



**U.S. Food & Drug Administration
Office of Regulatory Affairs
Division of Federal- State Relations (DFSR)
Update**

**AFDO Annual Conference
June 21, 2010**

Joseph W. Reardon

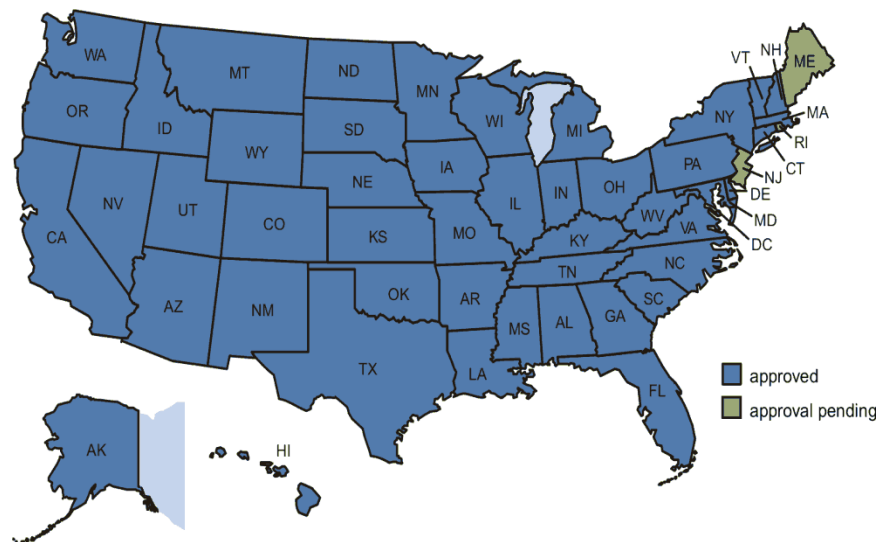
Director, Division of Federal-State Relations

Ellen Laymon

**Team Leader, Manufactured Food Regulatory Program
Standards (MFRPS)**

DFSR Mission

- Leadership
- Information
- Guidance
- Resource Management





Current Initiatives

- Food Safety Task Forces
- Rapid Response Teams
- Framework for Listening Sessions
- Improve response and communication on current events
- Continued support of small conferences
- Program Standards (MFRPS)

Vision for the Future

- Defining Integrated National Food Safety System
- Utilize resources to better support customers
- Create dynamic communication platform
- Framework for feedback from state and local governments
- Establish Quality Management System
- Development & Integration Branch
- New Staff



Integrated Food Safety System “One Mission, One Program”

- Build on current collaborations
- Provide stronger, more uniform coverage from farm to table
- Maintain credibility through oversight
- Sustain through multi-year funding
- Increase customer service internally & externally





Contract Options

- Seafood HACCP
- Low Acid Canned Foods (LACF)/Acidified Foods (AF)
- Juice HACCP
- Sample Collections- Food and Feed (new)
- Audits –Phase II & III
- Manufactured Food Regulatory Program Standards (MFRPS)
- Environmental Sampling
- Domestic and Import Sample Collection
- Training
- Eggs (new)



Contracts 2009

<u>Program</u>	<u>States</u>	<u>Inspections</u>	<u>Amount</u>
Food	44	11,435	\$9.5M
Feed	36	5,684	\$2.5M
Tissue Residue	20	270	\$295K
MQSA	46	7,373	\$9.6M
Medical Device	1	20	\$85K
Milk Residue		<u>Data*</u>	<u>\$105K</u>
		24,782	\$22.09M

- 24,230 inspections over 260 work days = 93 inspections every day

*Analysis of over 4 million milk residue sample analysis



Grants/Cooperative Agreements 2009

<u>Programs</u>	<u># of States</u>	<u>Amount</u>
Food Protection Task Forces	24	\$200K
Food Emergency Response Network (FERN)		
– Biological		
– Microbiological		
– Radiation	34	\$10.0M
Ruminant Feed Ban Support (BSE)	12	\$3.0M
Rapid Response Teams	9	\$4.5M
Innovative Food Defense	4	\$160K

Rapid Response Teams

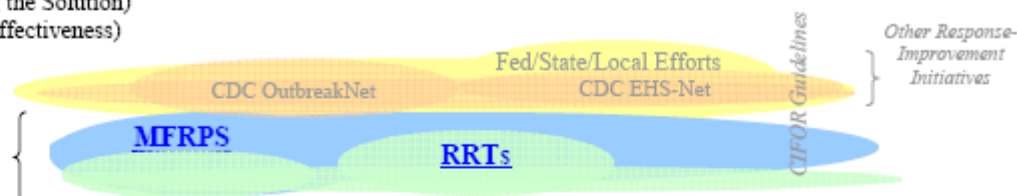
- 9 States/10 Districts Participating
 - 6 RRTs started in 2008 (CA, FL, MA, MI, MN, NC)
 - 3 RRTs started in 2009 (TX, VA, WA)
- 3-year Cooperative Agreement (\$500k/year)
- RRT Activities
 - Collaboration
 - Communications
 - Policies/Procedures
 - Resources/Training

Rapid Response Teams

Integration of the 4 Elements*

- Element #1:** Phases of a Food Incident/Emergency (The Need)
- Element #2:** Means to Improve Food Incident Response (Proposed Solution)
- Element #3:** Core Components (Building the Solution)
- Element #4:** Essential Traits (Assuring Effectiveness)

[Element #2] Means to Improve Food Incident Response



[Element #4] Essential Traits		[Element #3] Core Components	[Element #1] Phases of a Food Incident Response				
			Preparedness	Surveillance/ Detection	Investigation (Lab/Epi/Envi)	Mitigation/ Control	Recovery/ Prevention
A. Reassessment & Improvement (e.g. QMS)	B. Sustainability	A. Collaboration	Build relationships, team	Local, state, CDC, etc.	Multi-agency response	Recalls, enforcement	Industry, public, AARs
		B. Communication	Processes, practice	Notification	Reach contacts; share information; situational awareness	Industry, public	Education, recovery, reports
		C. Policies & Procedures	Develop/sustain	Implementation/ Execution	Implementation/ Execution	Implementation/ Execution	Improve
		D. Resources	Develop/sustain	Implementation/ Execution	Implementation/ Execution	Implementation/ Execution	Improve

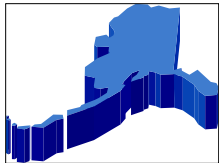
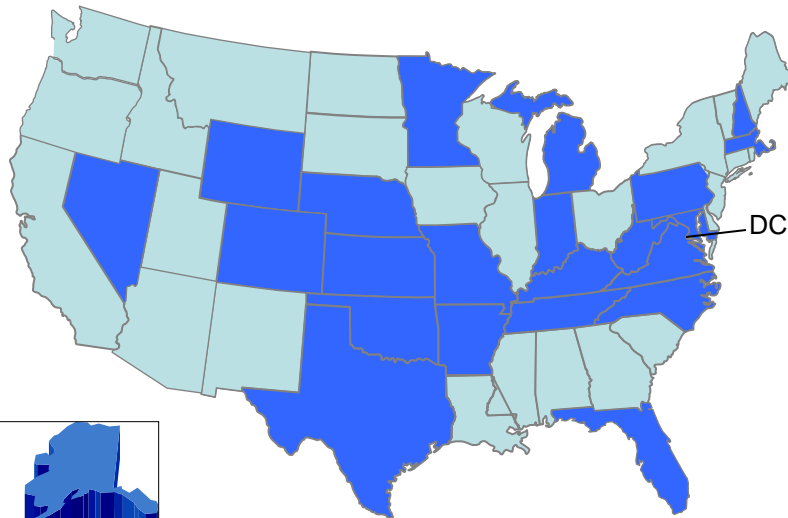
* "Matrix" - for use in the evaluation of RRTs (see example in associated Excel spreadsheet)



Rapid Response Team Project Goals

- Development of Metrics/Playbook
- Improved Infrastructure
 - Manufactured Food Regulatory Program Standards
- Strengthened Collaboration
 - Intra-state, inter-state, federal-state, inter-initiative/agency

Food Protection Task Force Program Grants



- Grant program supports meetings to foster communication among state, local, and tribal food protection, public health, agriculture, and regulatory agencies.
- Awarded to 24 States in 2009
- Increased funding from \$5,000 to \$10,000 per year in 2010
- 4 New States Awarded in 2010 (to be announced late June, early July)



Food Protection Task Force Program Goals

- Develop communications plan
 - Web-based Broadcasts, Social Networking, Website
- Media outreach/Press component
- Publish a Guidebook
- Potential National Conference
- Solicit feedback



Q & A



Ellen Laymon

**Manufactured Food Regulatory
Program Standards**

Development & Implementation Branch



Development & Implementation Branch

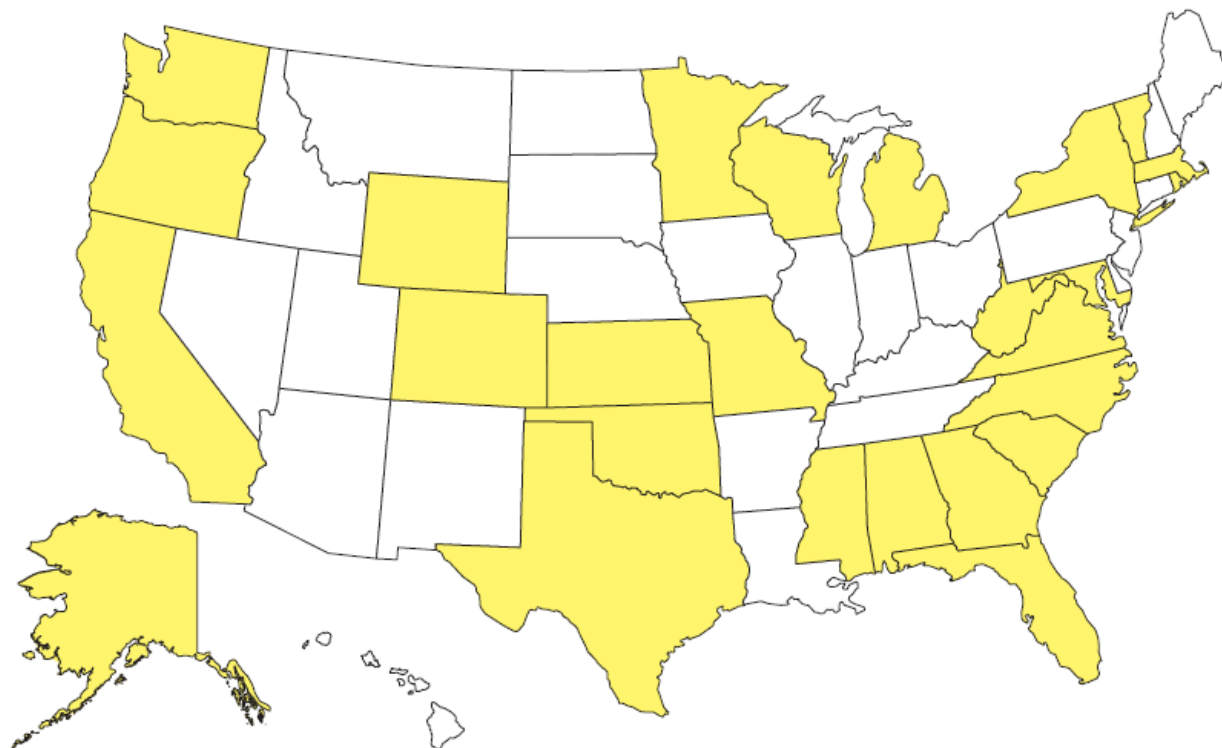
- Branch Manager
- Priscilla Neves
- 7 Additional Personnel



Manufactured Food Regulatory Program Standards

- 27 Programs have implemented
- 5 Pilot States in 2007
- 18 implemented standards in 2008
- 4 implemented standards in 2009
- 9 RRT states include implementation of standards

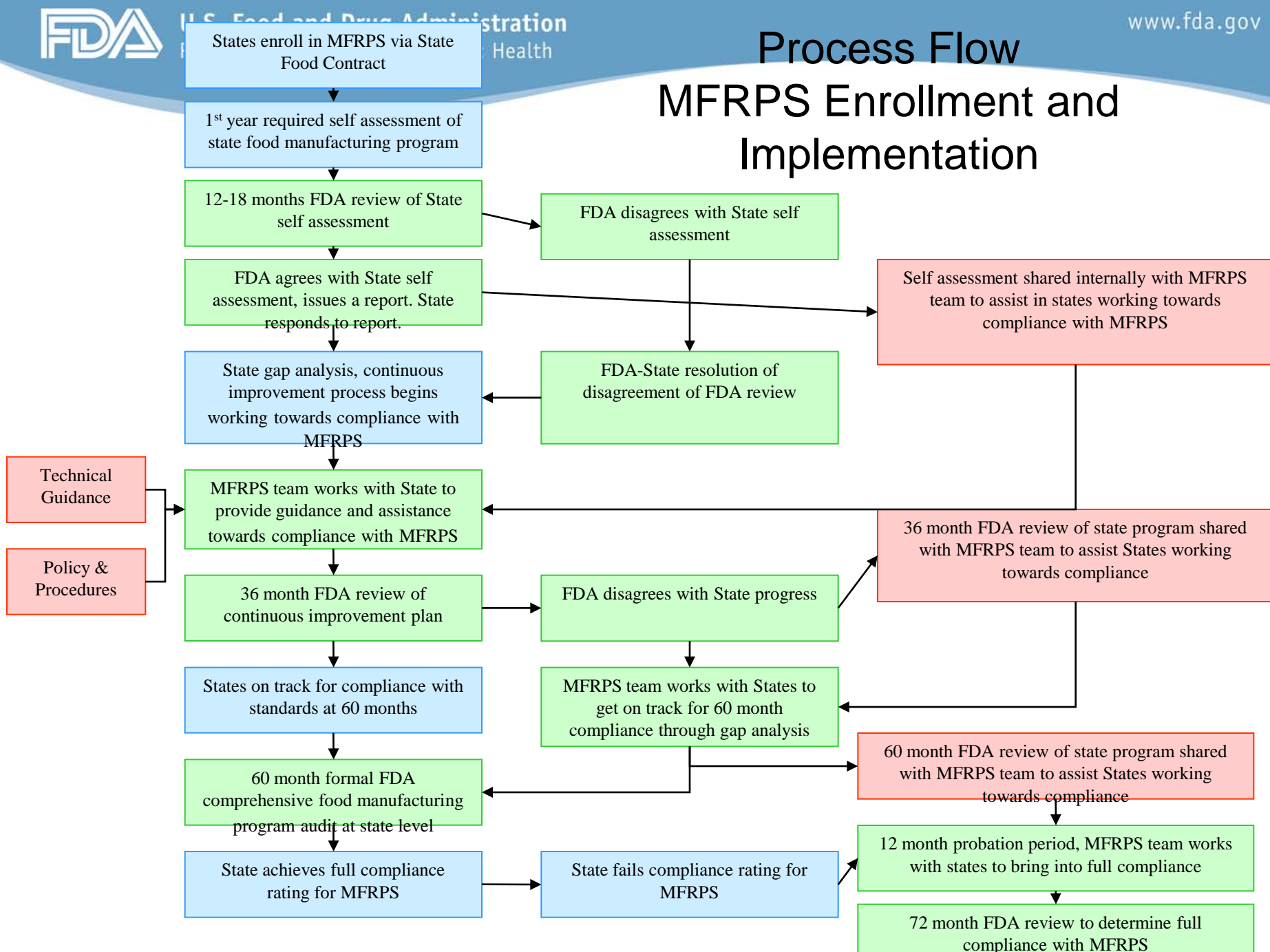
MANUFACTURED FOOD REGULATORY PROGRAM STANDARDS



The Manufactured Food Regulatory Program Standards (MFRPS) establish a uniform foundation for the design and management of state programs responsible for the regulation of food plants. The elements of the program standards describe best practices of a high-quality regulatory program. Achieving conformance with them will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation. Yellow is used to identify the States that are implementing the MFRPS.

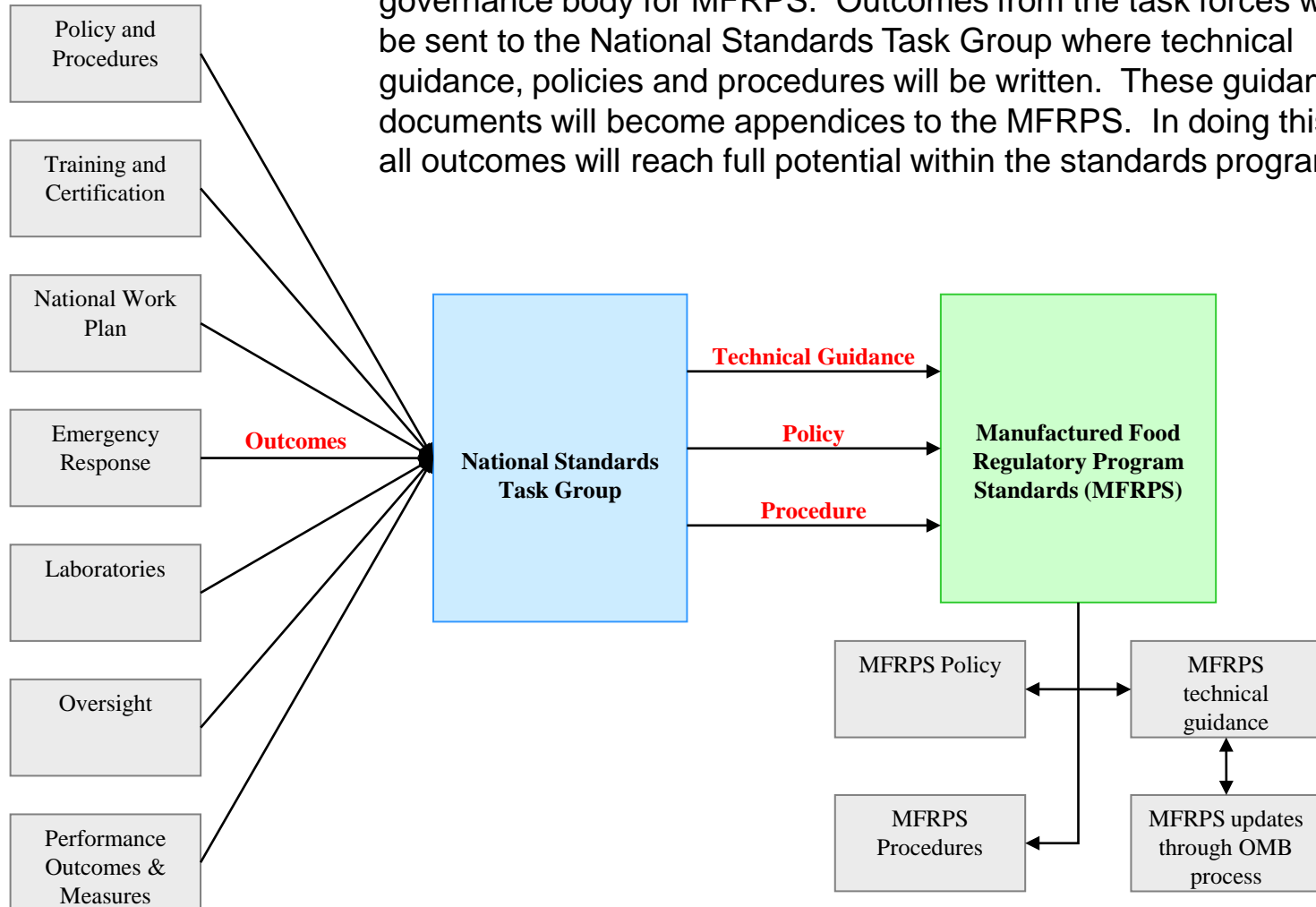
The MFRPS and both state and federal goals are to share the inspectional, enforcement and recall data between the agencies to provide for greater food protection. This data can be used to formulate better risk based prevention models that can be used by both federal and state agencies, target federal and state enforcement activities, facilitate recall information and provide for enhanced coverage of the food industry.

Process Flow MFRPS Enrollment and Implementation



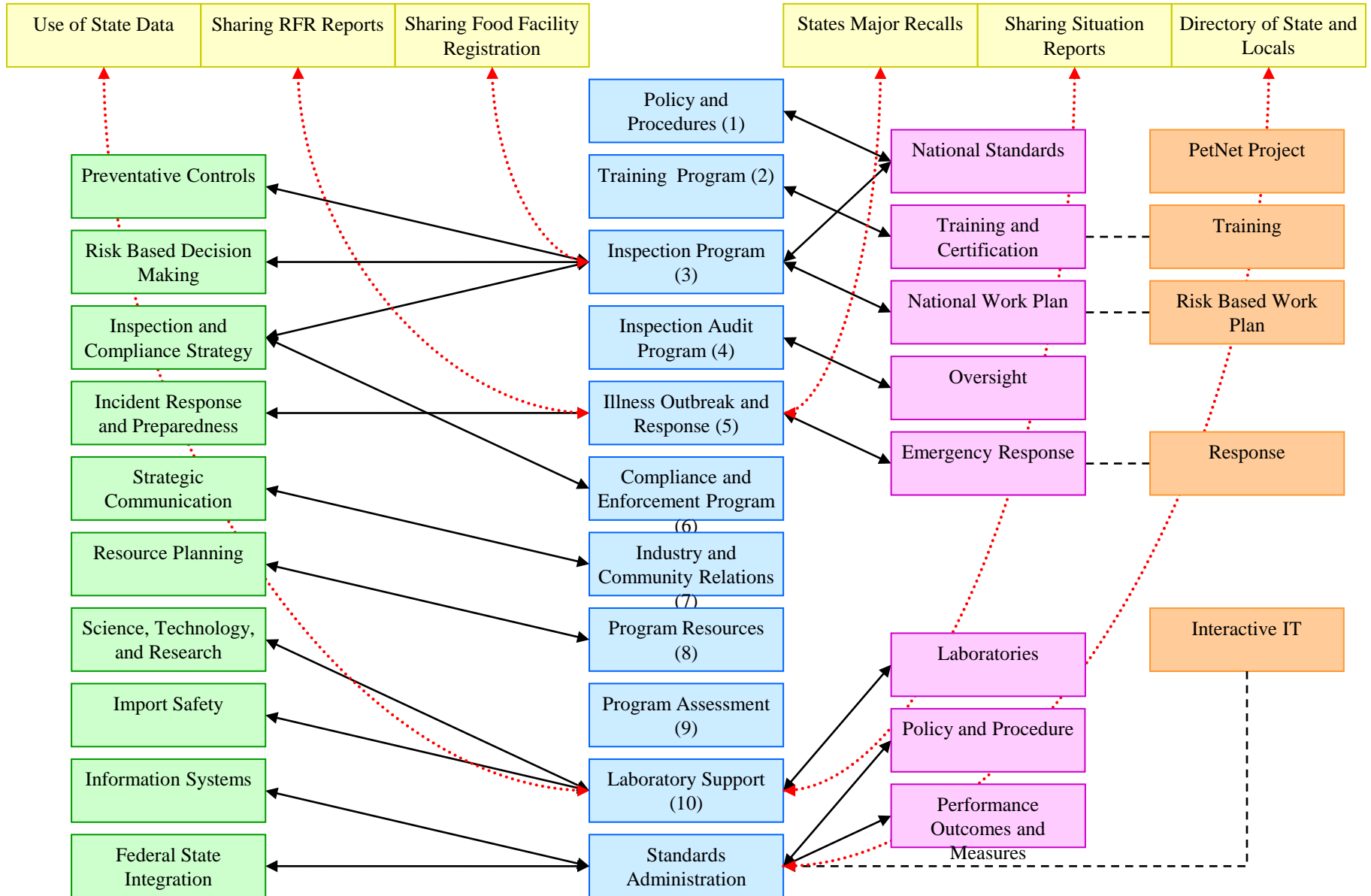
Governance/Structure

Scope: To maximize the potential of the Manufactured Food Regulatory Program Standards and to leverage the outcomes of the task forces, the National Standards Task Group will act as the governance body for MFRPS. Outcomes from the task forces will be sent to the National Standards Task Group where technical guidance, policies and procedures will be written. These guidance documents will become appendices to the MFRPS. In doing this, all outcomes will reach full potential within the standards program





Core Groups, Task Forces, Initiatives, Partnership for Food Protection Workgroups





Future of Manufactured Food Regulatory Program Standards

- Grassroots February 2010 Meeting
 - 10 States
 - Rockville, MD
- Develop framework for implementation of standards
- 11 Programs assessed by end of June 2010
- Foundation
- FDA Self-Assessment



Q & A

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