



# **U.S. Food & Drug Administration**

Office of Regulatory Affairs

Division of Federal-State Relations (DFSR)

**Joe Reardon, Director**

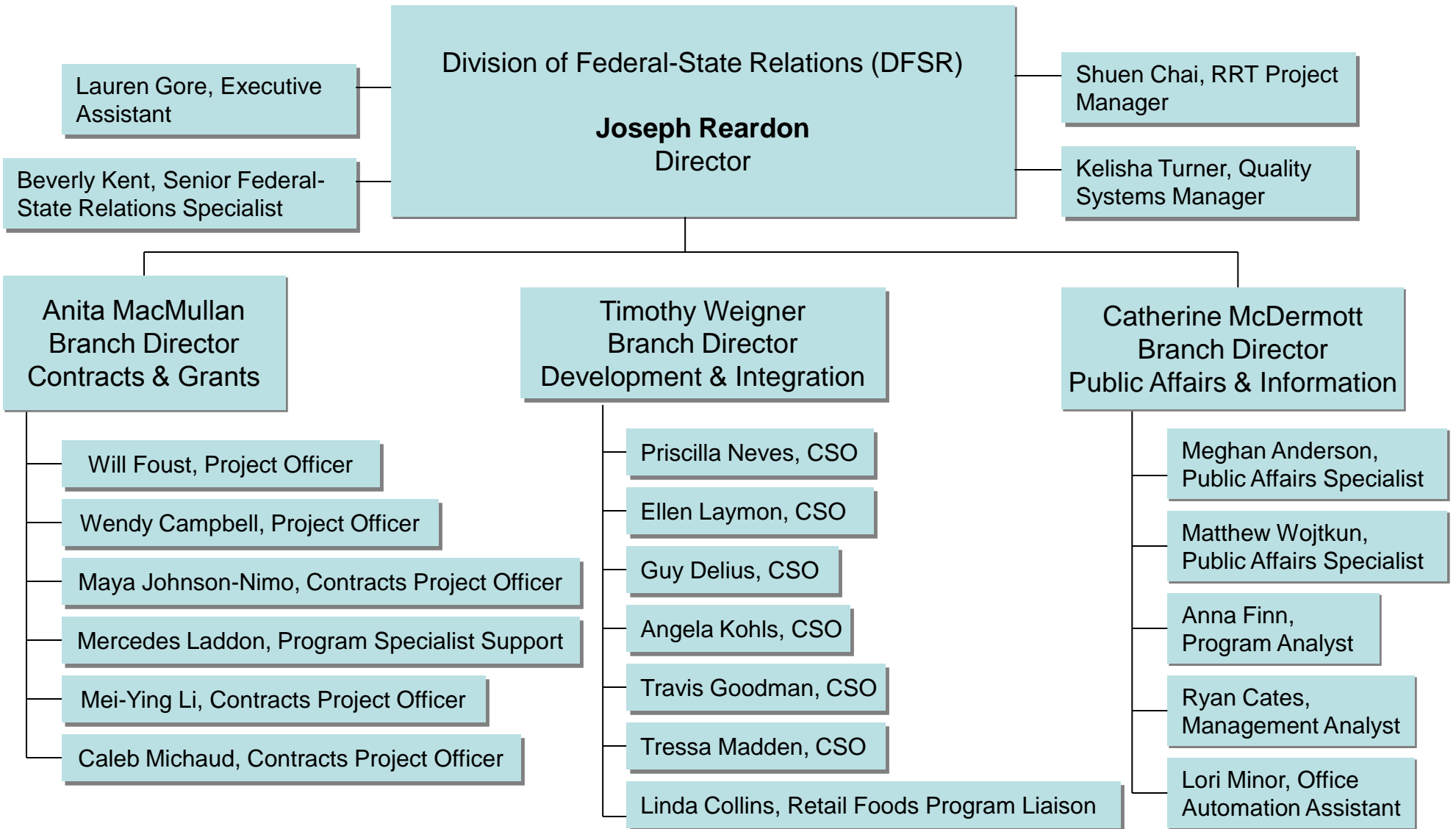
Central Atlantic States Association of Food and Drug Officials

May 17, 2011



# Outline

- Staffing of DFSSR
- DFSSR Initiatives with State Partners
- Program Standards: Food and Feed
- Grants and Contracts
  - Egg Contract
  - Food Protection Taskforce Conference Grant
  - Rapid Response Team Project Grant
- Food Safety Modernization Act



# DFSR Initiatives with State Partners

## National Standards

- Manufactured Foods Regulatory Program Standards (MFRPS)
- Animal Feed Regulatory Program Standards (*under development*)

## Contracts

- Food, Feed, MQSA
- Future Contracts: Egg Inspections, Menu Labelling

## Produce Safety Alliance

## Grants/Cooperative Agreements

- BSE, FERN, Food Safety Taskforces, Rapid Response Teams, etc.

## Information Sharing/Commissioning

- Food, Feed, Center for Tobacco Products (CTP)

## Communication with Public and State Partners

- Meetings/Workshops
- Websites
- Field Management Directive

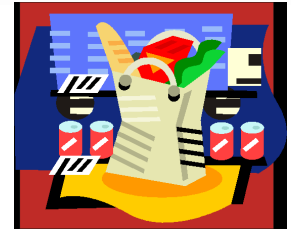
# Manufactured Food Regulatory Program Standards (MFRPS)

- 10 Standards to establish a uniform foundation for the design and management of state programs responsible for regulating food plants
- Institute a holistic quality assurance and standardization program
- FDA Program-Assessment Validation Audits (PAVAs) will be conducted at 12, 36, and 60 months

## **Program Standards**

1. *Regulatory Foundation*
2. *Training*
3. *Inspection Program*
4. *Inspection Audit Program*
5. *Food-related Illness and Outbreaks and Response*
6. *Compliance and Enforcement*
7. *Industry and Community Relations*
8. *Program Resources*
9. *Program Assessment*
10. *Laboratory Support*

# Manufactured Food Regulatory Program Standards (MFRPS)

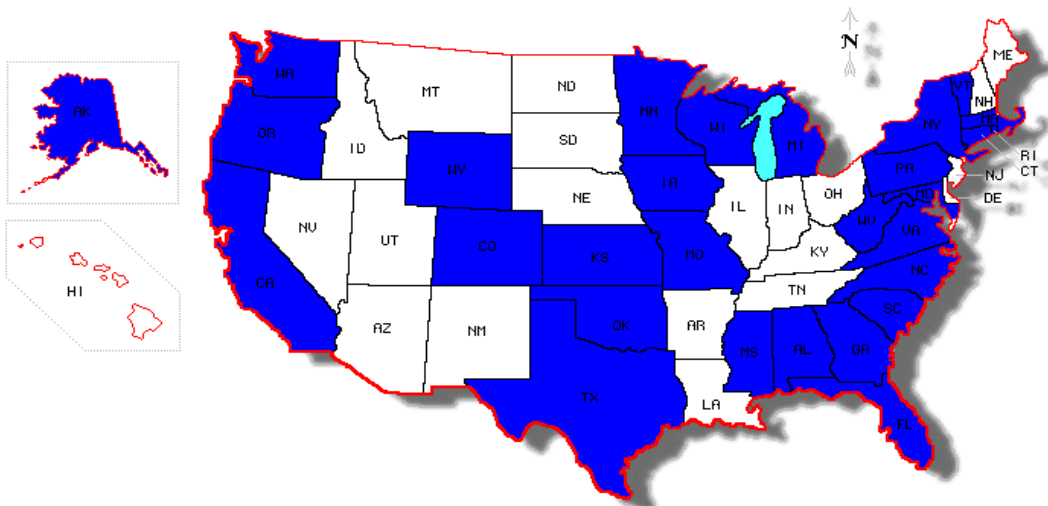


## Currently in 30 programs in 29 States

- 21 through food contracts
- 9 through Rapid Response Team Cooperative Agreements

## Development & Implementation:

- Grassroots Meeting: February 2010
- Regional Review Meetings: October 2010 (MD & OK)
- Monthly MFRPS state-federal conference calls
- To date: Completed 30 state visits for MFRPS implementation





# Feed Regulatory Program Standards



National  
Grain and Feed  
Association

HOME LOGIN

ABOUT NGFA | MEMBERSHIP | NEWS & ISSUES | MEETINGS | TRADE RULES/



**AAFCO**

Association of American Feed Control Officials

Press Release

FDA partners with the Association of American Feed Control Officials to  
develop Animal Feed Regulatory Program Standards

## FDA PARTNERS WITH AAFCO ON FEED REGULATORY PROGRAM STANDARDS (3/24/11)

The Food and Drug Administration (FDA) and Association of American Feed Control Officials (AAFCO) announced today that they have agreed to develop voluntary regulatory program standards for animal feed that will be used by federal and state agencies.

An announcement issued March 22 by AAFCO, the professional organization of state and federal feed regulatory officials, intended to promote uniformity, equivalence, and continuous improvement among feed regulatory programs. The Regulatory Program Standards developed in 2007 by FDA and AAFCO said the new standards will regulate programs addressing animal feed and pet food. The standards may encompass the following performance areas: 1) inspection practices and procedures; 2) quality assurance; 3) food/feed defense preparedness; 4) enforcement and compliance strategies; 5) education and outreach; 6) resource management; 7) food/feed defense preparedness; 8) education and outreach; 9) resource management.

The next step will be for a joint FDA-AAFCO committee to develop the regulatory program standards. Work has begun, and the committee's goal is to make the standards available to states sometime in 2012.

Through its involvement with AAFCO, the NGFA has strongly supported joint collaboration by FDA and AAFCO on training, education and inspection processes to enhance uniformity and reasonable application of regulatory standards.

For more information:

Kent Kitade, AAFCO Past President

916-445-2140

kkitade@cdfa.ca.gov

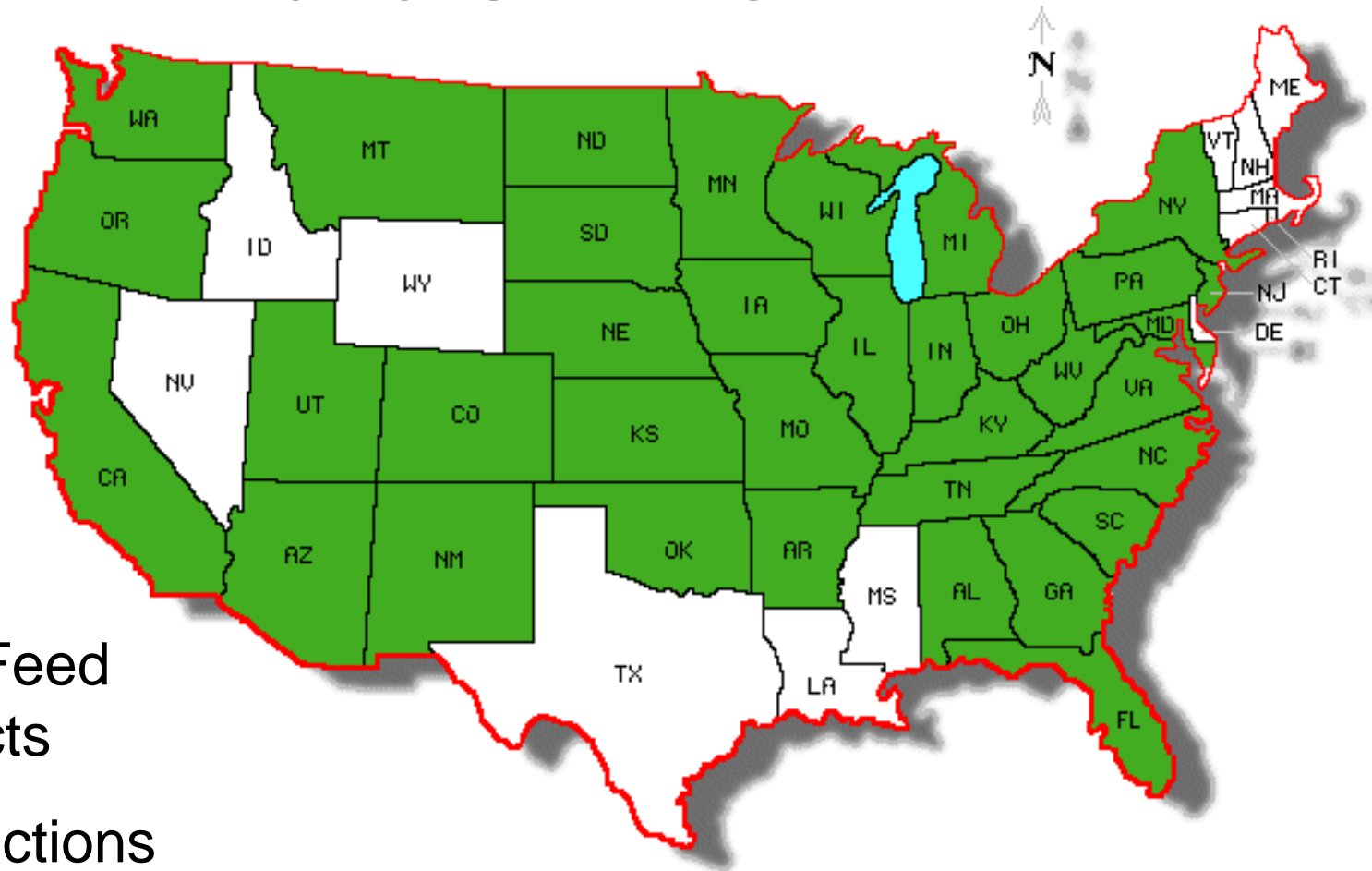
March 22, 2011: The Food and Drug Administration (FDA) will collaborate with the Association of American Feed Control Officials (AAFCO) to develop voluntary regulatory program standards for federal and state agencies responsible for regulating facilities that manufacture, package, distribute, or store animal feed, which includes pet food. The Animal

Under Construction





# FY 2010 State Contracts



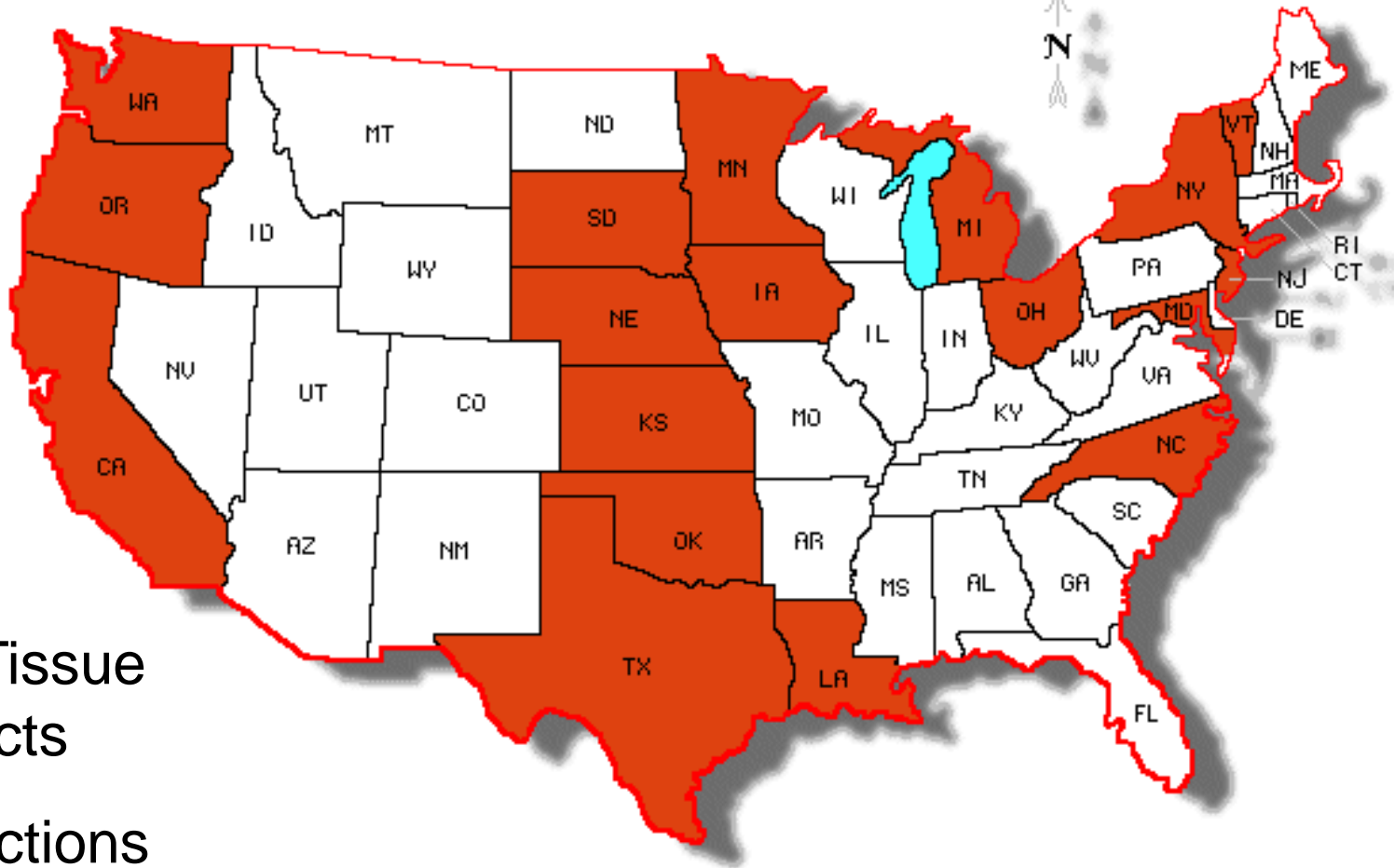
36 State Feed  
Contracts

5,400 Inspections

\$2.5 M



# FY 2010 State Contracts



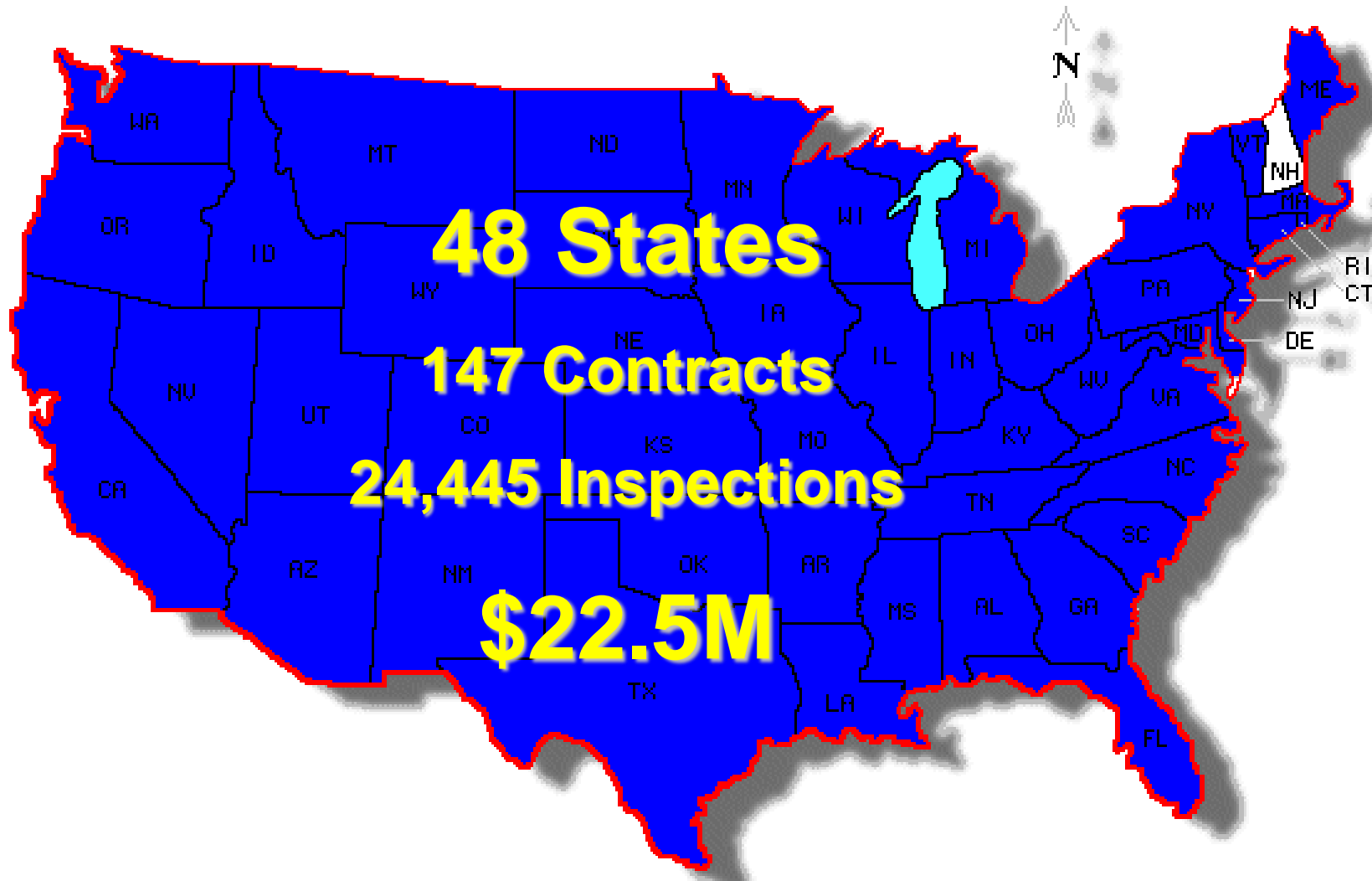
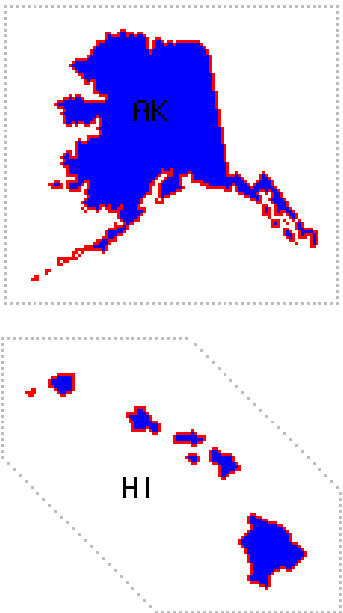
19 State Tissue  
Contracts

260 Inspections

\$363k

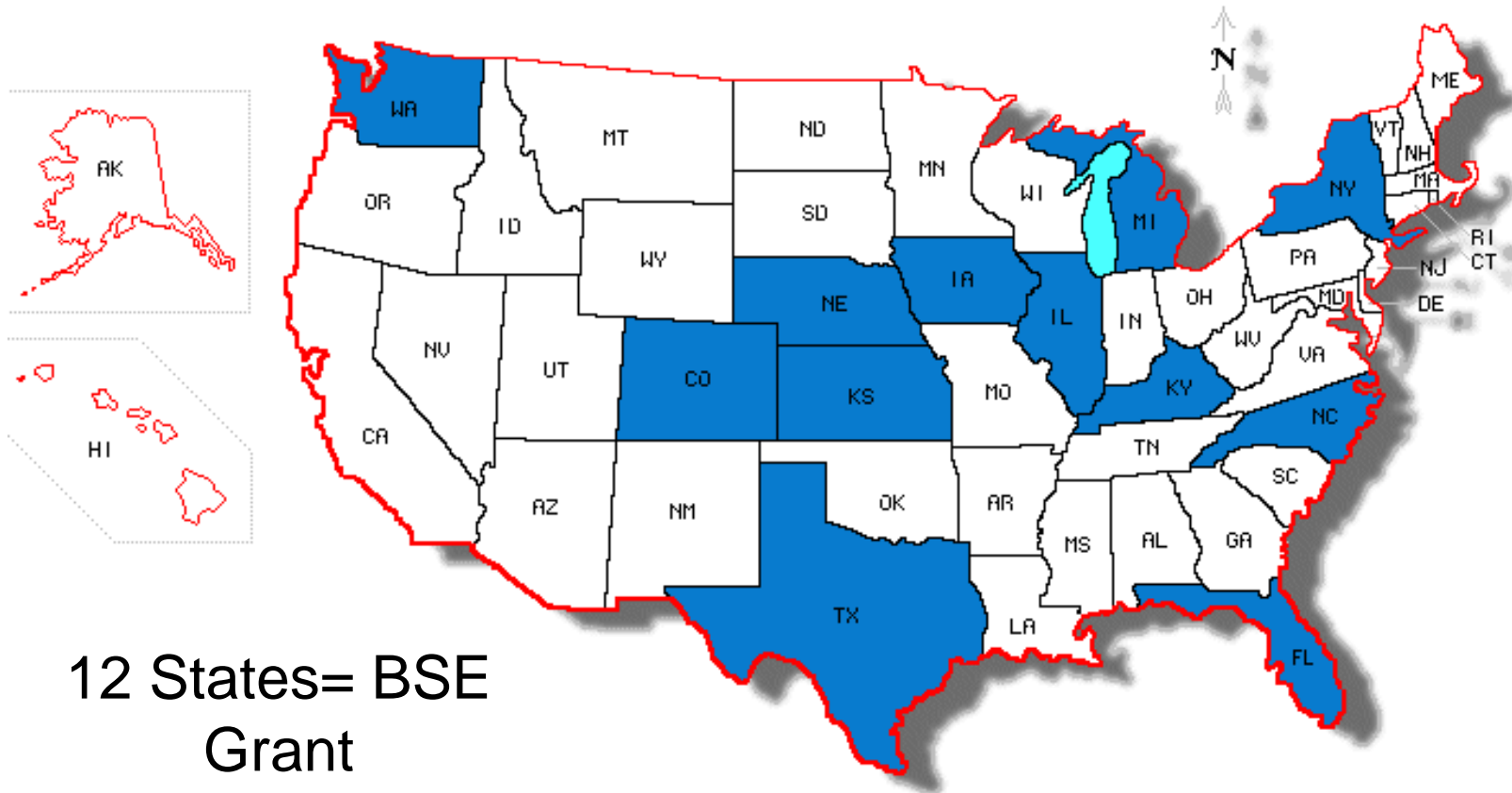


# FY 2010 State Contracts





# FY 2010 Grants/Cooperative Agreements

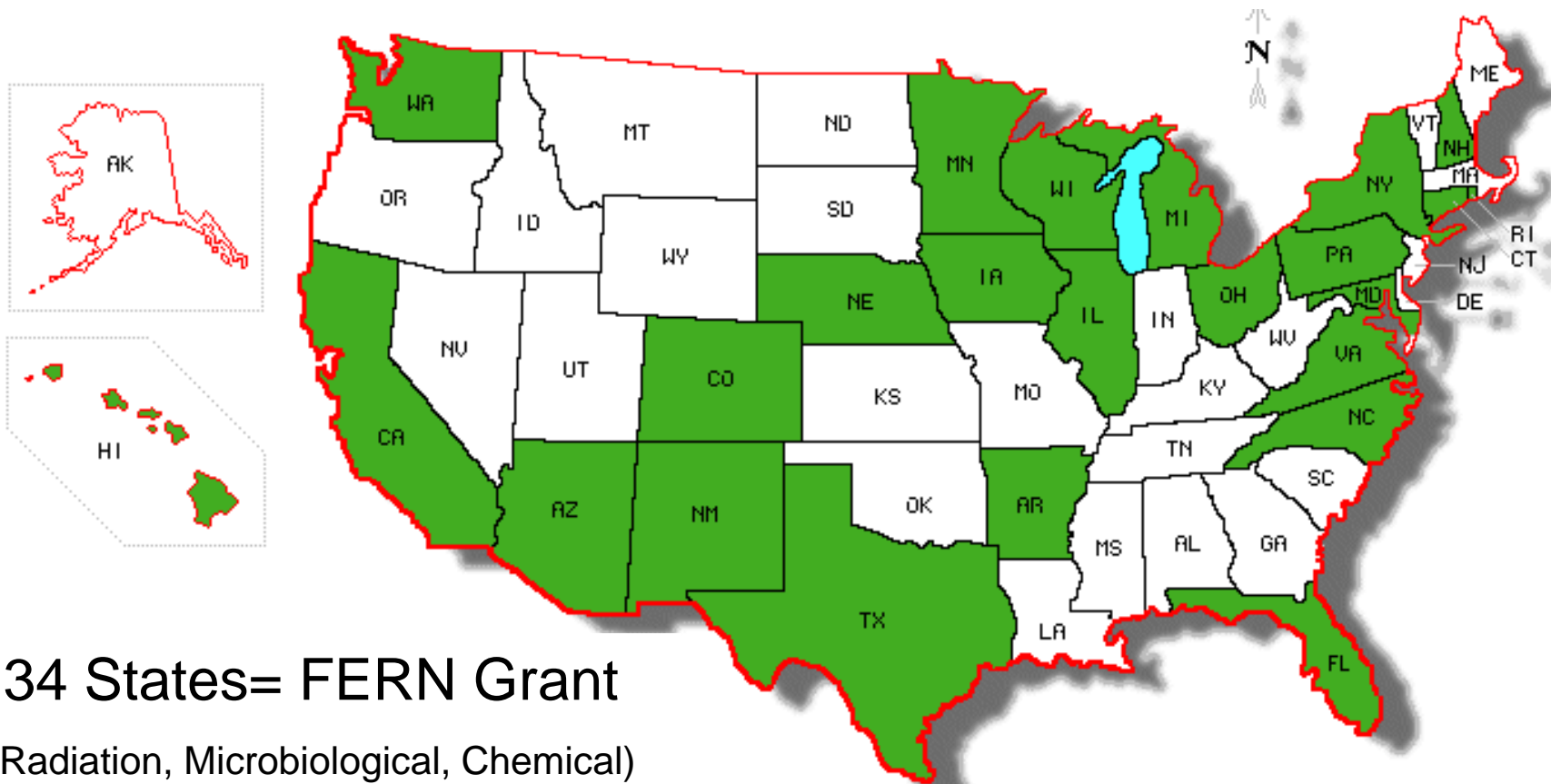


12 States= BSE  
Grant

\$22.5M



# FY 2010 Grants/Cooperative Agreements

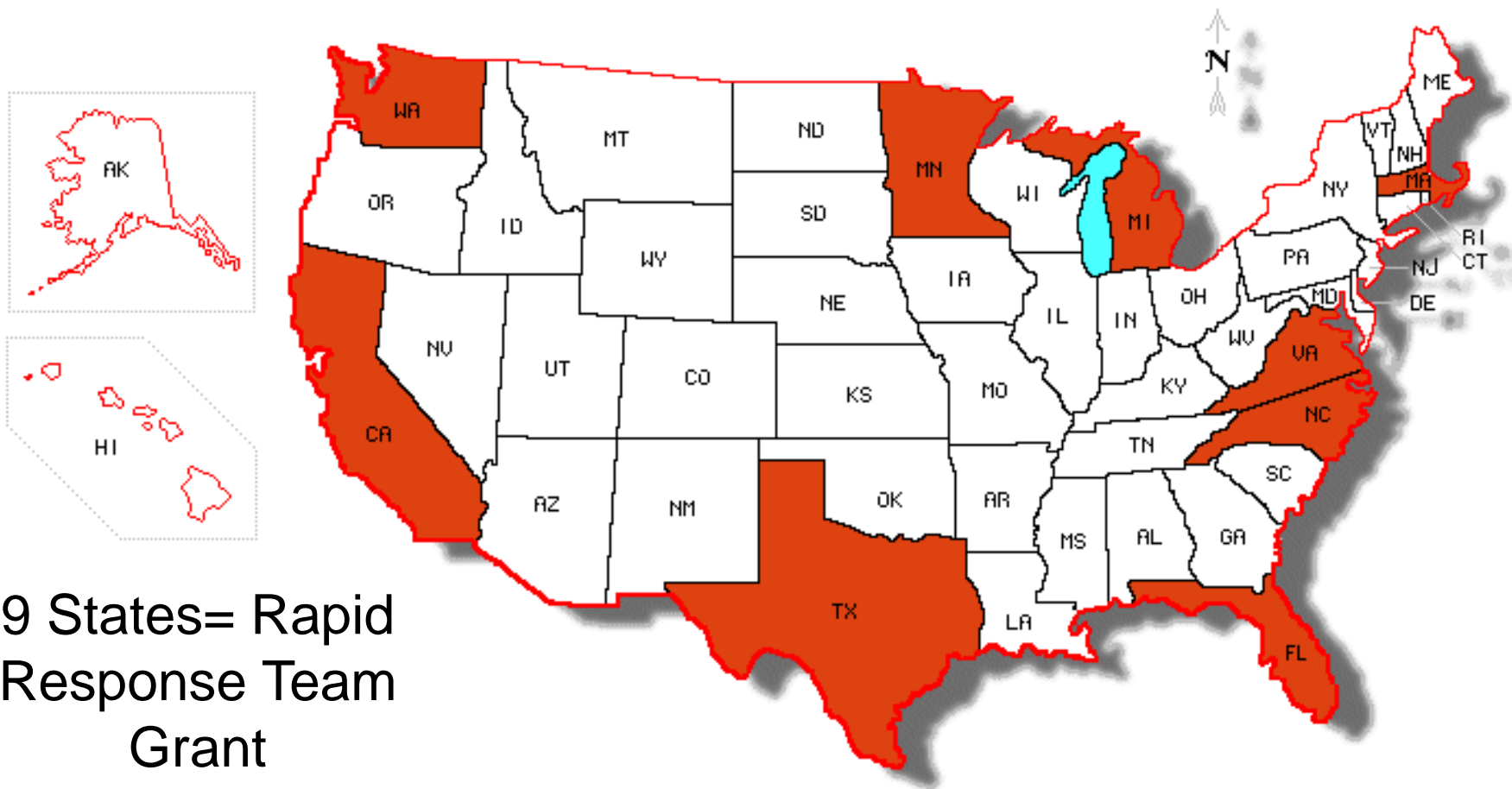


\$10M





# FY 2010 Grants/Cooperative Agreements



9 States= Rapid  
Response Team  
Grant

\$4.5M

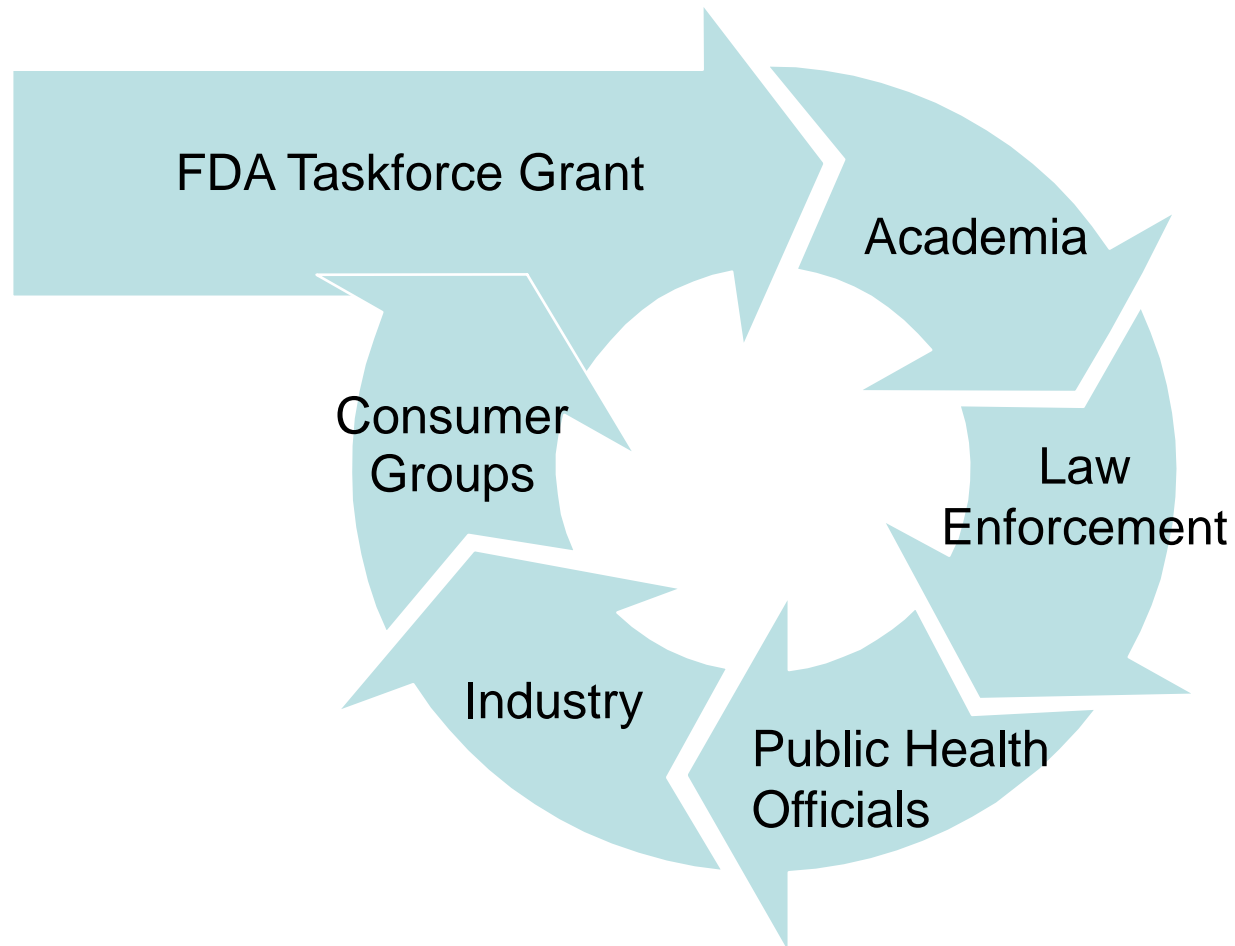


# FY 2011 Egg Contract

- Purpose: To conduct inspections of egg layer farms to assess compliance with 21 CFR 118 “The Egg Rule”
- Top 20 egg producing states were targeted for contracting
- Training
  - DFSR is supporting prospective state contractors to attend the required training

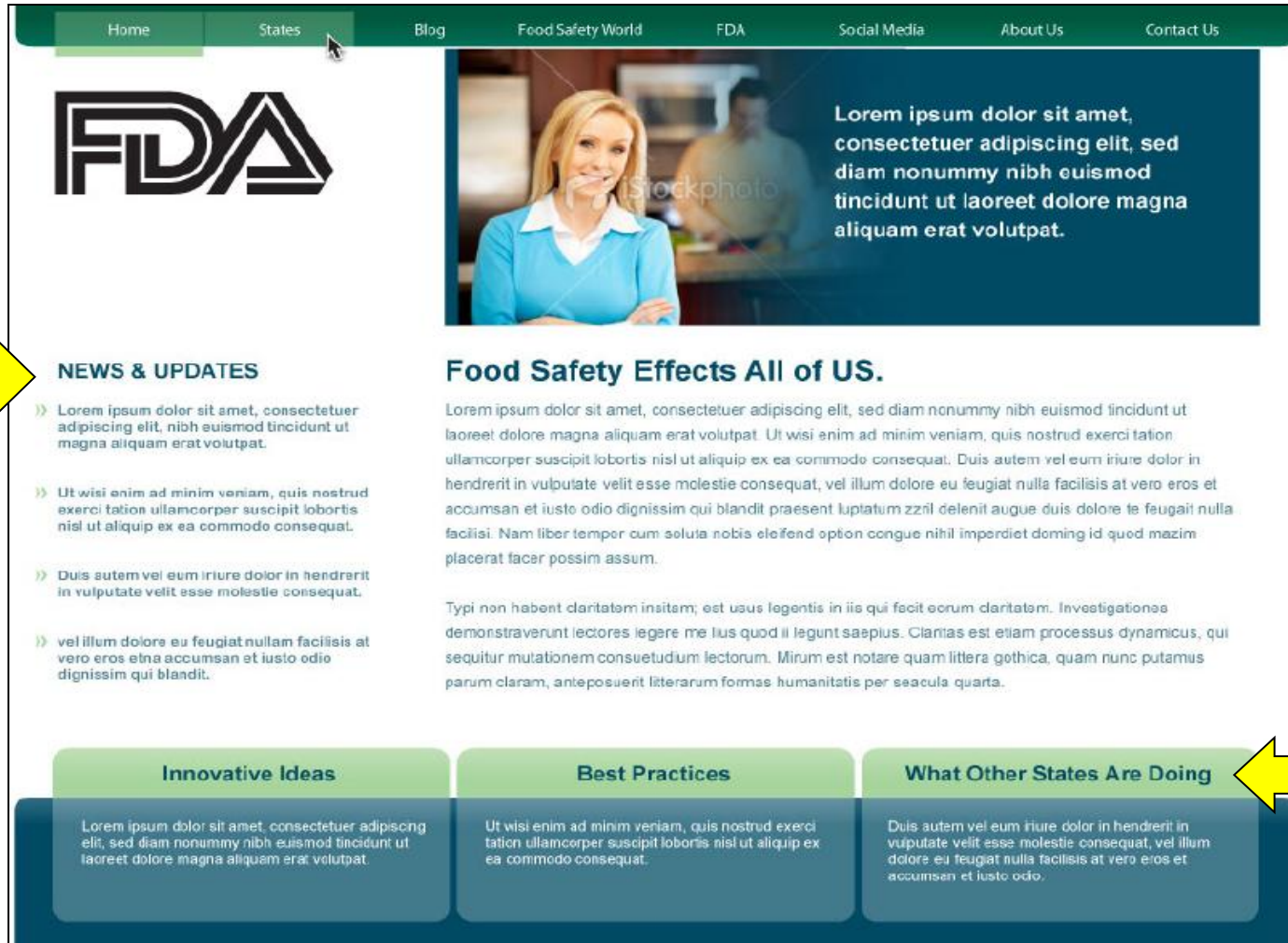


# Food Protection Taskforce Conference Program Grants

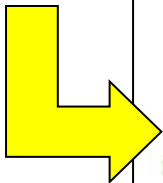




# Food Protection Taskforce Websites



News and Events



News in other states





# Rapid Response Teams

Rapid Response Teams (RRT) develop, implement, exercise, and integrate an all-hazards food and foodborne illness response capability to more rapidly react to potential threats to our food supply. In conjunction with other agencies, FDA district offices, and state emergency operations centers, the RRT's are another tool to enhance response capabilities.

## Background

- 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

## Project Goals

- Develop Rapid Response Capabilities (including ICS)
  - Playbook/Best Practices
  - Metrics - to measure/quantify effectiveness and value
- Improve Program Infrastructure
  - Implementation of the Manufactured Food Regulatory Program Standards (MFRPS)
- Strengthened Collaboration
  - Federal/State/Local
  - Across programs (health, ag, etc.)
  - Across initiatives (IFSS, CDC, etc.)



# 9 Pilot RRTs Build a Foundation for Rapid Response Capability Development

		<b>Phases of a Food Incident Response</b>				
<b>Core Components</b>	<b>Preparedness</b>	<b>Surveillance/ Detection</b>	<b>Investigation (Lab/Epi/Envi)</b>	<b>Mitigation/ Control</b>	<b>Post-Response/ Prevention</b>	
<b>A. Collaboration</b>		Use epi. info. from local/state/federal partners (Std. #5)				
<b>B. Communication</b>						
<b>C. Policies &amp; Procedures</b>	State Food Emergency Response Plan (FERP)					
<b>D. Resources</b>	Training plan for staff (RRT milestone; Std. #2)					

**Develop Measures**

5= FERP incorporated into state response plan; exercised regularly  
 4 = FERP incorporated into state response plan  
 3 = Have a plan representing public health stakeholders  
 2 = Have a plan representing the individual agency's responsibility  
 1 = No plan

# Communication with State Partners

- **Sharing/Exchange of Information**

- 50-State Conference Calls (quarterly and as needed)
- State workshops
- Dissemination of regulatory or pertinent information through the DFSSR Broadcast System
  - Recalls, Reportable Food Registry Reports, Weekly Reports
- Commissioning/Credentialing and Confidentiality Agreements

- **Activities among FDA Districts and States**

- Work-planning, recalls, assignments, outbreaks, facility inventory harmonization

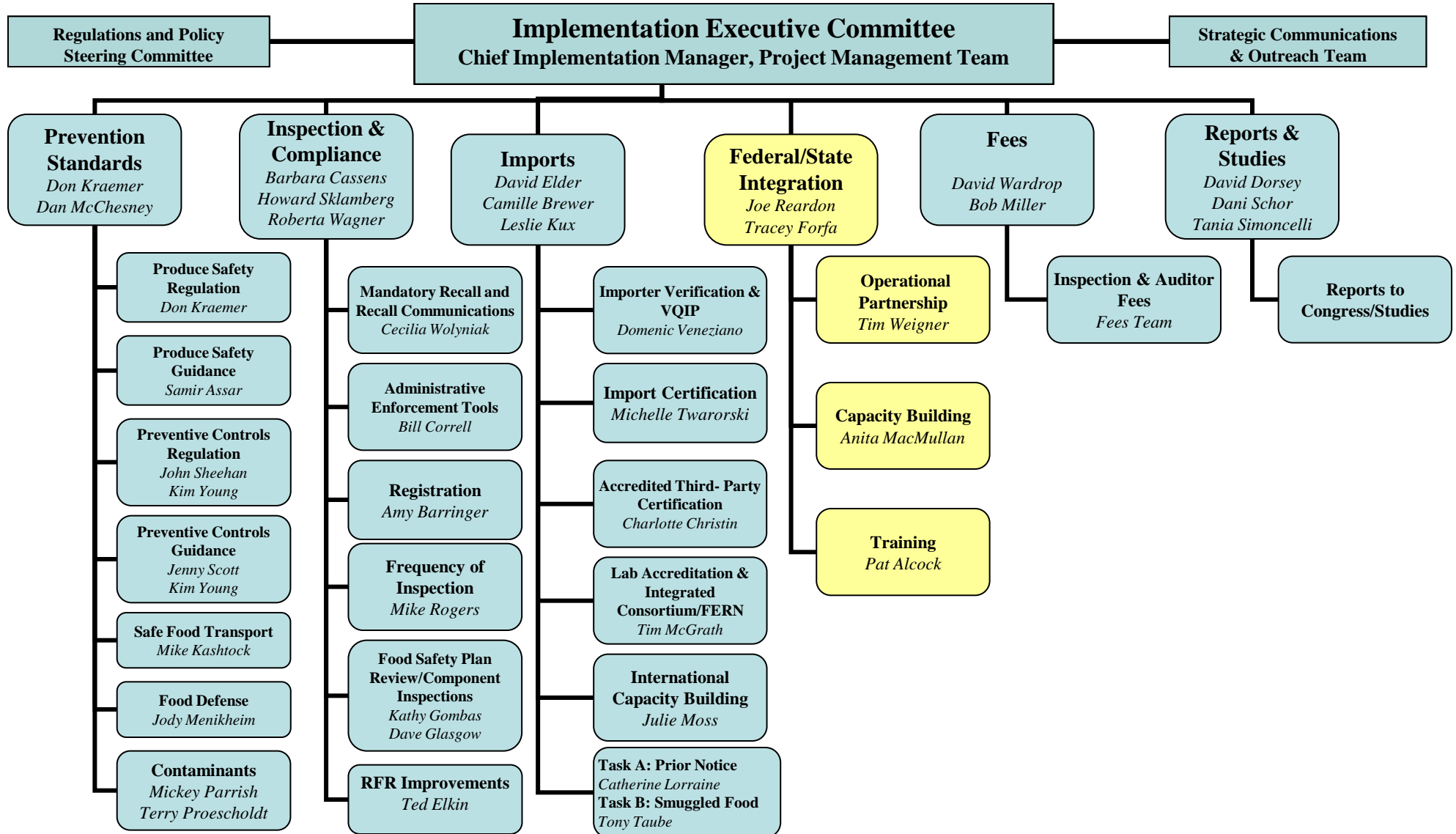
# Food Safety Modernization Act Implementation

- Federal-State Integration
  - Deliverable groups:
    - Operational Partnerships
    - Capacity Building
    - Training
  
  - Harmonize work with Partnership for Food Protection (PFP) activities





# FSMA Implementation Plan





**Operational Partnerships**

*Tim Weigner, Travis Goodman*

**Section 201:**

Targeting of Inspection Resources for Domestic Facilities, Annual Report

*Angela Kohls  
Maya Johnson-Nimo*

**Section 209:**

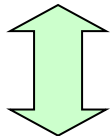
Improving the Training of State, Local, Territorial, and Tribal Food Safety Officers

*Tim Weigner  
Marybeth Willis*

**Section 210,  
Subsection 1009(f):**

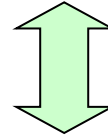
Enhancing Food Safety, Progress and Evaluation

*Linda Collins  
Travis Goodman*



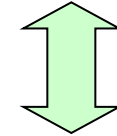
**PFP Workgroups:**

*National Workplan  
National Standards  
Oversight*



**PFP Workgroups:**

*Training*



**PFP Workgroups:**

*Performance Measures*



## Operational Partnerships

*Tim Weigner, Travis Goodman*

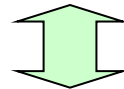
### Section 201:

Targeting of Inspection Resources for Domestic Facilities, Annual Report

**Scope of Responsibility:** “The Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memoranda of understanding, or other obligation.”

*Angela Kohls*

*Maya Johnson-Nimo*



### PFP Workgroups:

*National Workplan*

*National Standards, Oversight*



## Operational Partnerships

*Tim Weigner, Travis Goodman*

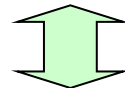
### Section 209:

Improving the Training of State, Local, Territorial, and Tribal Food Safety Officers

**Scope of Responsibility:** The Secretary shall set standards and administer training and education programs for the employees of State, local, territorial and tribal food safety officials... including programs for:

- Scientific training
- Training to improve the skills of officers and employees authorized to conduct inspections under sections 702/704
- Training to address best practices
- Training in administrative process and procedure and integrity issues
- Training in appropriate sampling and laboratory analysis methodology
- Training in building enforcement actions following inspections, examinations, testing and investigations.

*Tim Weigner  
Marybeth Willis*



### PFP Workgroups:

*Training*



## Operational Partnerships

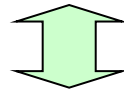
*Tim Weigner, Travis Goodman*

### Section 210, Subsection 1009(f):

Enhancing Food Safety, Progress and Evaluation

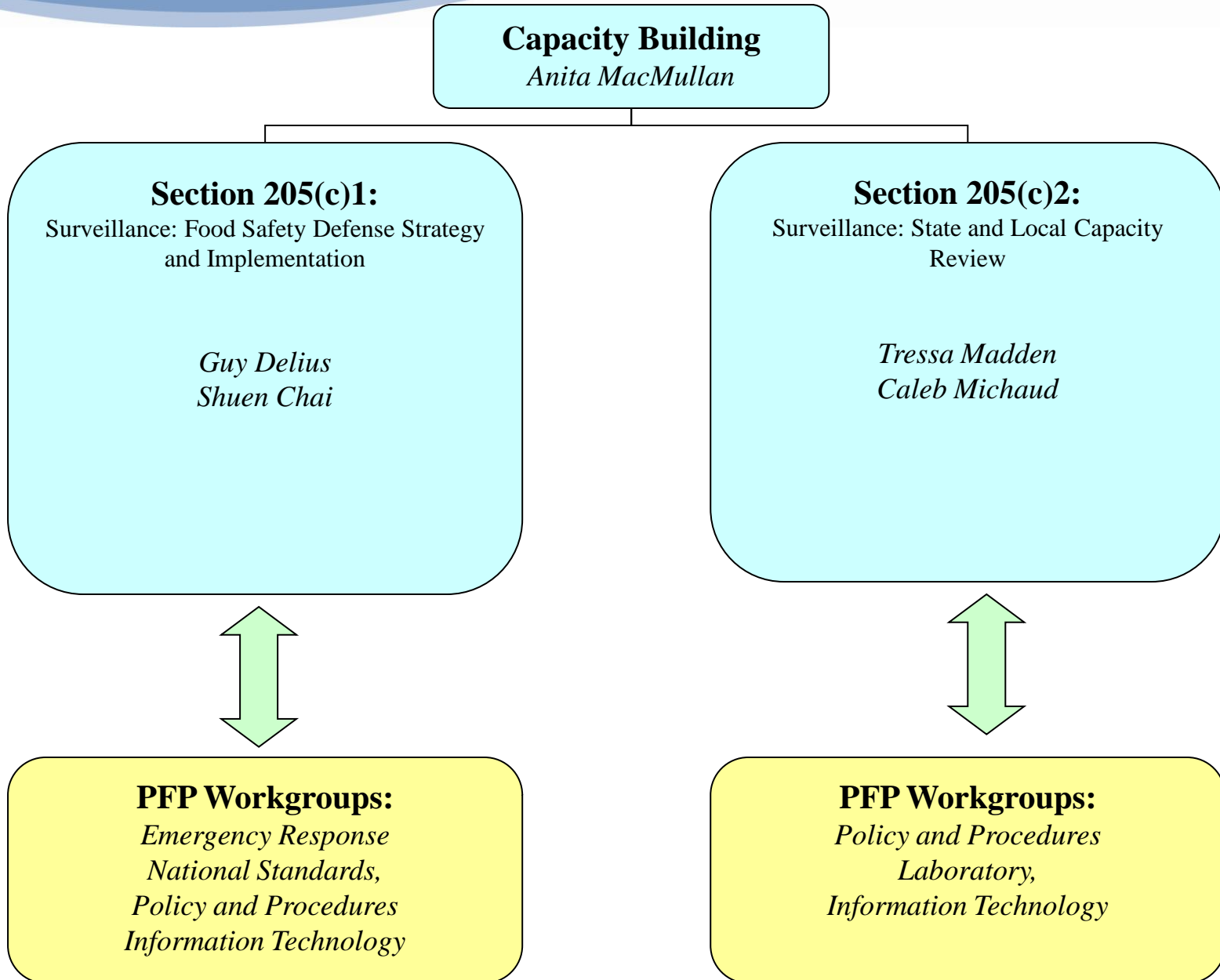
**Scope of Responsibility:** The Secretary shall measure the status and success of each grant program authorized under the Act. The Secretary shall take the performance of such a grant recipient into account when determining whether to continue funding for such a recipient.

*Linda Collins  
Travis Goodman*



### PFP Workgroups:

*Performance Measures*



## Capacity Building

*Anita MacMullan*

### Section 205(c)1:

Surveillance: Food Safety Defense Strategy and Implementation

**Scope of Responsibility:** The Secretary shall develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies in order to:

- Improve foodborne illness outbreak response and containment
- Accelerate foodborne illness surveillance and outbreak investigation, including rapid shipment of clinical isolates from clinical laboratories to appropriate State labs, and conducting more standardized illness outbreak interviews
- Strengthen the capacity of State and local agencies to carry out inspections and enforce safety standards
- Improve the effectiveness of Federal, State and local partnerships to coordinate food safety and defense resources and reduce the incidence of foodborne illness
- Share information on a timely basis among public health and food regulatory agencies, with the food industry, with health care providers, and with the public
- Strengthen the capacity of State and local agencies to achieve the goals described in section 108.

*Guy Delius, Shuen Chai*



### PFP Workgroups:

*Emergency Response, National Standards,  
Policy and Procedures, Information Technology*

## Capacity Building


*Anita MacMullan*

### Section 205(c)2:

Surveillance: State and Local Capacity Review

**Scope of Responsibility:** The Secretary shall, not later than one year after the date of enactment of the FDA FSMA, complete a review of State and local capacities, and needs for enhancement, which may include:

- A survey with respect to staffing levels and expertise available to perform food safety and defense functions
- Laboratory capacity to support surveillance, outbreak response, inspection, and enforcement activities
- Information systems to support data management and sharing of food safety and defense information among State and local agencies with counterparts at the Federal level
- Other State and local activities and needs as determined appropriate by the Secretary.

*Tressa Madden,  Michaud*

### PFP Workgroups:

*Policy and Procedures, Laboratory,  
Information Technology*



**Training**  
*Pat Alcock*  
*Will Dardick*

**Section 209:**

Improving the Training of State, Local, Territorial, and Tribal Food Safety Officers

**Scope of Responsibility:** The Secretary shall set standards and administer training and education programs for the employees of State, local, territorial and tribal food safety officials... including programs for:

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- Training in building enforcement actions following inspections, examinations, testing and investigations.

*Tim Weigner*  
*Marybeth Willis*



**PFP Workgroups:**  
*Training*



# Division of Federal State Relations

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DFSR Website:

<http://www.fda.gov/ForFederalStateandLocalOfficials/default.htm>