FDA Office of Partnerships

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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 Initiatives with State Partners

- National Program Standards
- Communication with Public & State Partners
- Alliances & Partnerships
- Commissioning
- Contracts, Grants & Cooperative Agreements
- FSMA Implementation
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
FDA Website

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

http://www.fda.gov/ForFederalStateandLocalOfficials/default.htm
Manufactured Food Regulatory Program Standards (MFRPS)

- 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

<table>
<thead>
<tr>
<th>Programs</th>
<th># of Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Protection Task Forces</td>
<td>15</td>
</tr>
<tr>
<td>Food Emergency Response Network (FERN)</td>
<td>34</td>
</tr>
<tr>
<td>Ruminant Feed Ban Support (BSE)</td>
<td>11</td>
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<tr>
<td>Rapid Response Teams</td>
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<tr>
<td>Innovative Food Defense</td>
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<tr>
<td>Small Science Conference Grants</td>
<td>10</td>
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<tr>
<td>FSMA Emergency Response &amp; Risk Based Inspections</td>
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<tr>
<td>Manufactured Food Regulatory Program Standards</td>
<td>37</td>
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<tr>
<td>ISO 17025:2005 Laboratory Accreditation</td>
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<tr>
<td>Voluntary National Retail Food Regulatory Program Standards</td>
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<tr>
<td>Integrated Laboratory System</td>
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<tr>
<td>Alliances</td>
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<td>Retail Association</td>
<td>1</td>
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<tr>
<td>FoodSHIELD</td>
<td>1</td>
</tr>
<tr>
<td>Farm Survey (NASDA)</td>
<td>1</td>
</tr>
</tbody>
</table>

**Total Funding**  
$44M
Food Protection Task Force Conference Program Grants

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.

- FDA Food Safety: Vegetarian AIP including Mushroom and Freshwater Concentrate Nipah Virus
- View information on FDA available in the “About” tab in the upper right of this website.
- State food safety and inspection service laws and manuals can be found.
- Vermont food safety & Consumer protection regulations and other information
- VT Department of Health - Food Safety regulations and other information

- Next meeting: March 12, 2014, 11:00-2PM, UVM Extension Office, Berlin, VT.
- Food Safety Task Force legislative event January 16, 2014, Vermont Statehouse Room 10 (food safety)
- Jan 14, 2013 meeting notes (including draft copies of March 15 meeting)
- Jan 15, 2013 meeting notes
- The Vermont Food Safety Summit was held on March 15, 2013 at Lake Morey Resort in Rockingham, VT.
- Sequester Expected to Have Big Impact on Food Safety, Details Unknown

Peanut Corp. Executives Plead Innocent
Chocolate-Covered Mars Bars Recalled for Salmonella Risk
Raw Milk Delivered to Twin Cities Twins Up Michael Hartmann
USDA Meat & Poultry Inspectors Start Year With Fresh Business
Rapid Response Teams (RRT)

A 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)

Updated: September 1, 2013

Summary:
- 14 Districts have RRTs
- 1 District has 3 RRTs
- 3 Districts have 2 RRTs
- 10 Districts have 1 RRT

<table>
<thead>
<tr>
<th>Region</th>
<th>Original RRTs</th>
<th>New RRTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Southeast Region</td>
<td>NC (ATL-DO)</td>
<td>GA (ATL-DO)</td>
</tr>
<tr>
<td>Central Region</td>
<td>MI (DET-DO)</td>
<td>PA (PHI-DO)</td>
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<tr>
<td>Southwest Region</td>
<td>FL (FLA-DO)</td>
<td>MS (NOL-DO)</td>
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<tr>
<td>Northeast Region</td>
<td>MA (NWE-DO)</td>
<td>NY (NYK-DO)</td>
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<tr>
<td>Pacific Region</td>
<td>WA (SEA-DO)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>CA (LOS-DO &amp;</td>
<td>SAN-DO)</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
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</tr>
</tbody>
</table>

= Original RRT State (Joined 2008/2009)
= New RRT State (Joined 2012)
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

- 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

<table>
<thead>
<tr>
<th>Program</th>
<th># of Awards</th>
<th>Inspections</th>
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<tbody>
<tr>
<td>Food</td>
<td>45</td>
<td>9,602</td>
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<tr>
<td>Feed</td>
<td>35</td>
<td>4,207</td>
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<tr>
<td>Egg</td>
<td>7</td>
<td>92</td>
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<tr>
<td>Tissue Residue</td>
<td>17</td>
<td>312</td>
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<tr>
<td>MQSA*</td>
<td>44</td>
<td>6,939</td>
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<tr>
<td>Medical Device</td>
<td>1</td>
<td>20</td>
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<tr>
<td>Milk Residue</td>
<td>1</td>
<td>Data**</td>
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<tr>
<td><strong>Totals</strong></td>
<td><strong>$24.9M</strong></td>
<td><strong>21,172</strong></td>
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</table>

*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

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

Â 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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