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United States Food and Drug Administration Food Safety Modernization Act

Submitted by: United States



**First Expert Meeting on Trade Facilitation Through
an APEC Framework on Food Safety
Modernisation
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U.S. FDA

Food Safety Modernization Act

(FSMA)

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FDA Food Safety Modernization Act (FSMA)

- Signed into US law January 2011
- Most sweeping change in FDA's food safety authority in more than 70 years
- Recognized regulatory challenges in a globalized world

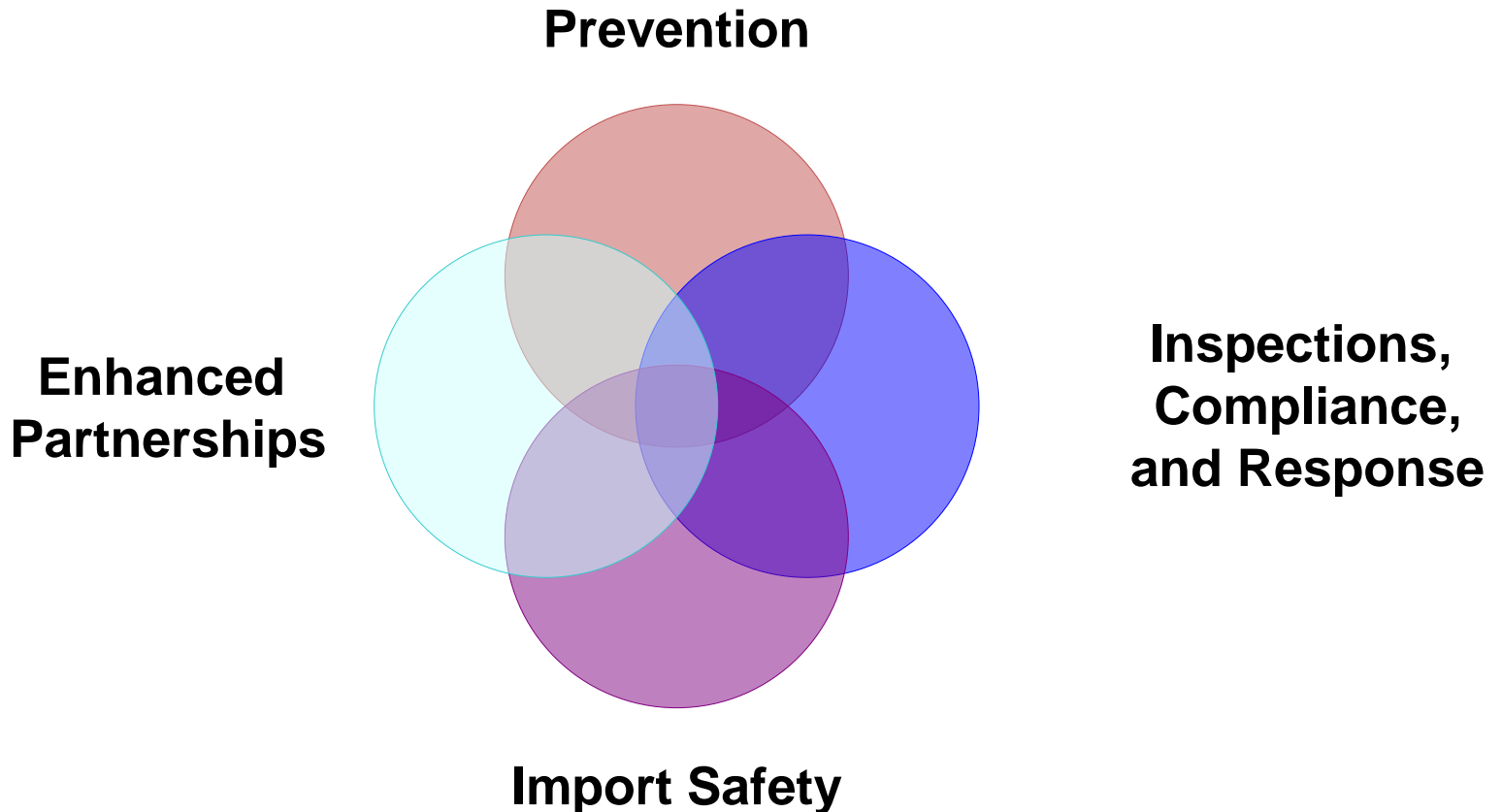
What's historic about the law?

- 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

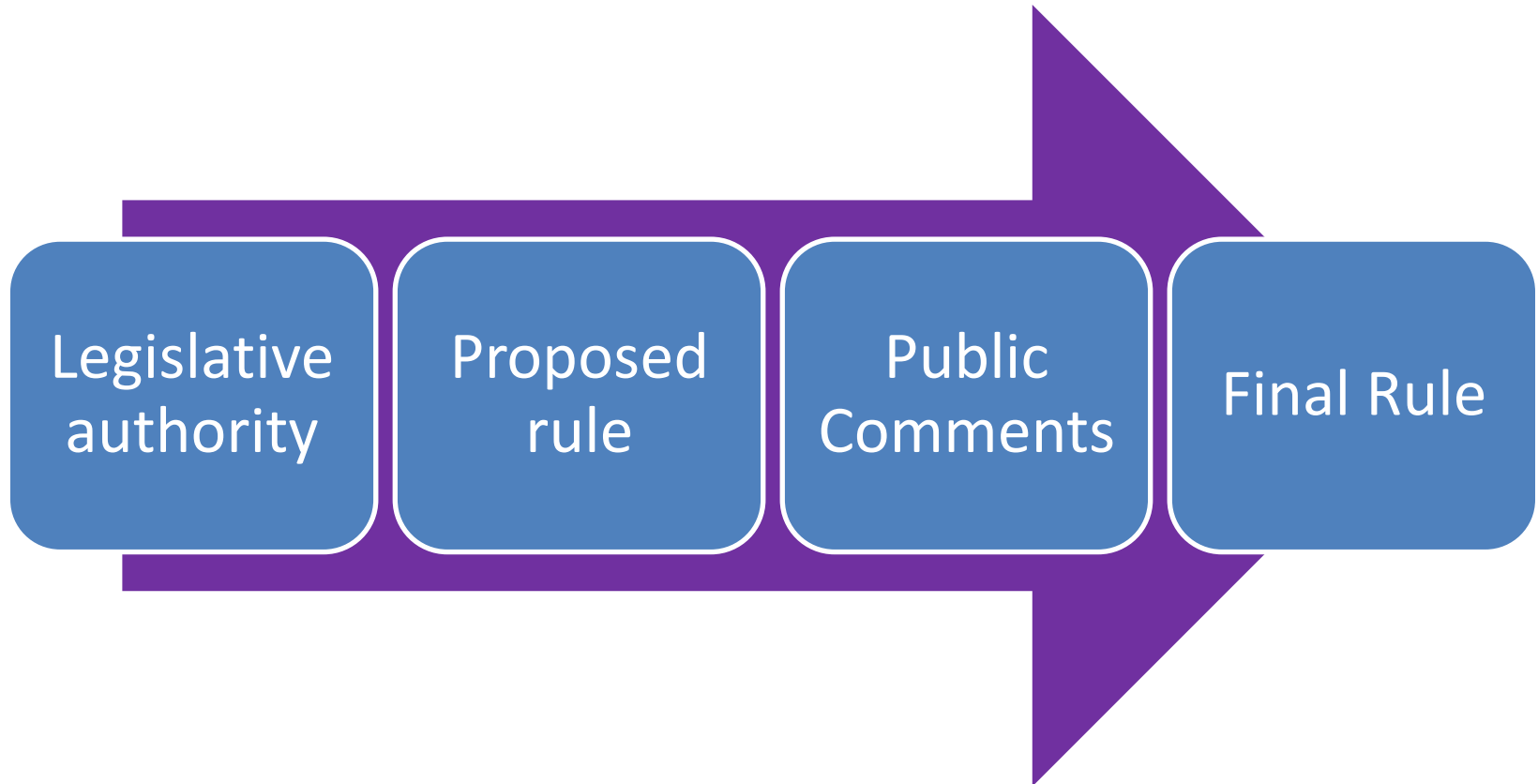
Food Safety Modernization Act



FSMA's Main Themes



FDA rulemaking process



Seven Foundational Final Rules

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Produce Safety
- Foreign Supplier Verification Program
- Accredited Third-Party Certification
- Sanitary Transportation
- Intentional Adulteration

Preventive Controls

- Requires human and animal food facilities to:
 - Evaluate hazards that could affect food safety
 - Identify and implement preventive controls to prevent hazards
 - Monitor controls and maintain monitoring records
 - Conduct verification activities

Produce Safety

- Establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables
- Applies to raw agricultural commodities for which FDA determines that such standards minimize the risk of serious adverse health consequences or death.

Intentional Adulteration

- Aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health
- Requires facilities to conduct vulnerability assessments of the food supply and determine mitigation strategies

Sanitary Transportation

- Requires persons engaged in food transportation to use sanitary transportation practices to ensure that food is not transported under conditions that may render it adulterated.
 - Contamination
 - Refrigeration for safety
- Partnership with Department of Transportation

Import Safety

- New system of food safety oversight for the 21st century
- Transformational shift from response to prevention
- Parity between domestic and imported foods
- Provides additional tools to hold industry accountable for producing safe food
- Can deny products entry if FDA access for inspection is denied

Import Safety - Programs

- Foreign Supplier Verification Program
 - Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements.
- Voluntary Qualified Importer Program
 - Allows for expedited review and entry; facility certification required

Import Safety - Programs

- Accredited Third-Party Certification Program
 - FDA can rely on accredited third parties to certify that foreign food facilities meet U.S. requirements
 - FDA has discretionary authority to require assurances of compliance for high-risk foods
 - Voluntary certification supports participation in VQIP

Inspection, Compliance, and Response

- Mandated inspection frequency
- New tools
 - Mandatory recall
 - Expanded records access
 - Expanded administrative detention
 - Suspension of registration
 - Enhanced product tracing
 - Third party laboratory testing

Inspections, Compliance, and Response

- Key Principles:
 - Focus on gaining industry compliance and reducing the risk of foodborne illness
 - Not a “One Size Fits All” approach
 - Recognition that not all situations are equal relative to risk and potential for public health impact
 - Interactive, cooperative inspections
 - Encourage industry to comply and make corrections on its own
 - Regulatory strategy that is dynamic

Enhanced Partnerships: Vital to Success

- State/local and international capacity building
- Increased emphasis on coordination with partners

Education, Outreach, and Technical Assistance

- Key Implementation Principle: Facilitate industry compliance with prevention-oriented standards through guidance; developing tools/resources for education, outreach and technical assistance

Industry Training: Alliances

- Food Safety Preventive Controls Alliance (FSPCA)
 - Curricula to train:
 - Facilities that manufacture, process, hold, and distribute human and animal food
 - Importers subject to the FSVP rule
 - Facilities subject to the intentional adulteration rule
- Produce Safety Alliance (PSA)
 - Curriculum to train the farming community
- Sprout Safety Alliance (SSA)
 - Curriculum to train sprout growers

FSMA Technical Assistance Network

- Goal: to provide a central, consistent source of outreach and technical assistance for stakeholders
- To submit a FSMA regulatory interpretation question, visit www.fda.gov/fsma

For more information

- Web site: <http://www.fda.gov/fsma>
- Subscription feature available

