



FERN

Uniting Federal, State and Local Laboratories for Food Emergency Response

Food Emergency Response Network (FERN) Overview

Mission of FERN

- 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
 - HSPD-5: Management of Domestic Incidents
 - HSPD-7: Critical Infrastructure Identification, Prioritization, and Protection
 - HSPD-8: National Preparedness
 - HSPD-9: Defense of U.S. Food and Agriculture

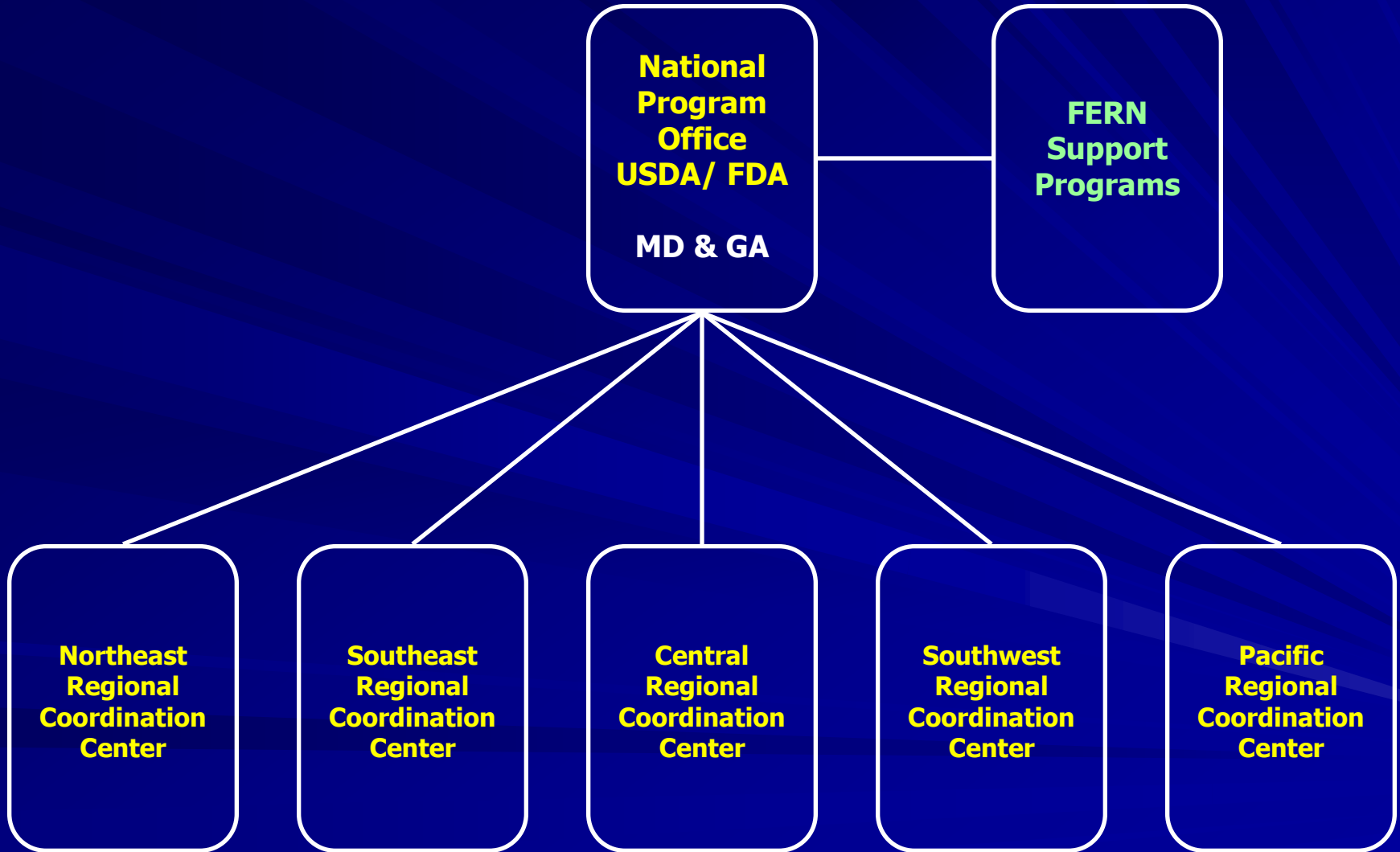
FERN Objectives

- **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

- 170 Laboratories representing 50 US States and Puerto Rico have satisfactorily completed FERN Laboratory Qualification Checklists
 - Affiliations:
 - 39 Federal (FDA, USDA/FSIS, USDA/AMS, DHS, CBP)
 - 114 State/ Universities
 - 17 Local
 - Disciplines:
 - 134 Microbiological
 - 111 Chemistry
 - 36 Radiochemistry

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)

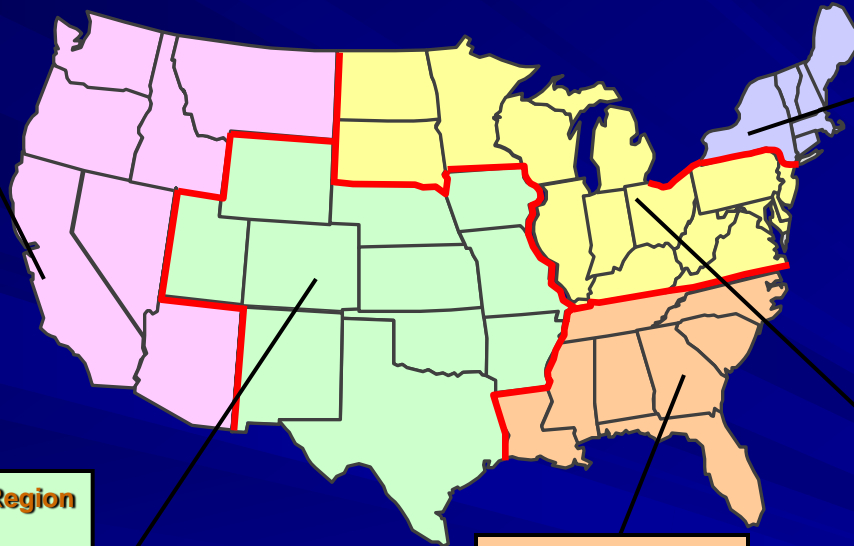
Regional Coordination Centers (RCC): an Integrated Approach

- 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

Pacific Region

- Alaska
- Arizona
- California
- Hawaii
- Idaho
- Montana
- Nevada
- Oregon
- Washington



Northeast Region

- Connecticut
- Maine
- Massachusetts
- New Hampshire
- New York
- Rhode Island
- Vermont

Southwest Region

- Arkansas
- Colorado
- Iowa
- Kansas
- Missouri
- Nebraska
- New Mexico
- Oklahoma
- Texas
- Utah
- Wyoming

Southeast Region

- Alabama
- Florida
- Georgia
- Louisiana
- Mississippi
- North Carolina
- South Carolina
- Tennessee

Central Region

- Delaware
- Illinois
- Indiana
- Kentucky
- Maryland
- Michigan
- Minnesota
- New Jersey
- North Dakota
- Ohio
- Pennsylvania
- South Dakota
- Virginia
- West Virginia
- Wisconsin

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
- 3 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)

FERN Tools for Emergency Response Testing Efforts

- FERN Website LabDIR
 - Stores laboratory capability and capacity data for common analytes of concern
 - All FERN labs required to complete this data and verify on a yearly basis
 - Used by FERN NPO & RCC to assess FERN capacity and capability to respond to an emergency
- eLEXNET
 - Data reporting
 - Document management & storage related to emergency testing

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.

FERN website

- LabDIR
- Activation Module
- Training and Proficiency Test Registration
- FERN NPO can run queries on capacity and capability
- New Features coming!
 - FERN calendar
 - Data Entry

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 Agreements

Cooperative Agreements - administered by FDA and USDA/FSIS to support FERN's mission and objectives. The FY11 Cooperative Agreement Program (CAP) funds:

- **25 State Laboratories (FSIS CAP)**
 - Method development/validation
 - Increase capability/capacity (micro, chem, and rad)
 - Training Program
- **3 Cooperative Agreements (FSIS CAP)**
 - Development & support of the FERN Website
 - PT Program & Post-Training Check Samples
- **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)- CAES**
 - “Go-to” labs: PT’s, surveillance, emergencies (Melamine, Oil Spill)
- **5 State Radiochemistry Laboratories (FDA CAP)**
 - “Go-to” labs: PTs, surveillance, emergencies

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

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

- 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. **Two of the three labs that ran chemical reopening analyses for the DWH event were FERN cCAP labs.**
 - 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.

CAES activities within FERN

- **Deepwater Horizon Event-** Tested 104 samples (~1000 individual specimens) for the presence of PAHs.
- Samples from LA, AL and FL
- **Arsenic in juices-** tested samples for a number of different juices for total As.
- New risk assessment released July 12 set a new LOC of inorganic As in apple juice (10 ppb).
- That new rule is presently open for public comment (60 days). Go to www.regulations.gov.

Next steps for FERN

- Continue to establish criteria for FERN Activation and National emergency response coordination
- Communicate FERN objectives, policies and current activities with ICLN & other networks
- Enhance collaboration among FERN labs within a region, i.e. tailored response plans
- Expand FERN capacity and capability
- Leverage existing resources, responsibilities, and roles to maximize cost effectiveness
- Continue to align FERN with a risk-based approach

For Further FERN Information

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