IAFP Food Law PDG Webinar:
The Food Safety Modernization Act
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Pressures on the U.S. Food Safety System

- Emerging pathogens and our ability to detect them;
- Maintaining adequate monitoring of the increasing volume of imported foods;
- Maintaining adequate inspection of commercial food facilities, including the growing number of large food processing plants; and
- The growing number of people at high risk for foodborne illnesses.
Anatomy of a Modern Food Safety Law

Preventative Process Controls

Performance Standards

Federal/State Cooperation

On-Farm Controls

Import Controls

Enforcement

Inspections

Registration of Food Establishments

Research and Education

SAFER FOODS
FDA Food Safety Modernization Act

- Food companies are now required to:
  - Implement HACCP-type food safety plans and food defense plans
    - Conduct a hazard analysis and implement preventive measures on their production lines to ensure the food they produce is safe
  - Register every two years
  - Provide food safety plans and associated records to FDA inspectors
  - Meet performance standards set by FDA for controlling hazards
  - Control their imported ingredients

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Modern Performance Standards

- Legislation requires FDA to address “known food safety risks”
- “Science-based” and “contaminant-specific” limits can be issued by guidance, action level or regulation by FDA
  - Establishes the targets process controls must achieve
  - Provides a basis for FDA monitoring (and if necessary enforcement)
  - Tailored for “product or product classes” but not be “facility specific”
Defining Preventive Controls

- “Risk-based, reasonably appropriate” controls covering
  - Sanitation
  - Employee training
  - Environmental monitoring programs “to verify the effectiveness of pathogen controls”
  - Food allergen control
  - Recall plan
  - Good Manufacturing Practices
  - Supplier Verification
Recordkeeping/Record Access Requirements

- Food safety plan
  - Hazard analysis
  - Preventive controls
- Monitoring records
- Verification steps
  - Environmental and product testing
- Corrective action records
- Recall plan
- Foreign supplier verification records
- Tracking records (for high-risk foods)
Improving On-Farm Authorities

- FDA will set science-based minimum standards for safe production of high-risk raw agricultural commodities (fruits and vegetables)

- FDA will provide specific criteria for farm practices and worker sanitation

- FDA will pilot test farm-to-fork, fork-to-farm traceability
Import Controls, Including Certification

- Extending FDA’s Reach Beyond U.S. Borders
  - Importers subject to greater accountability by FDA
  - Assessment of foreign food safety programs
  - Certification that foreign food meets U.S. standards
  - Inspection authority with power to refuse entry
Imports

- Food importers will be required to ensure their foreign suppliers comply with U.S. food safety laws
  - Foreign Supplier Verification Programs must be in place 2 years after enactment

- FDA can require high-risk imported food to be certified as complying with U.S. law
  - FDA can begin immediately process of determining which food imports require certifications

- FDA to establish program for accrediting private auditors to perform certifications
  - Regulations to implement certification program must be promulgated in 18 months
  - System for recognizing accrediting bodies required no later than 2 years after enactment
Inspection Mandates

- **Inspections** - FDA is now required to inspect high risk food processors regularly
  - High-risk once in 5 years for first 5 years and once every 3 years thereafter
  - Non-high risk once in 7 years for first 7 years and once every 5 years thereafter
  - 600 foreign facilities in first year, doubling every year over next five years
- **Assistance** - FDA may rely on inspections by other Federal, State and local agencies conducted under agreements or contract
Expected Timelines

- Registration
  - First biennial registration period is Oct. 1 to Dec. 31, 2012
- Regular inspections of all plants with more frequent inspections of some plants based on risk
  - Inspection schedules apply immediately
- Process control auditing of safety plans Compliance with FSMA required in 18 months for large facilities, 2 years for small businesses and 3 years for very small businesses
- Access to food safety records, sampling and testing
  - Effective date same as for compliance with FSMA
Enforcement

- Federal regulators will have authority to:
  - Detain food that may be adulterated or misbranded
  - Recall tainted food from the market
  - Penalize persons or organizations for failing to recall foods when required
  - Suspend registration of a facility that produces food causing serious adverse health consequences or death
Improving Surveillance

- CDC is required to:
  - Coordinate federal, state and local surveillance systems
  - Develop improved epidemiological tools to improve outbreak attribution
  - Engage states to improve foodborne illness outbreak and response, and to accelerate investigations
  - Name five State Health Departments as Integrated Food Safety Centers of Excellence
Thank you!

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