

# Overview

## FDA Food Safety Modernization Act

Barbara Cassens

FDA District Director

WAFDO 2011



U.S. Food and Drug Administration  
Protecting and Promoting Public Health  
[www.fda.gov/fsma](http://www.fda.gov/fsma)

FDA FOOD SAFETY  
MODERNIZATION ACT





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**FDA FOOD SAFETY  
MODERNIZATION ACT**



# 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*



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# Agenda

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



# 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

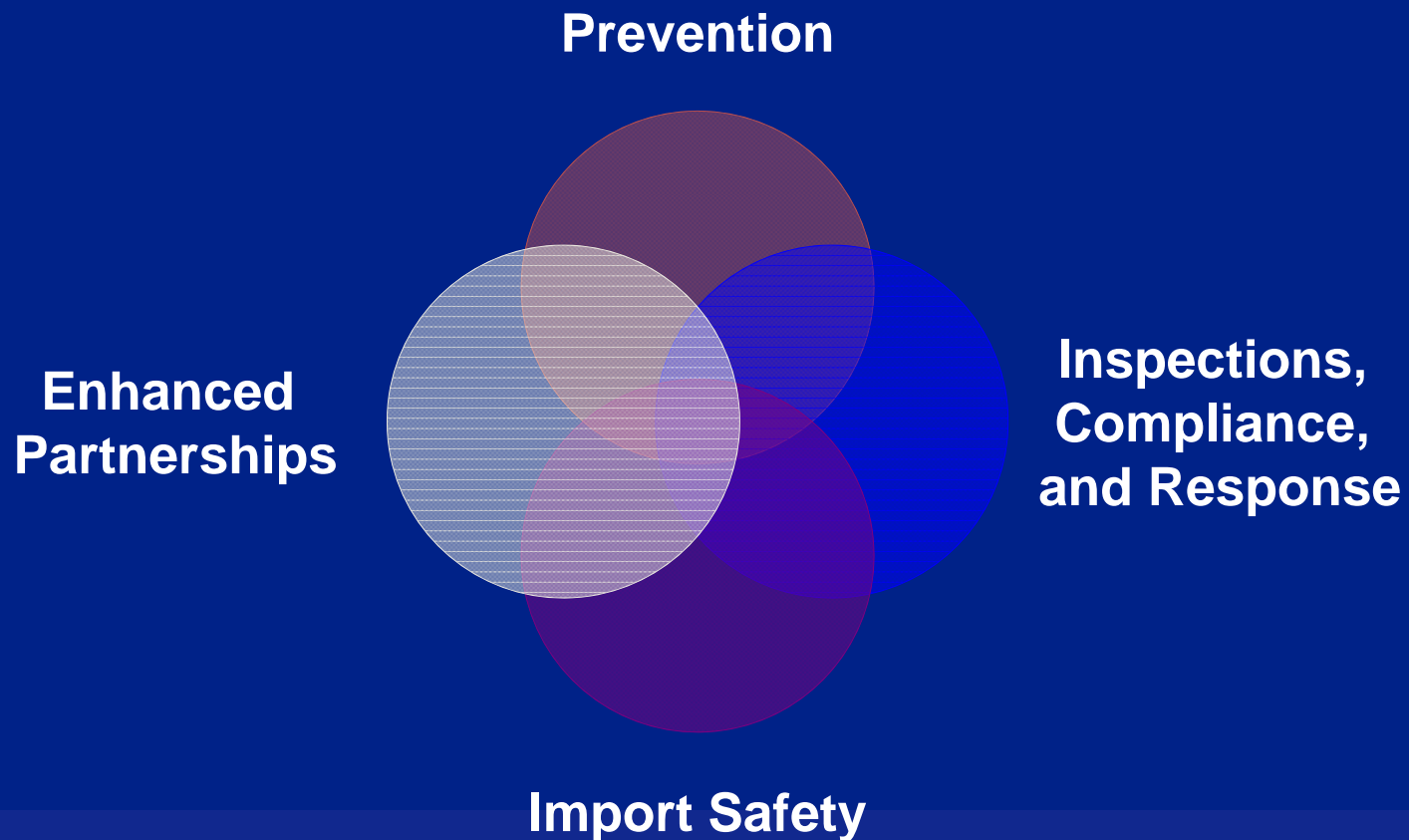


# What's so historic about the law?

- 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



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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
  - Enhanced product tracing
  - Third party laboratory testing



# 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

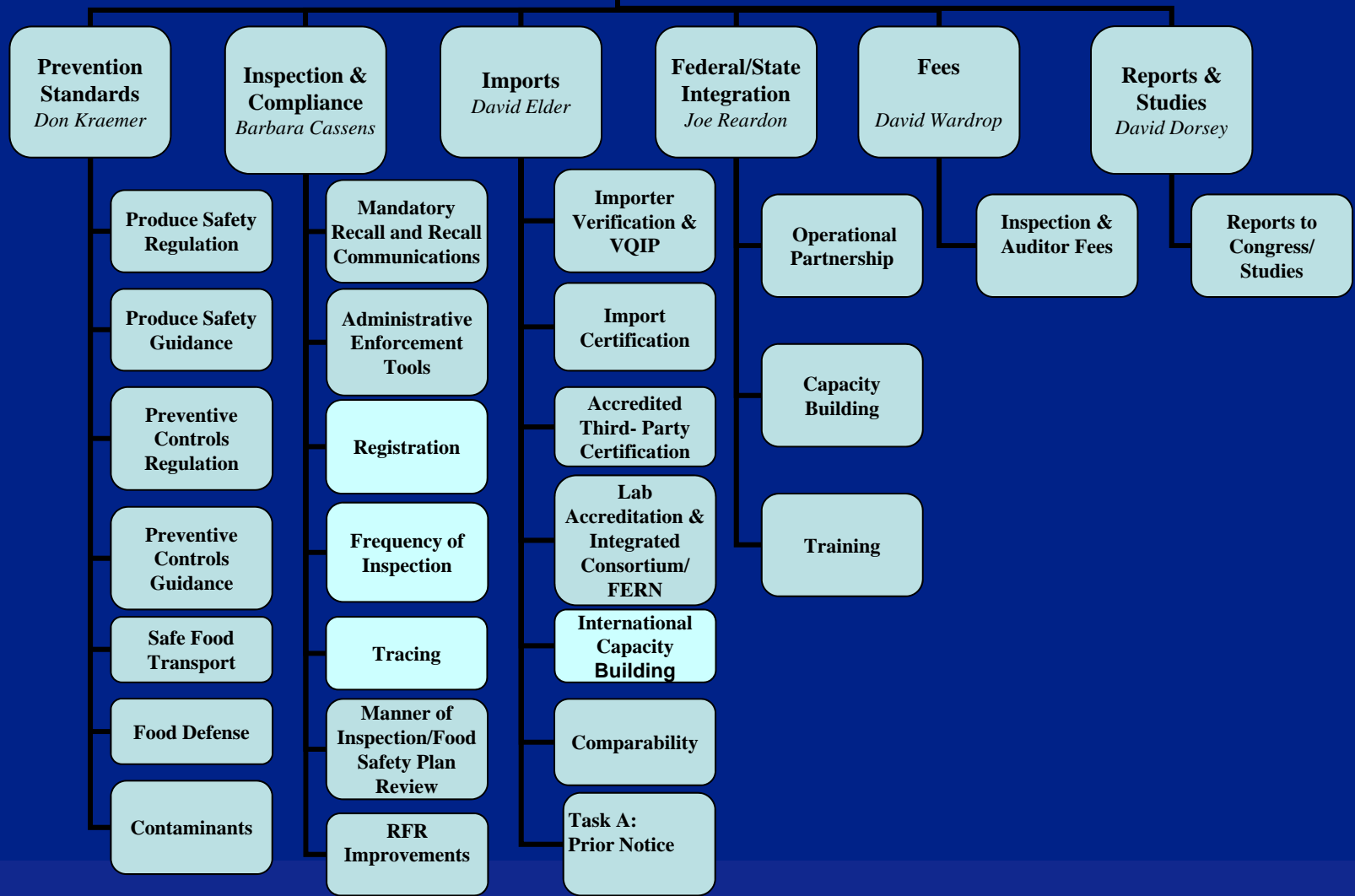
# Implementation Approach

- 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*



# 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



# Completed Projects (as of Aug. 1, 2011)

- Updated list and more information can be found at [www.fda.gov/fsma](http://www.fda.gov/fsma)
- Fees (107)
- New dietary ingredients (113)
- Anti-smuggled food strategy (201)
- Registration of Food Facilities
- Prior Notice of imported food shipments (304)
- Administrative detention of food (207)
- Consumer-friendly web search for recalls (sec. 205)
- Guidance to Seafood Industry on food safety hazards (sec. 103)



# So, what's something new?



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# What is EFIPS?

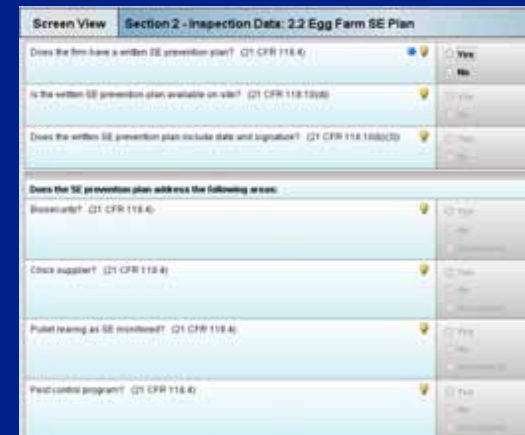
A new method to conduct investigations electronically.



**Hardware**



**Software**



**Electronic  
Questionnaire**

Goal of the proof of concept (POC) is to determine the effectiveness and efficiency of such a system compared to the traditional narrative-based method

# Hardware

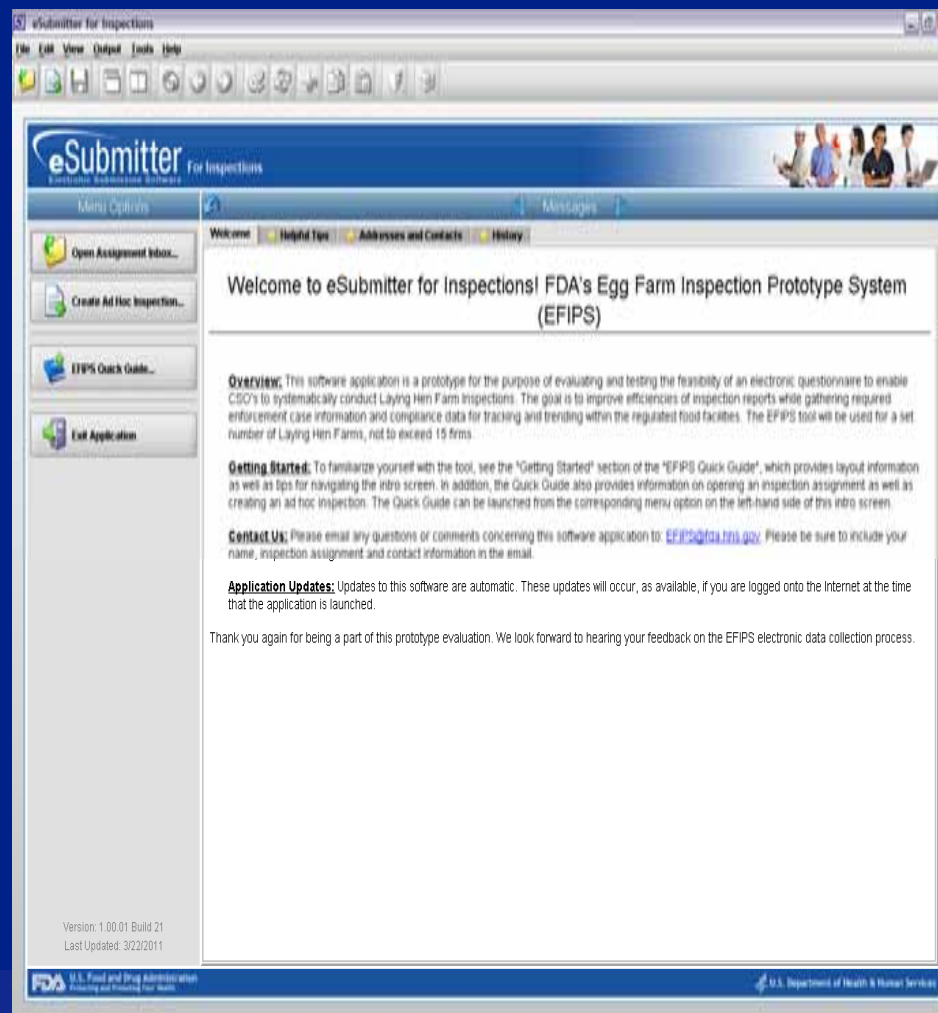
- Tablet-based
- Stylus-based touch screen
- Handwriting Recognition
- Windows Operating System
- Rugged
- Easy to clean (health care setting sanitation)
- Has camera and can



[Panasonic H1 Health Tablet PC](#)  
(no, it is not an iPad)

# Software

- eSubmitter developed by BAH
- Clean Interface
- Easily customizable for other commodities
- Integrates with existing FDA system (i.e. Turbo EIR)

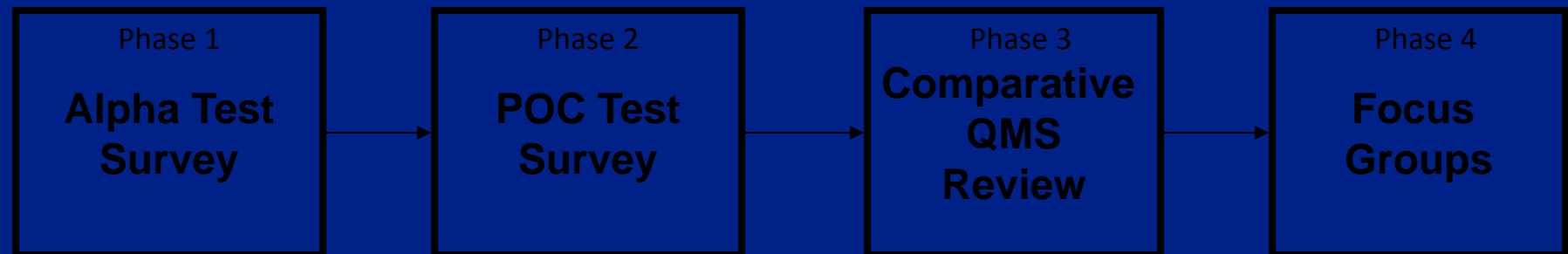


# Electronic Questionnaire

- Runs within eSubmitter
- Uses skip logic for efficiency
- Checklist based with options for drop down menus and narrative boxes
- Fields such as firm information can be pre-populated

Screen View	Section 2 - Inspection Data: 2.2 Egg Farm SE Plan	
Does the firm have a written SE prevention plan? (21 CFR 118.4)		<input checked="" type="radio"/> Yes <input type="radio"/> No
Is the written SE prevention plan available on site? (21 CFR 118.10(d))		<input type="radio"/> Yes <input type="radio"/> No
Does the written SE prevention plan include date and signature? (21 CFR 118.10(b)(3))		<input type="radio"/> Yes <input type="radio"/> No
<b>Does the SE prevention plan address the following areas:</b>		
Biosecurity? (21 CFR 118.4)		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Incomplete
Chick supplier? (21 CFR 118.4)		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Incomplete
Pullet rearing as SE monitored? (21 CFR 118.4)		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Incomplete
Pest control program? (21 CFR 118.4)		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Incomplete

# Evaluation Methodology



- 1 Investigator from Philadelphia District
- Not acting in regulatory capacity
- Targeted inspection (hen house only)

- 5 Investigators using it 3 times each (15 total)
- Capture potential benefit of using tool multiple times
- Not acting in regulatory capacity
- Mix of comprehensive Inspection (includes environmental sampling) and targeted inspections

- EFIPS-generated report versus traditional method
- Review group includes a Director of Investigative Branch (DIB), Compliance Officer, Director of Domestic Field Investigations, and Evaluation Staff member

- User-directed changes to questionnaire
- Project team to determine next steps after POC

# Outreach

- Public Meetings
  - Preventive Controls
  - Inspection and Compliance
  - Comparability and Import Practices
  - Imports
- Numerous listening sessions, meetings, presentations
- FSMA web page has subscription service for immediate updates.



**Food**

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<b>Food Safety</b>
▶ <b>Food Safety Modernization Act (FSMA)</b>
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

**Resources for You**

- [FDA Implementation Timeline](#)
- [Recalls, Market Withdrawals, & Safety Alerts](#)

**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 ▶

**What's New**

- [Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Not 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 2011](#)  
July 5, 2011
- [Anti-Smuggled Food Strategy Fact Sheet](#)  
July 3, 2011

[More on What's New...](#)

**How to Participate**

**Main Topics**

Snapshots of the different elements of the FSMA homepage found at <http://www.fda.gov/fsma>

**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...](#)

**Contact Us**

FSMA@fda.hhs.gov  
Food and Drug Administration  
5100 Paint Branch Pkwy  
Wiley Building, HFS-009  
Attn: FSMA Outreach  
College Park, MD 20740

# For more information

**FDA** Consumer Health Information  
www.fda.gov/ohrt

## Food Bill Aims to Improve Safety

**R**ecent data from the Centers for Disease Control and Prevention show that one in six people in the United States suffers from food-borne illness each year. Over the past few years, high-profile outbreaks related to various foods, from spinach and peanut products to eggs, have underscored the need to make continuous improvements in food safety.

The Food Safety Modernization Act (FSMA) gives FDA a mandate to pursue a system that is based on science and addresses hazards from farm to table, putting greater emphasis on preventing food-borne illness. The concept is simple: The better the system handles producing, processing, transporting, and preparing foods, the safer our food supply will be.

Under the provisions of FSMA, Congress will be required to develop and implement written food safety plans. FDA will have the authority to better respond and require recall when food safety problems occur, and FDA will be able to better ensure that reported foods are as safe for consumers as foods produced in the U.S.

FDA Commissioner Margaret A. Hamburg, M.D., says the bill—also known as the Obama bill—is expected



- Web site is at: [www.fda.gov/fsma](http://www.fda.gov/fsma)
- Subscription feature available
- Send questions to [FSMA@fda.hhs.gov](mailto:FSMA@fda.hhs.gov)