An Update of FDA Produce Safety Activities

Mickey Parish, Ph.D.
Senior Advisor, Office of Food Safety
FDA/CFSAN
Outline

• Food Safety Modernization Act Overview
• Produce Related Activities
FDA Food Safety Modernization Act of 2011
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
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

Enhanced Partnerships

Inspections, Compliance, and Response

Import Safety
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

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 and Recall Communications
- Administrative Enforcement Tools
- Registration
- Frequency of Inspection
- Tracing
- Manner of Inspection/Food Safety Plan Review
- 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 to Congress/Studies

Reports & Studies
David Dorsey
- Strategic Communications
- Outreach Team – Sharon Natanblut

Mandatory Recall and Recall Communications

Frequency of Inspection

Administrative Enforcement Tools

RFR Improvements

Comparability

Task A: Prior Notice

FDA FOOD SAFETY MODERNIZATION ACT

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

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

Produce Related Issues
• **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
Snapshots of the different elements of the FSMA homepage found at http://www.fda.gov/fsma
Food Bill Aims to Improve Safety

Recent data from the Centers for Disease Control and Prevention show that one to 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 strengthen the U.S. food supply by ensuring food safety and addressing threats 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 to and resolve recalls when food safety problems occur, and it will have greater authority to prevent food-borne illness outbreaks and improve the safety of food from farm to table.

FSMA is part of a larger effort to improve food safety, including the FDA Food Safety Modernization Act (FSMA) Act of 2011. Chairman Margaret A. Hamburg, M.D., says the FSMA—which President Barack Obama signed into law in 2011—will be a game changer in reducing foodborne illness and improving food safety in the United States.

For more information

- 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 orange grove, corn field.

Dwight D. Eisenhower
Questions ?