Report to Congress

Report to Congress on the Food Emergency Response Network

Submitted Pursuant to Section 202(b) of the FDA Food Safety Modernization Act, Public Law 111-353

U.S. Department of Health and Human Services

Food and Drug Administration

_____Date_____

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Introduction

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

On January 4, 2011, President Obama signed into law FSMA (Public Law 111-353). Section 202(b) of FSMA requires the Secretary of the U.S. Department of Health and Human Services (HHS), in coordination with the Secretary of the U.S. Department of Agriculture (USDA); the Secretary of the U.S. Department of Homeland Security (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 methods 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 third report in response to this mandate. Prior reports can be found on FDA's FSMA Reports and Studies website.

Background

Following September 11, 2001, 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 assigned to 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 cooperative agreements supply critical funding to select state member laboratories, increasing national capability and capacity. This funding support facilitates the ability of these laboratories to serve as first responders during food emergencies.

FERN has proven its ability to respond to large-scale food emergencies. 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 vital in aiding in the recovery from emergencies such as the Deep Water Horizon oil spill in 2010 and the Japanese nuclear reactor failure in 2011, thus helping affected economies and increasing consumer confidence in the food supply.

FERN Organizational Structure

FERN is jointly coordinated by HHS's FDA and the USDA's Food Safety and Inspection Service (FSIS). Each agency has FERN National Program Office (NPO) management and coordination staff in place to direct FERN activities and support programs, including method development, training, proficiency testing, surveillance sampling, and electronic communications. Additionally, FERN Regional Coordination Center (RCC) staff members are in place across the country to work closely with the laboratories located in their geographical area. This structure has not changed since the last posting of this report to Congress in 2013.

FERN Membership

FERN membership is open to public (federal, state, local, and tribal) food testing laboratories that perform regulatory and/or diagnostic analytical work. As of January 2017, FERN has 166 laboratory members (31 federal, 104 state, 16 local, 3 military, and 12 university) located in all 50 states and Puerto Rico. FERN membership since its inception in 2004 to the present is outlined in Table 1.

Table 1. Number of FERN Member Laboratories from 2004 to 2017

Calendar 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
2014-2015	170
2016-2017	166*

** Reduced due to state and federal lab closures*

FERN Federal Partners

FERN consults with federal partners for expertise and input regarding FERN support programs and activities. Such partners include: 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 (CDC) Laboratory Response Network (LRN). The FERN NPO coordinates a monthly conference call with the FDA 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. FERN is also a member of the Integrated Consortium of Laboratory Networks (ICLN), a group of federally sponsored analytical laboratory networks tasked with responding to chemical, biological, radiological, and nuclear events.

FSMA Support

FSMA contains many laboratory-related provisions, and FERN or FDA's laboratory network can play a vital role in enabling FDA to achieve its mandate. As FERN broadens its role beyond that designed solely for emergency scenarios, FERN could be instrumental in expanding domestic testing capacity (Sec. 110), be a major contributor to ICLN activities (Sec. 203), increase foodborne illness surveillance capacity (Sec. 205), and improve training programs for state, local, territorial, and tribal food safety officials (Sec. 209).

Increasing Laboratory Capacity: FERN Cooperative Agreements and ISO/IEC 17025:2017 Accreditation for State Food Testing Laboratories

FERN Chemistry, Microbiology, and Radiochemistry Laboratory Cooperative Agreement Program

FERN cooperative agreements increase national capability and capacity by awarding funds to selected state member laboratories to establish harmonized methods and analytical platform performance standards; develop, validate, and implement new analytical methods to meet FERN needs; and establish other laboratory operations and protocols that support data confidence. These funds are used to procure equipment, reagents, and supplies required by the laboratories to carry out the mission of FERN and to hire dedicated personnel, as well as to participate in projects covered under the cooperative agreements. Specific projects, methodology development, and other assignments involving the cooperative agreement laboratories are developed by the FERN NPO in consultation with FDA, FSIS/FERN leadership, and other federal partners. These projects and assignments utilize the laboratories to increase national capability and capacity for responding to national food events and to serve as first responders during food emergencies. Personnel funded by the FERN Cooperative Agreement Program (CAP) serve both the FERN analytical programs as well as their state programs. These FERN CAP awards fund work in all FERN analytical areas: chemistry, microbiology, and radiochemistry. Requests for applications (RFAs) and awards are published in the *Federal Register* and managed separately by FDA and FSIS. Fiscal year (FY) 2016 began a new FERN CAP funding cycle.

A historical accounting of the FDA- and FSIS-managed FERN CAP awards is shown in Table 2.

Table 2. Number of FDA- and FSIS-Managed FERN CAPs from 2005-2017

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

Year	FDA FERN Cooperative Agreements	FSIS FERN Cooperative Agreements
2009	14 Chemistry; 5 Radiochemistry	25 Microbiology; 4 Program Support
2010	15 Microbiology; 14 Chemistry; 5 Radiochemistry	25 Microbiology/Chemistry; 4 Program Support
2011-2015	15 Microbiology; 14 Chemistry; 5 Radiochemistry	25 Microbiology/Chemistry; 2 Program Support
2016-2017	14 Microbiology; 14 Chemistry; 5 Radiochemistry	20 Microbiology/Chemistry; 2 Program Support

ISO/IEC 17025:2017 Accreditation for State Food Testing Laboratories

In the effort to establish national laboratory standards and implement a fully integrated national food safety system, laboratory accreditation has been identified as an important element for ensuring the integrity and accuracy of the laboratory testing. Accreditation also supports the traceability and accountability of results generated by a laboratory that are submitted to a food regulatory agency, including FDA, for enforcement actions. Investment in laboratory accreditation for the nation's food and feed testing laboratories provides added value for the mission of protecting the public health by providing greater high-quality laboratory data submitted to food regulatory agencies. Accreditation of food and feed testing laboratories, especially FERN laboratories, also helps to facilitate more rapid acceptance and utilization of laboratory data by food regulatory agencies. This promotes faster response times to both intentional and unintentional threats to the nation's food supply.

In 2012, an ISO/IEC 17025 cooperative agreement opportunity was opened to FERN laboratories to support the Manufactured Food Regulatory Program Standards (MFRPS). The ISO/IEC 17025 cooperative agreement program (ISO program) is an FDA funding opportunity for state regulatory labs to become accredited to ISO 17025. Although the ISO program is independent of the FERN CAPs, one of the ISO program's requirements is that the applying state lab be a member of FERN. It is not a requirement that the applying state lab be a FERN CAP lab. The intended outcome of the ISO/IEC 17025 cooperative agreement is for microbiological and chemical food analyses performed on behalf of state manufactured-food regulatory programs to be conducted within the scope of ISO/IEC 17025 accredited laboratories. This will be accomplished by preparing the primary food testing laboratories for state manufactured-food regulatory programs to achieve and maintain ISO/IEC 17025 laboratory accreditation. Data generated by recipient state laboratories not only increases the confidence of that state in the data for its own enforcement purposes but will also be made available for consideration in FDA enforcement actions as well as for surveillance purposes. Laboratory accreditation will also assist state manufactured-food regulatory programs in achieving conformance with MFRPS with the goal of achieving a nationally integrated food safety system.

Of the FERN human food testing laboratories, 34 are currently being funded to support ISO/IEC 17025 accreditation and 22 of these FERN labs have achieved accreditation using funds from the cooperative

agreement with FDA. In FY 2016, the ISO/IEC 17025 accreditation support was expanded to 20 animal feed testing labs in support of the Animal Feed Regulatory Program Standards (AFRPS). The FERN NPO is also working collaboratively with the Association of Public Health Laboratories (APHL) to perform outreach and provide guidance on the laboratory accreditation process to laboratories not currently funded by an ISO/IEC 17025 cooperative agreement.

Enhancement of Foodborne Illness Surveillance

ISO/IEC 17025 Cooperative Agreement State Sampling Plans

As part of the ISO/IEC 17025 cooperative agreement, funded laboratories are required to develop and implement a food surveillance sampling plan within their states. These plans are submitted to FDA as a requirement of the cooperative agreement. In February 2015, as part of its FDA/FERN ISO award, the South Carolina Department of Health laboratory collected and analyzed samples of one firm's ice cream products. *Listeria monocytogenes* was recovered from these state surveillance samples. These positive samples prompted additional sample analysis in Texas, which found additional positive ice cream samples. A large-scale investigation and response was initiated at multiple manufacturing facilities in multiple states. The *L. monocytogenes* isolates from these ice cream samples were eventually found to be genetically linked to 10 illnesses (including 3 deaths) across four states (Kansas, Arizona, Oklahoma, and Texas). The testing from this South Carolina State surveillance sample eventually resulted in a nationwide recall of the firm's ice cream products due to *L. monocytogenes*.

In April 2015, another FDA/FERN ISO-supported laboratory, this one at the Nebraska Department of Agriculture, made the decision to expand its surveillance sampling plan to include ice cream samples based on the findings of the initial ice cream samples. Nebraska found *L. monocytogenes* in a sample of ice cream manufactured by a second firm, and these findings triggered a second nationwide recall of ice cream products for *L. monocytogenes* contamination.

These state sampling plans are developed as part of the ISO/IEC 17025 cooperative agreement requirements and support the implementation of the MFRPS within the states. This enhanced surveillance sampling provides a mechanism for states to expand their routine food testing programs and to increase the likelihood of detecting foodborne pathogens.

FDA Domestic and Imported Avocado Testing

Fifteen FERN Microbiology Cooperative Agreement Program (MCAP) laboratories have participated in the first FDA large-volume surveillance assignment analyzing imported and domestic avocados for the presence of *Salmonella* and *L. monocytogenes*. This is the first time FERN laboratories have been utilized for such a large-scale FDA assignment, testing up to 1,600 avocado samples in a 1-year period. The FERN NPO led several efforts, including data reporting, analytical data package submittal, analytical review, communication within FDA Centers and between the FERN and FDA laboratories, and enforcement action on positive samples. From May 2014-August 2015, FERN MCAP laboratories tested more than 1,100 avocado samples for *Salmonella* and *L. monocytogenes*, and their sample results were used in supporting regulatory decisions.

For the FY2017 European Union Audit Assignment, FERN Chemistry CAP laboratories are being used to analyze 320 milk samples for toxic metals. This is part of a larger assignment involving FDA laboratories to analyze other products in addition to the milk samples.

Support of Integrated Consortium of Laboratory Networks Activities

In May 2015, FERN participated in the ICLN Radiological Confidence Building Competency Test full-scale exercise. FERN's goal in participating in this exercise was to assess the network's ability to conduct food safety assessment and post-event food surveillance in a nuclear or radiological event that involves alpha and beta radioactivity. FDA's Winchester Engineering and Analytical Center prepared samples of apple juice spiked with known amounts of Sr-90 and Pu-239. Over 300 spiked samples were analyzed over a 7-day period by the 17 laboratories that participated in this exercise. This exercise tested the ability of FERN to actively respond to a food radiological event by assessing the analytical capability and capacity of the participating labs and their ability to submit sample results through electronic data reporting portals.

Improving the Training of State, Local, Territorial, and Tribal Food Safety Officials

In the 13 years since the inception of FERN, the Network has trained over 1,389 analysts from federal, state, and local laboratories on chemical, microbiological, and radiochemical analytical techniques in products in 140 FERN-sponsored courses. This training program serves to increase the analytical capabilities of FERN member laboratories and the capability and capacity of the network to quickly respond to a foodborne outbreak or emergency event. This training, when properly sustained over time, provides a critical element necessary in keeping the FERN laboratories as an important front line of food defense to help prevent and respond to deliberate attacks.

Conclusion

FERN integrates most of 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. FERN focuses on preparedness through awareness, surveillance, prevention, and capacity-building programs and seeks to build response and recovery surge capacity.

Since 2004, the number of FERN member laboratories has grown from 8 to 166. Additionally, 56 state FERN laboratories, representing 42 states, are being funded by ISO/IEC 17025 cooperative agreements. Together, these components represent the major components of a fully integrated national food safety system with mutually acceptable analytical data.