



# **Multi-State/SAADRA Joint Regional Workshop**

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# Agenda

- ▣ Food Safety Modernization Act Overview
- ▣ Federal-State Implementation

# Why Is the Law Needed?

- ▣ Globalization
  - 15 percent of U.S. food supply is imported
- ▣ Food supply more high-tech and complex
  - More foods in the marketplace
  - New hazards in foods not previously seen
- ▣ Shifting demographics
  - Growing population (about 30%) of individuals are especially “at risk” for foodborne illness

# 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: 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

# 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

# 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 for consumers to find recall information

# 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 Progress (as of August 1, 2011)

- ▣ Fees (sec. 107)
- ▣ New dietary ingredients ( sec.113)
- ▣ Anti-smuggled food strategy (sec. 201)
- ▣ Registration of Food Facilities (sec. 103)
- ▣ Prior Notice of imported food shipments (sec. 304)
- ▣ Administrative detention of food (sec, 207)
- ▣ Consumer-friendly web search for recalls (sec. 205)
- ▣ Guidance to Seafood Industry on food safety hazards (sec. 103)

Updated list and more information can be found at:  
[www.fda.gov/fsma](http://www.fda.gov/fsma)

# Outreach

- ▣ Public Meetings
  - Preventive Controls (April 20, 2011)
  - Inspection and Compliance (June 6, 2011)
  - Comparability and Import Practices (March 30-31, 2011)
  - Imports (March 29, 2011)
  
- ▣ Numerous listening sessions, meetings, presentations
  
- ▣ FSMA web page has subscription service for immediate updates.

# Rulemaking Process

- ▣ Rulemaking is open and public.
- ▣ Draft rules are published on [www.regulations.gov](http://www.regulations.gov)
- ▣ Time is allowed for public comment, and FDA is required to consider significant comments during the rulemaking process.
- ▣ Check [www.fda.gov/fsma](http://www.fda.gov/fsma) to find out what is open for comment.

# Targeting of Inspection Resources for Domestic Facilities

## Section 201

- ▣ Reliance on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memoranda of understanding, or other obligation
- ▣ The Manufactured Food Regulatory Program Standards will provide the foundation and framework to accept work conducted by State and local agencies
- ▣ FDA has created an independent audit group that will objectively ensure uniform implementation of the Standards

# Improving the Training of State, Local, Territorial, & Tribal Food Safety Officers Section 209

- ▣ Set standards and administer training and education programs for State, local, territorial and tribal food safety officials
- ▣ A contract or memorandum of understanding shall serve as the funding mechanism and will include provisions to ensure adequate training
- ▣ This will result in inspection staff being uniformly trained to conduct testing, examinations, inspections, and investigations providing greater consistency and equivalency among State programs

# Enhancing Food Safety

## Section 210

- ▣ Provides a legislative mandate, through the grant process, for direct investment in the infrastructure in State and local capacities to carry out food safety programs
- ▣ Eligible entities will be able to:
  - Build the food safety capacity of the laboratories
  - Build the infrastructure and capacity of food safety programs
- ▣ The grant will work to increase capabilities and capacities of State programs



# Surveillance

## Section 205

- ▣ A review of State and local capacities as well as needs for enhancement will be completed no later than one year after the date of enactment
- ▣ This review will assess the current status of State and local food and agricultural regulatory program capacity and needs for enhancement
- ▣ A review of current surveys and data gathered from national associations has resulted in the identification of significant gaps. Additional surveys will be conducted to ensure sufficient data coverage
- ▣ The combined results of the surveys will be used to develop and implement strategies to leverage and enhance food safety and defense capacities of State and local agencies

# Additional FSMA Sections Requiring Federal-State Interaction

- ▣ Section 108 – Report to Congress on the National Agriculture and Food Defense Strategy
- ▣ Section 110 – Two year timeline, report to Congress describing outreach, education and training provided to States and local governments to build State and local food safety and defense capabilities
- ▣ Section 202 – Lab accreditation and capacity

# Produce Rule

- ▣ This rule considers the risk posed by practices and commodities.
- ▣ Focuses on identified routes of microbial contamination
- ▣ Certain produce which is rarely consumed raw is excluded from regulation as are commodities subject to commercial processing such as retorting.
- ▣ The rule allows for variances, alternatives to some provisions.
- ▣ Allows additional time for small farms to comply

# Preventive Controls for Human Food

- ▣ Confirm industry's primary role in food safety through a requirement for a written food safety plan
- ▣ Focuses on prevention of hazards
- ▣ Risk based
- ▣ Allows for exemptions and modified requirements

# Cantaloupe Pilot Project

- ▣ Two seminars conducted by NCDA&CS and NCSU Cooperative Extension in April
- ▣ Covered food safety topics specifically for cantaloupe producers; sanitation; water; equipment; environmental sampling; validation
- ▣ On-farm outreach portion is voluntary - provide an assessment of the farming operation to help identify potential concerns with regard to future federal food safety rules and regulations

# Three Additional Proposed Rules Are Still In Progress:

- ▣ Preventive Controls for Animal Feed
- ▣ Foreign Supplier Verification Program
- ▣ Accredited Third Party Certification

# Rapid Response Teams (RRT)

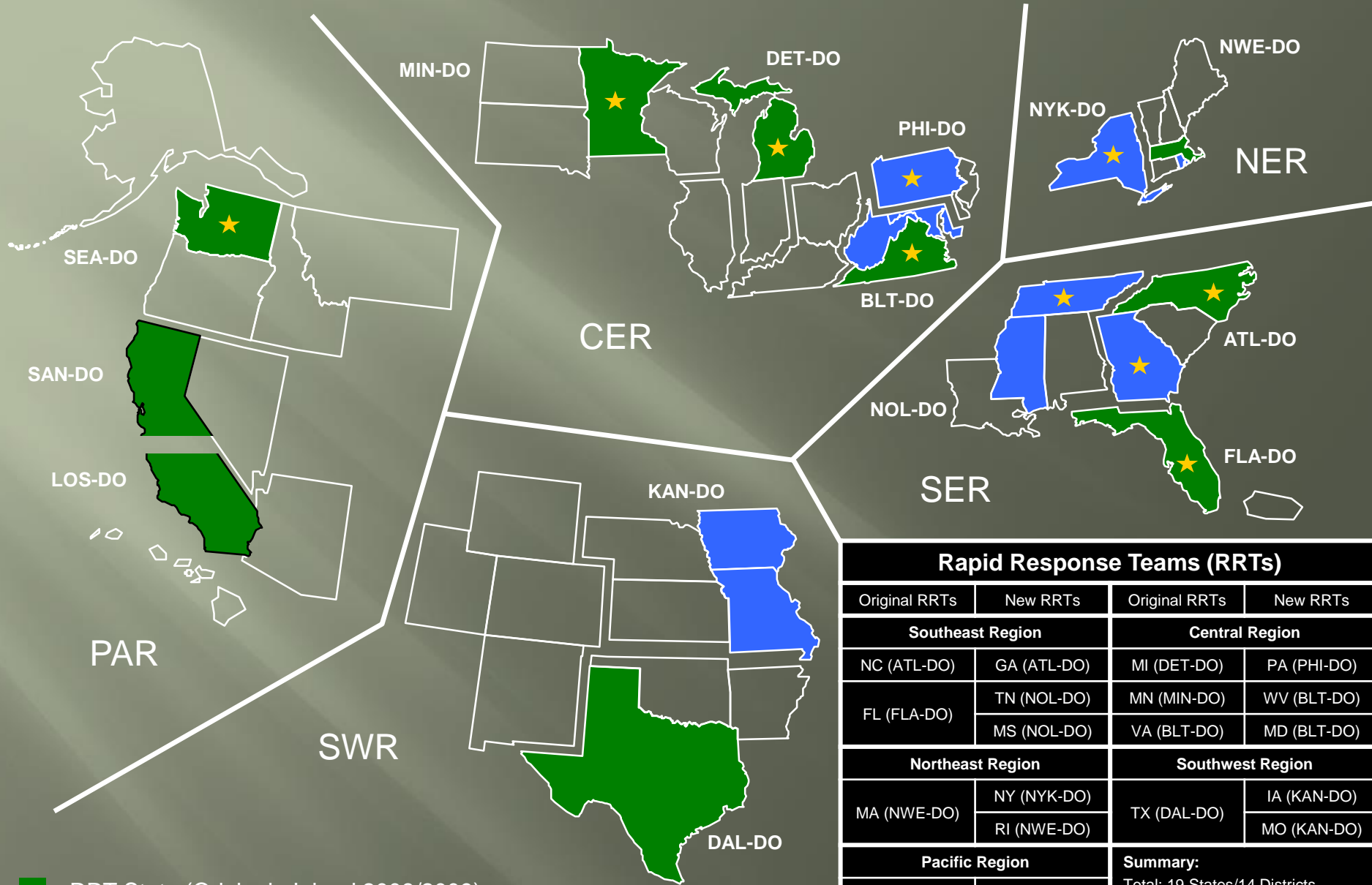
- ▣ Multi-year Cooperative Agreement
  - Awards range from \$300,000 - \$500,000
- ▣ Develop Rapid Response Capabilities
  - RRT Manual (Best Practices)
  - Metrics
- ▣ Improve Program Infrastructure
  - MFRPS Implementation
- ▣ Strengthen Federal/State/Local Collaboration
  - Across programs (health, agriculture, etc)
  - Across initiatives (IFSS, CDC FoodCORE, etc)

## Did You Know?

9 RRTs are in Public Health Agencies

10 RRTs are in Departments of Agriculture

# Rapid Response Teams (Original & Additions from 2012 RFA)



■ = RRT State (Original- Joined 2008/2009)

■ = New RRT State (Under 2012 RFA)

★ = Department of Agriculture

Rapid Response Teams (RRTs)			
Original RRTs	New RRTs	Original RRTs	New RRTs
<b>Southeast Region</b>		<b>Central Region</b>	
NC (ATL-DO)	GA (ATL-DO)	MI (DET-DO)	PA (PHI-DO)
FL (FLA-DO)	TN (NOL-DO)	MN (MIN-DO)	WV (BLT-DO)
	MS (NOL-DO)	VA (BLT-DO)	MD (BLT-DO)
<b>Northeast Region</b>		<b>Southwest Region</b>	
MA (NWE-DO)	NY (NYK-DO)	TX (DAL-DO)	IA (KAN-DO)
	RI (NWE-DO)		MO (KAN-DO)
<b>Pacific Region</b>		<b>Summary:</b>	
WA (SEA-DO)	N/A	Total: 19 States/14 Districts	
CA (LOS-DO & SAN-DO)		•2008: 6 States/7 Districts	
		•2009: 3 States/3 Districts	
		•2012: 10 States/7 Districts	





**THANK YOU!**

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