Report to Congress

The Food Emergency Response Network

FY 2024

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





U.S. FOOD & DRUG ADMINISTRATION

Executive Summary

Enclosed for your consideration is the fourth report to Congress on the Food Emergency Response Network (FERN). This report is intended to satisfy the reporting obligation in Section 202(b) of FSMA.

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 "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."

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Acronym List

510(k)	premarket notification
ANDA	abbreviated new drug application
FDA	Food and Drug Administration
FY	fiscal year (October 1 to September 30)
NDA	new drug application
OCC	Office of the Chief Counsel

I. 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, FSMA was signed 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—

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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 2024 is the fifth 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

II. 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 a subset of 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. The current iteration of cooperative agreement supporting the FERN is the Laboratory Flexible Funding Model (LFFM)[2], a 5-year cooperative agreement that began in 2020.

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. The most recent activations of the FERN to support national emergencies were *Cronobacter* in powdered infant formula event in 2022 and lead in cinnamon fruit puree products in 2023-2024. To ensure that FERN is prepared to respond in the event of a Highly Pathogenic Avian Influenza (HPAI) activation impacting the food supply, FDA developed HPAI emergency use methods to screen and subtype HPAI in select foods and shared these methods with states to ensure state laboratories have the capability to test for HPAI in 2024-2025.

When not responding to emergencies, the FERN maintains readiness of network analytical capabilities and coordination procedures by conducting surveillance. Through multiple iterations of FDA and the Food Safety Inspection Service (FSIS) cooperative agreements with FERN laboratories over the last decade, over 100,000 samples have

[2] https://www.fda.gov/food/funding-opportunities-provided-office-domestic-partnerships/grants-cooperative-agreements-food

been analyzed. This surveillance protects public health by identifying adulterated product and removing it from the marketplace, informs prevention by identifying problems early before they can cause illness or injury, and provides evidence that the U.S. food supply is among the safest in the world.

III. FERN's Organizational Structure

FERN is jointly coordinated by FDA, which is under HHS, and the 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 most recently submitted report to Congress on FERN (2019) and provides state laboratory partners with an efficient single interface to multiple federal agencies with complementary food safety missions.

IV. FERN's Membership

FERN's membership is open to publicly funded laboratories (i.e., federal, state, local, tribal, and territorial). As of October 2024, FERN has 170 laboratory members (34 federal, 106 state, 16 local, 14 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
2020 - 2022	170
2023 - 2024	170

** Reduced due to state and federal lab closures*

V. FERN's Federal Partners

Inter-agency collaboration is at the core of the FERN mission and all activities. Federal inter-agency collaboration is critical as FERN is a jointly managed FDA – USDA FSIS network, and many state agencies participating in FERN also have laboratory divisions that participate in other federal laboratory networks (e.g., for environmental and clinical testing). This need for inter-disciplinary collaboration (which often aligns with inter-agency collaboration) is echoed in federal agency commitments to a OneHealth[3] approach to developing public health related intervention strategies.

FERN consults with federal partners for expertise and input regarding its support programs and activities. For example, FERN communicates with the Laboratory Response Network (LRN) of the Centers for Disease Control and Prevention (CDC) regarding activities that may affect laboratories participating in both LRN and FERN such as methods and proficiency tests or exercises.

FERN is a member of the Integrated Consortium of Laboratory Networks (ICLN)[4], a group of federally sponsored analytical laboratory networks tasked with responding to chemical, biological, radiological, and nuclear events. The purpose of the ICLN is to "create the basis for a system of laboratory networks capable of integrated and coordinated response to, and consequence management of, acts of terrorism and other major incidents that require laboratory response capabilities." The membership of ICLN includes U.S. Department of Homeland Security (DHS), FDA, USDA, CDC, U.S. Environmental Protection Agency, U.S. Department of Energy, U.S. Department of State, U.S. Department of Defense, U.S. Department of the Interior, and the Federal Bureau of Investigation. ICLN facilitates cooperation and coordination among the agencies involved in federal analytical laboratory operations and provides continuous opportunity to engage with other federal partners and networks on a wide range of activities via routine meetings, establishing workgroups for specific topics, and conducting multi-network exercises (both tabletop and live sample). FERN is an active participant in ICLN workgroups and exercises. In FY 2024, FERN participated in the monthly ICLN Coordination Group meetings, as well as Interlaboratory Comparability/Quality Assurance, Methods Detection, and Radiological Laboratory workgroups. FERN has participated in all ICLN exercises, most recently tabletop exercises in 2018 and 2021, and Integrated Laboratory Coordination Exercises (ILCE) with live samples in 2022 and 2024. These exercises allow laboratory networks to utilize electronic data interface, standard operating procedures, communication tools, and ICLN structure to simulate disaster response where multiple laboratory networks

[3] https://www.fda.gov/animal-veterinary/animal-health-literacy/one-health-its-all-us

[4] https://www.icln.org/

are simultaneously activated. The most recent real-time testing simulation (February 2024) involved the (notional) intentional release of a toxin/poison via two distribution mechanisms by an extremist group. Nine FERN laboratories participated in this exercise, analyzing 52 environmental samples.

In 2024, FDA undertook a reorganization that, among other things, aligned human food testing centers into the new, unified Human Foods Program (HFP)[5]. This streamlined organization combined the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Food Policy and Response (OFPR), as well as certain offices from FDA's Office of Regulatory Affairs (ORA). The reorganization streamlined oversight of food within FDA and allowed for a more complete and comprehensive human food testing structure within the HFP. FDA's internal laboratories, as well as our state laboratory partners in the FERN, continue to support animal food testing and work closely with Center for Veterinary Medicine (CVM). The FERN NPO also 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.

[5] https://www.fda.gov/about-fda/fda-organization/fda-modernization-efforts-establishing-unified-human-foods-program-new-model-field-operations-and

VI. FSMA Support

FSMA contains many laboratory-related provisions, and the FERN plays a vital role in enabling FDA to achieve these mandates. FERN laboratories, in addition to offering additional capability and capacity during emergency scenarios involving biological, chemical and radiological threats to our food system, also produce surveillance and signals laboratory data for domestic and imported food products to support critical analytical needs through funded cooperative agreement activities (FSMA Sec. 110), see Food Defense Preparedness (VIII) and Surveillance and Response (IX) sections of this report. In addition, FERN is a major contributor to ICLN activities (FSMA Sec. 203), see Federal Partners (V) section of this report. FERN also provides proficiency testing and improves access to training programs for state, local, territorial, and tribal food safety officials (FSMA Sec. 209), see FERN PT Program (XI) section of this report.

VII. Enhancing Laboratory Capacity and Capability: FERN's Cooperative Agreements

A historical accounting of the FDA- and FSIS-managed FERN cooperative agreement program (CAP) awards is shown in Table 2. This report focuses on the FDA cooperative agreements and associated accomplishments.

Table 2. Number of FDA and FSIS-Managed FERN CAPs from 2005-2024

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/Radiochemistry; 4 Program Support
2011-2015	15 Microbiology; 14 Chemistry; 5 Radiochemistry	25 Microbiology/Chemistry/Radiochemistry; 2 Program Support
2016-2017	14 Microbiology; 14 Chemistry; 5 Radiochemistry	20 Microbiology/Chemistry/Radiochemistry; 2 Program Support
2018-2019	14 Microbiology; 14 Chemistry; 5 Radiochemistry	20 Microbiology/Chemistry/Radiochemistry; 2 Program Support
2020	55 laboratories[6]: 46 Microbiology; 33 Chemistry; 18 Radiochemistry (some labs participate in multiple disciplines)	20 Microbiology/Chemistry/Radiochemistry; 2 Program Support
2021-2023	55 laboratories: 46 Microbiology; 33 Chemistry; 18 Radiochemistry (some labs participate in multiple disciplines)	11 Microbiology/Chemistry/Radiochemistry; 2 Program Support

[6] Increase in number of CAP laboratories is due to roll-out of new CAP (Laboratory Flexible Funding Model)

2024	55 laboratories: 46 Microbiology; 33 Chemistry; 18 Radiochemistry (some labs participate in multiple disciplines)	8 Microbiology/Chemistry/Radiochemistry; 2 Program Support

FERN and ISO 17025 Cooperative Agreements (2005 – 2020)
FERN has supported state human and animal food testing laboratory capacity and capability via multiple iterations of cooperative agreements, going back to 2005. Both FDA and FSIS FERN issue cooperative agreements where eligible applicants are state FERN member laboratories, see Table 2.

The purpose of the FDA FERN cooperative agreements (2005-2020) was to increase national capability and capacity by establishing 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. The FERN cooperative agreements funded work in the disciplines of chemistry, microbiology, and radiochemistry.

In 2012, FDA issued an ISO/IEC 17025 cooperative agreement program to assist state laboratories in becoming accredited for microbiological and chemical food analyses performed for the state manufactured food regulatory program and meet Standard 10 of the Manufactured Food Regulatory Program Standards (MFRPS)[7]. These ISO/IEC 17025 cooperative agreements included support for Whole Genome Sequencing (WGS) in support of the GenomeTrakr program[8]. The ISO 17025 cooperative agreements were expanded in 2016 to support animal food testing laboratories in support of the Animal Food Regulatory Program Standards (AFRPS)[9], specifically Standards 10 and 11.

Laboratory Flexible Funding Model (LFFM) Cooperative Agreement Program (2020 – Present)

In September 2020, FDA transitioned FERN and ISO 17025 cooperative agreement program funding to the Laboratory Flexible Funding Model (LFFM). This change consolidated funding mechanisms to enhance laboratory preparedness and response capabilities to support the mission of FERN. Eligibility to apply for the LFFM cooperative agreement is limited to FERN member laboratories.

[7] https://www.fda.gov/food/regulatory-program-standards-food/manufactured-food-regulatory-program-standards-mfrps

[8] https://www.fda.gov/food/whole-genome-sequencing-wgs-program/genometrakr-network

[9] https://www.fda.gov/food/regulatory-program-standards-food/animal-food-regulatory-program-standards-afrps-preventive-controls-cooperative-agreement-program

The LFFM aims to enhance the capacity and capabilities of state human and animal food testing laboratories in support of an integrated food safety system. This is achieved through prioritized sample testing and food defense preparedness in the areas of microbiology, chemistry, and radiochemistry, as well as method development and capacity/capability development projects that support and expand food safety and food defense testing. Through LFFM, our nation's laboratories are prepared, equipped, and continuously exercised for response to intentional and unintentional adulteration of our food supply by biological, chemical, and radiological agents.

The LFFM provides 14 tracks, or distinct project areas, for laboratories to choose from, including support for human and animal food surveillance, WGS, food defense, method development/validation, and capacity/capability development (implementing new types of testing) (See Table 3). FDA decided to move to a flexible funding model based on recommendations from a 2016 FDA Science Board sub-committee review of the FERN cooperative agreements. The goals were to 1) make the program more flexible, organized, and maximize impact; 2) offer tiered funding to reflect differences in volume and level of effort of activities undertaken by grantees; 3) combine similar initiatives that involve the same applicant pool and consolidate funding for efficiency; and 4) allow FDA to better analyze return on investment and report program outcomes.

Table 3. Number of Laboratories per LFFM Track, 2023-2024

Track	Number of Labs	Track	Number of Labs
Micro – Food Defense (M-FD)	12	Chem – Food Defense (C-FD)	11
Micro – Human Food (M-HF) Product Testing	25	Chem – Human Food (C-HF) Product Testing	26
Micro – Animal Food (M-AF) Product Testing	18	Chem – Animal Food (C-AF) Product Testing	15
Micro – Whole Genome Sequencing (WGS)	31	Chem – Capability/ Capacity Development (C-C/C)	9
Micro – Capability/ Capacity Development (M-C/C)	18	Rad – Food Defense (R-FD)	18
Sample Collection	31	Rad – Capability/ Capacity Development (R-C/C)	0
Method Development/Validation (MDV)	23	Data Exchange Implementation (New development)	1

VIII. Enhancement of Food Defense Preparedness

Through the LFFM, 27 state agencies are funded for food defense tracks to ensure laboratory surge capacity for the analysis of foods and food products related to intentional contamination of food intended to cause widespread harm with microbiological, chemical and/or radiological contaminants. See Table 3 (M-FD, C-FD, R-FD Tracks). Some laboratories participate in more than one discipline. These labs participate in FDA-requested exercises, and/or surveillance activities to support and maintain readiness, participate in national special security event exercises, as available, and maintain preparedness to rapidly respond to a suspected or confirmed intentional contamination event involving human or animal food. This includes ensuring that BSL2+ and/or BSL[10] facilities are certified, if necessary, and fully functional, analysts are trained and have passed competency exercises, equipment is in working order, and reagents and supplies are available. These laboratories augment FDA capacity and participate in testing associated with suspected or credible threats to the food supply, as requested by FDA.

In addition to ensuring adequate national capacity for analytes of food defense (intentional contamination) significance, the LFFM food defense tracks also support method development and validation to ensure that food defense methods are robust, broad, and use current technology to encompass new and emerging threats. One example of this type of work is in the Radiochemistry food defense track during 2022-2023, where 12 laboratories participated in a multi-laboratory study for a total radioactive strontium method utilizing multiple technologies, evaluating three FDA-regulated commodities (leafy greens, milk, and grains (rice)). The project was led by one of the LFFM laboratories, the University of Iowa Hygienic Laboratory, and the final results are pending publication and approval as a FERN method. This project expands network capability and preparedness for potential future incident responses requiring rapid radioactive strontium evaluation.

Beyond the primary scope of analytes of food defense significance, LFFM food defense laboratories are leveraged to support specialized analyses that FDA lacks adequate capability for, such as *Legionella*. Between 2022 and 2024, two (2) LFFM Micro Food Defense laboratories supported testing as part of multiple for-cause inspection assignments for *Legionella* in domestic cruise ships. In the most recent assignment (June - October 2023), 314 subsamples of bulk water and biofilm swabs samples were collected and tested by the Michigan Department of Health and the Maryland Department of Health. Testing results from the first sampling assignment in

[10] BSL2+ and BSL3 laboratories have the capability to handle infectious agents that are not permitted in a general lab setting (e.g., Anthrax).

2022, in addition to FDA inspectional findings, were part of a Warning Letter[11] issued to the cruise line in 2023.

[11] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/american-cruise-lines-641736-01242023

IX. Enhancement of Foodborne Illness and Contaminant Surveillance & Response

The LFFM human and animal food product testing tracks aim to enhance surveillance testing capacity and capability of state partners, producing a large quantity of sample outputs to be used by FDA and states for risk assessment, tracking and trending, identifying emerging issues, and informing future sampling initiatives or other activities. LFFM marked the first time FDA implemented a continuous, coordinated, national surveillance sampling program with state partners.

LFFM sampling is planned based on the food product (commodity) and the specific pathogens (hazards) it will be tested for, referred to as "commodity-hazard pairs". Commodity-hazard pairs may be proposed by FDA or the state; sampling plans are developed as a collaborative effort between FDA and state agencies. Planning for LFFM surveillance is integrated with FDA's work plan for inspections. Several commodity-hazard pairs collected under LFFM support public-facing FDA Prevention Strategies[12], including soft fresh queso fresco-type cheese, imported enoki and wood ear mushrooms, bulb onions, and the FDA Leafy Green STEC Action Plan[13]. States may also pivot planned sampling to address emerging and urgent needs such as outbreaks and other emergency response situations.

Between September 2020 and June 2024, state programs participating in LFFM have collected and analyzed 71,541 samples of human and animal food products for microbiological and chemical hazards. These samples have resulted in numerous public health actions, including 89 recalls, 31 firms added to import alerts, 2 country-wide import alerts, 89 FDA Warning Letters, or 1 Consent Decrees, 18 consumer advisories, and 3 outbreak notices.

This surveillance has had a powerful and beneficial impact on outbreak response and prevention:

- **PREVENTION:** Surveillance samples can identify and prompt preventive work to address a facility contamination issue before it causes an outbreak
    - In 2022, two LFFM states (Pennsylvania Dept. of Agriculture and Florida Dept. of Agriculture and Consumer Services) identified Listeria monocytogenes in peaches that were traced back to the same packing house in California. California's Rapid Response Team

[12] https://www.fda.gov/food/outbreaks-foodborne-illness/post-outbreak-response-and-prevention-strategies-enhance-food-safety-updated-january-17-2025

[13] https://www.fda.gov/food/foodborne-pathogens/leafy-greens-stec-action-plan

(RRT)[14] conducted an investigation at the packing house and found the same strain of *L. monocytogenes* at the facility. The firm conducted corrective actions. Read more in this APHL-published success story.[15]
    - In 2023, an LFFM sample of soybean sprouts was confirmed positive for *L. monocytogenes* and traced back to a sprout producer in Massachusetts by the Virginia Division of Consolidated Laboratory Services and Virginia Dept. of Agriculture and Consumer Services. Massachusetts Dept. of Agricultural Resources collected environmental swabs which were analyzed by FDA and WGS determined that the L. monocytogenes from the LFFM sample was highly related to the L. monocytogenes isolated from the firm, and from another product sample tested by New York Dept. of Agricultural and Markets approximately 6 months earlier. FDA issued a Warning Letter[16] to the facility and is monitoring its corrective actions.
- **CONTROL:** Surveillance samples can identify an outbreak which public health investigators didn't know was happening, or solve an outbreak being investigated, but with an unknown food vehicle.
    - In 2023, the South Carolina Dept. of Agriculture collected a sample of dog food, which was tested by the South Carolina Dept. of Public Health and confirmed to contain *Salmonella* Kiambu. WGS linked the *Salmonella* from the dog food to illnesses in seven people, six of whom were less than a year old. This illness cluster had not previously been picked up for epidemiologic investigation by public health surveillance systems due to the size, geographic dispersion, and length of time between cases. Ultimately the firm issued a broad recall of all products produced from the facility that produced the original product that was sampled. An outbreak advisory[17] was posted. This surveillance sample identified and stopped the outbreak, preventing future illnesses and deaths. In November 2024, FDA issued a Warning Letter[18] for the facility that produced the pet foods.

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[14] https://www.fda.gov/food/integrated-food-safety-system-ifss/rapid-response-teams-rrts-human-and-animal-foods

[15] https://aphl.org/resources/resource-detail/teamwork-proves-fruitful-in-foodborne-outbreak-prevention--state-rrts-identify-issues-and-remove-unsafe-products-from-commerce

[16] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/chang-and-son-enterprises-inc-679517-05312024

[17] https://www.fda.gov/animal-veterinary/outbreaks-and-advisories/fda-and-cdc-investigate-cases-salmonella-linked-pet-food-made-mid-america-pet-food-multiple-brands

[18] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mid-america-pet-food-llc-681516-11222024

- In 2024, the Hawaii Dept. of Health collected and analyzed a sample of cotija cheese and found *L. monocytogenes.* WGS linked the *L. monocytogenes* from the cheese to a multi-state cluster of listeriosis illnesses that dated back to 2014, including 23 hospitalizations and two deaths. This cluster had been investigated twice before, in 2017 and 2021, and closed due to inability to identify a specific brand of queso fresco type cheese. The epidemiological investigation was re-opened based on this sample, and FDA conducted environmental swabbing at the facility which identified the same strain of *L. monocytogenes* in the facility (matching the product sample and clinical illnesses). Ultimately the firm issued a broad recall of all products produced in the facility and an outbreak advisory[19] was posted. In a span of 3.5 weeks (from LFFM sample result to recall of all products from the firm), this surveillance sample solved a 10-year mystery and stopped an ongoing outbreak, preventing future illnesses and deaths. In October 2024, FDA entered into a consent decree[20] of permanent injunction against the firm.

- **PIVOT:** Planned surveillance samples can be pivoted to support urgent testing needs in the early stages of an outbreak to identify the breadth and scope of the contamination.
  - In 2021, one LFFM laboratory (Office of the Texas State Chemist) pivoted planned surveillance to test Sportmix brand dog and cat foods produced by Midwestern Pet Foods LLC in response to a December 2020 recall of select lots of pet food due to reports of animal illnesses and deaths. A total of 20 products were collected between January 2-6, 2021, and seven samples contained elevated aflatoxin levels ranging from 30 to 377 ppb. The firm issued an expanded recall of all products made with corn from a specific facility on January 11, 2021. The Office of the Texas State Chemist samples were cited as evidence in the Warning Letter[21] issued to Midwestern Pet Food in 2021.
  - In 2022, the FERN activated LFFM laboratories to support surge capacity testing for *Cronobacter* in a coordinated laboratory response to the recall of powdered infant formula. Three LFFM laboratories (Maryland Department of Health — Laboratories Administration, Ohio Department of Agriculture, and West Virginia Department of Agriculture) provided surge capacity to FDA, as well as states that were not able to perform their own

[19] https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-listeria-monocytogenes-queso-fresco-and-cotija-cheese-february-2024

[20] https://www.fda.gov/news-events/press-announcements/federal-court-enters-consent-decree-against-rizo-lopez-foods-inc-following-multistate-outbreak

[21] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/midwestern-pet-food-613845-08092021

analyses for product linked to complaints. Leveraging state partners for *Cronobacter* testing was important to the response strategy. LFFM laboratories utilized funds to support testing within their state that aligned with the testing criteria sent out through 50-state messaging. LFFM labs tested 128 samples with 212 analyses, as some samples were tested for *Cronobacter* and *Salmonella*. From these 128 samples, 4 samples tested positive for *Cronobacter sakazakii* and none tested positive for *Salmonella*. All positive sample isolates were sequenced and did not match any current clinical cases in the database. Since these were opened product/containers and a nationwide recall was currently ongoing no further action was taken by FDA.

- In 2023, after the recall of WanaBana apple cinnamon fruit puree pouches due to elevated lead levels associated with acute toxicity in children, there was an urgent need to assess the extent and scope of the contamination through sampling of cinnamon and non-cinnamon flavors of fruit purees associated with the manufacturer. The FERN activated LFFM laboratories to pivot sampling to collect and analyze these high priority samples. Within 6 calendar days (4 business days), 12 LFFM laboratories and state regulatory programs collected 97 samples for toxic element analysis and one laboratory conducted X-ray fluorescence (XRF) testing on the packaging material to investigate whether the packaging might be contributing to the lead contamination. The results of the testing confirmed only apple cinnamon fruit puree pouches were affected. Samples taken by two LFFM states, Maryland Dept. of Health and Pennsylvania Dept. of Agriculture confirmed elevated lead levels and were cited in Warning Letters issued to the foreign manufacturer Austrofood and retailer Dollar Tree. Samples taken by North Carolina Department of Agriculture and Consumer Services were also cited in the Warning Letters but were not collected and analyzed under LFFM.

- **EXPAND:** Surveillance sampling can expand what we know about a contaminated product and help identify the source(s) and affected supply chains.
  - Routine samples of enoki mushrooms collected by Missouri Department of Health and Senior Services and Maryland Department of Health in late 2022 and early 2023 found two strains of L. monocytogenes. These strains were linked by WGS to an ongoing outbreak investigation. Importantly, the strains were found in brands not implicated in the outbreak investigation or not covered by recalls previously issued as part of the outbreak response. These samples informed the traceback investigation, identified other distribution channels, and helped confirm the source of the outbreak.
  - Following the apple cinnamon fruit puree pouch investigation that was attributed to contaminated cinnamon, LFFM laboratories were asked to expand planned testing to collect ground cinnamon and other select cinnamon-containing products from Ecuador. As of December 2024, 15

LFFM samples of ground cinnamon from six states have resulted in four FDA consumer advisories and eight recalls due to elevated levels of lead. While these products contain lead at a level significantly lower than the ground cinnamon used to produce the apple cinnamon fruit puree pouches that caused illness, FDA continues to monitor and issue consumer advisories for products containing elevated lead out of concern that prolonged exposure to these products may be unsafe and contribute to elevated levels of lead in the blood. This is aligned with FDA's goals outlined in Closer to Zero.

Beyond the immediate public health impacts, there is great value in the aggregate data (>10,000 samples/year) for risk assessment and other activities, such as: baseline exposure assessment, developing future assignments, and informing policy development. An example of this impact is how LFFM sampling contributes to Closer to Zero[22]. Annually, more than half of the testing in the Chemistry – Human Food product testing track is dedicated to analyzing toxic elements in a wide variety of human foods, including baby foods and foods commonly consumed by children (in 2023-2024, 1,852 out of 3,354 samples analyzed were for toxic elements). Some of the sampling is aligned with products for which the agency has published draft or final guidance action levels for one or more toxic elements. Other sampling is for commodities where FDA lacks adequate data on the occurrence of toxic elements, which is critical to informing development of future action levels.

LFFM also supports sequencing of enteric pathogens isolated from food and environmental sources. Between September 2020 and June 2024, laboratories participating in the WGS track sequenced 21,634 isolates sourced from current and historical surveillance and outbreak investigations, as well as academic or international partnerships for historical isolates. This work strengthens the database of food and environmental sequences and is the way public health investigators identify linkages between clinical, food, and environmental isolates and investigate sources.

[22] https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods

X. Improving Data Reporting between State, Local, Territorial, and Tribal Food Safety Laboratorians

FERN Portal

The FERN Portal (www.fernlab.org) is a secure online website, with access limited to FERN member laboratories. It is housed on the CoreSHIELD platform and is a sister portal to FoodSHIELD, ICLN, the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), and others. The FERN Program manages all core program areas and activities through the FERN Portal, and it is the primary communication and collaboration tool used to manage the LFFM. For example, data reporting for all of the LFFM microbiological and chemical surveillance testing is managed through the FERN Portal, as are Proficiency Testing (PT) registration, training course registration, and access to FERN-approved methods. The FERN Portal also houses a directory for each of the member laboratories, containing information about laboratory organization, personnel, analytical capabilities, methods, and equipment. The FERN Portal has historically been supported by FSIS via a cooperative agreement.

Food Safety Data Exchange (FSDX)

To facilitate data reporting from state laboratories directly into FDA's internal database used to house FDA collection and sample results data, FDA developed the Food Safety Data Exchange (FSDX). The FSDX, formerly known as the ORA Data Exchange, is a unified platform for the sharing of food safety regulatory data between FDA and state and local regulatory partners. The FSDX consists of two systems that facilitate secure, electronic data exchange: the System-to-System (formerly known as NFSDX) and the Partners Portal. Integrating FDA systems with those of our regulatory partners, System-to-System is a web service that provides bi-directional system-to-system communication between FDA IT systems and those of our regulatory partners, including state, local tribal, territorial and foreign regulatory agencies. By facilitating and automating data transfers, System-to-System increases the sharing of accurate, timely, complete, and relevant food safety data so that it can be analyzed and acted upon.

Currently, six state laboratories share laboratory sample results through the FSDX and we routinely exercise this data exchange functionality through targeted assignments where FDA collects samples that are analyzed and sample results are reported into the FSDX. In 2024, approximately 1,752 state laboratory sample results (including samples collected by FDA and analyzed by states, and samples collected and analyzed by states) were reported through this system.

XI. Improving the Training and Proficiency of State, Local, Territorial, and Tribal Food Safety Laboratorians

FERN Training Opportunities

Training is a critical component of our integrated food safety and food defense federal and state laboratory activities. Since the inception of FERN, we have trained over 1,400 analysts from federal, state, and local laboratories on chemical, microbiological, and radiochemical food analytical methods. 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 safety and food defense to help prevent and respond to natural contamination events as well as potential deliberate attacks on the U.S. food system.

Three FERN-designated training courses were offered by FDA in FY24. FERN-designated training courses are FDA courses specifically offered for state FERN member laboratories for the purpose of training state laboratorians on FDA methods and supporting harmonization of testing methods between FDA and state laboratories. Additionally, FDA identified analysts from FERN member laboratories to attend FDA laboratory training courses when extra space was available. A total of 50 state or other federal agency analysts attended FDA training courses in FY24.

To expand the number of training opportunities for FERN member laboratories, FDA has provided funding to some LFFM laboratories through the Capacity/Capability Development Track to host training courses for other states. Two of these courses were held in 2024: a course on PCR fundamentals hosted by the New Hampshire Public Health Laboratory, and a course on shiga-toxin producing *E. coli* screening and confirmation methods hosted by the Virginia Division of Consolidated Laboratory Services. These courses provide hands-on practical experience to laboratory analysts.

FSIS has supported state laboratories in development of virtual training courses to be posted on the FERN Portal and made available on-demand for FERN member laboratories. In FY 2024, the *Listeria* identification virtual training course~~s~~ was completed and posted, joining the *Salmonella* identification virtual training course posted in FY 2023. These courses are especially important for addressing turnover and providing quick and easy access to foundational training courses for new microbiological staff.

FERN Methods Coordination Committee (MCC)
The FERN MCC is the reviewing and approval body for FERN methods. FERN provides validated methods for hazards of food safety and food defense significance, particularly when there is no other standard or federal agency compendial method validated for foods available. FERN methods are shared with other federal agencies and, where possible, harmonized with other ICLN member laboratory networks who may be looking at the same hazards in other matrix types (clinical, water, animal, plant, etc.). Method development, validation, and harmonization work is active in all analytical areas.

FERN Proficiency Testing (PT) Program
Since 2004, the FERN has issued 142 PTs and 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. 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. The FERN PT Program focuses on providing PTs and exercises for analyte/matrix combinations that reflect recent public health or regulatory events, and/or are difficult to procure from commercial sources. This program provides member laboratories with valuable opportunities for building or maintaining capabilities and increasing their lab capacity.

XII. Conclusion

FERN integrates most of the nation's food testing laboratories at the federal, state, local, tribal and territorial levels into a network that is able to respond to events involving biological, chemical, or radiological contamination of food. FERN focuses on preparedness through proficiency testing, training, inter-agency collaboration, surveillance, prevention, and capacity/capability building programs to support response and recovery.

Since 2004, the number of FERN member laboratories has grown from eight to 170. Currently, 55 state FERN laboratories, representing 40 states, are funded through the FDA LFFM cooperative agreement. Together, these programs support a fully integrated national food safety and security system with mutually acceptable analytical data.

This report was prepared by FDA's Human Foods Program.
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