
IAFP Food Law PDG Webinar:
The Food Safety
Modernization Act
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Caroline Smith DeWaal

Food Safety Director

Center for Science in the Public Interest

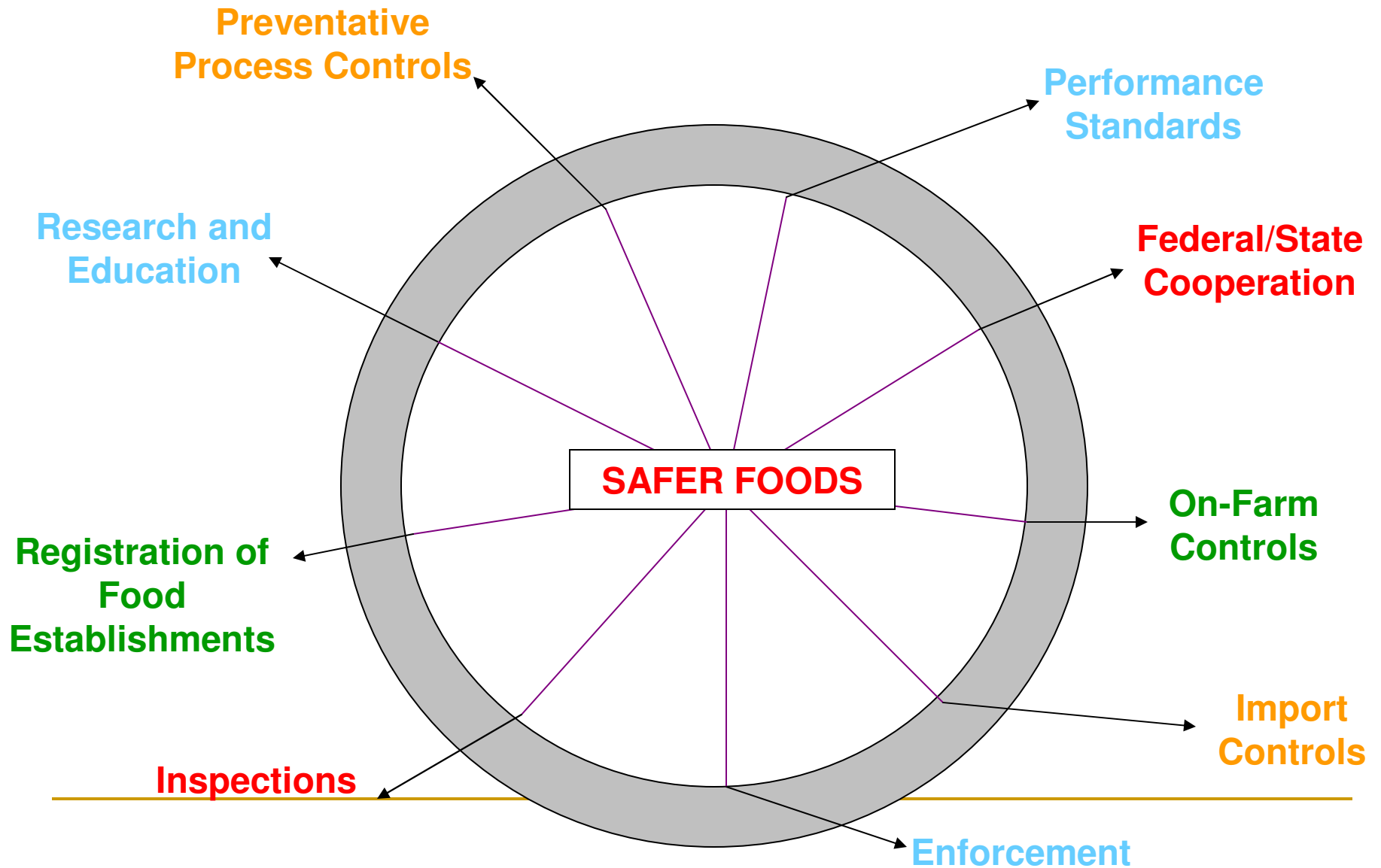


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Pressures on the U.S. Food Safety System

- 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



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

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!

Caroline Smith DeWaal
Center for Science in the Public Interest
1220 L St., NW Suite 300
Washington, DC 20005
Phone: (202) 777-8377
Fax: (202) 265-4954

E-mail: cdewaal@cspinet.org
On the internet: www.cspinet.org and
www.safefoodinternational.org

