



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

FDA Office of Partnerships

Tressa Madden, MPH, RES
Consumer Safety Officer

OP Overview

October 14th, 2014



Cooperation & Collaboration: A daily priority for the FDA

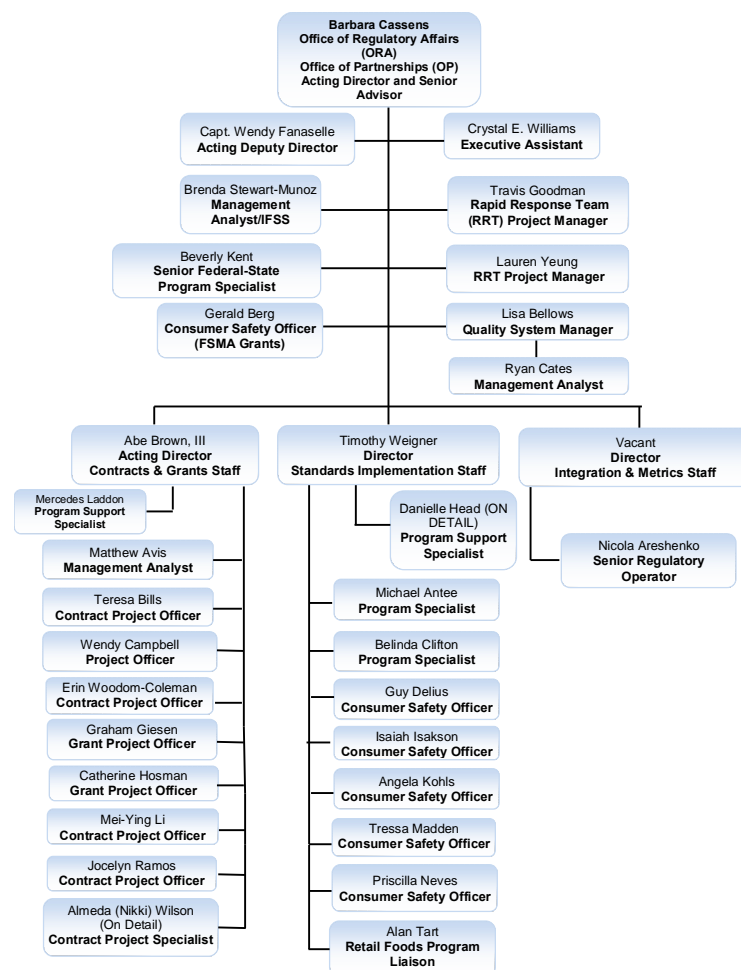
*“We will **strengthen our collaborations** with other public health agencies and leverage the expertise and resources of our colleagues at the **international, federal, state, and local levels** to ensure effective solutions for the American people.”*

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs



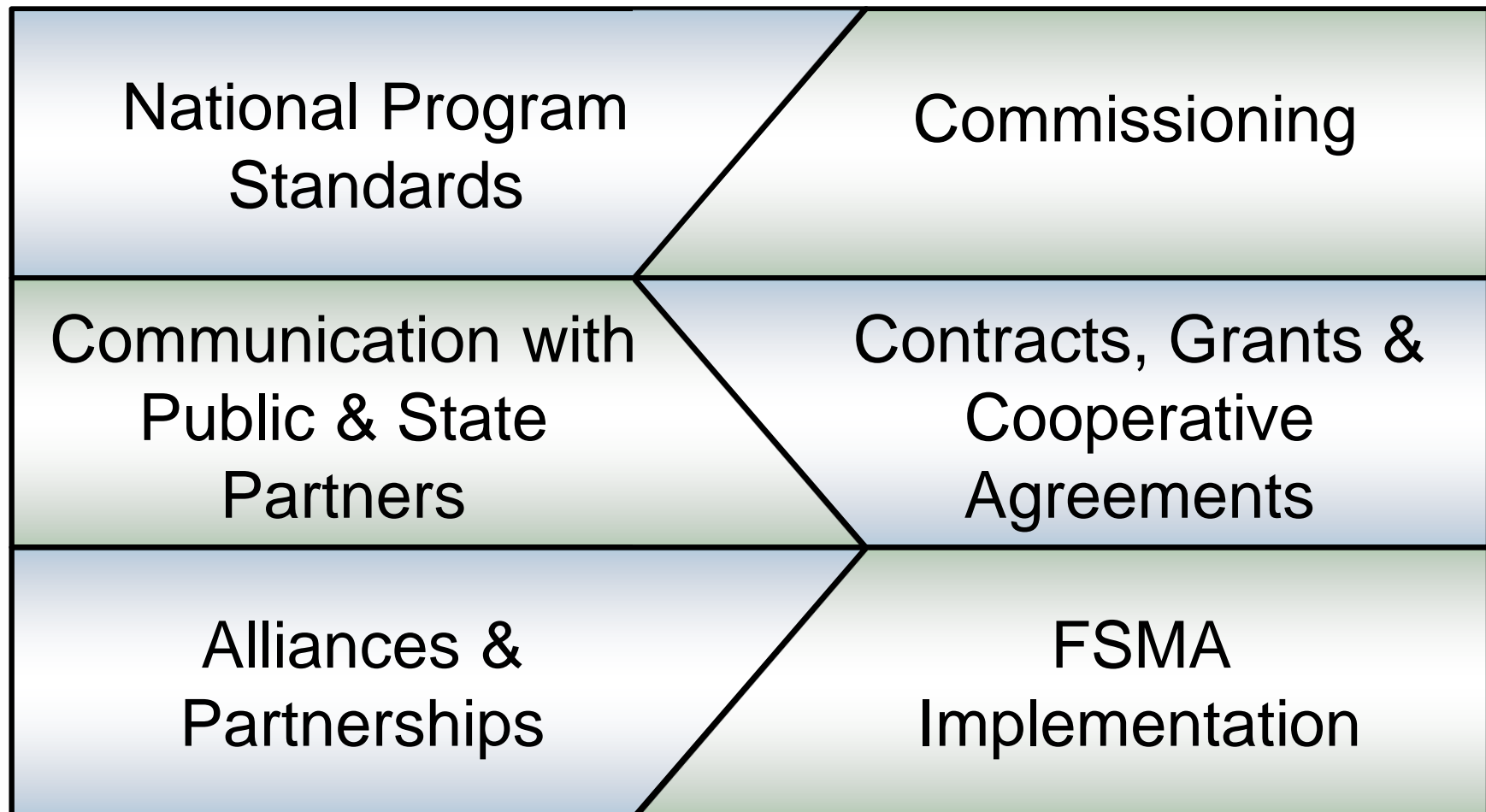


OP Organizational Chart





OP Initiatives with State Partners



Commissioning

- ” **Pre-decisional, commercial confidential or trade secret information**
- ” **Pocket Credential: Inspections & Sampling**
- ” **Background checks**
- ” **Over 2600 traditionally commissioned officials**
- ” **Over 1200 officials commissioned for tobacco**



Did You Know

20.88 Confidentiality Agreements has moved to the Office of Policy and Risk Management.

Directory of State & Local Officials

- “ Hosted through the Association of Food and Drug Officials (AFDO)
 - . <http://www.afdo.org/DSLO>
- “ Searchable
- “ Contains State and Local regulatory officials
 - . Contacts for food, animal feed, animal health, and food defense functions



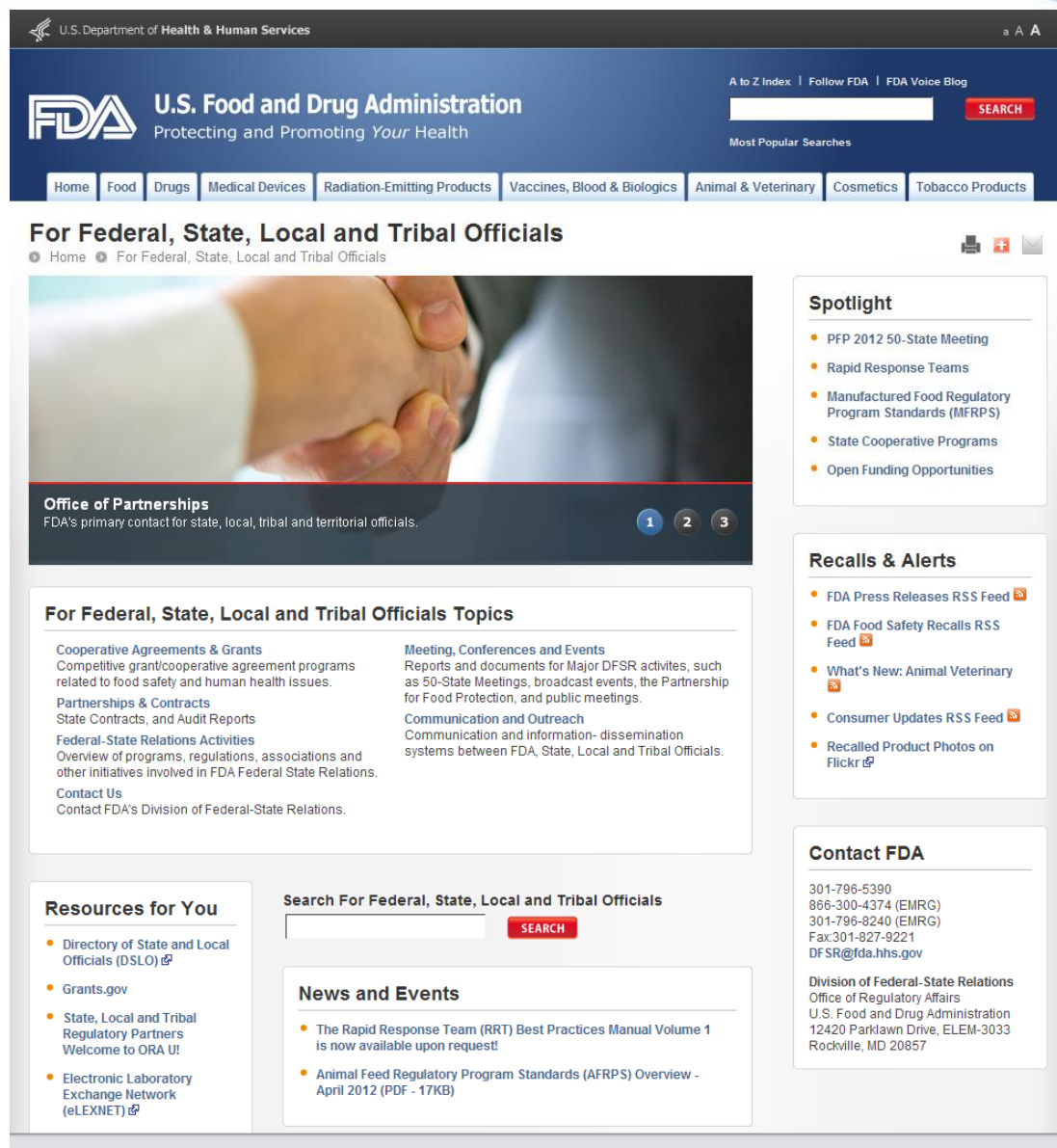


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FDA Website

- “ Links to public documents & information
- “ OP Accomplishments
- “ Program Summaries
- “ Funding Opportunities
- “ Contact Information



The screenshot shows the FDA website's page for Federal, State, Local and Tribal Officials. The header includes the FDA logo, the text "U.S. Food and Drug Administration Protecting and Promoting Your Health", and a search bar. Below the header is a navigation menu with links to Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled "For Federal, State, Local and Tribal Officials" and features a large image of hands shaking. Below the image is a section titled "Office of Partnerships" with a description: "FDA's primary contact for state, local, tribal and territorial officials." To the right of this section is a "Spotlight" box listing several programs: PFP 2012 50-State Meeting, Rapid Response Teams, Manufactured Food Regulatory Program Standards (MFRPS), State Cooperative Programs, and Open Funding Opportunities. Below the "Office of Partnerships" section is a "For Federal, State, Local and Tribal Officials Topics" section with links to Cooperative Agreements & Grants, Partnerships & Contracts, State Contracts, and Audit Reports, Federal-State Relations Activities, Meeting, Conferences and Events, Communication and Outreach, and Contact Us. To the right of this section is a "Recalls & Alerts" box listing several RSS feeds: FDA Press Releases RSS Feed, FDA Food Safety Recalls RSS Feed, What's New: Animal Veterinary, Consumer Updates RSS Feed, and Recalled Product Photos on Flickr. Below the "Topics" section is a "Resources for You" box listing links to the Directory of State and Local Officials (DSLO), Grants.gov, State, Local and Tribal Regulatory Partners Welcome to ORA U!, and Electronic Laboratory Exchange Network (eLEXNET). To the right of this section is a "Search For Federal, State, Local and Tribal Officials" box with a search bar and a "SEARCH" button. Below the search box is a "News and Events" box listing two items: "The Rapid Response Team (RRT) Best Practices Manual Volume 1 is now available upon request!" and "Animal Feed Regulatory Program Standards (AFRPS) Overview - April 2012 (PDF - 17KB)". To the right of the "News and Events" box is a "Contact FDA" box listing the contact information for the Division of Federal-State Relations, Office of Regulatory Affairs, U.S. Food and Drug Administration, 12420 Parklawn Drive, ELEM-3033, Rockville, MD 20857.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
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Most Popular Searches

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

For Federal, State, Local and Tribal Officials

Home For Federal, State, Local and Tribal Officials



Office of Partnerships
FDA's primary contact for state, local, tribal and territorial officials.

1 2 3

For Federal, State, Local and Tribal Officials Topics

Cooperative Agreements & Grants
Competitive grant/cooperative agreement programs related to food safety and human health issues.

Partnerships & Contracts
State Contracts, and Audit Reports

Federal-State Relations Activities
Overview of programs, regulations, associations and other initiatives involved in FDA Federal State Relations.

Contact Us
Contact FDA's Division of Federal-State Relations.

Meeting, Conferences and Events
Reports and documents for Major DFSR activities, such as 50-State Meetings, broadcast events, the Partnership for Food Protection, and public meetings.

Communication and Outreach
Communication and information- dissemination systems between FDA, State, Local and Tribal Officials.

Spotlight

- PFP 2012 50-State Meeting
- Rapid Response Teams
- Manufactured Food Regulatory Program Standards (MFRPS)
- State Cooperative Programs
- Open Funding Opportunities

Recalls & Alerts

- FDA Press Releases RSS Feed
- FDA Food Safety Recalls RSS Feed
- What's New: Animal Veterinary
- Consumer Updates RSS Feed
- Recalled Product Photos on Flickr

Resources for You

- Directory of State and Local Officials (DSLO)
- Grants.gov
- State, Local and Tribal Regulatory Partners Welcome to ORA U!
- Electronic Laboratory Exchange Network (eLEXNET)

Search For Federal, State, Local and Tribal Officials

SEARCH

News and Events

- The Rapid Response Team (RRT) Best Practices Manual Volume 1 is now available upon request!
- Animal Feed Regulatory Program Standards (AFRPS) Overview - April 2012 (PDF - 17KB)

Contact FDA

301-796-5390
866-300-4374 (EMRG)
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Fax:301-827-9221
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Office of Regulatory Affairs
U.S. Food and Drug Administration
12420 Parklawn Drive, ELEM-3033
Rockville, MD 20857

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

Manufactured Food Regulatory Program Standards (MFRPS)

Manufactured Food Regulatory Program Standards

September 2013



The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and has been assigned OMB control number 0910-0601.

To request a copy of the standards go to:

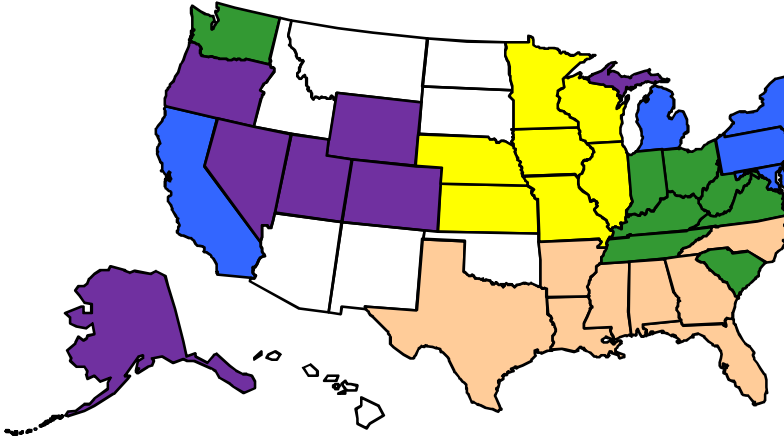
http://www.fda.gov/ora/fed_state/default.htm

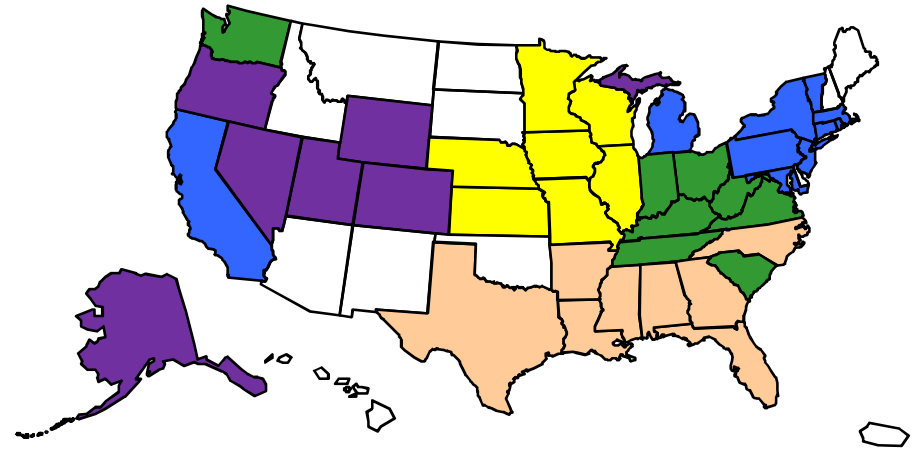
U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

OMB Control No. 0910-0601
Expiration Date: 09-30-2016

- “ Uniform foundation for the design and management of state programs responsible for regulating food manufacturers
- “ Institute a comprehensive quality assurance & standardization program

Building a Stronger MFRPS Community

- “ **40 programs in 39 States**
- **Increased from 28 programs in 2010 to 40 programs in 2013**
- ” **FoodSHIELD: Workgroup & Quarterly Webinar**
- ” **MFRP Alliance**
- **3rd Annual MFRPS Training March 10-13, 2014.**
 - **Strengthen: Community, Collaboration, Resources, and Program Advancement**
- 





National Program Standards: Animal Feed Regulatory Program Standards (AFRPS)

- “ National Standards for feed inspection programs**
- “ Joint project of the FDA and Association of American Feed Control Officials (AAFCO)**
- “ Committee established in 2011 to develop Standards**
- “ Draft document completed in 2012**
- “ Final document released in 2014**
- “ 13 State Programs Enrolled (obligated)**





National Program Standards: Voluntary National Retail Foods Regulatory Program Standards (VNRFRPS)

- ” Standards provide:**
 - . A guide to design and management of a retail food program**
 - . A program foundation**
 - . A tool to evaluate the effectiveness of food safety interventions**
- ” Over 600 regulatory jurisdictions enrolled**
- ” Additional information available at**
<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/default.htm>



FY14 Grants & Cooperative Agreements

Programs	# of Awards
Food Protection Task Forces	15
Food Emergency Response Network (FERN)	34
Ruminant Feed Ban Support (BSE)	11
Rapid Response Teams	18
Innovative Food Defense	2
Small Science Conference Grants	10
FSMA Emergency Response & Risk Based Inspections	33
Manufactured Food Regulatory Program Standards	37
ISO 17025:2005 Laboratory Accreditation	30
Voluntary Natl Retail Food Regulatory Program Standards	35
Integrated Laboratory System	1
Alliances	2
Retail Association	1
FoodSHIELD	1
Farm Survey (NASDA)	1
Total Funding	\$44M



Food Protection Task Force Conference Program Grants

FDA Taskforce Grant

Academia

**Consumer
Groups**

**Law
Enforcement**

Industry

**Public Health
Officials**

Current Grantees

" 14 States



The Vermont Food Safety Task Force consists of Vermont stakeholders committed to improving food safety through education, coordination, collaboration and communications.

REGULATIONS



- [FDA Food Safety Modernization Act including Produce Safety and Preventive Controls Proposed Rules](#)
–(QW) More information on FSMA available in the "News" tab in the upper right of this website.
- [USDA Food Safety and Inspection Service \(Meat and poultry regulations\)](#)
- [Vt. Agency of Agriculture Food Safety & Consumer protection regulations and other information](#)
- [Vt. Department of Health - Food Safety regulations and other information](#)

TASK FORCE MEETINGS



- Next meeting: March 12, 2012, 1-2:00PM, UVM Extension Office, Berlin, VT.
- Food Safety Task Force legislative event- January 16, 2012, 9-10AM- VT Statehouse Room 10 ([event summary](#))
- [Nov 14, 2012 meeting notes \(including draft agenda for March 12 meeting\)](#)
- [Sept 12, 2012 meeting notes](#)
- [June 12, 2012 meeting notes](#)
- The Vermont Food Safety Summit was held on March 22, 2012 at Lake Morey Resort in Fairlee, VT

FOOD SAFETY NEWS



- Peanut Corp. Executives Plead Innocent
- Chocolate-Covered Marshmallow Eggs Recalled for Salmonella Risk
- Raw Milk Deliveries to Twin Cities Trips Up Michael Hartmann
- USDA Meat & Poultry Inspectors Start Year With Brisk Business
- Sequester Expected to Have Big Impact on Food Safety; Details Unknown

Food Protection Task Force Mobile App



About Us Blog Food Safety Meetings

Recall Notifications

AT&T 4G 6:36 PM 81 %

← Meetings

May 2012


MAY 31 Quarterly Meeting >

August 2012

AUG 9 Quarterly Sector Meeting >

AT&T 4G 6:36 PM 81 %

← Food Safety Podcast

 **Unilever Issues Allergy Al...**
Unilever is voluntarily recalling pint containers of its Ben & Jerry's Chocolate Nougat Crunch Ice Crea...
Tuesday 12 June 2012

Recall Notification Report...
CB Foods, Inc., an El Monte, Calif. establishment, is recalling approximately 55,757 pounds of por...
Monday 11 June 2012

Best Maid Cookie Compa...
Best Maid Cookie Company of River Falls, Wisconsin is recalling Sienna Bakery brand Oatmeal Walnut Raisi...
Friday 8 June 2012

Voluntary Recall Of Pasta...

Progress bar and playback controls (Previous, Play, Next buttons)

Rapid Response Teams (RRT)

” Multi-year Cooperative Agreement to improve response

- . Unify & coordinate partners
- . Develop effective models that can be replicated by others

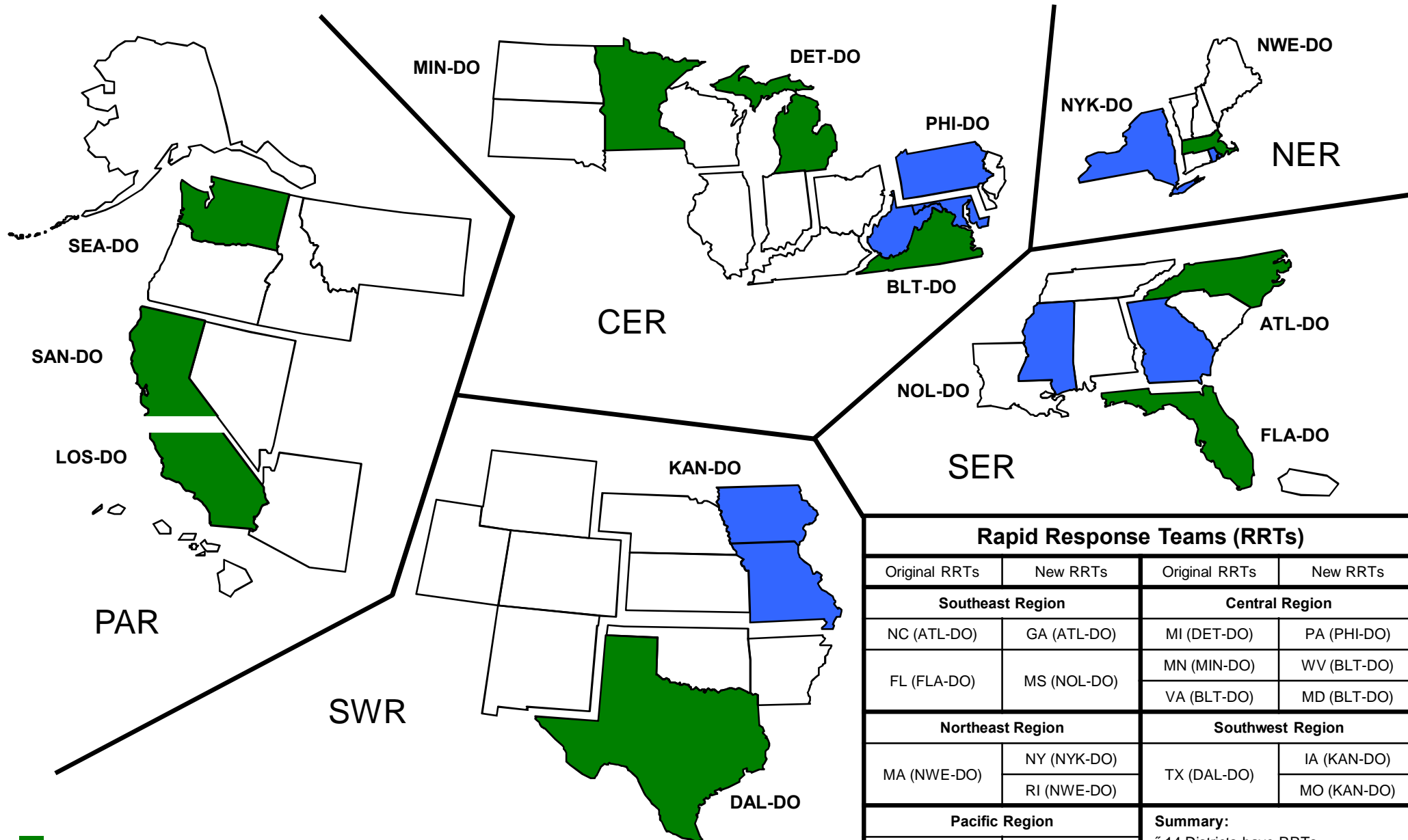


Did You Know

9 RRTs are in Public Health Agencies

9 RRTs are in Departments of Agriculture

Rapid Response Teams FY13 (2013-2014 Grant Year)



■ = Original RRT State (Joined 2008/2009)

■ = New RRT State (Joined 2012)

Rapid Response Teams (RRTs)

Original RRTs	New RRTs	Original RRTs	New RRTs
Southeast Region		Central Region	
NC (ATL-DO)	GA (ATL-DO)	MI (DET-DO)	PA (PHI-DO)
FL (FLA-DO)	MS (NOL-DO)	MN (MIN-DO)	WV (BLT-DO)
		VA (BLT-DO)	MD (BLT-DO)
Northeast Region		Southwest Region	
MA (NWE-DO)	NY (NYK-DO)	TX (DAL-DO)	IA (KAN-DO)
	RI (NWE-DO)		MO (KAN-DO)
Pacific Region		Summary:	
WA (SEA-DO)	N/A	~ 14 Districts have RRTs	
CA (LOS-DO & SAN-DO)		~ 1 District has 3 RRTs	
		~ 3 Districts have 2 RRTs	
		~ 10 Districts have 1 RRT	

RRT Program Outcomes

” Strengthen Federal/State/Local Collaboration

- . FDA, State (food and feed), lab, epi, locals

” Improve program infrastructure

- . District/State response teams
- . ICS (Unified command)
- . After Action Reviews & Reports
- . Capability Assessment (Metrics)



Did You Know

9 RRT grantees are in
Public Health Agencies

9 RRT grantees are in
Departments of Agriculture



Building a RRT

- “ State-District collaboration to minimize barriers to effective field response
- “ RRT Structures are unique, but share a common core
- “ RRT Capacity Building Process & Mentorship Framework
 - . 3 Phases: incremental capacity building
- “ Mentorship (original & new RRTs)



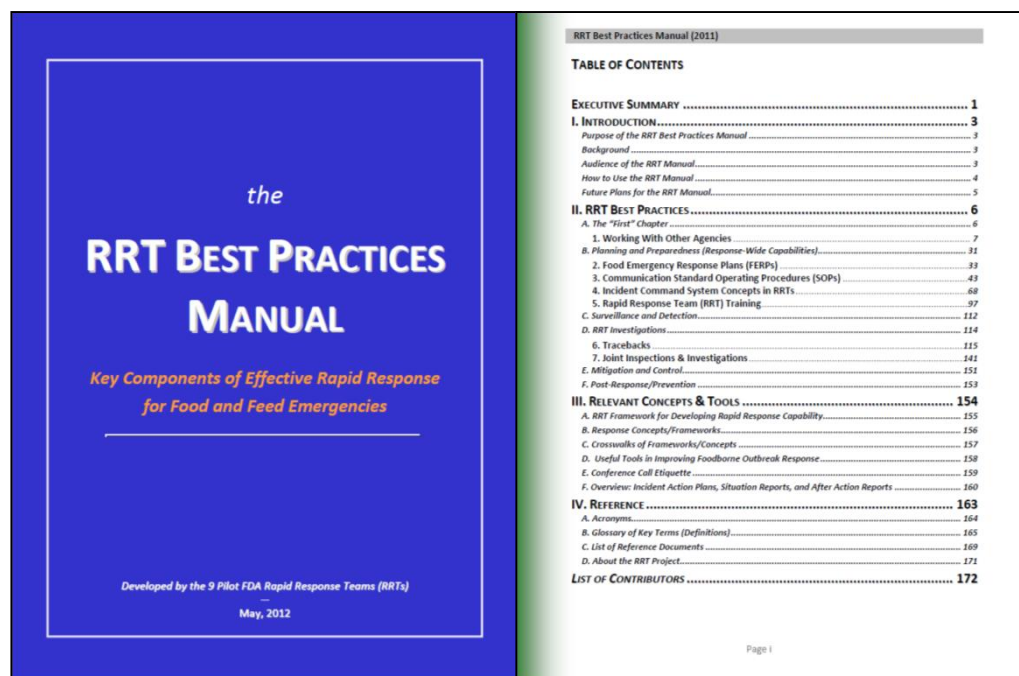
High Profile Outcomes

- **2011: Mold in Snokist Applesauce (WA & NC RRTs)**
- **2011: *Salmonella* Agona in Papaya (TX RRT)**
- **2011: *E. coli* O157:H7 in in-shell Hazelnuts (MI, MN & CA RRTs & WI)**
 - Article published in the Journal of Food Protection
- **2012: *Salmonella* in Diamond Petfood (MI RRT)**
 - Resultant large scale recall
- **2013: *Cyclospora* in bagged salad mix and cilantro (IA & TX)**
 - 2 separate, concurrent outbreaks
- **2014: *Listeria* in soft Mexican cheeses (MD & VA)**
 - Inter-RRT collaboration, resulted in suspension of facility registration



RRT Best Practices Manual – 2013 Edition

- “ Developed by multi-disciplinary, multi-jurisdictional working groups
- “ Reviewed by many partners
- “ Request at OP-ORA@fda.hhs.gov
- “ 14 total chapters



ISO/IEC 17025:2005 State Laboratory Accreditation

- “ **Purpose: Microbiological and chemical food analyses performed on behalf of State manufactured food regulatory programs conducted within the scope of an ISO/IEC 17025:2005 accredited laboratory**
- “ **31 programs participating**
- “ **Lab programs must:**
 - . **Submit a self assessment of laboratory accreditation progress/status, and a cost proposal**
 - . **Provide quality management personnel to ensure accreditation success**
 - . **Develop an Action Plan**
 - . **Develop a Proficiency Testing Plan**
 - . **Obtain training necessary to obtain accreditation**
 - . **Obtain and maintain accreditation**





FY14 Inspection Contract Programs

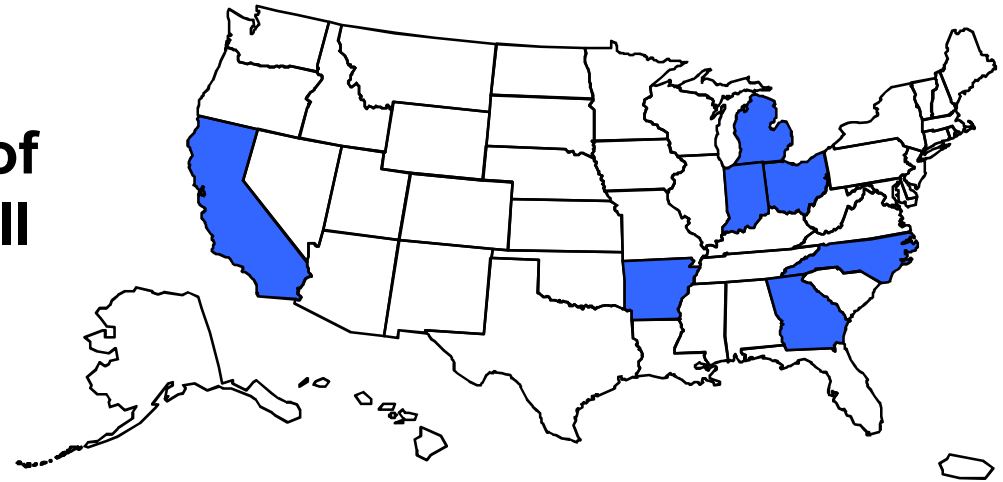
Program	# of Awards	Inspections
Food	45	9,602
Feed	35	4,207
Egg	7	92
Tissue Residue	17	312
MQSA*	44	6,939
Medical Device	1	20
Milk Residue	1	Data**
Totals	\$24.9M	21,172

**Mammography Quality Standards Act*

***Analysis of nearly 4 million milk residue samples*

Egg Inspection Contract

- ” Purpose: To conduct inspections of egg layer farms to assess compliance with 21 CFR 118
 - . “The Egg Rule”: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Transportation and Storage
- ” Awarded to 7 States
 - . 1 year Contracts
 - . Total Funding: \$225,000



 = FDA Contract with State



Then & Now: Investment in Federal-State Integration

Programs	FY2009 Funding	FY2014 Funding
Contracts (total)	\$15.5M	\$24.9M
Grants (total)	\$16.5M	\$44M
Food Protection Task Force	\$118K	\$127K
Food Emergency Response Network	\$8.9M	\$9.7M
Ruminant Feed Ban Support (BSE)	\$2.6M	\$2.3M
Innovative Food Defense	\$225K	\$200K
Small Science Conference	\$150K	\$285K
FSMA Emergency Response+Risk Based Inspections	None	\$3M
MFRPS implementation	None	\$9.6M
ISO	None	\$7.2M
RRT	\$4.5M	\$5.3M
Integrated Laboratory System	None	\$1.1M
Alliances (AFDO and NCSL)	None	\$450K
FoodSHIELD	None	\$496K
Farm Survey (NASDA)	None	\$600K
State Cooperative Programs (total)	\$105K	\$3.5M
Retail Standards/Association Coop Agreements	None	\$3M
Partnership Funds (Includes Dairy and Shellfish Programs)	\$105K	\$575K
Total Funding	\$32.1M	\$72.4M

Cooperative Programs

- ” **Retail Food**
- ” **Shellfish Sanitation**
- ” **Dairy**
- ” **FDA provides:**
 - . **Guidance & Technical Assistance**
 - . **Training & Certification**
- ” **Key players**
 - . **OP**
 - . **CFSAN**
 - . **ORA Retail Food, Shellfish & Milk Specialists**
 - . **ORA Regional Directors of State Cooperative Programs**





Retail Food Safety Initiative

- “ **Food safety at point of sale and service is an important part of FDA’s farm-to-table strategy**
- “ **Retail Initiative Task Force established**
- “ **Retail Initiative Action Plan posted on FDA Website**
 - . **Acknowledges key partnerships as part of an Integrated Food Safety System**
 - . **Establishes four primary goals**
- “ **Increase communication with foodservice and retail food store industries on Retail Initiative and other food safety topics of interest**
- “ **Partnerships Established in 2012**
 - . **Restaurant Partnership**
 - . **Retail Food Store Partnership**
 - . **Institutional Foodservice Partnership**



Partnerships & Alliances

- “ **Sprout Safety Alliance**
- “ **Produce Safety Alliance**
- “ **Food Safety Preventive Controls Alliance**
- “ **Manufactured Food Regulatory Program Alliance**
- “ **Alliance for Advancing a National Integrated Food Safety System**



Integrated Food Safety System (IFSS)

“A national IFSS must be built upon mutual reliance and respect among partner agencies, recognizing and understanding each participant’s roles, limitations, and authorities...”



- “ **Federal, State, local, tribal, & territorial regulatory & public health partners**
- “ **Working collaboratively across all jurisdictions**
- “ **To provide comprehensive, coordinated coverage of the food supply from farm-to-table**
- “ **Outcome: Prevention of foodborne illness in humans and animals**
- “ **Accomplished, in part, through the Partnership for Food Protection (PFP)**



IFSS Strategies

“ Vision achieved, in part, by:

- . Establishing and implementing national standards to ensure consistency across all jurisdictions**
- . Developing training & certification programs to establish a highly skilled workforce across all jurisdictions**
- . Implementing IFSS foundational elements**

IFSS Strategies



“ IFSS foundational elements:

- . Joint work planning including inventory sharing
- . Joint inspections where appropriate
- . Joint enforcement and compliance teams
- . Joint after action reviews of significant events
- . Joint responses to significant events
- . Immediate notification of egregious conditions

Partnership for Food Protection

- “ Brings together regulatory stakeholders to develop an IFSS
- “ Strengthened inspection, laboratory, and response capacity
- “ Biennially-held 50-State Workshops (2008-2014)



<http://www.fda.gov/regulatorypartners>
Under “Integrated Food Safety System”



PFP Best Practices

- “ **PFP Food/Feed Testing Laboratories: Draft Best Practices Manual**
- “ **PFP Information Technology Data Principles**
- “ **Model for Local Federal/State Planning and Coordination of Field Operations and Training**
- “ **National Program Standards Crosswalk Resources Paper**
- “ **Recycled Organic Waste as Animal Feed: A Recommendation for Regulatory Programs to Address Current Information Groups**





FDA Support for an IFSS

- “ **Office of Foods and Veterinary Medicine (OFVM) Changes**
 - . ***Added Director of Intergovernmental Affairs & Partnerships***

- “ **Office of Regulatory Affairs (ORA) Changes**
 - . ***Created Office of Partnerships (Formerly DFSR)***
 - . ***Added Senior Advisor for Fed-State Relations***
 - . ***Added District State Liaisons***
 - . ***Added District Emergency Response Coordinators***



FDA Support for an IFSS

- “ **New PFP governance structure and Governance Council contains senior leaders from across FDA’s Foods Program**
- “ **Add dedicated project managers for PFP WGs from across FDA’s Foods Programs**



Food Safety Modernization Act

“ Federal-State Integration Deliverable Groups

. Operational Partnerships

- Sections 201, 209, 210

. Capacity Building

- Sections 205c1, 205c2

. Training

- Section 209

“ Harmonize with PFP Workgroups





FSMA Sec. 201 – Targeting of Inspection Resources for Domestic Facilities

- “ **FDA reliance on inspections conducted by other agencies under agreement**
 - . **States conduct 60% of Federal inspections under contract**
- “ **Role of MFRPS and AFRPS**
 - . **Provide **uniformity and consistency** among Federal & State Inspection Programs**
- “ **Independent Audit Group**
 - . **Ensure uniform implementation of Standards**



FSMA Sec. 209 – Improving the Training of State, Local, Territorial and Tribal Officers

- “ **Set standards and administer training and education programs for food safety officials**
- “ **Training areas include:**
 - **Scientific; best practices; sampling & laboratory; building enforcement actions; inspections under 702/704**
- “ **Provide **consistency and equivalency** among Federal & State Programs**
- “ **We must invest in training**
 - **A contract or MOU will provide support for this effort**



FSMA Sec. 210 – Enhancing Food Safety

- “ Direct investment in the infrastructure of State and local capacities
 - . Grants****
- “ Eligible entities will be able to:
 - . Build the infrastructure and capacity of food safety programs****



FSMA Sec. 210 – Deliverables

Progress: Grant awards to enhance food safety

- “ Building the Capacity of State, Local, Territorial, and Tribal Food Regulatory Agencies to Undertake Examinations, Inspections, and Investigations and other Related Food Safety Activities Under Section 702 of the FD&C Act**
- “ Building the Capacity of Food Safety Entities to Protection Public Health in Response to a Notification under Section 1008 of the FD&C Act or a Recall of Foods**

FSMA Sec. 205(c)(2) – Surveillance: State and Local Capacity

- “ A review of State and local capacities to be completed no later than one year after the date of enactment
- . Staffing levels & expertise
 - . Laboratory capacity
 - . Information systems
 - . Other State/local activities and needs





FSMA Sec. 205(c)(1) – Capacity at the State and Local Level

- “ The Survey will enable the development of strategies to leverage and enhance capacities to improve the following (205c1):**
- . Foodborne illness surveillance, outbreak response and containment**
 - . Inspections & safety standards**
 - . Partnerships & Information sharing**



Addressing Challenges in the Path Ahead

- “ **Budget cuts and extensive furloughs of State & local employees**
 - . **Reduced capacity at State & local levels**
- “ **We must continue to invest in crucial areas**
 - . **National Program Standards**
 - . **Training & Certification Programs**
 - . **Information Technology Structure**



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OP-ORA@fda.hhs.gov

OP Website:

www.fda.gov/regulatorypartners