

# FERN Methods



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## In The Beginning....



- Initially methods made available by FDA in response to need for available food testing methods to support the CDC LRN
- Interim methods posted on eLEXNET

## Current Status: FERN Interim Methods

- Developed and Implemented Methods:
    - 8 microbiological
    - 22 chemical
    - 1 radiological
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A new beginning .....

**THE** FERN Methods Committee, a sub-group of the FERN labs met face to face. Their purpose ..... to supply FERN labs with valid screening and confirmatory analytical methods for foods.

## FERN Methods Committee



- First meeting; May, 2004
- Representatives from:
  - USDA – FSIS
  - FDA – CFSAN
  - FDA – ORA
  - DOD
  - 2 states
  - CDC by teleconference

## May 2004 meeting goals



- Obtain a clearer focus for the method committee's function
- Establish a vision with an organized set of objectives
- Establish the type of methods that will be used by FERN

## Results of First Meeting

- Call for methods to be submitted
- SOP drafted for method evaluation
- Core group formed for technical review
- Interagency communication and cooperation toward validated methods - ICLN
- One method put through technical review process using SOP

## FERN Method Acceptance SOP

For Validated Methods from State, Local, Fed labs:

- Submit Validation Packet to FERN
- Review for Suitability
- National Program Office Recommends for evaluation
- Technical Review committee reviews technical merit
- Reject/Recommend?
- Approve and post

## Where do FERN Methods come from?

- Current, validated methods used by State, Local, Federal labs
- Newly developed, modified, and validated methods
- Interim FERN Methods undergoing validation by FERN labs or through Cooperative Agreements

## Cooperative Agreements

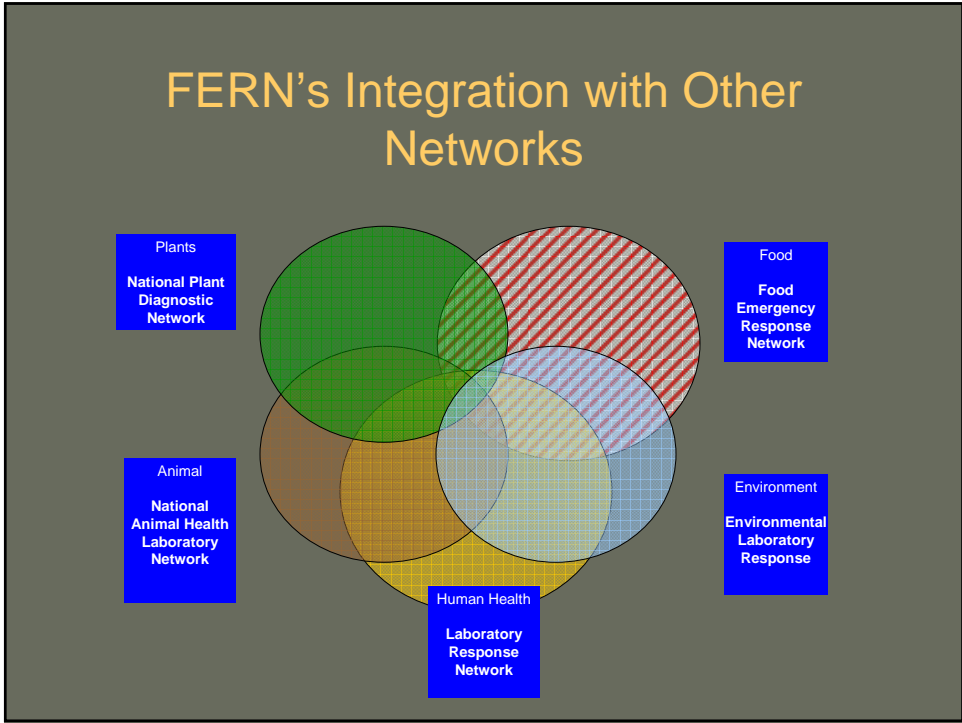
- Validate Interim FERN methods posted on eLEXNET
- Utilize FSIS and FDA regulated food matrices for validation
- Interactive process between cooperators and FERN to produce useful deliverables
- Provide data through eLEXNET for use by FERN labs

## Method Validation Processes

- Follow AOAC model for single-lab validations – spiked samples
- Extend to multiple lab validations – spiked samples
- Necessary for field trials using real food specimens because of the complex nature of various food matrices
- Submit validation packet to FERN

## Workgroups

- Ad hoc workgroups have been established to evaluate interim methods for possible harmonization
- Participants include, FSIS, FDA, CDC, States
- Examples: B. anthracis screening, DIG-ELISA for Bot toxin, Y. pestis screening for training at Mod-1



## Integrated Consortium of Lab Networks

### Vision:

"A U.S. homeland security infrastructure with a coordinated and operational system of laboratory networks that provide timely, high quality, and interpretable results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response."

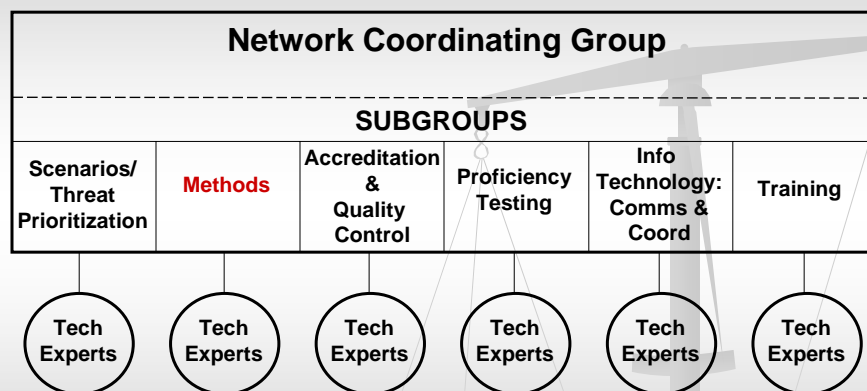
### Purpose of the Agreement

- Define Federal relationships by establishing a leadership structure
- Respect existing network policies and procedures

## ICLN Next Steps

- Network Coordinating Group (NCG) work plan
  - Matrix of Responsible Federal Agency roles
  - Identify network gaps
  - Information management
  - Proficiency testing requirements
  - Training and sampling guidance
  - Testing methods, including promoting standardization where appropriate

## ICLN NCG Organizational Structure



- Subgroups are functional elements of NCG
- Access to Technical Experts occurs via Subgroups

## NCG Methods Subgroup

### Charter

The process of methods development and validation is time consuming and expensive. The purpose of the NCG methods subgroup is to determine needs and identify available and in process methods and provide a mechanism to coordinate development, validation, and deployment. Facilitate cross collaboration between networks and agencies to increase efficiency, transparency, and consistency.

## NCG Methods Subgroup

### Objectives

- ✓ Facilitate information exchange on the best practices for the analysis of priority analytes
- ✓ Ensure that appropriately validated methods are available for all priority agents and matrices
- ✓ Promote the harmonization of methods between agents and networks (interoperability)

## Future Method Efforts

- Exercise the SOP – funnel validated methods through
- Target methods for FERN workgroups to prepare for validation
- Work to harmonize with other networks where possible

