



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

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# FDA Food Safety Modernization Act

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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*



## Agenda

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



## 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

**Slide 4**

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**CLC2** Catherine L Copp, 1/18/2011

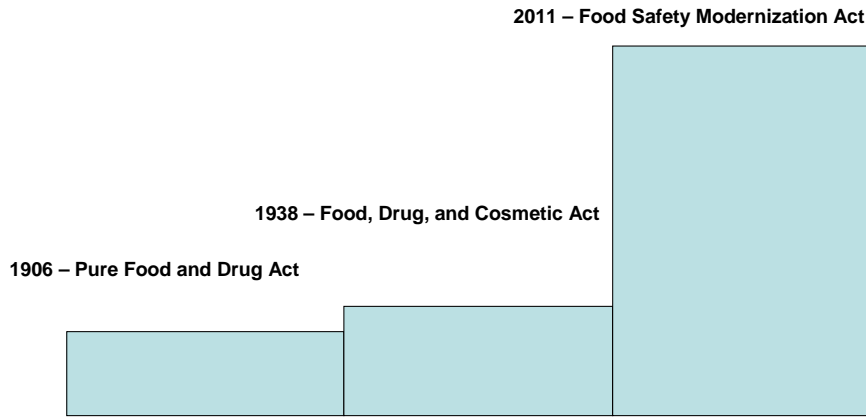


## Why is the law needed?

- 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



## New law updates authority and tools





## 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



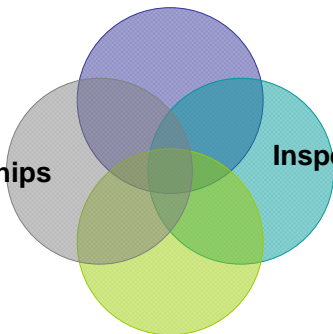
# Main Themes of the Legislation

Prevention

Enhanced Partnerships

Inspections, Compliance,  
and Response

Import Safety





## Prevention: The cornerstone of the legislation

- Comprehensive preventive controls for 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



## Inspection, Compliance, and Response

- Mandated inspection frequency
  - Considering 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 to find recall information



## Implementation: FDA is prepared

- Experience in preventive controls
- Implementation process in place
- Much work already underway



## 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



## Implementation Approach

- Coalition needed
- Transparency a priority
- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to do so



## Priorities

- **Prevention**
  - Mandatory preventive controls for facilities (FR 18 months)
  - Produce safety standards (FR 2 years)
  - Intentional contamination (FR 18 months)
- **Inspection, Compliance, and Response**
  - Administrative detention (IFR 120 days)
  - Recall (Upon enactment)
  - Suspension of registration (180 days)
- **Imports**
  - Foreign supplier verification program (Guidance and FR 1 year)
  - Accredited third-party certification program (FR 2 years)
  - Mandatory certification for high risk foods (Upon enactment)

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- Combination Products
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- Pediatrics
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**Public Health Focus**

- Radiation Safety
- Warning: FDA Agent Impersonator Scam
- Food Safety Modernization Act (FSMA)
- Read FDA's 1st speech on new Food Safety Law
- Minority Health
- FDA on Flickr and Facebook
- Proposed Cigarette Product Warning Labels
- FDA-TRACK

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**Regulatory Information**

**News & Events**

- April 13, 2011 - FDA approves new treatment for liver cancer

**Spotlight**

- FDA Strategic Priorities 2011-2015
- HHS 2012 Budget Announced - FDA Budget
- Transparency
- Expanded Access to Investigational Drugs
- Strategic Plan for Risk

**Safety**

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Press releases about recalled products issued within the last 60 days are published on this page with the most recent press release displayed at the top of the list. To view press releases by product area, please select the Food, Drugs, Animal Health, Biologics or Medical Devices tabs above.

Date	Brand Name	Product Description	Reason/ Problem	Company	Details/ Photo
05/13/2011	<a href="#">Shabtai Gourmet</a>	Cookies	Undeclared Egg	Cinderella Sweets	
05/12/2011	<a href="#">Mann's, Safeway's Eating Right</a>	Vegetable products containing tomatoes	Salmonella	Mann Packing Co., Inc.	

**Spotlight**

- Improving Recall Information for Consumers
- Identifying Recalled Products
- FDA Food Safety Modernization Act (FSMA)
- Product Recalls Mobile Phone App
- Food Safety Alerts and Tips Widget



## First New Rules Under FSMA

Effective July 3, 2011

- (1) Allows FDA to administratively detain food for up to 30 days that it believes has been produced under insanitary or unsafe conditions.
- (2) Requires anyone importing food into the U.S. to inform the FDA if any country has refused entry for the same product, including food for animals.



## For more information



### Food Bill Aims to Improve Safety

Recent 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 sprouts and peanut products to eggs, have underscored the need to make continuous improvements to food safety.

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

Under the provisions of FSMA, FDA will be required to develop and implement written food safety plans. FDA will have the authority to better respond and regulate on all identified safety problems and FDA will be able to better ensure the imported foods are as safe as the ones grown in the U.S.

For more information, contact  
Hollie M. Ryan, Director, Office of  
Public Health & Outreach, at 202-205-2091



- [www.fda.gov/fsma](http://www.fda.gov/fsma)
- [www.foodsafety.gov](http://www.foodsafety.gov)
- [fsma@fda.hhs.gov](mailto:fsma@fda.hhs.gov)



## Menu & Vending Machine Labeling

Sec. 4205 of the Patient Protection and Affordable Care Act of 2010

- **Two proposed rules**
  - Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments
  - Food Labeling; Calorie Labeling of Articles of Food in Vending Machines
- **Comment at [www.regulations.gov](http://www.regulations.gov)**
  - FDA-2011-F-0172 (menu) by 6/6/11
  - FDA-2011-F-0171 (vending machine) 7/5/11





## Menu & Vending Machine Labeling (cont.)

- Would ensure calorie labeling on menus and menu boards in chain restaurants, retail food establishments, and vending machines with 20 or more locations, doing business under the same name and offering for sale essentially the same menu items.
- Movie theaters, airplanes, bowling alleys, and other establishments whose primary purpose is not to sell food would not be subject to these regulations.
- Among many other issues, the proposed rule invites the public to comment on whether additional types of food establishments should or should not be covered by the new rules.
- For more information:  
<http://www.fda.gov/Food/LabelingNutrition/ucm217762.htm>





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## QUESTIONS?

