



Food Safety Modernization Act

“I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action.”



*Margaret A. Hamburg, M.D.,
Commissioner of Food and Drugs*

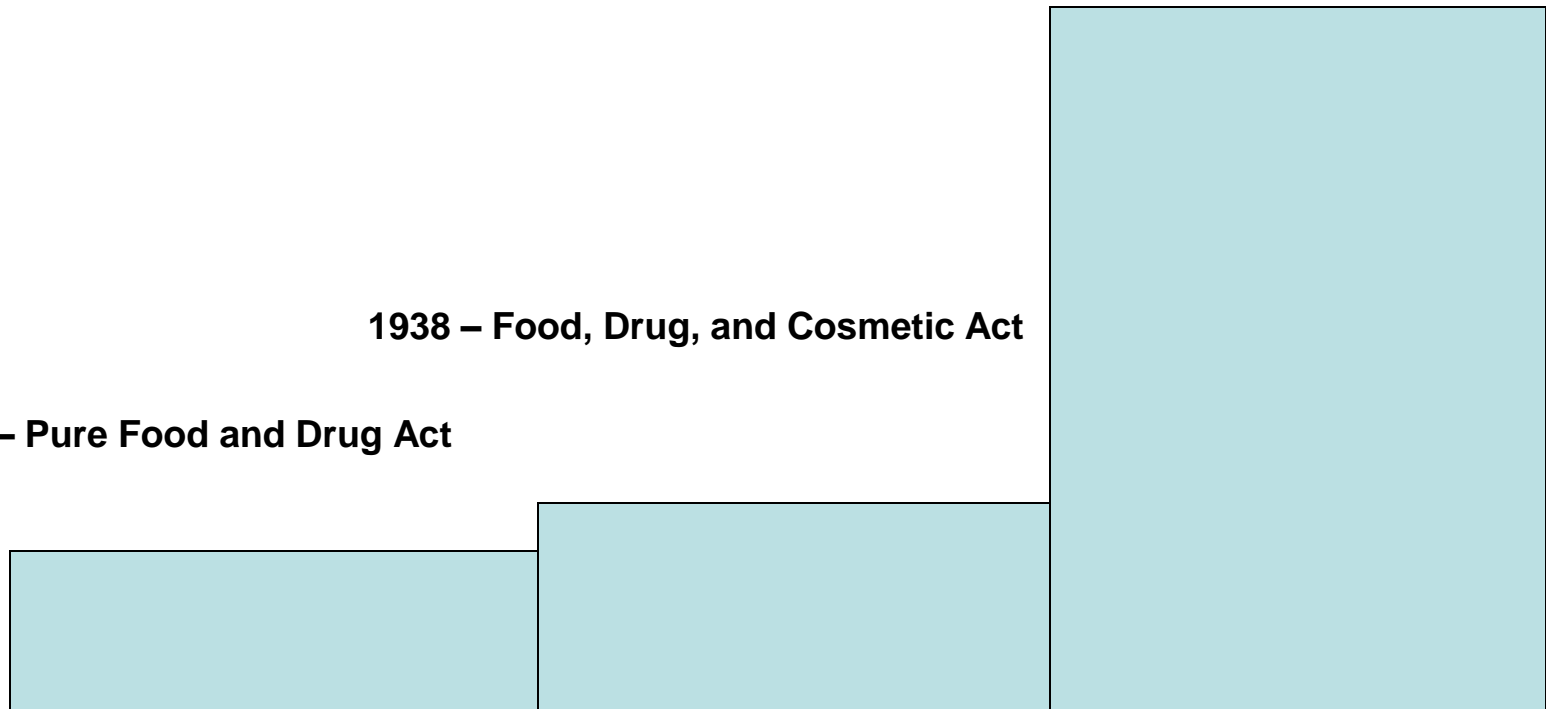


New law updates authority and tools

2011 – Food Safety Modernization Act

1938 – Food, Drug, and Cosmetic Act

1906 – Pure Food and Drug Act





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



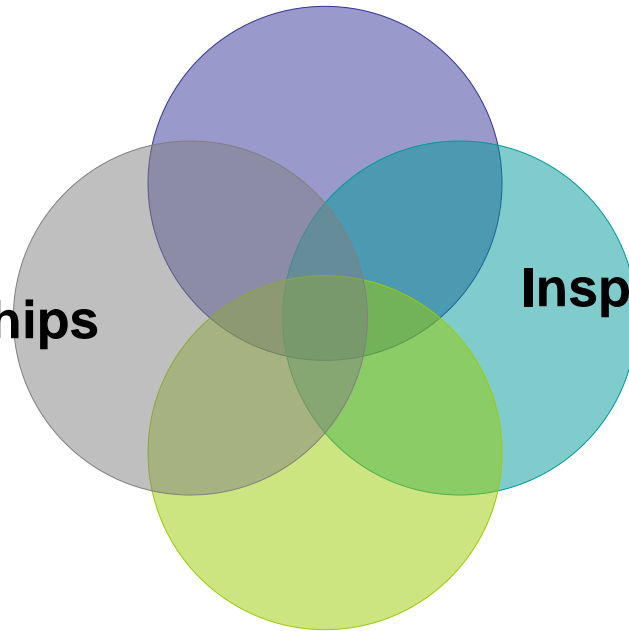
Main Themes of the Legislation

Prevention

Enhanced Partnerships

**Inspections, Compliance,
and Response**

Import Safety





Prevention:

The cornerstone of the legislation

- Comprehensive preventive controls for food 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



Inspection, Compliance, and Response

- Mandated inspection frequency
 - Considering 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 to find recall information



Resource Challenges

- Resources will be a continuing issue on the path to building a new food safety system
- FDA must adapt to make the best use of every resource in the current climate
- Critical to leverage work accomplished under federal and state systems



Engaging Stakeholders

- FDA is committed to full, transparent engagement with all stakeholders
 - Government colleagues: state, local, tribal
 - Public health experts
 - Industry
 - Consumers
- Multiple forums for outreach planned
 - Regular meetings and stakeholder calls
 - On-line updates on the status of implementation
 - Substantive dialogue on key issues



Implementation: FDA is prepared

- Experience in preventive controls
- Implementation process in place
- Much work already underway



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



Implementation Approach

- Coalition needed
- Transparency a priority
- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to do so



Priorities

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



For more information

FDA Consumer Health Information
www.fda.gov/consumer

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—which President Barack Obama is expected



- www.fda.gov
- www.foodsafety.gov



50-State Workshop: A United Approach to Public Health

50-State Workshop (August 2010)

- Highlighted progress of Partnership for Food Protection (PFP) workgroups
- Shared work of FDA Integrated Food Safety System (IFSS) workgroups
- Recognized current resource crisis, consequences and benefits of sharing resources



50-State Workshop: A United Approach to Public Health

- Strategic level discussions and input on challenges to building an integrated food safety system
 - Prioritized recommendations to further the development of a national integrated food safety system



Supporting a Common Vision

Federal, State and Local partners are joining forces to refine and implement a shared vision for an integrated food safety system.



United States Animal Health Association





Integrated National Food Safety System

***Federal, State, local, tribal and territorial partners
working collaboratively to:***

- Implement national uniform standards
- Develop a national work plan to assure coverage of the food supply
- Establish training and certification programs
- Ensure quality systems and mechanisms to generate and share consistent and meaningful data
- Provide oversight and accountability
- Sustain the program



Institute of Medicine Report: Enhancing Food Safety, The Role of FDA

Recommendation 7-1:

“The FDA should utilize the surveillance, inspection, and analytic systems and resources of state and local governments in a fully integrated food safety program. As a prerequisite to such integration, the FDA should work with the states and localities to harmonize their programs by providing adequate standards and overseeing their implementation, beginning with those states that meet such standards.”



Original Partnership for Food Protection Workgroups

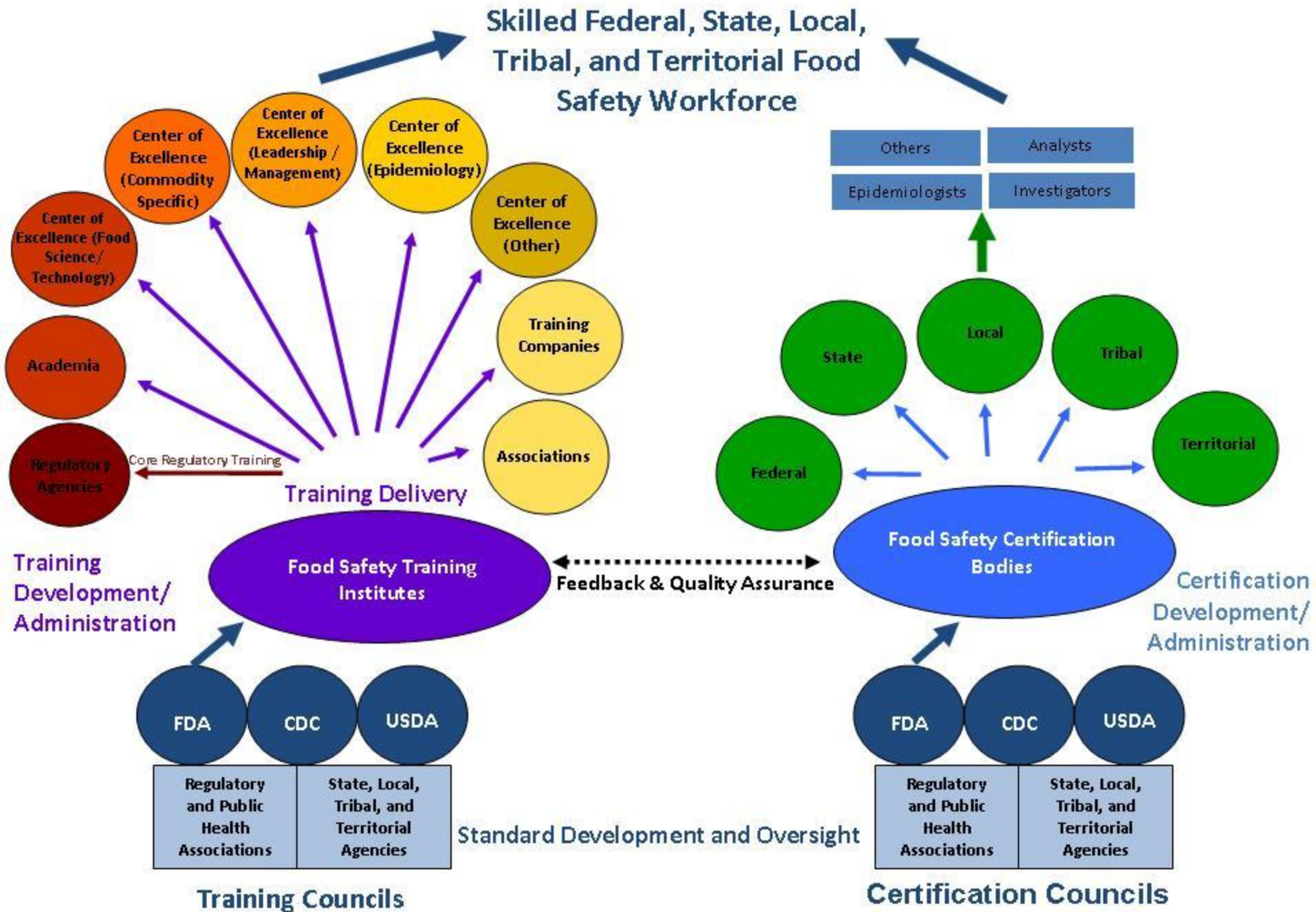
- **Training**
- **Interactive Information Technology**
- **Risk-based Workplanning**
- **Response**
- **PetNet**



Integrated Food Safety System Task Groups

- **National Standards**
- **Policy and Procedures**
- **Training and Certification**
- **National Workplan**
- **Emergency Response**
- **Laboratories**
- **Oversight**
- **Performance Measures and Outcomes**

Draft Integrated Food Safety Training and Certification Systems





Moving Forward

Work groups were determined to be a key element for success because they require collaboration and build a sense of community



Partnership for Food Protection to Build an Integrated Food Safety System

- **Information Technology**
- **Laboratories**
- **National Standards**
- **Workplanning**
- **Oversight**
- **Metrics**
- **Policy & Procedures**
- **Response**
- **Training & Certification**
- **PetNet**



FSMA Implementation

Fed-State implementation team is reviewing FSMA in relation to PFP workgroup activities to identify correlations to ensure supportive activities are accurately captured and to avoid duplication of effort



Food & Feed Assignments

PFP workgroups are charged to develop, implement & evaluate two separate integrated food safety assignments

- **collaborative assignment development**
- **all 5 FDA regions will be involved**
- **results will identify successes and gaps that can be utilized as we work towards development of a national work plan**



Funding

FY11 President's budget included \$15M for cooperative agreements/grants to the States and \$9M to IFPTI for training BUT...



Questions?