



Establishing a Fully Integrated National Food Safety System with Strengthened Inspection, Laboratory and Response Capacity

U.S. Food and Drug Administration
February 2010

Current challenges to ensuring a safe food supply

- Globalization
- Economic adulteration / intentional contamination
- Shifting demographics
- Changing consumption patterns



Current challenges for the food safety system

- Lack of resources
- Outdated laws
- Insufficient strategic planning
- Inadequate coordination across multiple agencies and jurisdictions

Change is Coming

- Supported by President Obama and White House Food Safety Working Group
- Industry, consumers and experts are aligned like never before
- Legislation



Food Safety Enhancement Act of 2009

- **1. Creates an up-to-date registry of all food facilities serving American consumers:**
 - Requires all facilities operating within the U.S. or importing food to the U.S. to register with the FDA annually.

FSE Act of 2009

- **2. Generates resources to support FDA oversight of food safety:**
 - Requires registered facilities to pay an annual registration fee of \$1,000 in order to generate revenue for food safety activities at the FDA;
 - requires registered facilities to pay for FDA's costs associated with reinspections and food recalls;
 - allows FDA to charge a fee to domestic firms requesting export certificates for exported food.

FSE Act of 2009

- **3. Prevents food safety problems before they occur:**
 - Requires all facilities operating within the U.S. or importing food to the U.S. to implement safety plans that identify and protect against food hazards. FDA would have the authority to specify minimum food safety plan requirements and to audit food safety plans.

FSE Act of 2009

- **4. Requires safety plans for fresh produce:**
 - Directs FDA to issue regulations for ensuring the safe production and harvesting of fruits and vegetables.

FSE Act of 2009

- **5. Increases inspections of food facilities:**
 - Sets a minimum inspection frequency for all registered facilities.
 - **High-risk facilities at least once every six to 18 months**
 - **Low-risk facilities at least once every 18 months to three years**
 - **warehouses that store food at least once every three to four years**
 - **Refusing, impeding, or delaying an inspection is prohibited.**

FSE Act of 2009

- **6. Improves traceability of food:**
 - Enhances FDA’s ability to trace the origin of tainted food in the event of an outbreak of foodborne illness.
 - FDA would be required to issue regulations
 - require food firms to maintain the full pedigree of the **origin** and **previous distribution history** of the food
 - link that history with the subsequent distribution history of the food;
 - establish an interoperable record to ensure fast and efficient traceback.

FSE Act of 2009

- **7. Enhances the safety of imported food:**
 - As an additional layer of protection, FDA can require food to be certified as meeting all U.S. food safety requirements by the government of the country from which the article originated or by certain qualified third parties.
 - Third party certifying entities must meet strict requirements to protect against conflicts of interest with the firm seeking certification.

FSE Act of 2009

- **8. Expands laboratory testing capacity:**
 - Requires FDA to establish a program to recognize laboratory accreditation bodies and to accept test results only from duly accredited laboratories.
 - Gives FDA the ability to require laboratories to send test results to FDA.

FSE Act of 2009

- **9. Provides strong, flexible enforcement tools:**
 - Provides FDA new authority to issue mandatory recalls of tainted foods
 - Strengthens criminal penalties and
 - Establishes civil monetary penalties that FDA may impose on food facilities that fail to comply with safety requirements.

FSE Act of 2009

- **10. Creates fast-track import process for food meeting security standards:**
 - Permits FDA to develop voluntary security guidelines for imported foods.
 - Importers meeting the guidelines would receive expedited processing.

FSE Act of 2009

- **11. Enhances the safety of infant formula:**
 - Enhances FDA's ability to assure the safety of new infant formulas before they go on the market.

FSE Act of 2009

- **12. Advances the science of food safety:**
 - Directs the Secretary to include food in an active surveillance system to assess more accurately the frequency and sources of human illness.
 - The Secretary is also directed to identify industry and regulatory approaches to minimize hazards in the food supply.

FSE Act of 2009

- **13. Enhances FDA's ability to block unsafe food from entering the food supply:**
 - Strengthens FDA's authority to administratively detain unsafe food products.
 - Grants FDA "quarantine" authority under which the agency may restrict or prohibit the movement of unsafe food products from a particular geographic area.

FSE Act of 2009

- **14. Directs FDA to assess the use of carbon monoxide in certain foods:**
 - Requires FDA to conduct a safety review of the use of carbon monoxide in meat, poultry, and seafood products.

FSE Act of 2009

- **15. Enhances transparency of GRAS program:**
 - Requires posting on FDA’s website of documentation submitted to FDA in support of a “generally recognized as safe” (GRAS) notification.

FSE Act of 2009

- **16. Requires country-of-origin labeling and disclosure:**
 - Requires all processed food labels to indicate the country in which final processing occurred.
 - Requires food manufacturers to identify the country of origin for all ingredients on their websites.
 - Requires country-of-origin labeling for all produce.

Vision for the Future

Focus on **preventing** foodborne illness by:

- Developing prevention-oriented standards
- Responding rapidly and effectively
- Ensuring optimal use of all available resources, which means:

Building an integrated national food safety system

Build on Current Work

- Food Protection Plan as a foundation
- August 2008 50-State Meeting → Partnership for Food Protection Work Groups
- Information sharing
- Contracts, grants and cooperative agreements
- Training and certification

Integrated National Food Safety System

- Develop standards to ensure consistency
- Train and certify a highly skilled workforce
- Work across jurisdictions to ensure protection of the entire food supply from farm to table
- Create mechanisms for data sharing
- Ensure use of quality systems
- Build oversight and accountability

Shared Vision for an Integrated Food Safety System

- FDA, CDC, USDA, and Federal, state and local partners are working together to develop and implement vision
- Vision document shared with Federal, state, and local partners (available on www.fda.gov)

Shared Vision for an Integrated Food Safety System

- FDA has received feedback on and support for the vision paper from:
 - Association of Food and Drug Officials (AFDO)
 - Association of American Feed Control Officials (AAFCO)
 - National Association of State Departments of Agriculture (NASDA)
 - Association of Food and Drug Officials of the Southern States (AFDOSS)
 - National Association of County and City Health Officials (NACCHO)

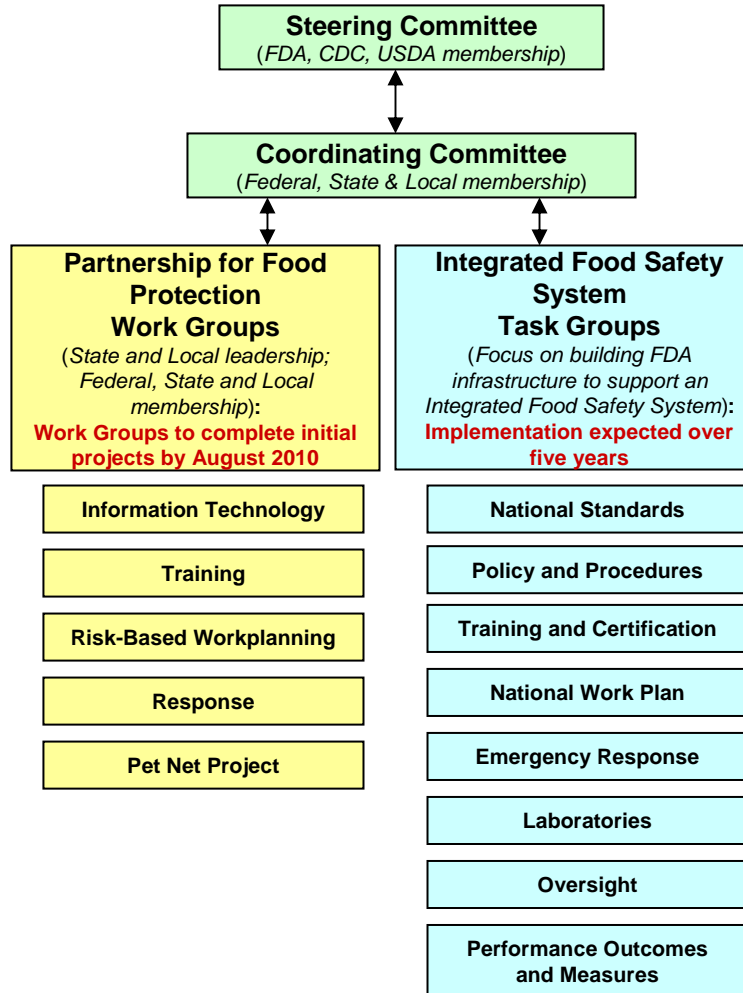
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Partnership for Food Protection Work Groups



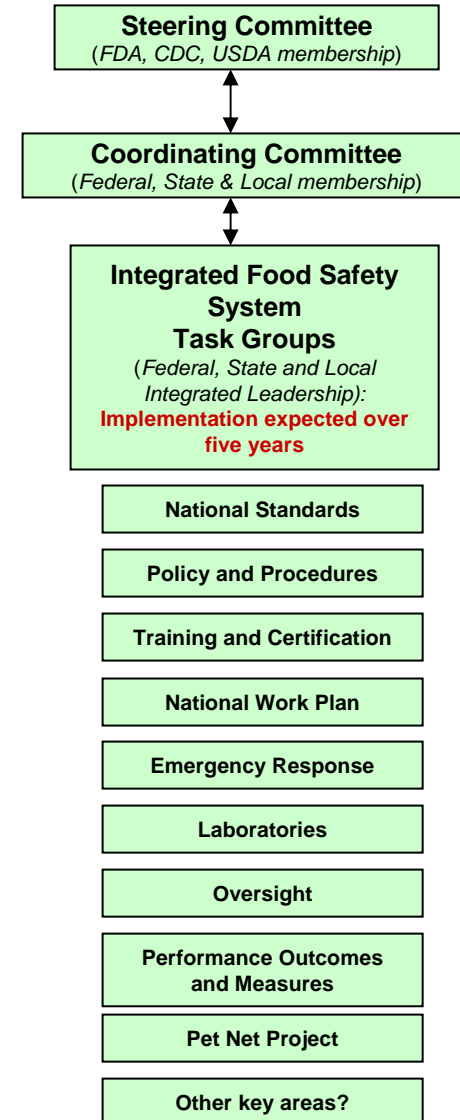
PRESENT

Partnership for Food Protection Work Groups and Integrated Food Safety System Task Groups



FUTURE

Integrated Food Safety System Task Groups



An Integrated Food Safety System will result in:

- **National Standards**
 - Uniform inspectional coverage and sample collection and analysis
 - Greater use of each other's analysis and observations in protecting public health
- **National Work Plan**
 - Improved targeting of resources
 - Expanded inspections and sample collection coverage

An Integrated Food Safety System will result in:

- **Training and Certification Programs**
 - High level of scientific quality in data collection and inspections
 - Consistent best-practice approaches and capacity across state and local agencies
- **Laboratory Program**
 - Consistent and meaningful data for compliance, surveillance, and environmental samples

An Integrated Food Safety System will result in:

- **Integrated Response**
 - Coordinated, faster and more effective response to food safety events

- **Program Oversight**
 - Auditing to ensure performance meets the program standards

What is necessary for success?

- Support from stakeholders
- Engagement from partners
- Multi-year investment
 - Federal - Local - Territorial
 - State - Tribal
- Information sharing infrastructure

Summary of the Change

- Build on current collaborations
- Provide stronger, more uniform coverage from farm to table
- Maintain credibility through oversight
- Sustain public health infrastructure through multi-year investment

Outcome: *Reduced incidence of foodborne illness*

Conclusion

A fully integrated national food safety system is a critical component to the President's overall public health focused food safety framework

