



Division of Federal-State Relations

Ellen Laymon, Consumer Safety Officer, Standards Specialist



Western Association of Food & Drug Officials

August 11, 2011

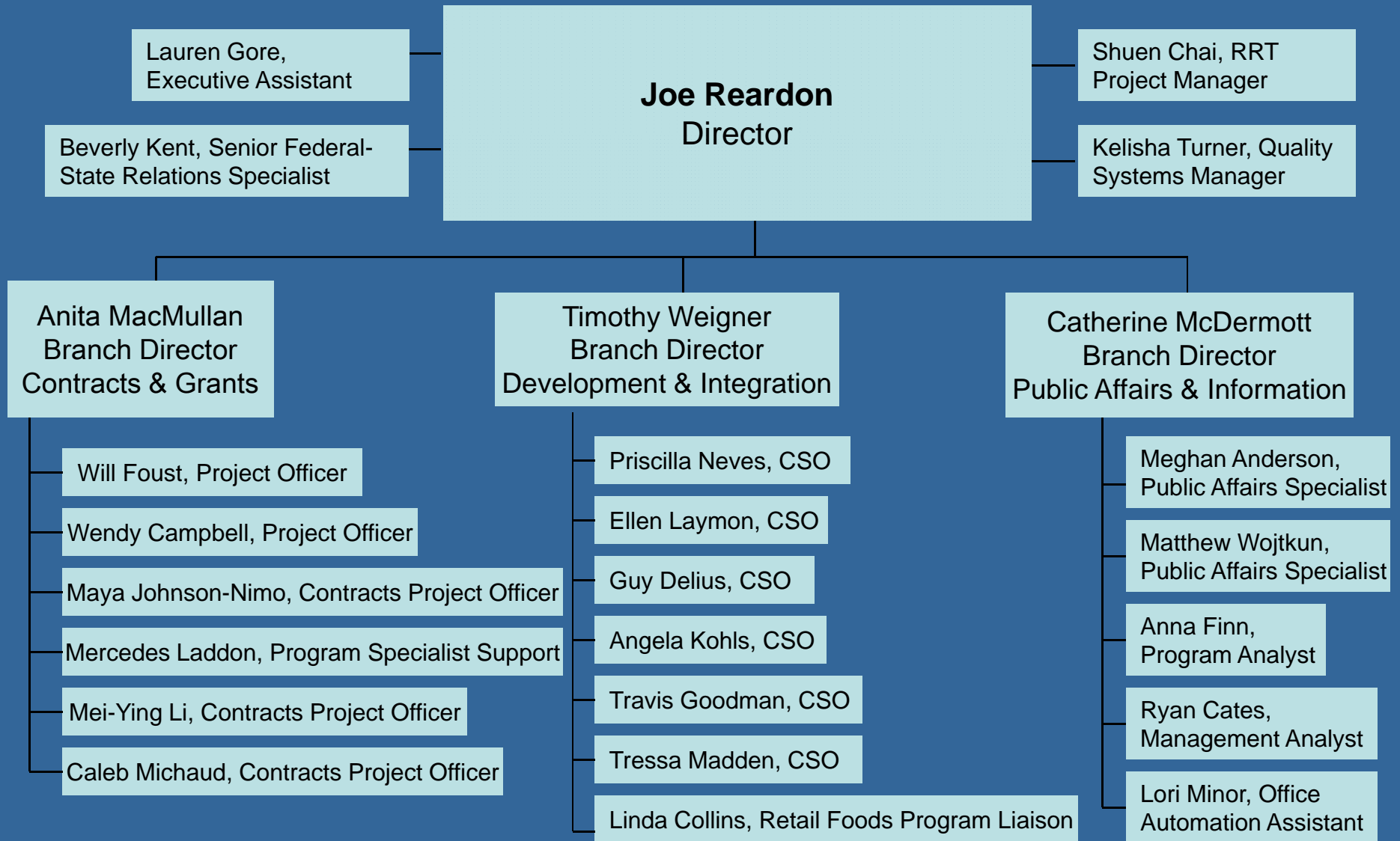


Outline

- Staffing of Division of Federal-State Relations (DFSR)
- DFSR Initiatives with State Partners
- Communication with State Partners
- Quality Management System
- Program Standards: Food and Feed
- Grants and Contracts
 - Egg Contract
 - Food Protection Taskforce Conference Grant
 - Rapid Response Team Project Grant
- Food Safety Modernization Act (FSMA) Implementation



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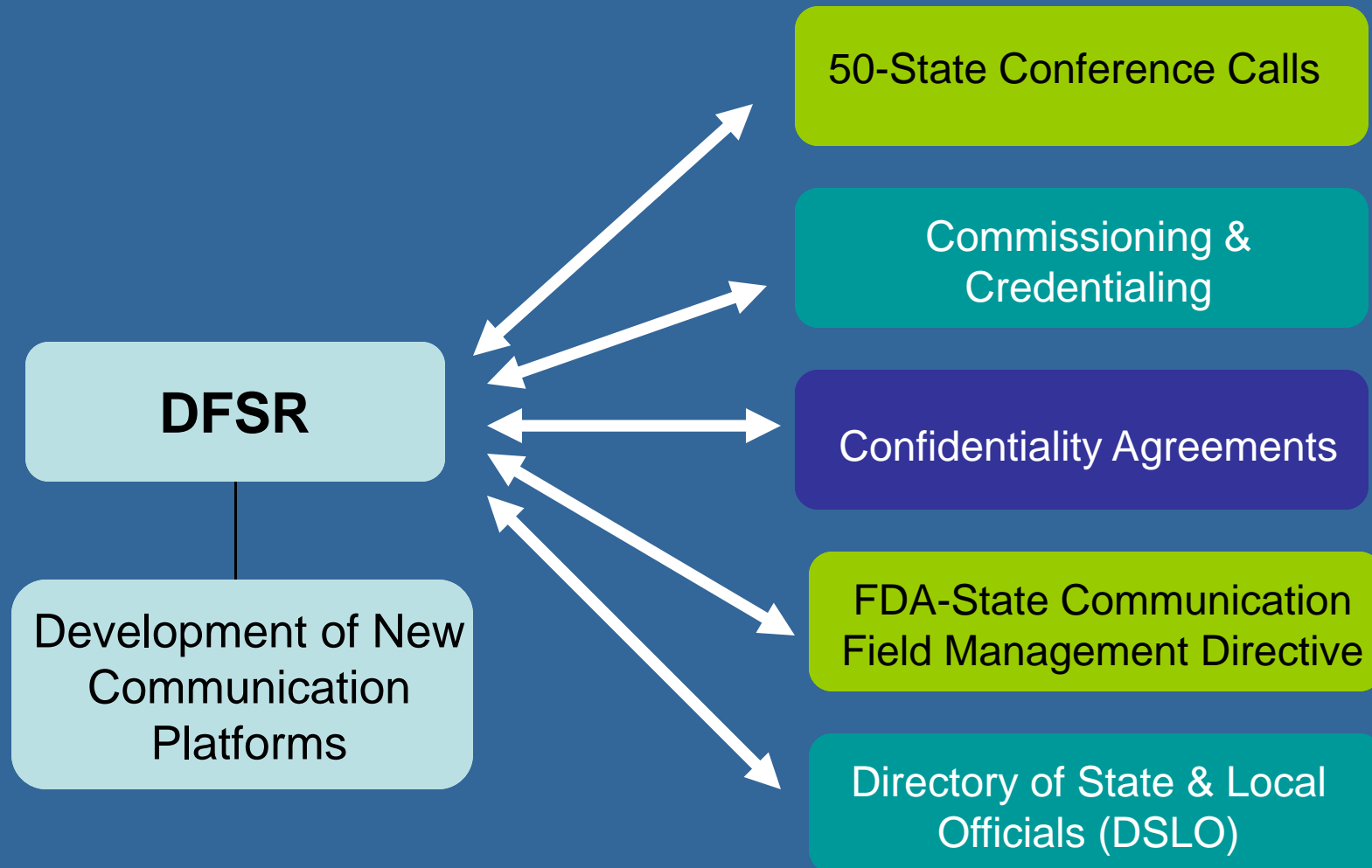


Initiatives with State Partners





Communication with State Partners





Division of Federal-State Relations

FDA / Office of Regulatory Affairs / Quality Management System (QMS)





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 (PAVA) will be conducted at 18, 36, and 60 months (external to DFSSR)

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*

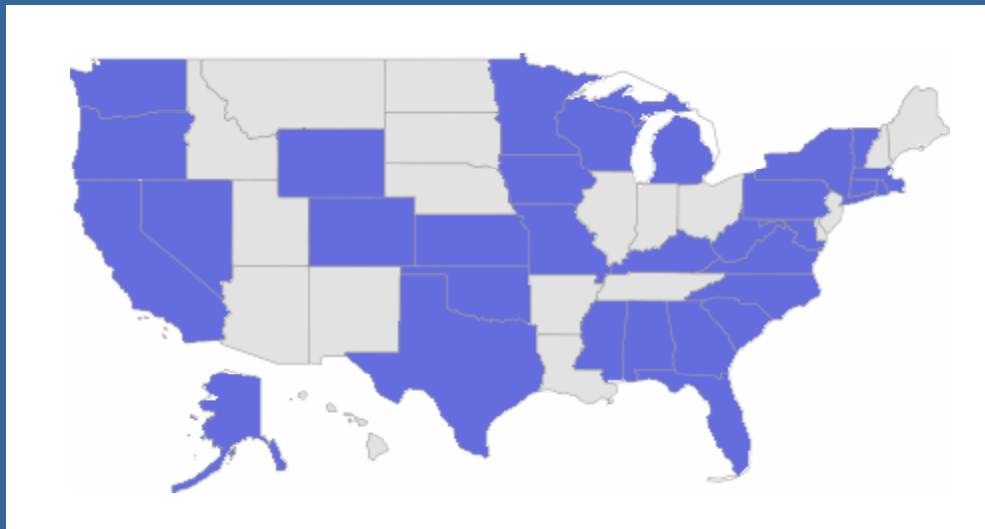


Manufactured Food Regulatory Program Standards (MFRPS)



Currently in 31 programs in 30 States

- 22 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 JOINING

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

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) will collaborate to develop regulatory program standards for animal feed that can be used by federal and state agencies.

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

The next step will be for a joint FDA-AAFCO committee to develop the regulatory program standards. Work will be made 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.



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

For more information:
Kent Kitale, AAFCO Past President
916-445-1140
kkitale@aaeco.org

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 animal feed that can be used by state agencies responsible for regulating facilities that manufacture, package, distribute, store, transport, and sell animal feed, which includes pet food. The Animal Feed Regulatory Program Standards (AFRPS) will be modeled after the Manufactured Food Regulatory Program Standards that was successfully launched in 2007 and will similarly represent a significant step in promoting uniformity, equivalency and continuous improvement among feed regulatory agencies – all critical in a successful national integrated food safety system.

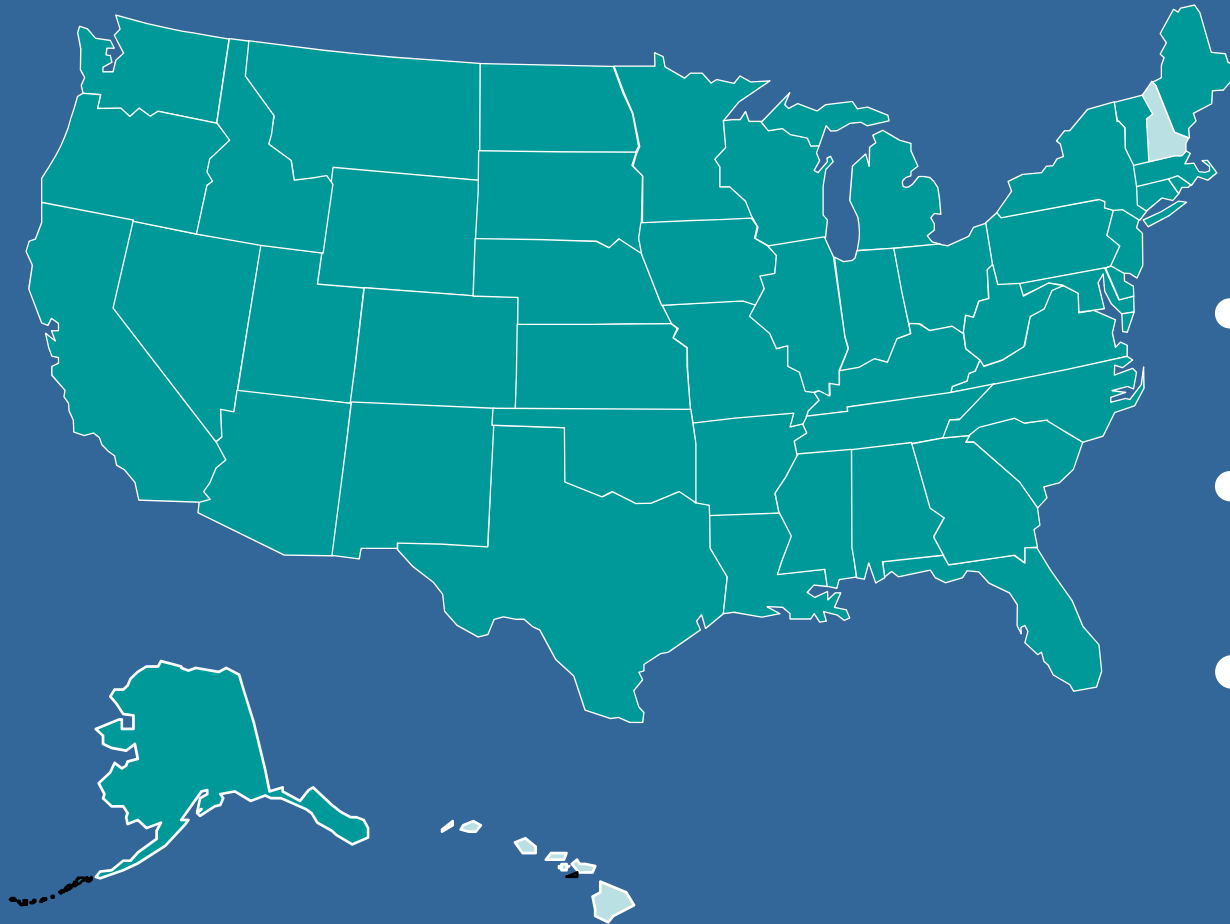
Joseph Reardon, Director of FDA's Division of Federal State Relations (FDA/DFSR) made the announcement earlier this year at the 2011 AAFCO Midyear Meeting.

Chad Linton, AAFCO president said, "AAFCO and FDA understand the importance of promoting uniformity across the agencies and will work efficiently and diligently to produce a positive and valuable Animal Feed Regulatory Program Standard that can be used by the states and FDA. We thank the committee members for their dedication and commitment in creating universal standards that will play a critical role in ensuring the safety of our nation's food supply."

Under Construction



FY 2010 Contracts

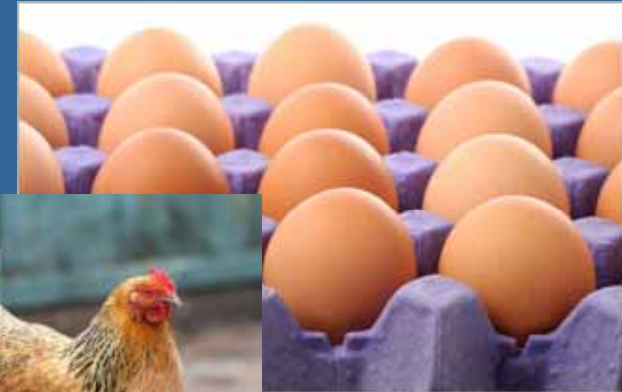


- 48 States
- 147 Contracts
- \$22.5M

 = FDA Contract with State

FY 2011 Egg Contract

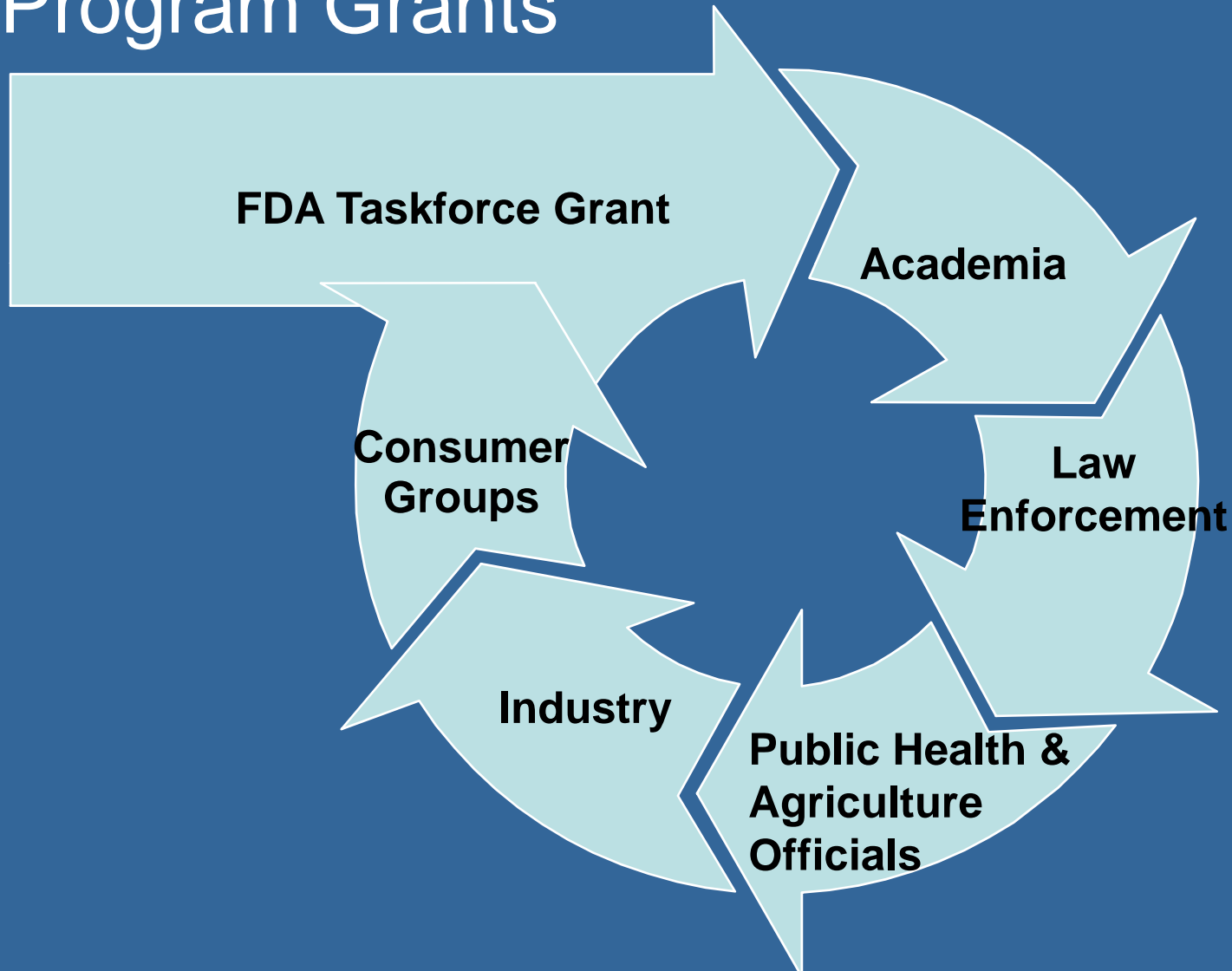
- Purpose: To conduct inspections of egg layer farms to assess compliance with 21 CFR 118 “The Egg Rule”
- Awarded to 10 States in May 2011
- Training
 - DF SR is supporting prospective state contractors to attend the required training





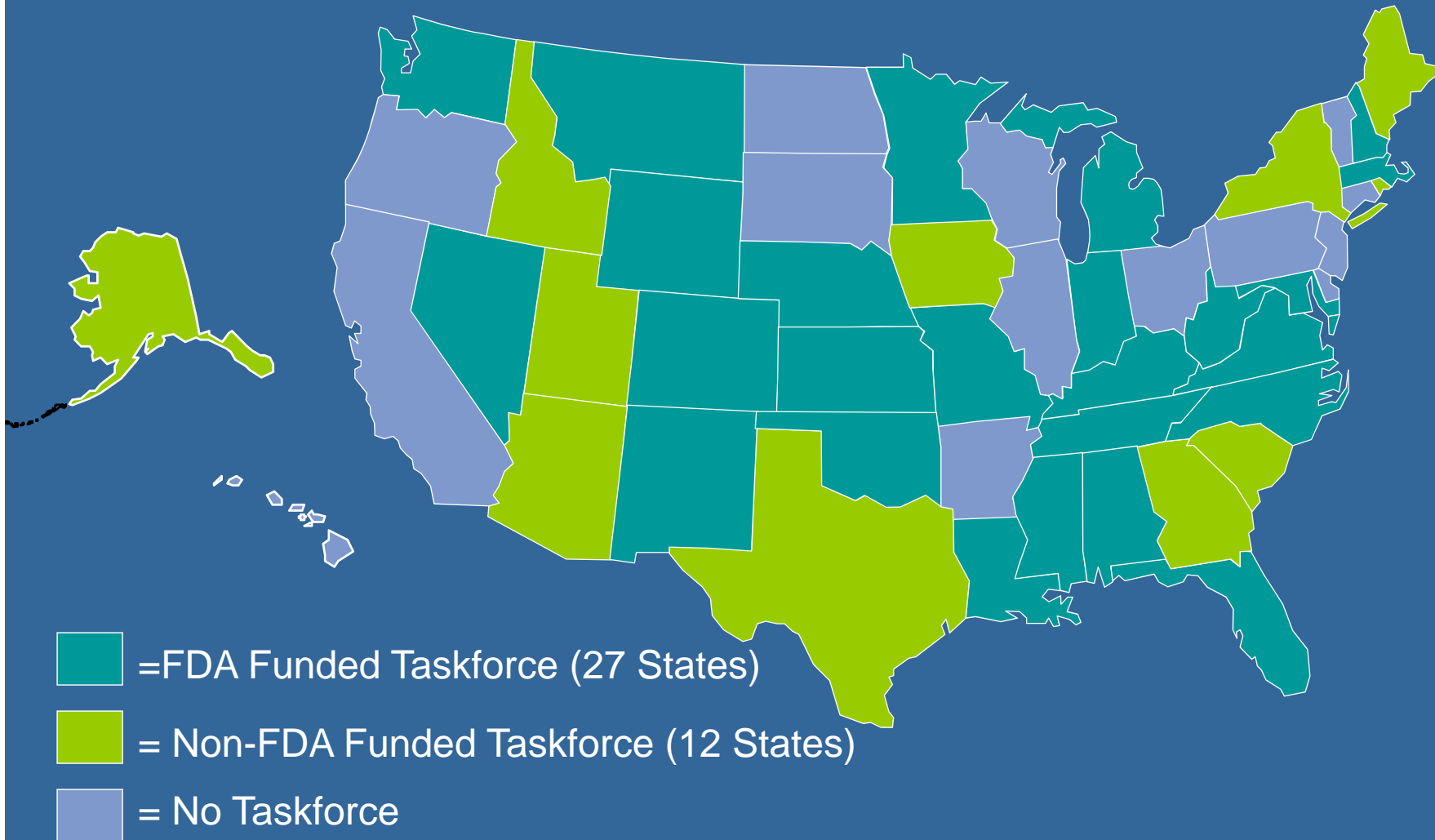
Division of Federal-State Relations

Food Protection Taskforce Conference Program Grants





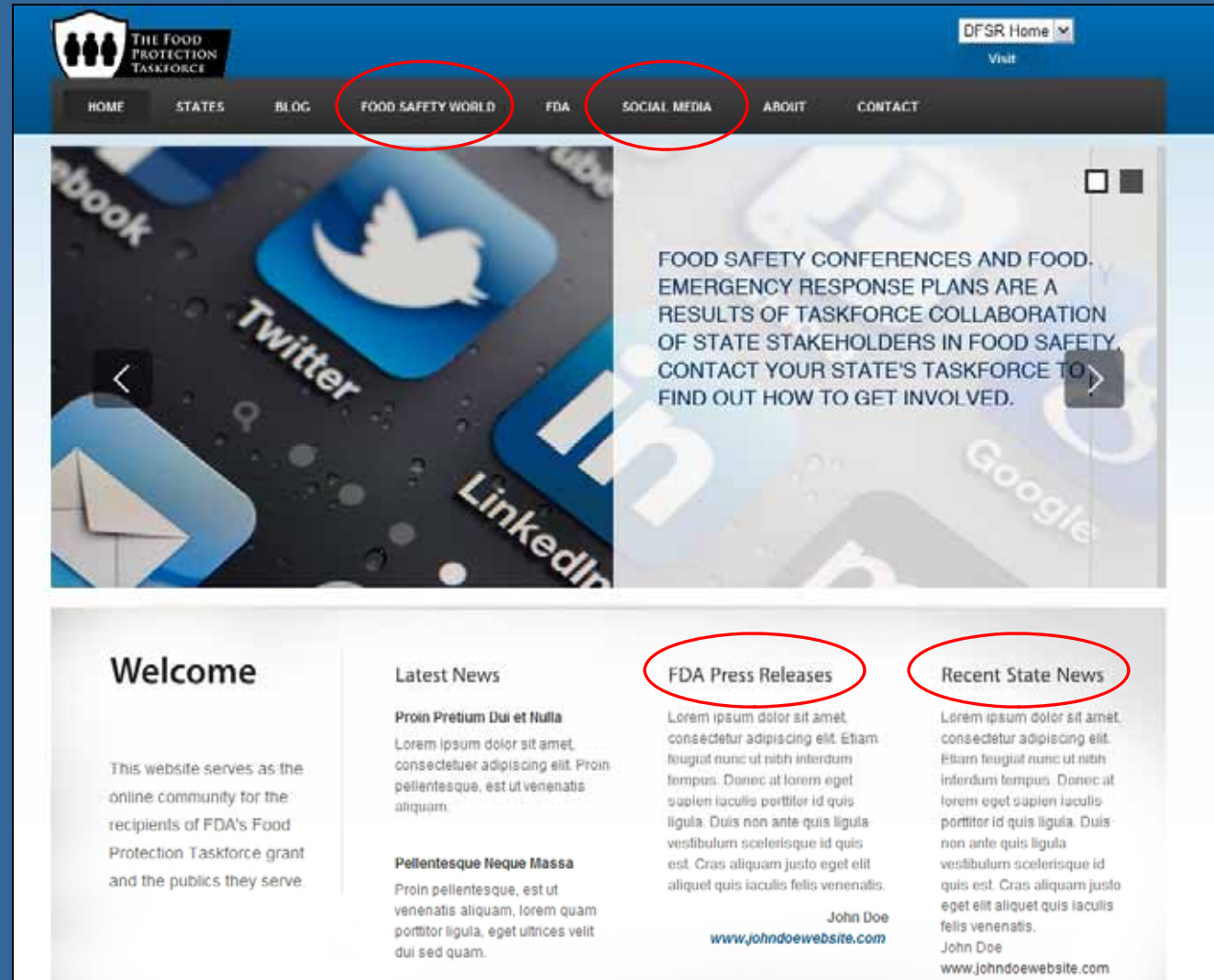
FDA Funded and Non-Funded Taskforces





Food Protection Taskforce Websites

- FDA Press Releases
- Food Safety News
- Social Media
- News in other State Taskforces





Rapid Response Teams – 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.)



RRT Playbook – Current Status

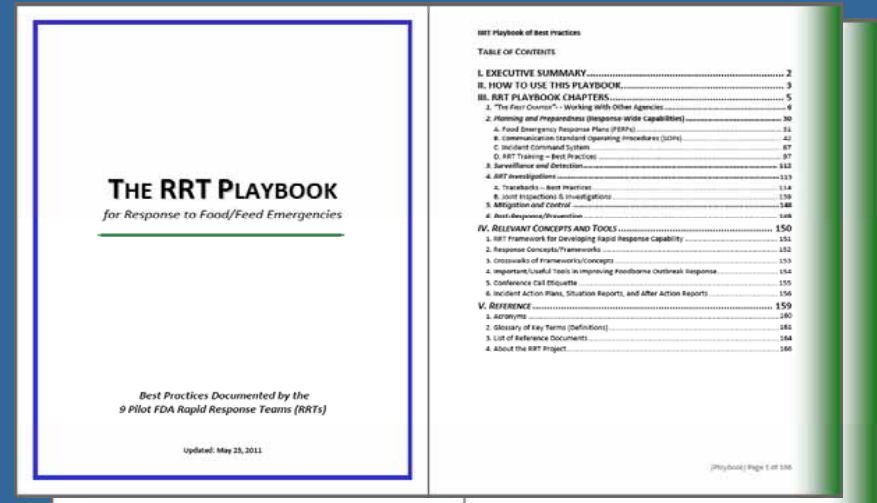
- Currently:

- 7 Chapters Completed

1. Food Emergency Response Plan
2. Communication SOPs
3. Working with other Agencies
4. ICS
5. Training
6. Tracebacks
7. Joint Investigations

- Next (as of June 9, 2011 – Memphis):

- Metrics for 2 Chapters: Training, Joint Inspections/Investigations)
- Additional Chapters: Recalls, Industry/Other Relationships, Environmental Assessments, AARs/Hotwashes





9 Pilot RRTs Build a Foundation for Rapid Response Capability Development

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



Division of Federal-State Relations

Food Safety Modernization Act Implementation



Federal-State Integration:
Operational Partnerships, Capacity Building, Training



Implementation Executive Committee

Chief Implementation Manager, Project Management Team

Regulations and Policy Steering Committee

Strategic Communications & Outreach Team

Prevention Standards
Don Kraemer
Dan McChesney

Inspection & Compliance
Barbara Cassens
Howard Sklamberg
Roberta Wagner

Imports
David Elder
Camille Brewer
Leslie Kux

Federal/State Integration
Joe Reardon
Tracey Forfa

Fees
David Wardrop
Bob Miller

Reports & Studies
David Dorsey
Dani Schor
Tania Simoncelli

Produce Safety Regulation
Don Kraemer

Produce Safety Guidance
Samir Assar

Preventive Controls Regulation
John Sheehan
Kim Young

Preventive Controls Guidance
Jenny Scott
Kim Young

Safe Food Transport
Mike Kashtock

Food Defense
Jody Menikheim

Contaminants
Mickey Parish
Terry Proescholdt

Mandatory Recall and Recall Communications
Cecilia Wolyniak

Administrative Enforcement Tools
Bill Correll

Registration
Amy Barringer

Frequency of Inspection
Mike Rogers

Manner of Inspection/Food Safety Plan Review
Kathy Gombas
Dave Glasgow

Tracing
Sherri McGarry

RFR Improvements
Ted Elkin

Importer Verification & VQIP
Domenic Veneziano
Brian Pendleton

Import Certification
Michelle Twaroski

Accredited Third-Party Certification
Charlotte Christin
Toni Ravelli

Lab Accreditation & Integrated Consortium/FERN
Tim McGrath

International Capacity Building
Julie Moss
Katherine Bond

Comparability
Julie Callahan

Task A: Prior Notice
Kelli Giannattasio

Operational Partnership
Tim Weigner

Capacity Building
Anita MacMullan

Training
Pat Alcock

Inspection & Auditor Fees
Fees Team

Reports to Congress/Studies



Division of Federal-State Relations

Operational Partnerships: Tim Weigner, Travis Goodman

Section 201:
Targeting of Inspection
Resources for
Domestic Facilities,
Annual Report

Angela Kohls
Maya Johnson-Nimo

PFP Workgroups:
National Workplan
National Standards
Oversight

Section 209:
Improving the Training
of State, Local,
Territorial, and Tribal
Food Safety Officers

Tim Weigner
Marybeth Willis

PFP Workgroup:
Training

Section 210:
Enhancing Food
Safety

Travis Goodman
Linda Collins

PFP Workgroup:
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
- Other obligation

*Angela Kohls
Maya Johnson-Nimo*

PFP Workgroups: *National Workplan, National Standards, Oversight*



Training: Pat Alcock, Will Dardick

Section 209a(a):

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

Scope of Responsibility: The Secretary shall set standards and administer training and educations 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

Pat Alcock, Will Dardick

PFP Workgroup: Training



Operational Partnerships: Tim Weigner, Travis Goodman

Section 209a(b)1:

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

Scope of Responsibility: The Secretary, pursuant to a contract or memorandum of understanding between the Secretary and the head of a State, local, territorial, or tribal department or agency, is authorized and encouraged to conduct examinations, testing, and investigations for the purposes of determining compliance with the food safety provisions of this Act through the officers and employees of such State, local, territorial, or tribal department or agency.

A contract or memorandum described under paragraph shall include provisions to ensure adequate training of such officers and employees to conduct:

- Examinations
- Testing
- Investigations

The contract or memorandum shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations, testing, or investigations performed pursuant to this section by the officers or employees of the State, territorial, or tribal department or agency.

Tim Weigner, Marybeth Willis

PFP Workgroup: Training



Operational Partnerships: Tim Weigner, Travis Goodman

Section 210:
Enhancing Food Safety

Grants to Enhance Food Safety: The Secretary is authorized to make grants to eligible entities to:

- Undertake examinations, inspections, and investigations, and related food safety activities under section 702
- Train for the examination, inspection, and investigation of food manufacturing, processing, packing, holding, distribution, and importation, including as such examination, inspection, and investigation related to retail food establishments
- Build the food safety capacity of the laboratories
- Build the infrastructure and capacity of the food safety programs to meet the standards as outlined in the grant application
- Take appropriate action to protect the public health in response to a notification under section 1008, including planning and otherwise preparing to take such action; or a recall of food under this Act.

Travis Goodman, Linda Collins

PFP Workgroup: Performance Measures



Capacity Building: Anita MacMullan

Section 205(c)1:
Surveillance: Food
Safety Defense
Strategy and
Implementation

*Guy Delius
Shuen Chai*

PFP Workgroups:
*Emergency Response
National Standards,
Policy and Procedures
Information Technology*

Section 205(c)2:
Surveillance: State and
Local Capacity Review

*Tressa Madden
Caleb Michaud*

PFP Workgroups:
*Policy and Procedures
Laboratory,
Information Technology*



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, Caleb Michaud

PFP Workgroups: *Policy and Procedures, Laboratory, Information Technology*



FDA Division of Federal-State Relations

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FSMA Website:

<http://www.fda.gov/Food/FoodSafety/FSMA>