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## **FERN Microbiology and Radiological Proficiency Activities**

**Foodborne Pathogen Analysis  
Conference  
2005**

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## **FERN Support Programs/ Sub-Committees**

- **Training**
- **Proficiency Testing**
- **Method Development/Validation**
- **Surveillance**
- **Electronic communication**

## **FERN Proficiency Testing Subcommittee**

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- **Standard Operating Procedures developed by FERN sub-committee.**
  - Process ensures participating laboratories can demonstrate ability to successfully conduct the analysis of CT samples.
- **Committee meets on a quarterly basis via conference call**

## **FERN Proficiency Testing Program**

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- **Goal: To provide proficiency testing for FERN laboratories for the chemical, radiological and microbiological analysis of counter terrorism food samples**

## **FERN Proficiency Testing Program**

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- **The Laboratory Quality Assurance Branch, Division of Compliance, CFSAN will oversee and manage the microbiology testing program**
- **The FDA's Winchester Engineering and Analytical Center will oversee and manage the radiological testing program**
- **The FDA's Forensic Chemistry Center and the Division of Natural Products, CFSAN, will oversee and manage the chemistry testing program**

## **FERN Proficiency Testing Program**

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- **Grading Criteria:**
  - **Accuracy of the laboratory results**
  - **Ability of the laboratory to follow the prescribed algorithm for confirmation**
  - **Timeliness in which the laboratory report their results**

## Pilot Proficiency Testing Program

- Conducted April 2004 with 18 Federal and State laboratories
- Proof of concept for National Network
- Micro and chemistry samples sent to participating laboratories (Strychnine, *Salmonella*)
- Practiced coordination and communication protocols
- Evaluated sample preparation, transportation, receipt, and timeframes.
- Method identification – data for validating standard methods
- Data entry- identify eLEXNET mechanism regarding user roles, data handling, and reporting

## Proficiency Testing

- Microbiological PT sample for *Bacillus anthracis* issued November 29, 2004. *This was a joint PT sample with LRN involving 66 laboratories.*
- Radiological PT sample for Cesium 137 issued December 6, 2004 to 25 laboratories.
- Chemical PT sample for Colchicine was issued February 2005 to 35 chemistry laboratories with LC/MS capabilities

## ***Bacillus anthracis* Milk PT Exercise**

- -17 laboratories failed to pass this PT exercise
- **Reasons for failure:**
  - Technical issues and/or incorrect results
  - Failure to follow testing algorithm
  - Reporting problems (with both LRN and eLEXNET reporting systems)
  - Timeliness/late reporting

## **Radiological Proficiency Test**

- Cs-137 samples were sent to 25 laboratories
- Participants were instructed to analyze the sample for Cs-137 and naturally-occurring K-40 by gamma-ray spectrometry according to their previously approved protocols, and to report results in units of Bq/kg to WEAC via fax and into eLEXNET with 1- $\sigma$  uncertainty, decay-corrected to December 1, 2004, for each detector system use

## **Radiological Proficiency Test**

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- **All 25 laboratories (100%) acknowledged receipt of the sample**
- **Of 23 laboratories reporting results, 21 (91%, or 84% of all laboratories) reported satisfactory values for Cs-137 and 21 (91%, or 84% of all laboratories) reported acceptable results for K-40.**

## **Follow Up**

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- **Individual laboratories having unsatisfactory results were contacted to discuss problems associated with their performance**
- **Feedback on the performance of the *B. anthracis* method is being collected**
- **Feedback on the eLEXNET data entry reporting process is being collected**

## **Next Steps for FERN PT Program**

- **Develop more detailed data base of FERN laboratory capabilities and capacities**
- **Expand proficiency testing program to additional agents and food matrices**
  - **i.e., conventional and exotic microbiological agents**
- **Shorter announcement period for PT samples**

## **Additional Next Steps**

- **Integrated Consortium of Laboratory Networks (ICLN), Network Coordinating Group (NCG) has developed several technical committees**
- **Proficiency testing is one of these committees**
- **Committee members will include representation from the major laboratory networks (FERN, LRN, NAHLN, EPA, etc)**
- **The committee will work to develop standard procedures and policies for proficiency testing that can apply across laboratory networks when applicable**