



FERN

Uniting Federal, State and Local Laboratories for Food Emergency Response

The Food Emergency Response Network (FERN)

Integrating the Nation's Food Testing Laboratories to Improve Food Defense and Food Safety System

Michael McLaughlin, PhD

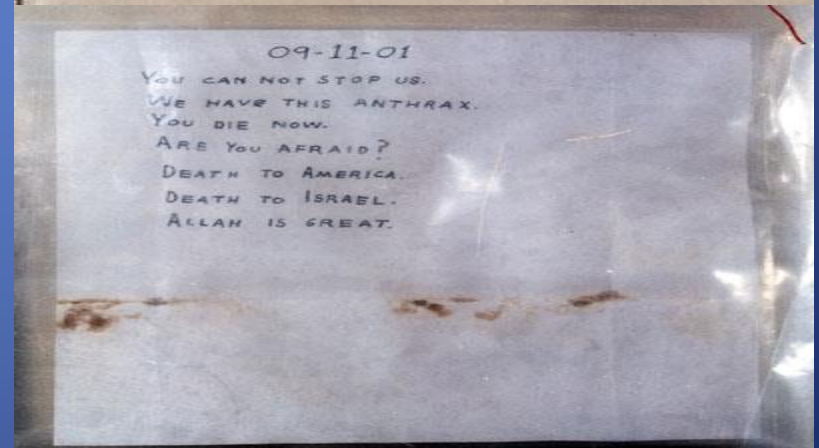
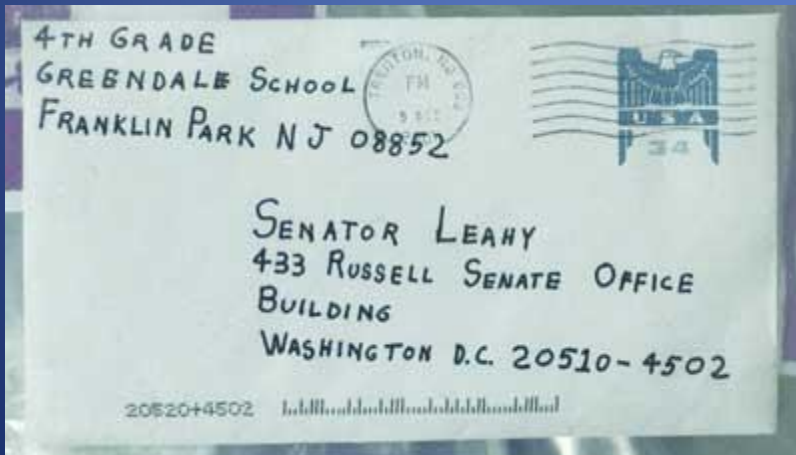
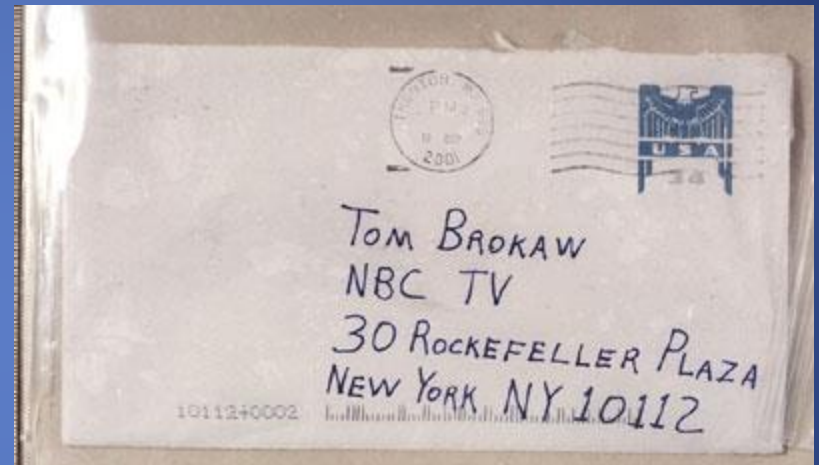
Srinu Chigurupati, DVM, PhD

Donald Burr, PhD

ORA/ORS



Why a FERN ?



The World Changed

- FERN emerged as a direct result of our experiences resulting from the dissemination of *Bacillus anthracis* via the mail
- Taught us new lessons and re-enforced old ones



Original FERN Mission - 2002

Integrate the nation's food-testing laboratories for the detection of intentionally added threat agents in food at the local, state, and federal levels.

A *comprehensive effort* aimed at the detection of biological, chemical and radiological agents in the full range of food commodities.

Expanded Mission of FERN - 2006

- Integrate the nation's multilevel food-testing laboratories to detect, identify, respond to and recover from a **bioterrorism** or **public health emergency/outbreak** involving the food supply

Mission Expansion:

- Transition from exclusively bioterrorism to inclusion of food safety
- Utilization of FERN cooperative agreement labs
- Integrated Food/Feed Safety System

FERN Objectives

- **Detection:** identification of biological, chemical, and radiological threat agents
- **Prevention:** operate targeted federal/state surveillance sampling programs
- **Preparedness:** strengthen laboratory capacities and capabilities
- **Response:** provide large-scale laboratory testing capacity
- **Recovery:** provide public assurance of food safety following an emergency

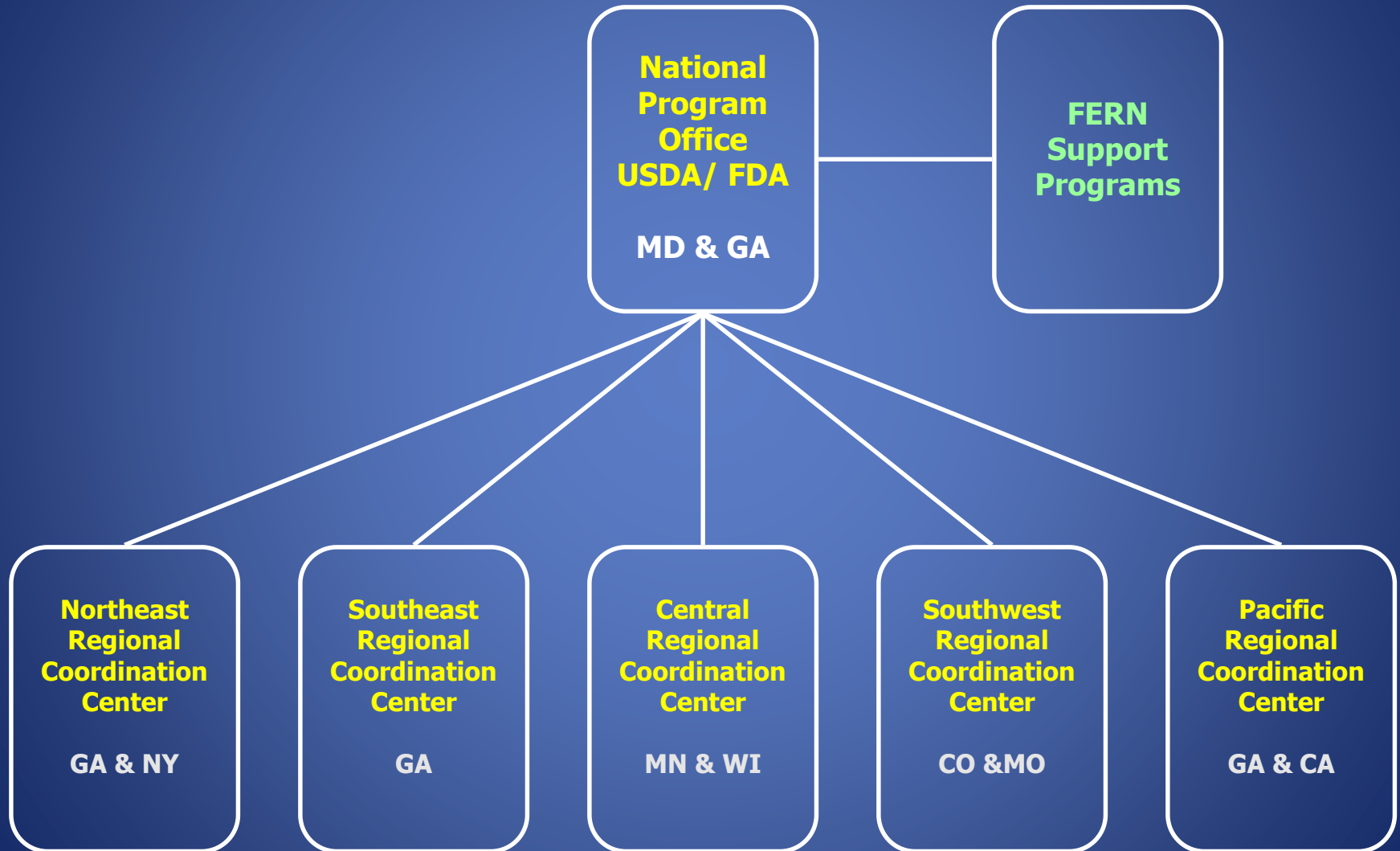
Laboratory Makeup

169 Laboratories

- Affiliations:
 - 39 Federal
 - 113 State
 - 17 Local
- Disciplines:
 - 133 Microbiological
 - 111 Chemistry
 - 36 Radiological
- Lab Testing Types:
 - 115 Food Safety (Outbreak)
 - 90 Food Safety (Regulatory/Routine)
 - 40 Agricultural Input
 - 22 Veterinary Diagnostic
 - 102 Environmental
 - 58 Clinical



FERN Organizational Chart



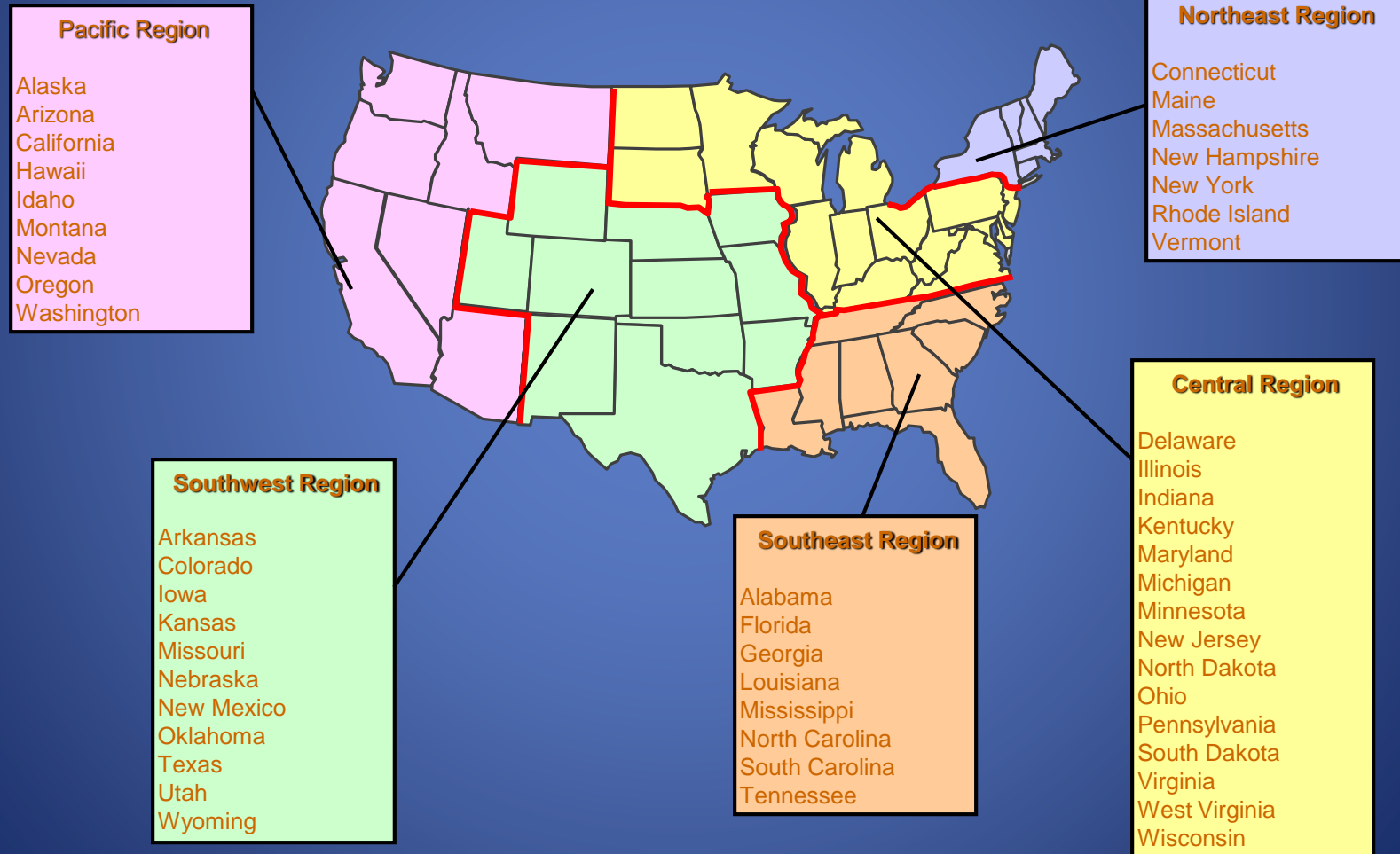
FERN National Program Office (FERN NPO)

- Responsible for day to day operation of FERN
- Manage and coordinate FERN Support Programs
- Coordinate national laboratory emergency response
- Responsible to the FERN Directorate (FDA & FSIS FERN Directors)

Regional Coordination Centers (RCC): an Integrated Approach

- Five RCCs are located through the U.S., one in each region and are staffed by FDA and FSIS.
- RCC Activities:
 - Identify laboratory capabilities (screening and confirmatory for all analytical areas) within the region
 - Identify needs of the region and convey those needs to the NPO
 - Coordinate regional response of laboratories during an emergency

Food Emergency Response Network Regions



FERN Support Programs

- **Method Development & Validation**

- FERN Methods Coordination Committee (MCC) is the reviewing and approval body for FERN Methods
- FERN Methods have been evaluated and shared with CDC/LRN, and harmonized with other lab networks
- Work continues on method development, validation, and harmonization in all analytical areas

- **Training Program**

- Over 600 people trained from all 50 states
- 6 Training Centers throughout the country
- Select agent training; Rapid detection methodology training
- Utilization of web-based training courses

- **Proficiency Testing/Readiness Program**

- Joint PT exercises with LRN, ICLN conducted when possible
- Aim for quarterly PT offerings

FERN Support Programs

- **Surveillance Programs**

- Assessing and demonstrating the effectiveness and capabilities of FERN
- Testing operating mechanism and protocols of FERN
- Demonstrating coordinated communication and data reporting

- **Electronic communications and collaboration**

- Data capture & exchange mechanism for FERN is the Electronic Laboratory Exchange Network (eLEXNET)
- FERN Website contains public information, member directory as well as laboratory capability & assessment information (LabDIR)

eLEXNET

- eLEXNET boasts a membership of 249 laboratories representing all 50 states
- **eLEXNET Activities:**
 - Reporting and Data Sharing Capabilities
 - Data entry (Manual and Automated Data Exchange)
 - Reporting (standard and ad hoc)
- **Food Safety Collaboration**
 - Laboratory/Data Expansion
 - Collaborative Features, Communication Tools
- **Methods Module**
 - Searchable Methods Library
 - Ability to submit methods (open to all eLEXNET member labs)
- **FERN & eLEXNET:** A dedicated FERN Portal was created for the FERN in 2008. The FERN Portal is used by FERN for communicative and collaborative purposes, as well as for data capture of FERN-directed analyses. It serves as the FERN's document repository and one of its main coordination tools.



[COMMUNITIES](#)

[REPORTS](#)

[PROFICIENCY TEST](#)

[COMPACT](#)

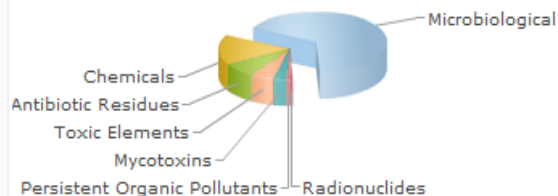
[DATA TOOLS](#)

[DIRECTORIES](#)

eLEXNET Dashboard (for the past 7 days)

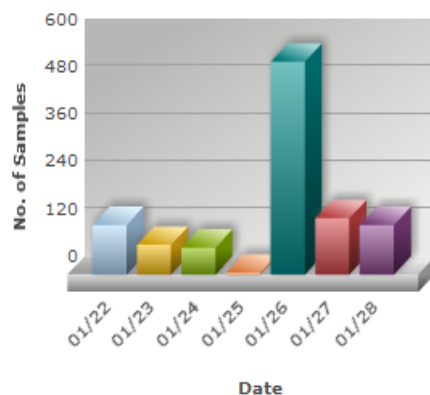
Dashboard and Activity data for the past 7 days ▼

Analytes by Test



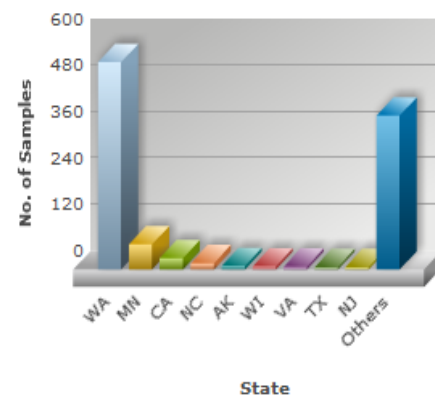
Shows analytes tested by discipline over the last 7 days.

Samples Received by Date



Shows the number of samples received by eLEXNET each day for the last 7 days.

Lab Activity By State



Shows top states with activity in the last 7 days including Federal, State and local labs within the state.

Interactive Data Analysis Tool (IDAT) - PILOT

Sample Analysis



The Sample Analysis Dashboard provides summary and detailed information about the samples available within eLEXNET. Data can

Data Quality



The Data Quality Dashboard provides information to help a lab understand the status of samples submitted to eLEXNET via the

eLEXNET Announcements

There are currently no Announcements to display.

eLEXNET Twitter Feed

Follow [@eLEXNET](#)



FDA/CFSAN Moffett Center

Access eLEXNET: Click the Logo



My Lab | Personnel | Testing | PT | Training | Lab Admin | PT Admin | Training Course Admin | Activation Admin | Calendar

My LabDIR Dashboard

FERN Event Center

Activations | PT | Training | Conference

TOX1 MLV FY 2015

 Access Activation Workzone

FY15 FSIS CAP Micro Food Defense Surveillance; Oct 2014 - Sep 2015

 Access Activation Workzone

FY15 FSIS Chemistry Food Defense Surveillance; Sep 2014 - Oct 2015

 Access Activation Workzone

FSIS - FERN CAP Round Robin Test of Unknown Chemicals in Foods CT

Laboratory Information

Name: FDA/CFSAN Moffett Center

Region: Central Region

Disciplines: Microbiology

PT LIN Number:

Micro	Chem	Rad
334	N/A	N/A

Lab Verification:

Your lab is verified.

Verification Dates: -

You must complete the lab assessment to verify the information.

Lab Tiering

Micro Points: 20



Upcoming Web Meetings

Web Meetings

FERN IT Advisory Meeting

 Enter Meeting

01/30/15 10:00AM EST

[View Details](#) [Accepted](#)

RRT Monthly Teleconference

 Enter Meeting

02/05/15 02:00PM EST

[View Details](#) [No Response](#)

FERN Cooperative Agreements

- A transfer of money, property, services or anything of value to recipients to accomplish a public purpose of support or stimulation.
- Requests For Applications – through Federal Register
- FERN currently has cooperative agreements in all three disciplines:
 - Microbiology
 - Chemistry
 - Radiological
- State laboratories, geographically dispersed.

FERN Cooperative Agreement Labs (cont.)

- **15 State Microbiology Laboratories (FDA CAP)**
 - Analyze samples for FDA/FERN (e.g. surveillance/emergency)
 - Some method development/validation work
- **14 State Chemistry Laboratories (FDA CAP)**
 - PT's, surveillance, emergencies (Melamine, Oil Spill)
- **5 State Radiochemistry Laboratories (FDA CAP)**
 - PTs, surveillance, emergencies

FDA Microbiology Cooperative Agreement Program (MCAP)

- Provide large-scale sample analyses
 - Outbreaks
 - Surveillance assignments
 - Surge capacity
- Uniformity of results – data acceptance
 - Common analytical platforms and methods
 - Training and proficiency testing
 - Building Quality System
 - Laboratory Accreditation (ISO/IEC:17025)
- **Model for Integrated Food/Feed Safety System (IFSS) and Partnership for Food Protection (PFP)**
 - One Mission - One Program
 - State lab data utilization
 - National standards
 - National work plan

FDA Microbiology Cooperative Agreement Program (MCAP) -Continued

- **Recent Accomplishments**

- Method Development/validation

- Multi-lab Validation (MLV) for extraction and qPCR of *E. coli* O157:H7 in ABI 7500 Fast system
 - MLV for *Listeria spp.* and *L. Monocytogenes* qPCR (ABI 7500 Fast)
 - MLV for *Salmonella* qPCR (ABI 7500 Fast)
 - *Vibrio* qPCR for isolates (BAX)

- Participated Surveillance Program

- 2011 Produce Surveillance collaborated with USDA Microbiological Data Program (MDP)
 - 2012 Democratic and Republican Convention Political Assignment

FDA Chemistry Cooperative Agreement Program

- Recent Accomplishments
 - Surveillance assignment for Arsenic in various fruit juices (total and speciation analyses). 4 labs for total As analysis and 2 for speciation.
 - Tested FDA regulatory samples from juice import bulletin for arsenic (FDA lab was overbooked)
 - Labs participate in a PT program which included testing sets for As and ricin in foods.
 - 2012 Democratic and Republican Convention Political Assignment

FERN Laboratory Response

- Examples of recent events where FERN member laboratories have assisted with method technical expertise and results/information sharing:
 - *E. coli* O157:H7 in spinach, 2006
 - *Salmonella* in peppers, 2008
 - Melamine in pet food and infant formula, 2007-2009
 - *Salmonella* in peanut butter, 2009
 - Deepwater Horizon Oil Spill, 2010
 - Radiological Crisis in Japan, 2011
 - Produce Surveillance collaborated with USDA Microbiological Data Program (MDP), 2011
 - Arsenic Testing in Rice and Juices, 2012
 - National Political Convention, 2012
 - FDA Large Scale Surveillance Assignment, 2014

Examples of FERN Laboratory Response

- *Salmonella saintpaul* Outbreak response activities (Summer, 2008)
 - FERN was activated in response to this outbreak
 - 12 FERN Microbiology Labs tested 290 pepper/cilantro/basil samples collected by the states in a FDA coordinated effort
 - FERN testing augmented and complemented concurrent FDA testing efforts (~550 samples)



Examples of FERN Laboratory Response

- *Salmonella Typhimurium* in Peanut Butter
 - 691 illnesses in 46 states
 - Use of state analytical data for outbreak/epi determinations
 - FERN labs utilized for a state-driven initiative to test manufacturing plant after clean up



Examples of FERN Laboratory Response

- **Melamine Outbreak response activities**

- FERN Chemistry Cooperative Agreement Program labs analyzed over 200 samples of protein products in 2007
- FERN Chemistry laboratories participated in the #09-06 CFSAN Melamine Import Assignment (2008-2009), assisting FDA in the analysis of milk and protein samples
 - Analyzed 340 samples, or ~20% of the total sample collection to date
 - Were a key factor in clearing an FDA sample backlog, which arose due to very high collection rates



Examples of FERN Laboratory Response

- **PAH analysis for Deepwater Horizon Oil Spill (Summer, 2010)**
 - FERN was activated in response to this emergency.
 - Chemistry CAP laboratories stood up for NOAA (GCMS) and Alternative (LCF) Methodologies
 - 2 FERN Chemistry CAP Labs (MN Dept of Ag and CT Agricultural Experiment Station) assisted FDA FCC in validation/development of Alternative LCF PAH method.
 - FERN provided surge capacity testing to augment and complement concurrent FDA testing efforts for Reopening of State Waters for shrimp, crab, finfish and oysters, as well as baseline sample testing.



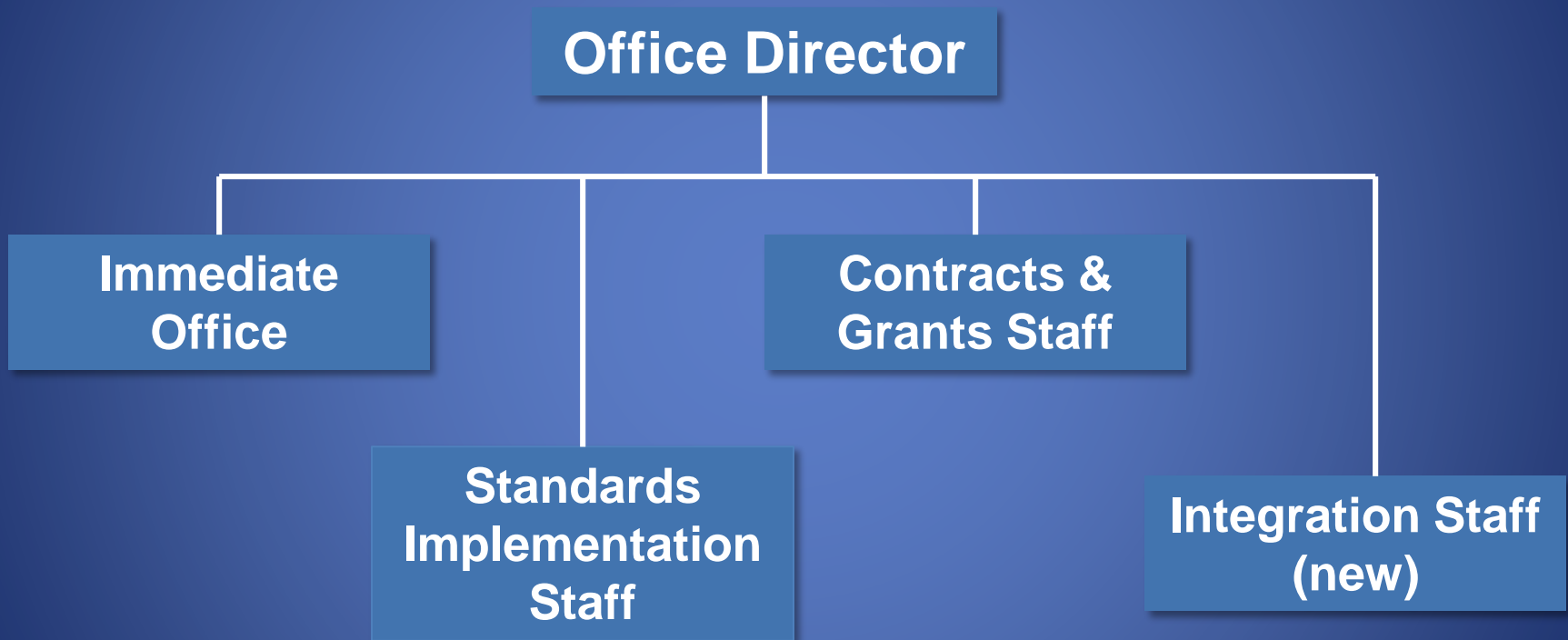
Office of Partnerships



CURRENT EFFORTS AND FUTURE PLANS FOR
BUILDING STAFF



Office of Partnerships Structure



Integration Staff (IS) (new)

- Tasked with developing metrics and other performance measures to determine progress of programs and processes that directly foster mutual reliance and/or an integrated food safety system and support the FSMA
- Foster collaborative food safety networks among public and private partners that enable their complementary and mutually beneficial efforts toward continuous improvement of FDA public health mission and goals

Integration Staff (IS)

- Staff are assigned to:
 - Grants and cooperative agreements for which they measure performance
 - One of three mutual reliance pilots to observe and measure performance
- Active members of Partnership for Food Protection Workgroups
- Participate in miscellaneous projects and assignments, such as:
 - Project management for short time line projects
 - Analyze pending legislation for impact on the FDA and/or national food supply

Grant and CAP Changes

- Expiring Grants To Be Renewed
 - FERN CAPs (Chem+Rad+Micro)
 - FoodSHIELD CAP
 - RRT CAPs (9 grantees)
- *Expiring Grants/Contracts Not To Be Renewed
 - BSE CAP
 - FSMA Grants
 - (10) Tissue Residue contracts

**Decision to not renew programs determined after discussions with OFVM, CVM and applicable district offices*

New Grant/CAP Funding Programs (FY15)

- AFRPS CAP (\$12.6MM total)
 - 24 grantees x \$300K/yr
 - Lab accreditation option
- ISO 17025 Accreditation CAP Expansion (\$3MM total)
 - 10 new grantees x \$300K/yr
- Retail CAPs Expansions (\$2.7MM total)
 - Retail Association (AFDO) CAP
 - Retail Standards CAP
- Tissue Residue CAP = \$800K total
- FoodSHIELD CAP Renewal = \$150K added
 - Added to \$250K funding already planned by OP + \$50K from CFSAN + \$50K from CVM

National Program Standards

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



U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Publication Date: January 30, 2014

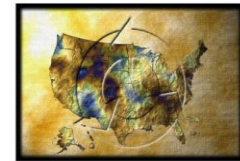
The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

OMB Control No. 0910-0760
Expiration Date: January 31, 2017

Voluntary National Retail Food Regulatory Program Standards – January 2011



Voluntary National Retail Food Regulatory Program Standards



"Standards of Excellence for Continual Improvement"

Developed and recommended by the U.S. Food and Drug Administration with input from federal, state, and local regulatory officials, industry, trade associations, academics, and consumers.

OMB Control No. 0910-0621
Expiration Date: 09-31-2014
Additional P.R.S. comment on the the following page.

Manufactured Food Regulatory Program Standards (MFRPS)

Manufactured Food Regulatory Program Standards

September 2013



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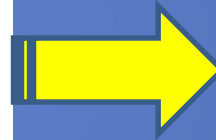
- First released in 2007 in response to an HHS OIG report recommending FDA take steps to promote “equivalency” among Federal and State food safety
- Using MFPRS to support FSMA Section 201 and IFSS:
 - Regulatory foundation
 - Training
 - Inspection and assessment
 - Compliance and enforcement
 - Outbreak and response
 - Laboratory support

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



Building Support for Animal Feed Programs



U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Publication Date: January 30, 2014

The collection of information has been approved by the Office of Management and Budget (OMB)
under the Paperwork Reduction Act of 1995.

OMB Control No. 0910-0760
Expiration Date: January 31, 2017

Support for Animal Feed Program Standards (AFRPS)

1st Year Goals and Opportunities

- Foundation Development
- Awareness / Communication / Participation
- Gathering and sharing resources
- 12 States enrolled under contract option

2nd Year Goals and Opportunities

- Cooperative agreement funding
- Growth with enrollment and implementation



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>

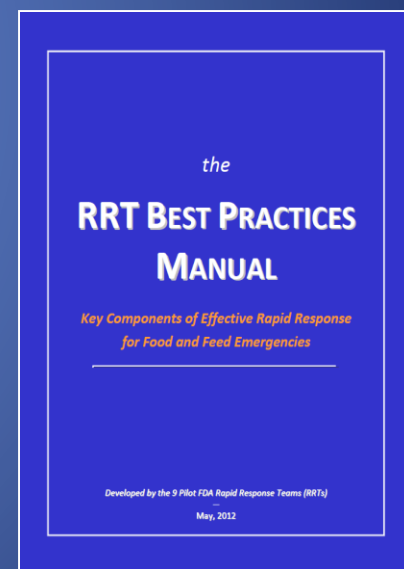
Cooperative Programs

- Retail Food
- Shellfish Sanitation
- Grade A Dairy
- FDA provides:
 - Guidance & Technical Assistance
 - Training & Certification
- Key players
 - OP
 - CFSAN
 - ORA Retail Food, Shellfish & Milk Specialists



Rapid Response Teams (RRT)

- 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)



Rapid Response Teams Accomplishments

Investigations

- 148 incidents investigated
 - 139 responses (94%)
 - 9 activations (6%)
- Wide Variety ('Other')
 - Complaint investigations
 - Recalls
 - Contamination events not linked to illnesses

Tracebacks

- 42 Tracebacks
 - 76% successfully identified source
- Informational
 - 57% identified source
- Regulatory
 - 85% identified source
- 8 both Informational & Regulatory



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



Future Sustainability

Workgroup's Charge – Develop a recommendation for a future funding model for MFRPS, RRT, and other related grant programs to streamline the numerous cooperative agreements/grants, improve outcomes and move closer to an IFSS

Workgroup's Proposal – Build strong food safety programs by combining similar cooperative agreements in 2018 (i.e. MFRPS, RRT, Task Force)

- Develop infrastructure and capacity
 - Implement standards
 - Well trained workforce
 - Focus on procedure development
 - Quality management/continuous improvement
- FDA tracks and evaluates progress Return on Investment (ROI)

Office of Partnerships Staff

