

Report to Congress

Biennial Report to Congress on the Food Emergency Response Network

**Submitted pursuant to Section 202 (b) of the FDA Food Safety
Modernization Act (P. L. 111-353)**

U.S. Department of Health and Human Services

Food and Drug Administration

_____ Date _____
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Executive Summary

This report is intended to satisfy the Food and Drug Administration's (FDA's) reporting obligation in Section 202(b) of the FDA Food Safety Modernization Act (FSMA) concerning the Food Emergency Response Network (FERN).

FERN is an integrated, secure laboratory system for federal, state, and local government agencies engaged in food safety and food defense activities. Currently consisting of 167 federal, state, and local laboratories, FERN is organized to ensure federal and state inter-agency participation and cooperation in the development and operation of the network. The system is jointly operated by the Department of Health and Human Service's Food and Drug Administration (HHS/FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS). These agencies coordinate with numerous partners, including the Rapid Response Teams (managed through FDA's Office of Regulatory Affairs), the Pesticide Data Program (managed through USDA's Agricultural Marketing Service), and the Centers for Disease Control and Prevention's (CDC) Laboratory Response Network (LRN).

FERN plays a critical role in food safety and food defense by integrating these food-testing laboratories into a network that is able to detect, identify, respond to, and aid in the recovery from emergencies involving biological, chemical, or radiological contamination of food. FERN also allows for the analytical testing of large numbers of samples in non-emergency situations. FERN's strengths lie in allowing participating government agencies to compare, share, and coordinate laboratory analysis findings and in strengthening the capacity of state laboratories. FERN Cooperative Agreement Program (CAP) grants supply critical funding to select state member laboratories, increasing national capability and capacity. This support facilitates the ability of these laboratories to serve as first responders during food emergencies and to test large numbers of samples during non-emergency situations.

FERN conducts numerous activities to ensure an integrated and secure laboratory system. It develops, validates, and coordinates laboratory methods to promote consistency nationwide, provides training to laboratory professionals on analytical methods, and conducts targeted surveillance testing for specific events or situations. FERN maintains a storeroom that contains reagents required for the methods used to detect biological, chemical, or radiological contamination of the food supply. The storeroom ensures a consistent supply of materials to FERN laboratories for response to outbreaks, and for participation in surveillance and proficiency testing events. FERN also maintains the Electronic Laboratory Exchange Network ([eLEXNET](#)) and the [FERN website](#). eLEXNET acts as the analytical data and official document repository for FERN, while the FERN website contains a public site and a non-public secured site containing a database of laboratory capability and capacity data, as well as serving a registration and tracking function for: (1) training programs, (2) activation exercises and events, and (3) proficiency testing offered by the network.

FERN has proven its ability to respond to large-scale food emergencies and non-emergency situations when surge capacity was necessary. It has been vital in responding to major outbreaks of foodborne disease attributed to many products, including spinach, pet food, and peanut butter. It has also been critical in aiding in the recovery from emergencies, such as the Deepwater Horizon oil spill and the Japanese nuclear reactor failure, thus helping affected economies and increasing consumer confidence in the food supply.

FSMA contains many laboratory-related provisions, and FERN will play a vital role in enabling FDA to achieve its mandate. Specifically, FERN will be instrumental in building domestic capacity (Section 110), continuing to be a major contributor to the Integrated Consortium of Laboratory Networks (ICLN) (Section 203), enhancing foodborne illness surveillance (Section 205), and improving the training of state, local, territorial, and tribal food safety officials (Section 209).

Overall, FERN has grown exponentially since its inception, particularly in the ability of member laboratories to participate in federal surveillance assignments. Beginning with FDA's and FSIS's response to the melamine contamination event in 2007, FERN CAP state laboratories have participated in federal assignments (both emergency response and non-emergency surveillance). This analytical participation by FERN state laboratories has facilitated achieving acceptance of state data by FDA and FSIS for regulatory action.

Another example of FERN's success is the recent progress in the implementation of the ICLN, which is led by the Department of Homeland Security (DHS), with FERN as an integral member. Successful implementation milestones for the ICLN include development of the Integrated Response Architecture—defining policies for successful operation of ICLN members in the event of an emergency, inventories of proficiency testing programs and training programs, and multiple readiness exercises.

Introduction

On January 4, 2011, President Obama signed into law FSMA (Public Law 111-353). Section 202(b) of FSMA requires the Secretary of HHS, in coordination with the Secretary of USDA, the Secretary of DHS, and state, local, and tribal governments, not later than 180 days after the date of enactment of FSMA and biennially thereafter, to prepare a report that describes “progress in implementing a national food emergency response laboratory network that:

1. provides ongoing surveillance, rapid detection, and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply;
2. coordinates the food laboratory capacities of State, local, and tribal food laboratories, including the adoption of novel surveillance and identification technologies and the sharing of data between Federal agencies and State laboratories to develop national situational awareness;
3. provides accessible, timely, accurate, and consistent food laboratory services throughout the United States;

4. develops and implements a method repository for use by Federal, State, and local officials;
5. responds to food-related emergencies; and
6. is integrated with relevant laboratory networks administered by other Federal agencies.”

The Secretary is required to submit the report to the relevant committees of Congress and to post it on the HHS website.

The following report is the second report in response to this mandate since the signing of FSMA on January 4, 2011.

Background

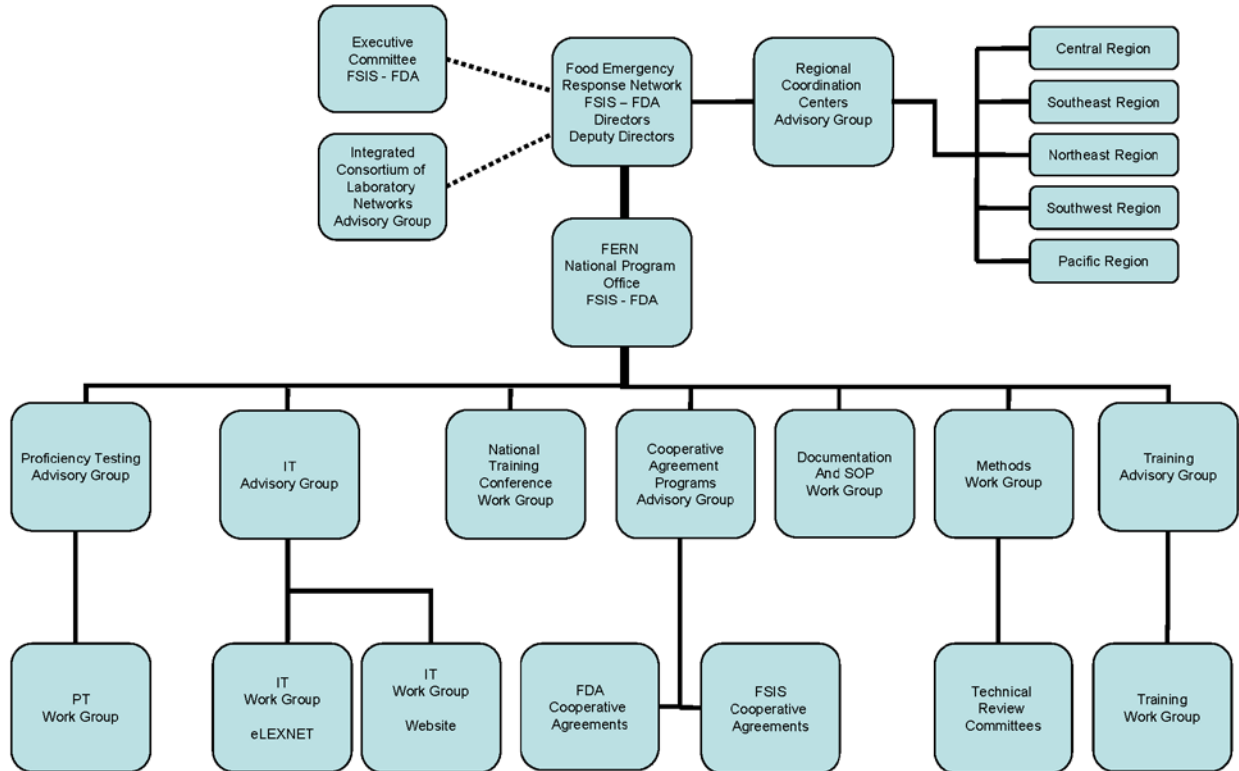
Following September 11, 2001, increased attention has focused on the risk of bioterrorism threats, particularly with regard to the nation's food supply. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 directed HHS/FDA responsibility for a wide-ranging program to protect the American public from attacks on the food supply. FERN was developed in 2004 in response to Homeland Security Presidential Directive 9 (HSPD-9), which established food as a critical infrastructure for the United States and charged agencies with developing a national food testing network.

FERN integrates the nation's food-testing laboratories at the federal, state, and local levels into a network that is able to detect, identify, respond to, and recover from emergencies involving biological, chemical, or radiological contamination of food. FERN is also a valuable asset in non-emergency situations when there is the need for surge capacity. The FERN structure (Figure 1) ensures federal and state inter-agency participation and cooperation in the formation, development, and operation of the network.

FERN works to protect food security by:

- allowing rapid detection of threat agents in the American food supply;
- preparing the nation's laboratories to be able to respond to food-related emergencies;
- offering significant surge capacity that enables laboratories to be activated as needed during emergencies, thus strengthening the nation's response towards widespread complex intentional or inadvertent food contamination; and
- enhancing the ability of the country to restore confidence in the food supply following a threat or an actual emergency targeting the nation's food supply.

Figure 1. FERN National Program Structure



The FERN National Program consists of the following components: the Executive Committee/FERN Directors; the National Program Office (NPO); the Support Programs, organized into advisory groups/working groups; and the Regional Coordination Centers (RCC's). This organization provides support and direction to the FERN laboratories comprised of all participating federal, state, and local laboratories.

Executive Committee/FERN Directors

The FERN Executive Committee is co-chaired by senior executives from the USDA/FSIS and HHS/FDA and the day-to-day operations of FERN are a joint venture between the two agencies. The Executive Committee provides senior input and

leadership from each agency to the FERN Directors and the NPO. The FERN Directors, one from FDA and one from FSIS, work closely with the Executive Committee and direct the NPO. The Directors are also members of the Network Coordinating Group of the ICLN.

National Program Office

The National Program Office has two locations: the FDA office is in Rockville, Maryland, and the FSIS office is in Athens, Georgia. Both are responsible for the day-to-day operation of FERN, which includes managing the FERN support programs, coordinating national laboratory emergency and non-emergency responses, and providing oversight of the RCC.

Support Programs

FERN has five support programs: (1) methods coordination, (2) training, (3) proficiency testing, (4) cooperative agreements, including surveillance assignments, and (5) electronic communications and collaborations. These programs provide input and direction through advisory groups consisting of FDA, USDA, and state members. These groups are supported by specialized working groups created on an ad hoc basis to address specific, more finite issues impacting the larger advisory group. Each of the programs supports the three analytical disciplines: chemical, microbiological, and radiological.

1. The FERN Methods Coordination program, working through the Methods work group, promotes consistency and quality of laboratory methods. It is responsible for determining method priorities for FERN, generating guidelines for submitting methods and soliciting method submissions from member laboratories, and reviewing and approving submissions to be considered as FERN methods. FERN also participates in method harmonization workgroups with other laboratory networks and programs, such as the CDC's LRN, through the ICLN.
2. The FERN training program promotes a well-trained cadre of laboratory professionals. It offers courses through both the FDA training program and three FSIS training centers, which are co-located with member laboratories and funded through cooperative agreements. A wide variety of training courses are offered in chemical, microbiological, and radiological methods. In the last eight years, from 2004 to 2012, FERN has developed more than 80 training courses, and more than 1,800 laboratory staff from federal, state, local, and international food laboratories have participated in training exercises since 2004.
3. The FERN proficiency testing program serves a quality control function and offers microbiology, chemistry, and radiochemical proficiency tests. The proficiency tests alternate between food safety and food defense threat agents, and also rotate between food matrices based on current events and risk assessments. The FERN proficiency testing program is active with other networks, participating in, and providing harmonized testing for, the ICLN. Participating networks have included the LRN-biological, LRN-chemical, and the U.S. Environmental Protection Agency's laboratory network.

4. FERN, through the cooperative agreement program, provides cooperative agreement funding for selected laboratories, selected in part based on qualifications and geographical distribution. Along with other requirements and duties, these laboratories participate in surveillance assignments for specific events or situations, such as during the Republican and Democratic National Conventions of 2008 and 2012, and the Presidential inaugurations in 2009 and 2013. FERN also assists in the ongoing targeted surveillance of the National School Lunch Program and imported food commodities.
5. Lastly, FERN coordinates, through the IT advisory group, electronic communications and collaborations through two separate systems: [eLEXNET](#) and the [FERN website](#). eLEXNET acts as the analytical data and official document repository for FERN. The FERN website contains a public site and a secured database of laboratory capability and capacity data. It also contains registration modules for trainings, meetings, activation/exercise events, and proficiency tests.

Regional Coordination Centers

The FERN RCCs are located in each of the five FDA regions across the United States and are staffed by both FDA and FSIS personnel. The primary responsibility of the RCCs is to identify needs of the region and convey those needs to the FERN NPO. RCCs establish operational and communication guidelines within each FERN region by: communicating their objectives, policies, and current activities; enhancing collaboration among FERN laboratories within a region; and providing an opportunity for individual regions to tailor response plans to their state policies and regional needs.

FERN Laboratories

FERN laboratories are able to respond to emergencies involving biological, chemical, and radiological contamination of food. Since 2004, FERN has successfully worked to strengthen the ability of our nation's food testing laboratories to respond to a food contamination event through several initiatives, including increasing the capability and capacity of member laboratories by using FERN support programs, as well as encouraging new laboratories to join the network. FERN laboratories are also involved in testing large numbers of samples during non-emergency situations.

FERN membership is open to public (federal, state, local, and tribal) food testing laboratories that perform regulatory and/or diagnostic analytical work. As of March 2013, FERN has 167 laboratory members (35 federal, 102 state, 17 local, 4 military, and 9 university), located in all 50 States and Puerto Rico. FERN member laboratories represent the large majority of food testing regulatory laboratories in the United States, including public health, agriculture, veterinary diagnostic, and environmental laboratories. At this point, it is estimated that about 85 percent of all eligible food regulatory laboratories in the United States are FERN members.

The growth of FERN since its inception in 2004 to its current level is documented in Table 1 below:

Table 1. Number of FERN Member Laboratories from 2004 to 2013

Year	Number of FERN Member Laboratories
2004	8
2005	88
2006	93
2007	134
2008	150
2009	158
2010	165
2011	172
2012	172
2013	167*

* Five laboratories closed due to state budget constraints

Membership in FERN is voluntary and FERN requires that all prospective members submit a Laboratory Qualification Checklist, containing basic laboratory capacity and capability information, and be willing to participate in FERN activities and directives. This checklist is reviewed by the FERN NPO to determine if a laboratory meets the criteria for participation in FERN. Upon acceptance into FERN, laboratories are then expected to complete a detailed self-assessment laboratory capacity and capability inventory, with a near 100 percent compliance, enabling the NPO to generate rapid laboratory capacity and capability assessment (housed electronically through the FERN website, in LabDIR), which must then be updated and verified on an annual basis to maintain active FERN membership status. This laboratory assessment inventory tool is used to quickly assess FERN capabilities and capacities for reacting to food emergencies or for large-scale testing of samples in non-emergencies. The FERN NPO queries the database for a specific analytical need and determines which laboratories are able to assist, as well as those laboratories' self-assessed sample capacity. FERN member laboratories complete network-wide capacity and capability inventories.

FERN laboratories are encouraged, although not required, to participate in any and all FERN activities. An exception to this rule applies to laboratories with FERN cooperative agreements. These funded laboratories are required to participate in a number of specified FERN support programs and activities, including surveillance assignments.

FERN Cooperative Agreements

FERN cooperative agreements increase national capability and capacity by awarding funds to selected state member laboratories. Funds support procurement of equipment and dedicated personnel, as well as projects covered under the cooperative agreement. These cooperative agreements work to address harmonization of analytical platforms,

methods, and other laboratory operations that support laboratory and data confidence and that can then be applied on a larger scale across FERN. The dedicated personnel serve both the FERN programs and the state programs.

These CAP laboratories are a critical component of any large-scale food emergency response or non-emergency situation where there is the need to test a large number of samples. The chemistry laboratories have been integral participants in such outbreaks and events, as in the melamine contaminations of pet food and infant formula and the Deepwater Horizon oil spill. In late 2011 and into 2012, FERN chemistry laboratories were also involved with FDA testing programs that analyzed over 280 fruit juices and rice products for the presence of arsenic. In addition, FERN laboratories were utilized to increase FDA field laboratory capacity. The analytical information provided to FDA by the FERN laboratories was used to evaluate the health hazards for these products. The microbiological laboratories, while not participating for FERN in any recent large-scale food outbreaks or events, have participated in events such as *E. coli* in spinach (2006), *Salmonella* in peppers (2008), and *Salmonella* in peanut butter (2009). The radiological laboratories were involved in testing foods related to the Japanese nuclear reactor failure (2011). Over 1,300 products were tested for the presence of radionuclides. All of the analytical work done in response to these events serves to promote the use of food regulatory data across all agencies—federal, state, and local—by utilizing the same laboratory standards as mandated by FSMA Section 203(a)(1).

Cooperative agreement requests for applications (RFAs) are published in the *Federal Register*. FERN cooperative agreements are awarded and managed separately through both FDA and FSIS. FSIS awards and manages 25 laboratory cooperative agreements, funding both microbiological/chemical projects and program support activities, as well as one non-laboratory cooperative agreement for support of the FERN website. FDA awards and manages a total of 34 cooperative agreements: 15 microbiological, 14 chemical, and 5 radiological (see Table 2 for a historical accounting of the FDA and FSIS managed FERN CAPs).

Table 2. Number of FDA and FSIS managed FERN CAPs from 2005 to 2013

Fiscal Year	FDA FERN Cooperative Agreements	FSIS FERN Cooperative Agreements
2005	8 Chemistry	18 Microbiology
2006	8 Chemistry; 2 Radiochemistry	17 Microbiology
2007	8 Chemistry; 5 Radiochemistry	17 Microbiology
2008	11 Chemistry; 5 Radiochemistry	21 Microbiology
2009	14 Chemistry; 5 Radiochemistry	25 Microbiology & 4 Program Support

2010	15 Microbiology; 14 Chemistry; 5 Radiochemistry	25 Microbiology/Chemistry & 4 Program Support
2011- 2013	15 Microbiology, 14 Chemistry 5 Radiochemistry	25 Microbiology/Chemistry & 2 Program Support

FERN Federal Partners

Throughout the evolution of FERN, the majority of the member laboratories have been simultaneously fulfilling the requirements of several federal programs with respect to food safety. Recognizing this, FERN has been pursuing opportunities for intra- and inter-agency collaborations and leveraging. The benefits of doing so are three-fold: 1) to maximize efficiencies and effectiveness of federal resources; 2) to streamline processes within our state laboratories by communicating similar messages and harmonizing priorities; and 3) to improve relations between federal and state partners by prioritizing concerns.

FERN routinely consults with federal partners for expertise and input regarding FERN support programs and activities. The FERN NPO coordinates a monthly conference call with FDA’s Center for Food Safety and Applied Nutrition (CFSAN) for transparency and cross-communication purposes. The FERN NPO also routinely communicates with other laboratory networks and programs to increase transparency and communication, as well as to identify potential areas for harmonization of activities and leveraging. Such partners include: Rapid Response Teams (managed through FDA’s Office of Regulatory Affairs), Pesticide Data Program (managed through USDA’s Agricultural Marketing Service), and the CDC LRN.

The FERN NPO is also an active member of the DHS’s ICLN, and several NPO staff are driving forces on ICLN subgroups, such as Proficiency Testing/Quality Assurance, Methods, Logistics, and Information Technology (IT). The FERN Directors participate in the ICLN Network Coordination Group to promote transparency and communication about FERN activities and discuss how FERN can better work with other ICLN members to meet the harmonization and standardization criteria, as set by the ICLN. FERN is an active participant in joint proficiency testing and tabletop exercises.

Progress in the implementation of the ICLN, with FERN as an integral member, includes: development of the Integrated Response Architecture consisting of defining policies for interoperability; inventories of networks’ proficiency testing programs and training programs; and readiness exercises. Incident response matrices have been developed, identifying roles and gaps. A secure web portal for data exchange between member networks has been established, along with Minimum Data Elements requirements across all networks belonging to the ICLN, to submit data into the secure web portal.

Progress in Implementing a National Food Emergency Response Laboratory Network

The following section describes FERN's progress in implementing a national food laboratory network that addresses the six areas enumerated in sections 202(b)(1)-(6) of FSMA:

(1) Provides ongoing surveillance, rapid detection, and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply:

Large-scale food emergencies requiring large scale testing of samples are complex and usually require a multi-tiered response that includes rapid detection and the ability to test many samples. Initial rapid detection of pathogen(s) or contaminant(s) may require new or modified methodologies that must be developed, improved upon, and ultimately verified for use in the laboratories. FERN is able to call upon the nation's leading food testing experts, both federal and state, to assist in this method development, and the subsequent necessary roll-out of the technology to the testing laboratories. One example of this work is the more rapid method developed and used for detecting *E coli* O157:H7 in spinach (2006). This method was developed by FERN and FDA, quickly validated for use, approved by the FERN Methods Committee, and implemented in the laboratories for use during the outbreak. It cut several days off of the existing method and was supported with reagents and supplies from the FERN Storeroom.

In addition, FERN provides capacity for non-emergency situations where there is a need for analytical testing of large numbers of samples.

FERN's ability to provide rapid detection and surge capacity was demonstrated during the two melamine-related incidents of 2007 and 2008-2009. In 2007, companion animal illnesses and deaths were linked to melamine-contaminated pet foods with ingredients imported from China. In 2008, melamine resurfaced as an adulterant added to infant formula and other food products (e.g., chocolate linked to products in China). During the 2007 incident, FERN laboratories were activated to assist with sample analyses (surge capacity). FERN's FDA and FSIS chemistry cooperative agreement laboratories, working with FDA's Forensic Chemistry Center (FCC), FSIS's Western Laboratory, and the National Animal Health Network (NAHLN), developed a screening method for melamine and its analogs. This method was used throughout this melamine event by FDA and FSIS laboratories and the eight FERN chemistry CAP laboratories that participated in the FDA Protein Surveillance Assignment. In 2008-2009, FERN laboratories were once again activated to assist with sample analyses, and new, faster methods were developed and validated by FDA for infant formula and other dairy products. These new methods were more sensitive than previous melamine detection methods and could therefore detect smaller amounts of the chemical. FERN laboratories analyzed a total 340 samples (about 20 percent of all assignment collections), and found 14 samples contaminated with melamine and/or its analogs. The use of the FERN chemistry CAP laboratories was a key factor in clearing an FDA sample backlog, which arose due to very high collection rates.

(2) Coordinates the food laboratory capacities of state, local, and tribal food laboratories, including the adoption of novel surveillance and identification technologies and the sharing of data between federal agencies and state laboratories to develop national situational awareness:

FERN coordinates the food laboratory capacities of state, local, and tribal food laboratories through the five regional coordination centers (RCCs) situated across the U.S. The regional coordinators associated with each region interact with the region's laboratories, assessing capacity and capability for the region, and reporting this information back to the FERN NPO. The coordinators are also tasked with assessments of laboratories' training needs, potential method issues, and any needs the laboratories might have that could affect readiness. The regional coordinators work closely with the regional coordination advisory group to ensure continuity of effort between the regions, and provide communication with the NPO. RCCs also disseminate information from the NPO, including situational awareness of national events and FERN activations, new method roll-outs, reagent issues, training opportunities, and general FERN business.

Communication is a critical component of a network, and FERN works diligently to provide the information necessary. Many different formats and venues are utilized to ensure that communication is effective and flows to and from the NPO. These include:

- A FERN Newsletter published quarterly;
- FERN-wide conference calls used for routine communication, as well as for events and activations;
- Regional calls – monthly and ad hoc;
- Monthly calls with laboratories participating in cooperative agreements;
- Weekly co-director coordination calls;
- Monthly NPO-RCC coordination calls;
- State participation on working groups and oversight groups; and
- FERN National Training Conferences that include general sessions and extensive breakout sessions. These meetings are very well attended, and may be the largest meeting of public food regulatory laboratories held yearly. Unfortunately, during the FY2010 and FY2011 budget cycles sufficient funds have not been made available to sponsor these very important meetings.

(3) Provides accessible, timely, accurate, and consistent food laboratory services throughout the United States:

FERN works diligently through the FERN support programs to provide more rapid, accurate, and consistent analytical testing. The NPO works with the member laboratories to promote the use of validated methods, including the development and validation of new methods for network usage. The NPO Proficiency Testing Program provides proficiency and competency testing to all of its member laboratories. To date, more than 45 proficiency testing activities have been provided. Additionally, FERN surveillance assignments, usually about four per year, provide all participants the opportunity to engage in the testing of samples that the FERN NPO can review and assess. The

diligence paid to communication by FERN also works to promote timely, accurate, and consistent laboratory services throughout FERN.

One example of FERN's ability to reduce the time needed for sampling is, as cited above, the more rapid method developed and used for detecting *E coli* O157:H7 in spinach in 2006. This new method cut several days off of the time required to obtain sample results. Another example is the more rapid method developed for testing seafood after the Deepwater Horizon incident. FDA and FERN Chemistry laboratories were able to develop and initiate a much more rapid analytical method for petroleum contamination. The laboratories were able to do this in a very short amount of time, facilitating the expedited opening of the fishing waters in the Gulf of Mexico after the event.

(4) Develops and implements a methods repository for use by federal, state and local officials:

FERN develops and implements a methods repository for use by federal, state, and local officials through the Methods Coordination Committee, which is responsible for generating Method Validation and Submission Guidelines, determining method priorities for FERN, soliciting method submissions from member laboratories, and reviewing and approving submissions as FERN methods. FERN also participates in method harmonization workgroups with other laboratory networks and programs, such as the CDC LRN, through the ICLN.

(5) Responds to food-related emergencies:

FERN has been activated for several microbiological and chemical emergencies where there has been a need for analytical testing of large numbers of samples, thus providing surge capacity for both federal and state lead investigation and response efforts. In addition, FERN can also respond to non-emergency situations where there is a need for surge capacity testing of large numbers of samples. In responding to a food-related emergency or large-scale testing need in a non-emergency situation, FERN can activate any of a variety of functions, from providing technical guidance and reagents to directing sample collection and analysis by member laboratories. FERN components have been activated in a number of situations, including those detailed below:

- *E. coli* in Spinach Outbreak (2006)
- Melamine in Pet Food (2007)
- *Salmonella* Saintpaul in Peppers (2008)
- Melamine in Infant Formula and Milk-Based Products (2008-2009)
- *Salmonella* Typhimurium in Peanut Butter (2008-2009)
- Deepwater Horizon Oil Spill (2010)
- Japan Nuclear Reactor Response (2011)
- Arsenic Testing in Fruit Juices and Rice Products (2011-2012)

E. coli O157:H7 in Spinach Outbreak (2006):

In August 2006, public health laboratories in the United States identified 238 cases of *E. coli* O157:H7 in 26 states linked to the consumption of fresh spinach. Overall, 52 percent of the cases were hospitalized and 16 percent had kidney failure. FERN was activated during this outbreak and provided access to reagents, technical guidance, screening, and culture methods. FERN monitored the situation to determine the need for surge capacity, and a harmonized FERN/LRN/CDC method was quickly reviewed and published electronically on the eLEXNET system for use in FERN laboratories. This process was expedited, reducing the method approval process from weeks to a few days.

Melamine in Pet Food (2007):

In the spring of 2007, there were reports of companion animal illness and death linked to pet foods with ingredients imported from China. Melamine and cyanuric acid were identified as the hazardous adulterants. The contamination issue spread when melamine was found to be present in other animal feed products. FERN was activated, and eight FERN chemistry CAP laboratories participated in the FDA Protein Surveillance Assignment. With federal and state assistance, FDA's FCC and USDA's Food Safety Inspection Service developed a new screening method for melamine and its analogs that was used in this analytical assignment. There was also a collaborative effort among states, USDA, and FDA to develop more sensitive methods for the analysis of melamine and cyanuric acid in animal tissue (fish, pork, etc.).

In addition to FDA laboratories, the state CAP laboratories that participated in FERN-directed analyses included:

- Arizona Department of Health Services
- California Animal Health and Food Safety
- Connecticut Agricultural Experiment Station
- Florida Department of Agriculture and Consumer Services
- State Hygienic Laboratory at the University of Iowa
- Minnesota Department of Agriculture
- New Hampshire Public Health Laboratory
- Virginia Division of Consolidated Laboratory Services.

Salmonella Saintpaul in Peppers (2008):

During the spring and summer of 2008, the second largest outbreak of *Salmonella* saintpaul (*S. saintpaul*) ever reported in the United States was identified by PulseNet (>1400 cases) in 43 States, the District of Columbia, and Canada. Initial epidemiologic reports indicated tomatoes as a potential common food source, but further investigation by FERN and other public health agencies and laboratories led to the identification of an indistinguishable *S. saintpaul* isolate from a jalapeño pepper, which was traced back through a distribution center in Texas to a grower in Mexico. FERN was activated, and

12 FERN microbiology laboratories analyzed pepper, cilantro, and basil samples collected through state and FDA coordinated efforts. FERN testing augmented and complemented concurrent testing by FDA. In all, FDA tested a total of 1,618 samples, and found 75 positives (39 unique *Salmonella* serotypes), and FERN tested a total of 290 samples and found 13 positives (six unique *Salmonella* serotypes).

In addition to FDA laboratories, the state laboratories that participated in FERN-directed analyses included:

- Florida Department of Agriculture and Consumer Services
- Pennsylvania Department of Agriculture
- Wisconsin Department of Agriculture, Trade and Consumer Protection
- Michigan Department of Agriculture
- New York Department of Agriculture and Markets
- Indiana State Department of Health
- California Department of Public Health Microbial Disease Laboratory
- California Department of Public Health Food and Drug Laboratory
- Minnesota Department of Agriculture
- Texas Department of State Health Services
- North Carolina Department of Agriculture
- Massachusetts State Laboratory Institute

Melamine in Infant Formula and Milk-Based Products (2008-2009):

In 2008, melamine resurfaced as an adulterant added to infant formula and other food products (e.g., chocolate linked to producers in China) and FERN was activated. New testing methods were developed and validated by FDA for infant formula and other dairy products. These methods were more sensitive than the melamine methods used in 2007 for pet food sampling. FERN used these new testing methods in the analysis of milk-based products for melamine.

In response to the contamination of infant formula and milk-based products, FERN chemistry laboratories assisted FDA in the CFSAN Melamine Import Assignment for the analysis of milk and soy protein-based samples (issued November 24, 2008). FERN laboratories analyzed a total of 340 samples (about 20 percent of all assignment collections), detected 14 instances of melamine and/or analogs, and were a key factor in clearing FDA's sample backlog, which arose due to very high collection rates.

FERN Laboratories that participated in FERN-directed analyses included:

- FDA's FCC
- FSIS-FERN Eastern Laboratory, Chemistry Branch
- Arizona Department of Health Services
- California Animal Health and Food Safety
- Connecticut Agricultural Experiment Station
- Florida Department of Agriculture and Consumer Services

- Hawaii Department of Agriculture
- Hawaii Department of Health
- Illinois Department of Agriculture
- Maryland Department of Agriculture
- Minnesota Department of Agriculture
- Montana Department of Agriculture
- New Hampshire Public Health Laboratory
- New Jersey Department of Health and Senior Services
- University of Iowa Hygienic Laboratory
- Virginia Division of Consolidated Laboratory Services
- Washington State Public Health Laboratory
- West Virginia Department of Agriculture

***Salmonella* Typhimurium in Peanut Butter (2008-2009):**

An outbreak in 2008-2009 led to 714 cases of *Salmonella typhimurium* infection in 46 States linked to consumption of products containing peanut butter produced by the Peanut Corporation of America (PCA) plant in Blakely, GA. More than 2,800 products were identified that contained peanut butter produced by this plant. Due to the limited scope of the incident, FERN laboratories were not officially activated, but there were strong contributions to the investigation from FERN laboratories in Minnesota, Michigan, Ohio, and Connecticut. FERN Storeroom reagents were made available as well as technical guidance, methods, and molecular fingerprinting (pulsed-field gel electrophoresis) support. Additionally, FERN assisted the North Carolina Department of Agriculture (a FERN member laboratory) in coordinating a sample overflow in their laboratory.

Deepwater Horizon Oil Spill (2010):

The Deepwater Horizon Oil Spill, caused by an explosion on a drilling rig on April 20, 2010, released several million barrels of crude oil into the Gulf of Mexico until the wellhead was capped on July 15, 2010. The oil from the Deepwater Horizon well contaminated a large number of Gulf-state fisheries in Louisiana, Alabama, Mississippi, and Florida, which resulted in an almost total shutdown of the industry. The National Oceanic and Atmospheric Administration (NOAA), FDA, and state governments cooperated in an effort to close state and federal waters to commercial fishing as a result of the public health threat from contamination of seafood by polycyclic aromatic hydrocarbons (PAHs), the principal contaminants of toxicological concern. To address this threat, a detailed protocol for reopening state and federal waters was implemented involving an extensive chemical testing program. This protocol outlined specific levels of concern for each PAH that the laboratories were tasked with measuring.

FERN laboratories (including FDA field laboratories and FERN CAP laboratories) were used to analyze these samples. Two methods were used in the chemistry testing portion of the protocol—a method developed by NOAA and a PAH screening method developed by FDA's FCC. FERN CAP laboratories (Connecticut Agricultural Experiment Station and Minnesota Department of Agriculture) were critical to the development and

implementation of this PAH screening procedure. Without the analyses performed by the FERN laboratories and the development of a more rapid screening method, the safe and expedited reopening of the Gulf-state fisheries would not have been possible.

Because of the extensive need for sampling, FERN was activated in May 2010 to enable all FERN laboratories, not just those that are funded through cooperative agreements, to conduct sampling. FERN began to assess network capabilities and capacities for the NOAA method, and selected FERN CAP laboratories, which were tasked with analyzing samples using this methodology. Additionally, the FERN Storeroom ordered and stocked standards and reagents required for performing the NOAA method. Reagent requests were filled on a prioritized basis, with first priority going to Gulf-state laboratories and laboratories conducting FERN-directed testing. Over the course of the FERN activation, 307 finfish, crab, oyster, and shrimp samples from Florida, Alabama, Mississippi, and Louisiana were analyzed for PAHs using the liquid chromatography-fluorescence detection (LC-FLD) alternative screening method as part of the state reopening process (performed by FDA's FCC, Connecticut Agricultural Experiment Station, and the Minnesota Department of Agriculture). Of those samples, 66 received parallel NOAA method analysis. In addition to the reopening samples, 88 state baseline samples were analyzed using the NOAA method. FERN was deactivated for this incident in November 2010.

FERN Laboratories that participated in FERN-directed analyses included:

- FDA's Arkansas Regional Laboratory
- FDA's Denver District Laboratory
- FDA's FCC
- FDA's Kansas District Laboratory
- FDA's Southeast Regional Laboratory
- Arizona Department of Health Services
- California Animal Health and Food Safety
- Connecticut Agricultural Experiment Station
- Florida Department of Agriculture and Consumer Services
- Minnesota Department of Agriculture
- Wisconsin Department of Agriculture, Trade and Consumer Protection

Japan Nuclear Reactor Response (2011):

On March 11, 2011, a magnitude 9.0 earthquake struck 130 miles off the eastern coast of Honshu, Japan's largest island. The ensuing tsunami resulted in loss of control of nuclear reactors in the Fukushima Daiichi complex. This culminated in radionuclide leakage to the atmosphere and ocean, causing widespread radioactive contamination of residential areas, agricultural land, and coastal waters. As part of FDA's effort to monitor and respond to potential foodborne radiation contamination of imported commodities from Japan, FERN was activated and readied their five radiation CAP laboratories. FERN laboratories' primary role was to assist FDA laboratories in the event that sample testing capacity was exceeded. In preparation for this role, these laboratories worked closely

with FERN NPO and FDA to validate emergency methodologies for foodborne gamma ray-emitting radionuclide contaminants. Over 1,300 products were tested for radionuclides over the course of the response.

FERN Laboratories that participated in the FERN activation:

- FDA's Winchester Analytical and Engineering Center
- Maryland Department of Health and Mental Hygiene
- New York State Department of Health
- Texas Department of State Health Services Laboratory
- Washington State Public Health Laboratories
- Wisconsin State Laboratory of Hygiene

Arsenic in Juices and Rice Products (2011-2013):

Elevated levels of inorganic arsenic in fruit juice and rice and rice products may present a hazard to public health. FDA has the responsibility for developing policy related to a large percentage of the nation's food supply. This activity includes assessing risk to consumers from ingestion of chemical contaminants that may be present in certain types of foods due to agricultural practices or through natural causes. In late 2011 and into 2012, FERN chemistry cooperative agreement laboratories were involved with FDA testing programs that analyzed for arsenic in fruit juices. FERN laboratories analyzed over 280 fruit juice and rice product samples for the presence of arsenic. In addition, FERN laboratories were utilized to increase FDA field laboratory capacity. Beginning in 2012, the chemistry cooperative agreement laboratories were used to analyze rice products for arsenic.

In order for FDA to properly assess exposure to, and risk from, arsenic in fruit juices and rice products, it needs adequate data about concentrations of arsenic in these foods. To obtain adequate data for rice and rice products, ORA and FERN Labs tested over 500 rice and rice products during FY 2012. To obtain adequate data for fruit juices, the same labs also tested 213 fruit juice samples in order to provide the arsenic data for a formal risk assessment. The data on fruit juices were used to produce a quantitative risk assessment for arsenic in fruit juice. FDA published the risk assessment for public comment on July 15, 2013. The risk assessment for arsenic in rice is under development at the time of this update.

FERN Laboratories that participated in FERN-directed analyses included:

- FDA's San Francisco District Lab
- FDA's FCC
- FDA's Kansas City District Laboratory
- FDA's Southeast Regional Laboratory
- California Department of Public Health Food and Drug Laboratory
- Arizona Department of Health Services
- Arkansas Public Health Laboratory

- Connecticut Agricultural Experiment Station
- Florida Department of Agriculture and Consumer Services
- Wisconsin Department of Agriculture, Trade and Consumer Protection
- Nebraska Department of Agriculture
- Minnesota Department of Agriculture

(6) Is integrated with relevant laboratory networks administered by other federal agencies.

The FERN NPO routinely communicates with other laboratory networks and programs to increase transparency and communication, as well as to identify potential areas for harmonization of activities and leveraging. Such partners include: Rapid Response Teams (managed through FDA Office of Regulatory Affairs), Pesticide Data Programs (managed through USDA Agricultural Marketing Service), and the CDC LRN.

The FERN NPO is also an active member of DHS's ICLN, and several NPO staff are driving forces on ICLN subgroups, such as Proficiency Testing/Quality Assurance, Methods, and IT. FERN Directors participate in the ICLN Network Coordination Group to promote transparency and communication about FERN activities, and discuss how FERN can better work with other ICLN members to meet harmonization and standardization criteria, as set by ICLN. All of these activities clearly depict FERN's integration with relevant laboratory networks administered by other Federal agencies.

Recent progress in the implementation of ICLN, with FERN as an integral member, includes development of the Integrated Response Architecture—defining policies for interoperability, inventories of networks' proficiency testing programs and training programs, and readiness exercises. Incident response matrices have been developed, identifying roles and gaps. An ICLN data portal that allows networks to share data has been established.

Key Components for Continued Success of FERN

FERN has demonstrated, through its responses to large-scale food emergency and non-emergency situations over the last seven years, that it is a robust national network of food regulatory laboratories, capable of providing timely analytical surge capacity support when additional laboratory assistance is needed. FERN has also shown that it can develop and utilize more rapid screening techniques and provide the technical support needed to disseminate these methods to the nation's food testing laboratories. However, resources are critical for continued success, especially for making further progress in FERN implementation. Key areas include:

Funding of the Network – FERN funded programs are essential in making an integrated response to large-scale food events possible. Providing FERN laboratories with training, proficiency testing, and supplies ensures that they are ready in the event of an emergency or a non-emergency where there is the need to analyze a large number of samples. It is important to restate that FERN is a voluntary organization of the nation's food regulatory

laboratories. If the individual laboratories were required to fund these necessary functions on their own, few laboratories would be able to do so.

Cooperative Agreement Funding – CAP laboratories are the first line of defense for food emergencies, as well as non-emergency situations requiring the testing of large numbers of samples; and in many cases provide capabilities and capacities not available in Federal regulatory laboratories, specifically with potential agents of bioterrorism. As noted above, CAP laboratories have responded to every activation of FERN in diverse ways. They have participated in surveillance assignments, outbreak sample testing, method development, method validation, and technical support. Due to consistent funding for cooperative agreements, FERN was able to ensure that these laboratories are equipped, supplied, trained, and standing by ready to assist on very short notice. A decrease in FERN cooperative agreement funding would reduce the effectiveness and capacity of the nation's response to foodborne emergencies, accidental or intentional, and would also diminish the ability to test large numbers of samples in non-emergency situations.

Interagency Agreement Funding – Many networks and federal agencies are working towards the common goal of protecting the food supply. FERN is a network that is at the forefront of national emergency response with respect to food and is a leader among these networks. The overlapping goals and missions of several of these agencies/networks are best addressed and met in a coordinated and unified manner to ensure the most efficient national response. While FERN has already demonstrated the ability of federal agencies (FDA, FSIS, CDC, and other ICLN agencies) to work collaboratively, there are insufficient resources to move forward with many important harmonization efforts. These include sharing samples among programs, harmonizing instrumentation and methodology, and developing standardized methods and reporting requirements. State partner laboratories have demonstrated willingness, competence, and enthusiasm to move forward with these efforts, as they address both federal and state priorities.

IT Challenges – FERN utilizes two IT systems, [eLEXNET](#) and the [FERN website](#), and both are critical to the success and functioning of all FERN programs, in both emergency and non-emergency situations. The FERN website houses the network's capability and capacity data, and can host webinars, training, proficiency testing exercises, activation/exercise event data and collaboration, and conferences. eLEXNET is the official document repository for FERN, and is used for workgroup management, document storage/sharing, and data reporting. The technical work for both systems is funded through agency contracts (from both FDA and FSIS), and is especially difficult to update and enhance, in part due to the complex nature of IT contracts and the sparse availability of funding. Maintenance of eLEXNET, the official document repository site, is more complicated because FERN is not the sole stakeholder in the system. This means that funding for eLEXNET must be divided between other agency stakeholders and FERN, greatly reducing the flexibility and amount of available funds. FSMA has numerous laboratory-related provisions, such as greater data sharing and capture capabilities. It is critical to adequately fund the existing IT systems in order to meet legislative expectations.

Conclusion

FERN integrates the nation's food-testing laboratories at the federal, state, local, and tribal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. It focuses on preparedness through awareness, surveillance, prevention, and capacity-building programs and seeks to build response and recovery surge capacity. FERN provides for an early means of detecting threat agents in the U.S. food supply and prepares the nation's laboratories to be able to respond to food-related emergencies, offering significant surge capacity that strengthens the nation's response towards widespread complex intentional or inadvertent food contamination. FERN has shown its ability to respond to large-scale food emergency events, as well as non-emergency situations where there has been the need to test large numbers of samples, since its inception in 2004. This ability of FERN to provide a cohesive response in both emergency and non-emergency situations, serves to enhance the ability of federal, state, and local agencies to restore and maintain confidence in the food supply following a threat or an actual emergency targeting the nation's food supply.