



**Implementing
the
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*





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What I will cover...


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


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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

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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

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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

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Main Themes of the Legislation

Prevention

Enhanced Partnerships

Import Safety

Inspections, Compliance, and Response

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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

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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

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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

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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

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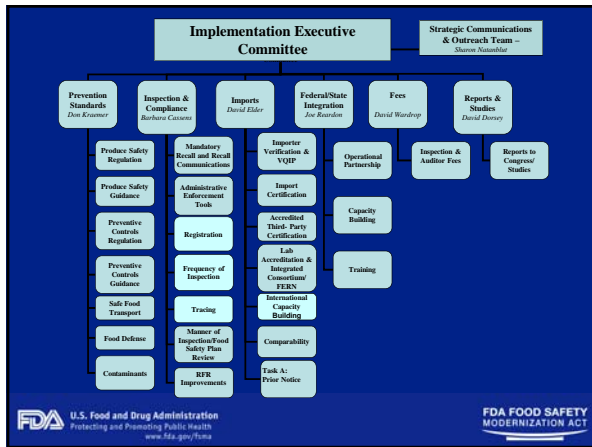
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Implementation Approach

- 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


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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

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Completed Projects (as of Aug. 1, 2011)

- Updated list and more information can be found at 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)

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So, what's something new?

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What is EFIPS?

A new method to conduct investigations electronically.

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|  |  |  |
| 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

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Hardware

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




[Panasonic HI Health Tablet PC](#)
 (no, it's not an iPad)

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Software

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




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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



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For more information



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