The <u>Laboratory Flexible Funding Model</u> (LFFM) is a cooperative agreement intended to enhance the capacity and capabilities of state human and animal food testing laboratories in support of an integrated food safety system.

LFFM activities are organized into distinct project areas, called <u>tracks</u>, some of which involve surveillance of human and animal foods for microbiological and chemical hazards (e.g., testing enoki mushrooms for *L. monocytogenes*, or pet foods for *Salmonella*). This document summarizes accomplishments for the Microbiology Human and Animal Food (M-HAF) Product Testing Tracks from 31 state laboratories between July 1, 2022, and June 30, 2023 (year three of the fiveyear LFFM cooperative agreement).

How many samples were collected and analyzed?

A total of 11,115 samples were collected and a total of 14,677 analyses were performed in the M-HAF Product Testing Tracks for LFFM Year 3. This represents 115% of the planned capacity for the M-HAF Tracks in Year 3 (12,700 analyses).

Testing Area	Total Number of Samples Collected and Analyzed
Human Food	8,406
Animal Food	1,785
NARMS ¹	924

Who collected the samples?

Samples are collected for a variety of reasons, including, but not limited to a state-proposed sample plan, emergency response and outbreak situations, or an FDA assignment. Most samples are collected and analyzed by state agencies, but samples may also be collected by other organizations (e.g., the FDA or a third party under contract) and submitted to LFFM laboratories for analysis. Two (2) laboratories participated in an FDA Imports Assignment, which ran from January to June 2023.

Collecting Organization	Human Food	Animal Food	NARMS
State Laboratory	1,918 (22%)	119 (7%)	924 (100%)
State Regulatory Program	6,442 (77%)	1,666 (93%)	
FDA	46 (1%)		

Collection Location (Facility Type)	Human Food	Animal Food	NARMS
Retailer	8,047 (96%)	1,173 (66%)	924 (100%)
Distributor, Manufacturer or Grower	313 (4%)	612 (34%)	
Importer (Port of Entry)	46 (1%)		

What pathogens were the samples analyzed for?

Analytical results for human and animal food samples, excluding NARMS, were reported for *Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7 and other STECs, and prohibited materials (i.e., mammalian protein in foods for ruminant animals, BSE). Some samples were analyzed for more than one pathogen.

Pathogen of Interest	Total Number of Samples Analyzed	Total Confirmed Positive
Salmonella species	7,819	26
Listeria monocytogenes	4,200	15
Shiga-toxin producing Escherichia coli (STEC)	989	0

¹ National Antimicrobial Monitoring System (NARMS)

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Pathogen of Interest	Total Number of Samples Analyzed	Total Confirmed Positive
Prohibited materials ²	257	0

Of the 41 confirmed *Salmonella* and *L. monocytogenes* positive samples, isolates from all 41 samples were sequenced and submitted to the National Center for Biotechnology Information. LFFM's Whole Genome Sequencing track supports state laboratory participation in <u>GenomeTrakr</u>.

Year 3 marked the first year that LFFM supported retail raw meat testing in support of the National Antimicrobial Resistance Monitoring System (NARMS). A total of 924 samples of raw ground pork and ground beef were analyzed for *Salmonella* and *Campylobacter*. NARMS maintains and publishes data reports on its <u>website</u>, including data from LFFM samples.

What human and animal food products were tested and what were the findings?

LFFM sampling is planned by food product (commodity), along with the pathogens (hazards) the food product will be analyzed 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. States may pivot planned sampling to address emerging and urgent needs such as outbreaks and other emergency response situations and may add additional pathogens at their discretion. Multiple laboratories may participate in any given commodity-hazard pair, and it is common for a single physical sample to be analyzed for more than one pathogen. The below tables are sorted by pathogen, followed by total number of samples positive per commodity.

Commodity	Hazard	Total # Samples Analyzed	Total # of Samples Positive
Extruded Cat Food (Kibble)	E. coli 0157:H7	159	0 (0%)
Extruded Dog Food (Kibble)	E. coli 0157:H7	151	0 (0%)
Dog and/or Cat Treats (Biscuits Only)	E. coli 0157:H7	110	0 (0%)
Ruminant Food + Ingredients	E. coli 0157:H7	1	0 (0%)
Ruminant Food + Ingredients	Prohibited materials (mammalian protein)	257	0 (0%)
Swine Food	Salmonella	217	5 (2%)
Peanut Meal	Salmonella	15	4 (27%)
Fish Meal	Salmonella	31	4 (13%)
Poultry Food	Salmonella	401	3 (1%)
Soybean Meal	Salmonella	51	2 (4%)
Distillers Products, AAFCO OP section 27	Salmonella	17	1 (1%)
Soybean Products, AAFCO OP section 84	Salmonella	15	1 (1%)
Extruded Cat Food (Kibble)	Salmonella	268	1 (<1%)
Extruded Dog Food (Kibble)	Salmonella	259	0 (0%)
Dog and/or Cat Treats (Biscuits Only)	Salmonella	209	0 (0%)
Wheat	Salmonella	38	0 (0%)

Animal Food Commodity-Hazard Pairs

² Prohibited materials testing involves detection of prohibited mammalian protein in foods for ruminant animals, as addressed by 21 CFR Part 589.2000 and 589.2001. Some mammalian proteins, such as milk, are allowed to be fed to ruminants, and positive samples are typically followed-up by investigation into what triggered the initial result and whether the sample is truly violative. In LFFM Year 3 we did not identify any violative samples.

Human Food Commodity-Hazard Pairs

Commodity	Hazard	Total # Samples Analyzed	Total # of Samples Positive
Enoki mushrooms	Listeria monocytogenes	199	11 (6%)
Fish, smoked	Listeria monocytogenes	804	2 (<1%)
Queso Fresco-Type Soft Cheese	Listeria monocytogenes	1758	1 (<1%)
Controlled environment agriculture leafy greens	Listeria monocytogenes	558	1 (<1%)
Dried Mushrooms	Listeria monocytogenes	483	0 (0%)
Soft-Serve Ice Cream/Yogurt mixes	Listeria monocytogenes	328	0 (0%)
Ready-to-eat refrigerated dips	Listeria monocytogenes	34	0 (0%)
Raw Milk Cheese	Listeria monocytogenes	25	0 (0%)
Tahini or Sesame Paste	Listeria monocytogenes	4	0 (0%)
Granola	Listeria monocytogenes	3	0 (0%)
Partially sprouted seed and nut products	Listeria monocytogenes	2	0 (0%)
Cashews, Raw	Listeria monocytogenes	1	0 (0%)
Tree nut-based cheese alternatives (e.g., cashew "cheese")	Listeria monocytogenes	1	0 (0%)
Dried Mushrooms	Salmonella spp.	486	3 (1%)
Tahini or Sesame Paste	Salmonella spp.	873	1 (<1%)
Partially sprouted seed and nut products	Salmonella spp.	545	1 (<1%)
Cashews, Raw	Salmonella spp.	995	0 (0%)
Granola	Salmonella spp.	951	0 (0%)
Fish, smoked	Salmonella spp.	800	0 (0%)
Tree nut-based cheese alternatives (e.g., cashew "cheese")	Salmonella spp.	648	0 (0%)
Controlled environment agriculture leafy greens	Salmonella spp.	558	0 (0%)
Queso Fresco-Type Soft Cheese	Salmonella spp.	137	0 (0%)
Cut and whole cantaloupe & watermelon	Salmonella spp.	109	0 (0%)
Onion (raw, whole)	Salmonella spp.	68	0 (0%)
Soft-Serve Ice Cream/Yogurt mixes	Salmonella spp.	50	0 (0%)
Ready-to-eat refrigerated dips	Salmonella spp.	40	0 (0%)
Raw Milk Cheese	Salmonella spp.	25	0 (0%)
Other (miscellaneous)	Salmonella spp.	7	0 (0%)
Enoki mushrooms	Salmonella spp.	6	0 (0%)
Controlled environment agriculture leafy greens	Shiga-toxin producing Escherichia coli (STEC)	558	0 (0%)
Other (miscellaneous)	Shiga-toxin producing Escherichia coli (STEC)	6	0 (0%)
Queso Fresco-Type Soft Cheese	Shiga-toxin producing Escherichia coli (STEC)	3	0 (0%)
Partially sprouted seed and nut products	Shiga-toxin producing Escherichia coli (STEC)	1	0 (0%)

What public health interventions resulted from positive samples?

This table lists public recalls and consumer advisories that resulted from LFFM positive samples in Year 3. Follow-up investigation activities are conducted for all positive samples, regardless of whether a recall occurred. Not all positive samples are violative or result in a recall. Follow-up investigation activities include notifying the responsible firm, discussing preventive measures and corrective actions with the firm, document collection/traceback, collecting additional samples, adding firms to import alert, and/or conducting an investigation at the facility.

Type of Notice	Link	Commodity	Hazard
Recall	Tai Phat Wholesalers, LLC Recalls "Three Coins Dried Mushrooms" Because of Possible Health Risk FDA	Dried mushrooms	Salmonella
Recall	Recall Press Release: TW4115 Black Fungus (Nam Meo)	Dried mushrooms	Salmonella
FDA consumer advisory	FDA Advises Restaurants and Retailers Not to Serve or Selland Consumers Not to Eat Product Labeled as Sun HongFoods, Inc. Enoki Mushrooms Sourced from China Due toPossible Listeria Contamination FDA	Enoki mushrooms	Listeria monocytogenes
FDA country- wide import alert	<u>FDA Expands Country-Wide Import Alert for Enoki</u> <u>Mushrooms to China FDA</u> (based on LFFM, FDA, and other state samples)	Enoki mushrooms	Listeria monocytogenes
FDA outbreak advisory	Outbreak Investigation of Listeria monocytogenes: Enoki Mushrooms (November 2022) FDA (includes LFFM samples from Maryland and Missouri)	Enoki mushrooms	Listeria monocytogenes
Recall	Utopia Foods Recalls "Enoki Mushrooms" Because of Possible Health Risk FDA	Enoki mushrooms	Listeria monocytogenes
Recall	Xin Ao International Group Corp. Recalls "Sss Enoki Mushroom" & "K-Fresh Mushroom" Because of Potential Health Risk FDA	Enoki mushrooms	Listeria monocytogenes
Recall	Jan Fruits Inc. Recalls Enoki Mushrooms Because of Possible Health Risk FDA	Enoki mushrooms	Listeria monocytogenes
State partner consumer advisory	Maryland Department of Health issues consumer advisory for Enoki Mushrooms	Enoki mushrooms	Listeria monocytogenes
State partner consumer advisory	News Releases from Department of Health Recalled enoki mushrooms sold in Hawai'i associated with potential Listeria contamination (hawaii.gov)	Enoki mushrooms	Listeria monocytogenes
Recall	TFP Nutrition Initiated Voluntary Recall of 16 lb. Bags of HEB TEXAS PETS Indoor Complete Dry Cat Food Because of Possible Salmonella Health Risk FDA	Kibbled cat food	Salmonella
Recall	Revolution Farms Announces the Voluntary Recall of Lettuce Because of Possible Health Risk FDA	Lettuce (Controlled Environment Agriculture)	Listeria monocytogenes
Recall	Seven Seas International USA, LLC Voluntarily Recalls Giant Food Private Label Wild Caught Alaskan Sockeye Smoked Salmon Because of Possible Health Risk FDA	Smoked salmon	Listeria monocytogenes
Recall	Seven Seas International USA, LLC is Voluntarily Recalling Biltmore Smoked Sockeye Salmon Because of Possible Health Risk FDA	Smoked salmon	Listeria monocytogenes
Recall	https://www.accessdata.fda.gov/scripts/ires/?Event=92319	Sprouted seed/nut butter	Salmonella

Type of Notice	Link	Commodity	Hazard
Recall	Rushdi Foods Issues a Voluntary Recall on One Lot of Their	Tahini	Salmonella
	Mighty Sesame Organic Tahini 10.9 oz Squeeze Bottle FDA		

Case study: LFFM surveillance of enoki mushrooms for Listeria monocytogenes

FDA has a <u>prevention strategy</u> for imported enoki and wood ear mushrooms, which have been implicated as the source of multiple multi-state *Listeria monocytogenes* outbreaks. LFFM surveillance sampling supports this prevention strategy. LFFM enoki surveillance in Year 3 was concurrent with a multi-state outbreak of Listeriosis linked to enokis. Three LFFM samples identified the outbreak strains in product and aided the traceback investigation to identify the source of the outbreak.

An LFFM sample of enoki mushrooms collected by Missouri Department of Health and Senior Services in late November was positive for *L. monocytogenes*. The sample resulted in an FDA-issued <u>safety alert</u> on December 17, 2022. At that time, the product was not linked to the active outbreak investigation. Whole genome sequencing subsequently revealed that the strain of *Listeria* found in the sample matched one of the two strains linked to illnesses in a <u>multi-state *Listeria*</u> <u>outbreak</u>. In early January 2023, Maryland Department of Health identified *L. monocytogenes* in two LFFM samples of enoki mushrooms with the same labelling as the Missouri sample. Whole genome sequencing revealed that both outbreak strains were present in the Maryland samples. These samples brought to light a distribution chain related to the ongoing outbreak, but not covered by the 12/13/22 or 1/13/23 Utopia Foods recalls. While neither Maryland nor Missouri had cases in the outbreak, their positive product samples helped confirm the traceback investigation and source associated with the outbreak. This case study demonstrates how surveillance sampling can support outbreak investigations.