

Report to Congress

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



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Introduction

This report is intended to satisfy the reporting obligation of the Food and Drug Administration (FDA or the Agency) under section 202(b) of the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) concerning the Food Emergency Response Network (FERN).

On January 4, 2011, President Obama signed FSMA into law. Section 202(b) of FSMA requires the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, the Secretary of Homeland Security, 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 the “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 of Health and Human Services is required to submit the report to the relevant committees of Congress and to post it on the U.S. Department of Health and Human Services (HHS) website.

The following report for 2019 is the fourth report in response to this FSMA mandate. Prior reports can be found on FDA’s FSMA Reports and Studies website.¹

¹ See “FSMA Reports & Studies,” at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-reports-studies>

Background

Following September 11, 2001, attention has focused on the risk of bioterrorism threats, particularly with regard to the nation's food supply. For example, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 assigned to FDA the responsibility for a wide-ranging program to protect the American public from attacks on the food supply. In addition, FERN was developed in 2004 in response to the 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 most of the nation's food testing laboratories at the federal, state, and local levels into a network that can detect, identify, respond to, and recover from emergencies involving biological, chemical, or radiological contamination of food.

FERN's cooperative agreements supply critical funding to select state member laboratories, increasing the national capability and capacity for food laboratory services. This funding facilitates the ability of these laboratories to serve as first responders during food-related emergencies.

FERN has proven its ability to respond to large-scale emergencies. For example, 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's Organizational Structure

FERN is jointly coordinated by FDA, which is under HHS, and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). Each agency has a FERN National Program Office (NPO) management and coordination staff to direct FERN-related activities and support programs, including method development, training, proficiency testing, surveillance sampling, and electronic communications. Additionally, FERN Regional Coordination Center (RCC) staff members across the country work closely with the laboratories located in their geographical area. This structure has not changed since the 2015/2017 report to Congress on FERN.

FERN's Membership

FERN's membership is open to public (i.e., federal, state, local, and tribal) food testing laboratories that perform regulatory and/or diagnostic analytical work. As of December 2019, FERN has 168 laboratory members (30 federal, 105 state, 16 local, 4 military, and 13 university) located in all 50 states and Puerto Rico. FERN's membership since its inception in 2004 to the present is outlined in Table 1.

Table 1. Number of FERN’s Member Laboratories from 2004 to 2019

Calendar Year	Number of FERN’s 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*
2018 - 2019	168

** Reduced due to state and federal lab closures*

FERN’s Federal Partners

FERN consults with federal partners for expertise and input regarding its support programs and activities such as the Pesticide Data Program (managed through USDA’s Agricultural Marketing Service) and the Laboratory Response Network (LRN) of the Centers for Disease Control and Prevention (CDC). 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. The membership of ICLN includes DHS, FDA, USDA, CDC, U.S. Environmental Protection Agency, U.S. Department of Energy, U.S. Department of State, U.S. Department of Defense and the Federal Bureau of Investigation. ICLN facilitates cooperation and coordination among the agencies involved in federal analytical laboratory operations.

FSMA Support

FSMA contains many laboratory-related provisions, and FERN and FDA’s laboratory network 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's Cooperative Agreements and ISO/IEC 17025:2017 Accreditation for State Food Testing Laboratories

FERN Chemistry, Microbiology, and Radiochemistry Laboratory Cooperative Agreement Program (CAP)

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, methods 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 safety and security events and to serve as first responders during food-related emergencies. Personnel funded by the FERN 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 five-year 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 2005-2019

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
2011-2015	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
2018-2019	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 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 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 laboratories 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 laboratory be a member of FERN. It is not a requirement that the applying state laboratory be a participant in the FERN CAP. 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.

As of December 2019, of the 36 FERN human food testing laboratories that were funded to support ISO/IEC 17025 accreditation, all but 2 of these FERN laboratories 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 laboratories in support of the Animal Feed Regulatory Program Standards (AFRPS). As of December 2019, all 20 of these laboratories have achieved ISO/IEC 17025 accreditation. 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. Several of these state sampling plans have been associated with regulatory voluntary recall actions, including the following: two unrelated nationwide recalls of ice cream products due to *L. monocytogenes* contamination (2015); frozen vegetables contaminated with *L. monocytogenes* (2017); pet food contaminated with *Salmonella* (2019); flour contaminated with pathogenic *E. coli* (2019); frozen peppers contaminated with *L. monocytogenes* (2019); and hard-boiled eggs contaminated with *L. monocytogenes* (2019).

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's Domestic and Imported Food Testing

Fifteen FERN Microbiology Cooperative Agreement Program (MCAP) laboratories participated in the first FDA large-volume surveillance assignment analyzing imported and domestic avocados for the presence of *Salmonella* and *L. monocytogenes* in 2014-2015. This was the first time FERN laboratories were utilized for such a large-scale FDA assignment, testing up to 1,600 avocado samples in a 1-year period. FERN laboratories have also provided additional testing capability to FDA for the 2011-2013 large-volume surveillance assignments of arsenic in rice products and arsenic in various juices.

In FY2017 European Union Audit Assignment, FERN Chemistry CAP (CCAP) laboratories were used to analyze 320 milk samples for toxic metals. This was part of a larger assignment involving FDA laboratories to analyze other products in addition to the milk samples.

FERN Chemistry CCAP laboratories completed testing for toxic elements and poisons/toxins in 1,212, 2,607, and 2,473 samples in FY2017, FY2018, and FY2019, respectively.

In addition, states reported samples tested for toxic elements and poisons/toxins for national readiness (exercise samples); proficiency testing/challenge samples; state incident response samples; and testing performed for other federal and state agencies using FERN CCAP-funded resources. The total number of samples tested for all FERN CCAP program areas was 5,292, 7,815, and 10,570, for FY2017, FY2018, and FY2019, respectively.

FDA CAP laboratories continue to perform surveillance of food hazard/commodity pairs to provide early detection of contaminated foods for removal from interstate commerce, or to provide valuable data on the prevalence of contaminants in our foods. In FY2019 and the first quarter FY2020, more than 10,500 samples were analyzed for various food pathogens, resulting in several positive findings and 11 voluntary recalls from industry.

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

Since the inception of FERN, the Network has trained over 1,400 analysts from federal, state, and local laboratories on chemical, microbiological, and radiochemical analytical techniques in 167 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 food-related emergencies. 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.

Over 95 proficiency testing exercises, designed to ensure that network laboratories are capable of efficiently and competently performing methods needed to address perceived and unforeseen threats to the safety of the nation's food supply, have been provided by FERN. These exercises are analyte-specific and encompass a broad range of identified threats, including select agents, conventional foodborne pathogens, chemical and biological intoxicants, and radionuclides. To

date, we have had 3,550 labs register for FERN proficiency testing exercises, which provides the labs with valuable opportunities for building or maintaining capabilities and increasing their lab capacity.

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 events 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 168. 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 and security system with mutually acceptable analytical data.