



Food Safety Modernization Act (FSMA)

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FSMA

- Congress passed FSMA w/ overwhelming bi-partisan majorities
- President signed into law on January 4, 2011



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■ Historic

- Involves creation of new food safety system
- Broad prevention mandate & accountability
- New system of import oversight
- Emphasizes partnerships
- Emphasizes farm to table responsibility
- Developed through broad coalition



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- FSMA calls for a number of rules (aka regulations) and guidances



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FSMA will be implemented over time, and the public will have opportunities to participate in the process



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- Rulemaking process:
 - FDA proposes a rule and requests comments
 - Comments are considered and final rule issued
 - Companies comply with rule based on effective date

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- Why?
 - Globalization
 - Food supply more complex and hi-tech
 - Shifting demographics



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- Why?
- Foodborne illness is a significant public health burden which is largely preventable



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- Foodborne illness largely preventable if everyone in global food chain held responsible and accountable at each step for controlling hazards that can cause illness



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Main themes





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- FDA has legislative mandate to require comprehensive, preventive-based controls across the food supply chain



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- Preventive controls include steps that a food facility would take to prevent or significantly reduce the likelihood of problems occurring



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■ Prevention

- cGMPs will form the foundation for preventive controls
- Training, environmental controls, allergen controls, recall plans, supplier verification



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■ Prevention Standards Mandates

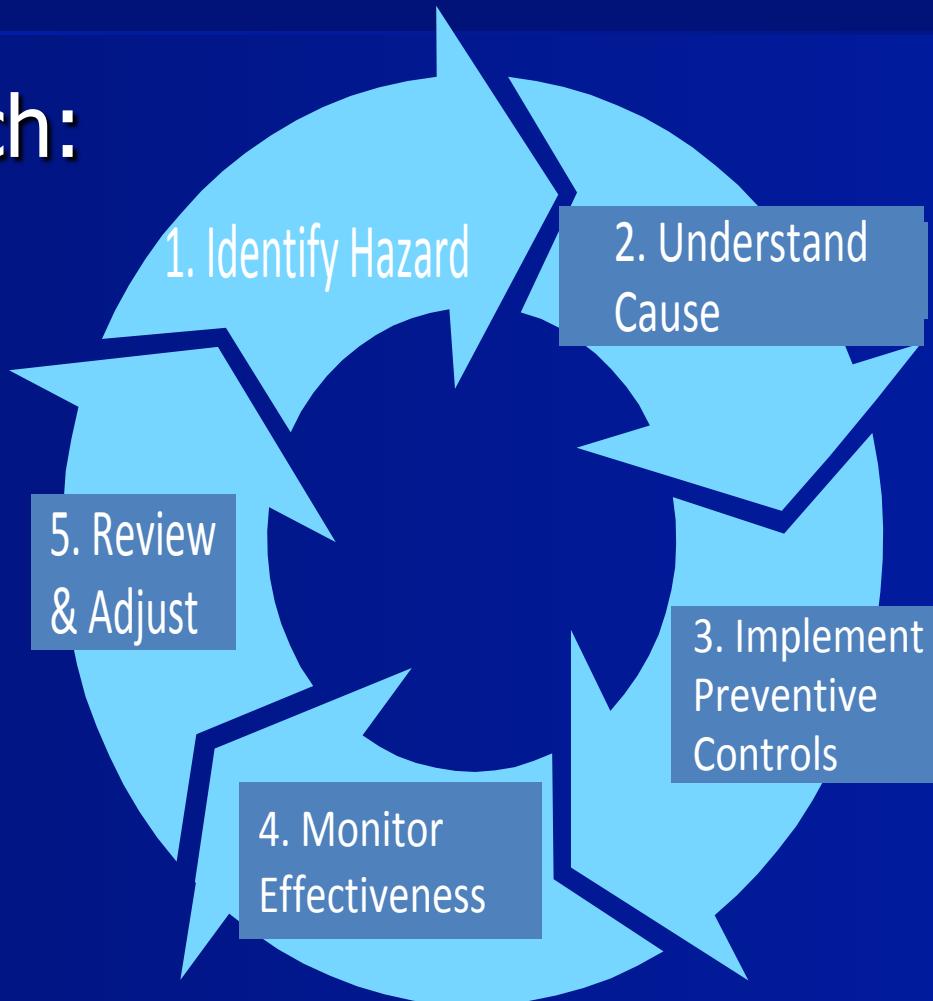
- Evaluate hazards
- Identify and implement preventive controls
- Monitor controls and maintain records
- Conduct verification activities



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Approach:





Prevention- Six major rules:

- Food preventive controls
- Feed preventive controls
- Prevention of intentional contamination
- Sanitary transportation
- Foreign supplier verification
- Produce safety



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■ Inspection and Compliance

- Inspection is important means of holding industry accountable for their responsibility to produce safe food



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- Inspections and Compliance
- Based on risk
- Innovative in approach



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- Inspection, Compliance & Response
 - Mandated inspection frequency
 - Considering new ways to inspect
 - New tools
 - Mandatory recalls
 - Expanded access to records
 - Expanded administrative detention
 - Suspension of registration
 - Enhanced product tracking
 - 3rd party lab testing



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- Inspections and Compliance
 - Records
- Expanded records access



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- Inspections and Compliance
 - Mandatory Recalls

- Anticipate recall authority will only be used in rare instances



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- Inspections and Compliance
 - Registration

- Facilities required to register will have to re-register every two years between October 1 and December 31 in even number years beginning in 2012



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- Inspections and Compliance
 - Registration

- Under certain circumstances FDA has authority to suspend a facility's registration



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- Inspections and Compliance
 - Administrative Detention

- Authorizes FDA to administratively detain articles of food that it has reason to believe is adulterated or misbranded



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■ Imported Foods

– 15% of US food supply is imported

- 50% fresh fruits
- 20% vegetables
- 75% of seafood



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■ Imported Foods

- Importers will be required to have a program to verify the food products they are bringing into the US are safe
(Foreign Supplier Verification Program)



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■ Imported foods

- FDA can require certification based on risk criteria that imported foods are in compliance with food safety requirements



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■ Imported Foods

–FDA can refuse admission of imported food if inspection refused



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■ Imported foods

- FDA will establish voluntary program through which imports may receive expedited review to their shipments if importer has taken certain measures to assure food safety



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- Enhanced Partnerships
 - Reliance on inspections by other agencies
 - State/local & international capacity building
 - National agriculture & food defense strategy
 - Consortium of laboratory networks