

An Update of FDA Produce Safety Activities

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U.S. Food and Drug Administration
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**FDA FOOD SAFETY
MODERNIZATION ACT**



Outline

- Food Safety Modernization Act Overview
- Produce Related Activities



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FDA Food Safety Modernization Act of 2011



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New law updates authority and tools

1906 Pure Food and Drug Act

Focusing on sanitation



1938 Food, Drug, and Cosmetic Act

Reacting to problems in marketplace

2011 Food Safety Modernization Act

Transforming efforts toward prevention & based on risk analysis



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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



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

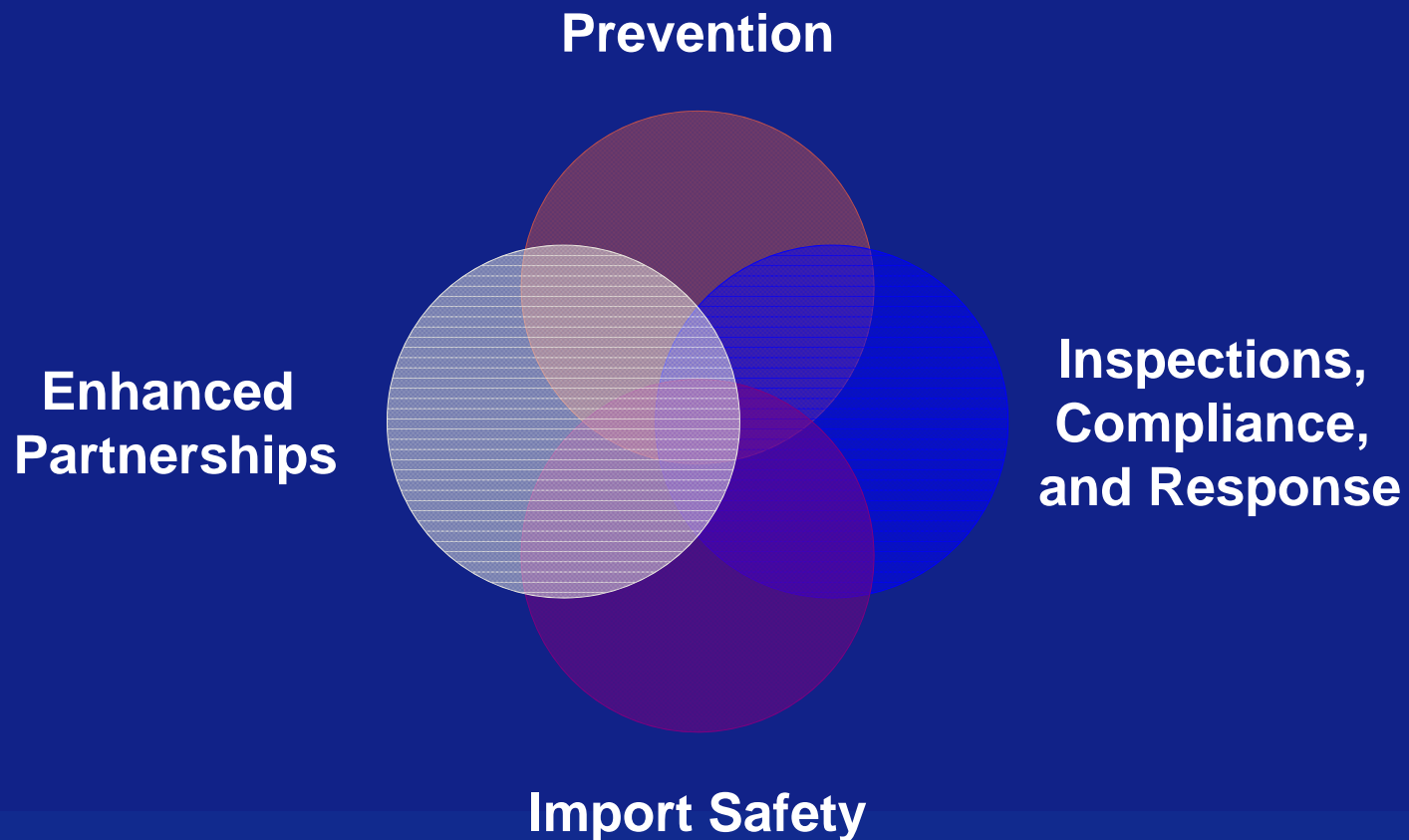


What's so historic about the law?

- 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



- FSMA focus on prevention
- Five major Preventive Control rules:
 - Food preventive controls (GMP modernization) and feed preventive controls
 - Prevention of intentional contamination
 - Sanitary transportation
 - Foreign supplier verification
 - Produce safety



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



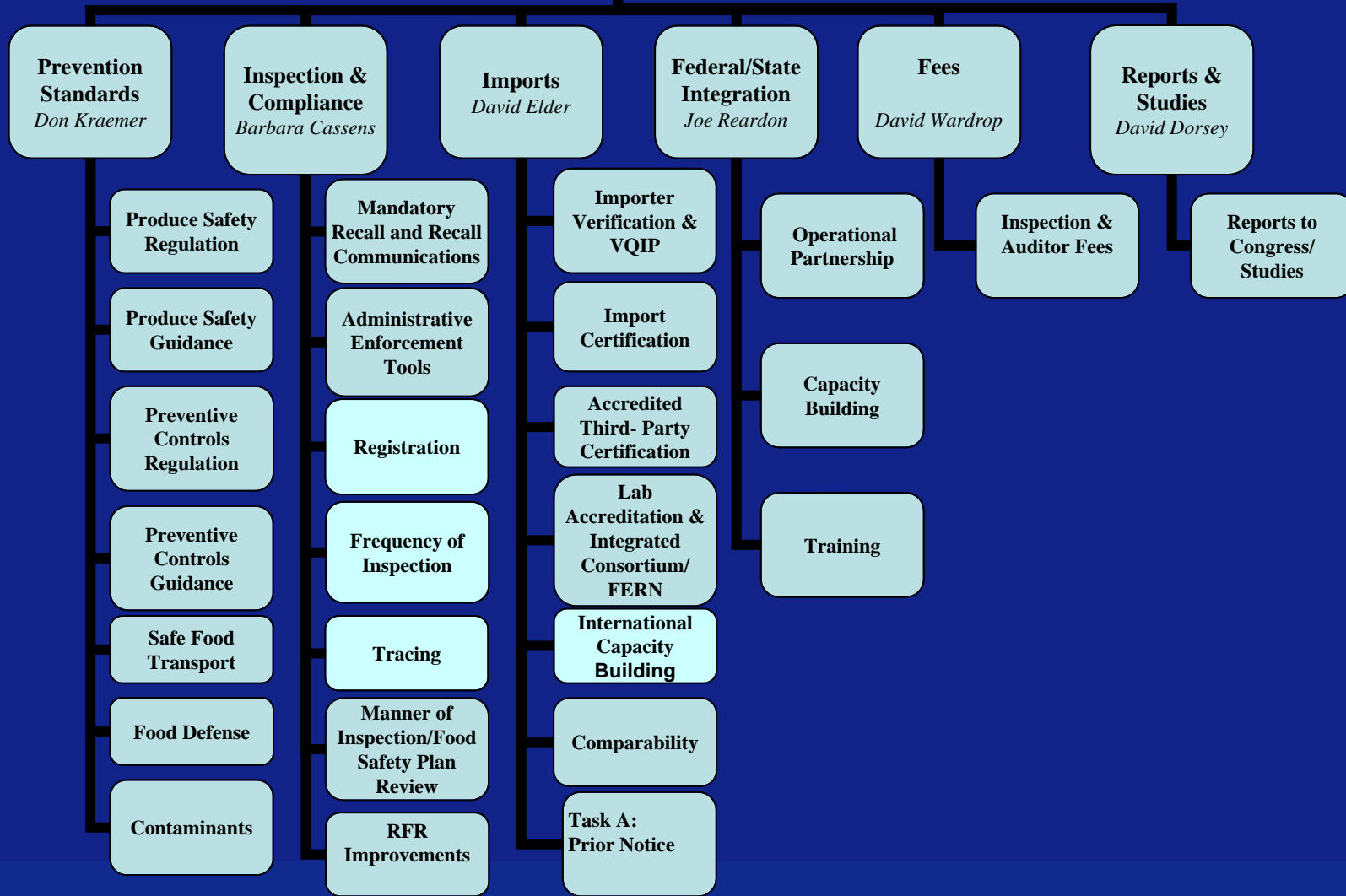
Implementation Approach

- 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



Outreach

- Public Meetings
 - Preventive Controls
 - Inspection and Compliance
 - Comparability and Import Practices
 - Imports
- Numerous listening sessions, meetings, presentations
- FSMA web page has free subscription service for immediate email updates. <http://www.fda.gov/fsma>



Priorities

- **Prevention**
 - Mandatory preventive controls for facilities (FR 18 months)
 - Produce safety standards (FR 24 months + comment period)
 - Intentional contamination (FR 18 months)
- **Inspection, Compliance, & Response**
 - Administrative detention (IFR 120 days)
 - Recall (Upon enactment)
 - Suspension of registration (180 days)
- **Imports**
 - Foreign supplier verification program (Guidance & FR 1 year)
 - Accredited third-party certification program (FR 2 years)
 - Mandatory certification for high risk foods (Upon enactment)



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Produce Related Issues



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- Produce Safety Regulation
 - Growing, harvesting, post-harvest handling of produce (e.g., trimming, washing, grading)
 - Packing of produce, where exempt from registration under the Bioterrorism Act
- Food Preventive Controls Regulation
 - Packing of produce, where subject to BT Act registration
 - Processing of produce (e.g., fresh cut)
 - Warehousing, shipping, receiving of produce



- Sanitary Transportation Regulation
 - Shipping, transportation, receiving of produce
 - Some overlap with Food Preventive Controls Regulation
 - Includes receiving by retail, shipping by farm
- Foreign Supplier Verification Regulation
 - Steps to assure compliance by foreign growers and shippers of produce



- Out of scope or exempt from most provisions:
 - “Tester Amendment”
 - Normally consumed cooked (e.g., potatoes, sweet potatoes, artichokes)
 - Produce destined for “kill step” processing (e.g., LACF, acidified)
 - Agronomic crops (e.g., grain, canola, cocoa, cottonseed, flaxseed, legumes, rice, soybean, sugar beets)



- Tester Amendment - exempt if:
 - Less than \$500,000 food sales, and
 - Majority of food sold to consumer, restaurant or retail establishment in same state or within 275 miles of farm
- Product traceability not the subject of this rule



Produce Safety Alliance

- Executive Committee
- Participation on Working Groups for curriculum development is encouraged
- Educational Conference
 - Held June 29-30 in Orlando



<http://producesafetyalliance.cornell.edu/psa.html>



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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

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

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

What's New | How to Participate | Main Topics

- Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Nomenclature 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: Meeting National Food Safety Goals
2011
July 5, 2011
- Anti-Smuggled Food Strategy Fact Sheet
July 3, 2011

More on What's New...

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 Customer Health Information
www.fda.gov/crhinfo

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 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 reasoning 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, companies will be required to develop and implement written food safety plans. FDA will have the authority to better respond and require recalls when food safety problems occur, and FDA will be able to better ensure that imported foods are as safe for consumers as foods produced in the U.S.

FDA Commissioner Margaret A. Hamburg, M.D., says the bill—reintroduced by Barack Obama—is expected



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

Take Home Message

- The new Produce Safety Rule will engage most produce farms in the U.S.
- Draft Produce Safety Rule is expected to publish in late 2011 or early 2012 with a subsequent 75 day comment period.
- Some aspects of the Preventive Controls Rule, and Sanitary Transportation Rule may also impact domestic produce farms.
- Exemptions to the rules will be applied as stated in FSMA. For example, the Tester Amendment will be applied to exclude certain small entities.



Producer Action Items

- Stay informed. Stay tuned to pertinent trade organizations and to www.fda.gov/FSMA for publication dates of regulations, guidance documents, reports and open dockets.
- Respond to the docket during the open comment period!



Farming looks mighty easy
when your plow is a pencil &
you're a thousand miles from the
~~corn field.~~ *orange grove*



Dwight D. Eisenhower



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Questions ?



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