional public health and regulatory partners are highlighted.



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~~Thanks for your attention!~~

Does anyone have any experiences with the FREE-B or any of the FDOT tools you'd like to share?

Please contact us @
FoodDefense@fda.hhs.gov with any
thoughts, questions, ideas



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Questions?



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