

Overview

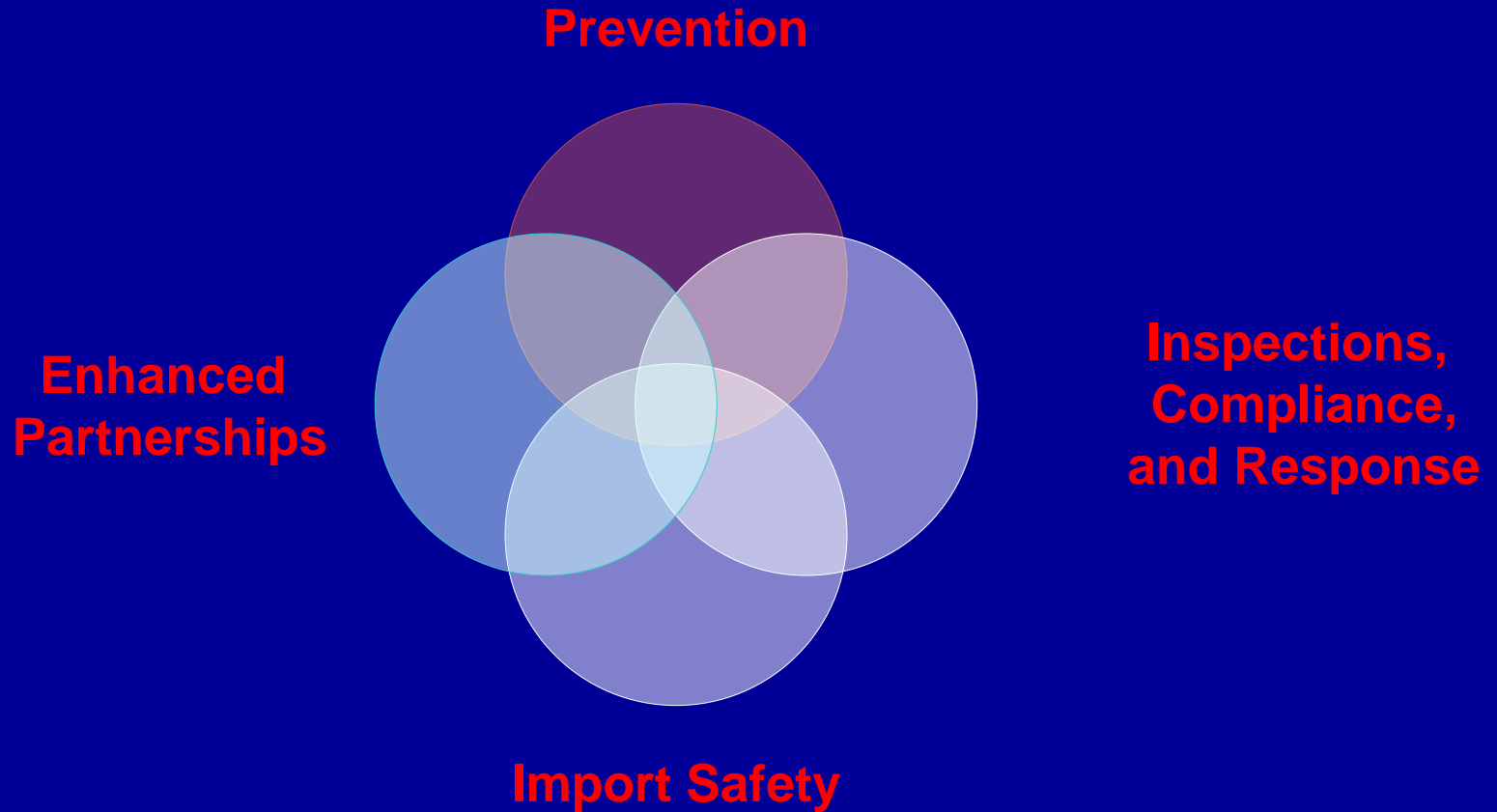
FDA Food Safety Modernization Act and Preventative Controls



Agenda

- Main themes of the law
- Provisions of the law and their significance
- Some proposed rules
- Preventative controls

Main Themes of the Legislation



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



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 to find recall information

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

Registration

- October 1 - December 31 of even years
- May be suspended if
 - Manufactured, processed, packed, received, or held SAHCODHA food
 - **And**
 - created, caused or is responsible for the condition;
 - **or** knew or had reason to know of the probability of the condition and packed, received, or held such food
- Suspended facilities may not engage in inter or intra state commerce



Expanded Administrative Detention

- Adulterated or misbranded food
- May not move the food or alter any detention marking
- Approved by the local DD and placed by an investigator
- FDA deadlines - 20 days, 30 days, 4 days

Expanded Records Access

- Expands section 414
 - Suspect article and those similarly affected
 - Reasonable belief food is adulterated and SAHCODHA
 - Reasonable probability food is SAHCODHA
- Access for requirements in new rules

Other New Tools

- Mandatory recall
- Enhanced product tracing
- Third party laboratory testing
- Re-inspection fees

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

Five Proposed Rules Establish Food Safety Framework

- Produce Safety Standards - Jan. 2013
- Preventive Controls for Human Food - Jan. 2013
- Foreign Supplier Verification Program - Jul. 2013
- Preventive Controls for Animal Food - Oct. 2013
- Accredited Third Party Certification - Jul. 2013

Key Aspects of Proposals

- Confirm industry's primary role on food safety
- Risk-based and flexible
- Address small business issues
- Extensive government, stakeholder Input

Preventive Controls for Human Food

Summary of Requirements

- Hazard Analysis and Risk-Based Preventive Controls
 - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Updated Good Manufacturing Practices

Who is Covered?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- Applies to domestic and imported food
- Some exemptions and modified requirements are being proposed

Hazard Analysis and Risk-Based Preventive Controls



Preventive Controls Required

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan
- Supplier approval and verification program?

Verification Required

- Validation
- Calibration
- Review of records
- Review of complaints, finished product and environmental testing?

Updated Good Manufacturing Practices

- Protection against allergen cross-contact
- Updated language; certain provisions containing recommendations would be deleted
- Mandated training?

Exemptions and Modified Requirements

- “Qualified” facilities:
 - Very small businesses (3 definitions being proposed—less than \$250,000, less than \$500,000 and less than \$1 million in total annual sales)
 - OR
 - Food sales averaging less than \$500,000 per year during the last three years AND
 - Sales to qualified end users must exceed sales to others

Exemptions and Modified Requirements

- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages

Exemptions and Modified Requirements

- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment
- Certain storage facilities such as grain elevators that store only raw agricultural commodities intended for further distribution or processing

Outreach and Technical Assistance Will Continue

- Public meetings
- Presentations
- Listening sessions
- Alliances
 - Produce Safety
 - Preventive Controls
 - Sprouts Safety
- Guidance documents

Partnerships will be essential

More Information Available

- Web site:
<http://www.fda.gov/fsma>
- Subscription feature available
- Send questions to
FSMA@fda.hhs.gov

The screenshot shows the FDA's website for the Food Safety Modernization Act (FSMA). The header includes the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Radiation. The main content area is titled "Food" and "The New FDA Food Safety Modernization Act (FSMA)". It features a sidebar with a "Food Safety" menu containing links to the FSMA Act, About FSMA, Full Text of the Law, Implementation & Progress, Dockets Open for Comment, Meetings, Hearings, and Workshops, Press Releases, Speeches, Statements, and Articles, Presentations & Print Material, Videos, Webinars, and Interviews, Frequently Asked Questions, and Translations of Key FSMA Resources. The main content area includes a section for "The New FDA Food Safety Modernization Act (FSMA)" with a description of the act and a link to "Get FSMA Updates by E-mail". Below this is a section for "International Capacity Building with Respect to Food Safety: Public Meeting" with a description and a "More >" link. At the bottom, there are sections for "Resources for You" (FDA Implementation Timeline, Recalls, Market Withdrawals, & Safety Alerts), "FSMA Mandates" (Federal/State Integration, Inspection & Compliance, Product Tracing, Imports, International Capacity Building), "Top Links", and "What's New" (Fees, Preventive Standards, Reports & Studies, Small Business).