FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Laboratory Flexible Funding Model (LFFM)

National Association of Dairy Regulatory Officials

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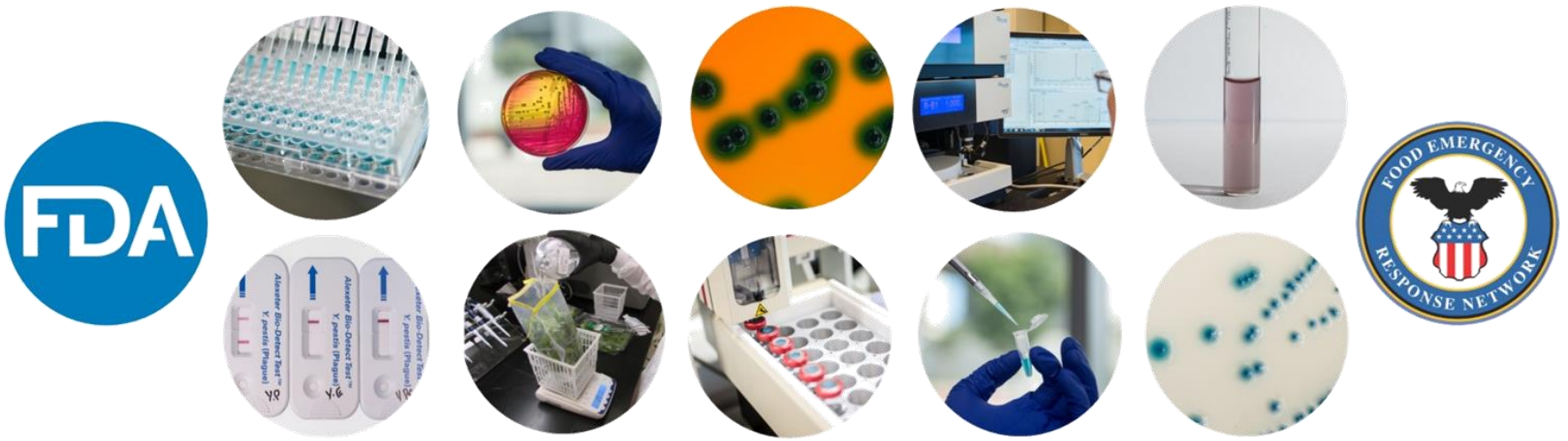
Information provided herein reflects the current thinking on the LFFM initiative. Like most other initiatives, plans and framework may evolve based on stakeholder input, regulatory priorities, data sharing infrastructure, and budget forecast.



The FDA Laboratory Flexible Funding Model (LFFM) is a comprehensive emergency response and surveillance cooperative agreement between FDA and FERN partner laboratories.

The LFFM is comprised of 14 Tracks (Projects) across 3 analytical disciplines (Micro, Chem, Radiochemistry). The LFFM exists to enhance the capacity and capabilities of state human and animal food testing laboratories in support of an integrated food safety system.

LFFM Purpose: What are we looking to achieve?

- The Laboratory Flexible Funding Model 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**.
- This project will strengthen and improve FDA's efforts to prevent foodborne illnesses and minimize foodborne exposures through building a nationally integrated laboratory science system.
- Funding equips our partner laboratories with additional resources that can be employed to build and increase sample throughput capacity within their state.

How is LFFM Structured?

In Year 4 of a 5-Year Cooperative Agreement Program

Cycle: July 1 – June 30, annually

14

Tracks (Projects) across Chemistry, Microbiology and Radiochemistry Disciplines

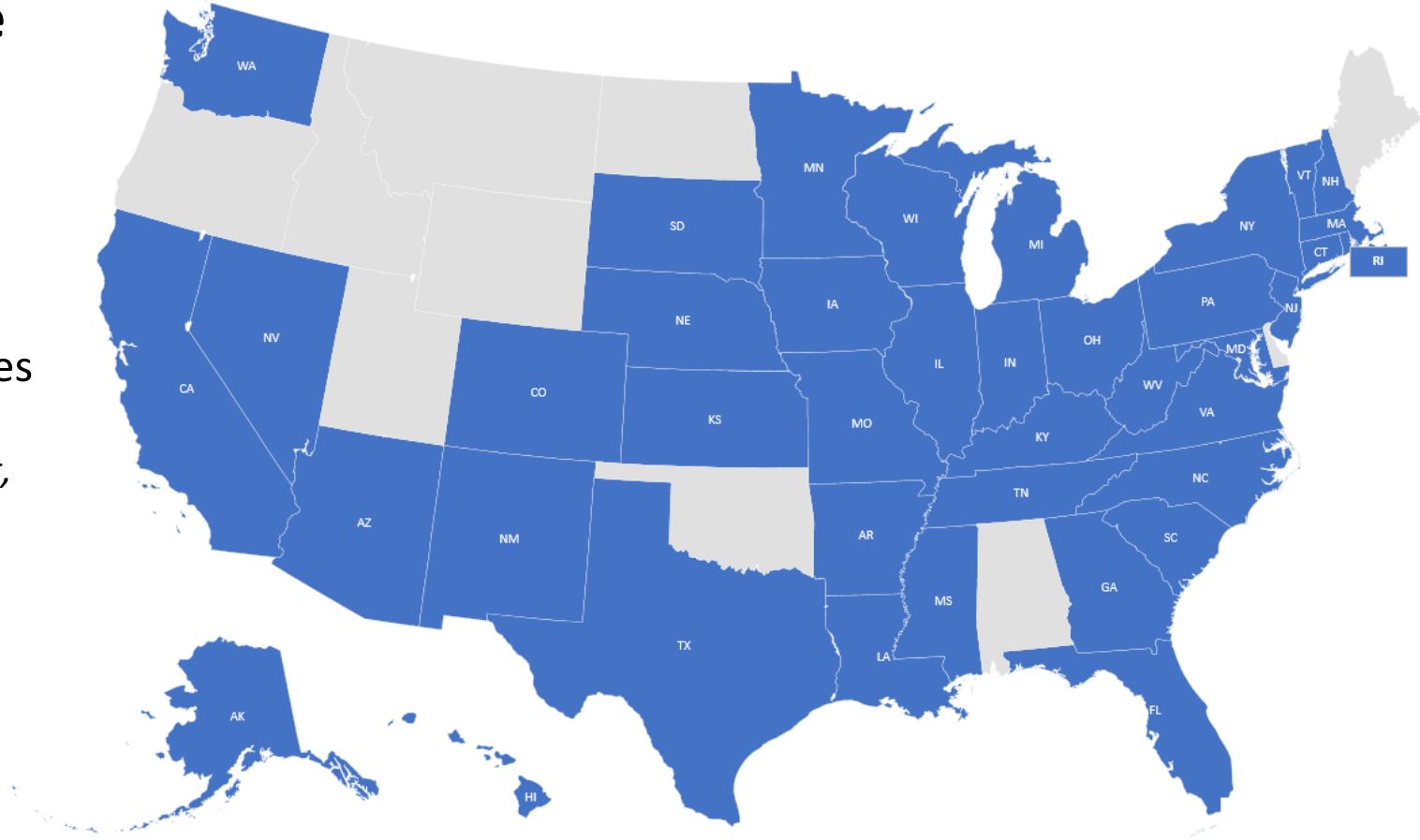
Food Defense, Human and Animal Food (HAF) Product Testing, Capacity/Capability Development, Whole Genome Sequencing (WGS) Method Development/Validation (MDV) Studies, Data Exchange, Sample Collection, Special Tracks

55

Laboratories across all tracks

40

States



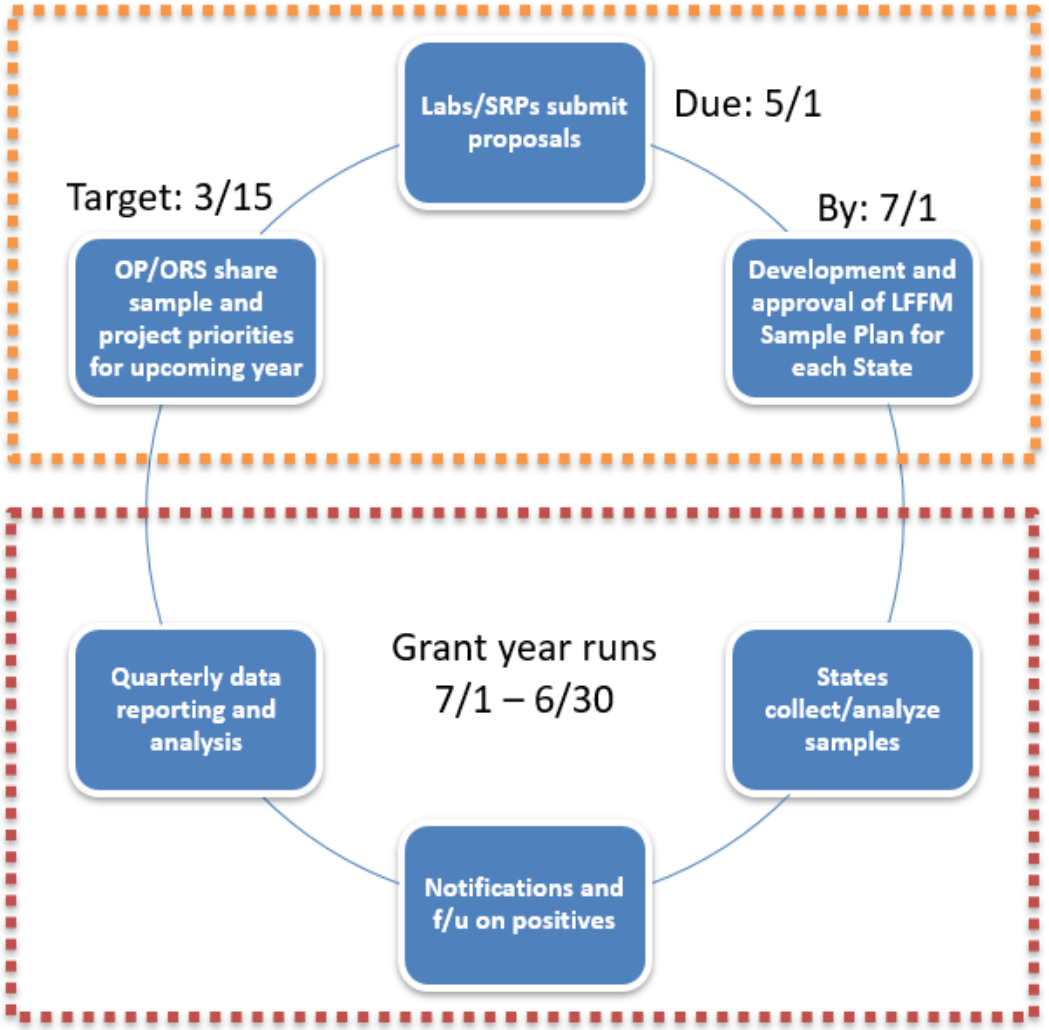
Year 4 Funding: ~$23.5M

Year 4 Tracks

Project Type	# Labs	# Samples	Project Type	# Labs	# Samples
Micro – Food Defense	12	n/a	**Chem – Food Defense**	11	n/a
Micro – Human Food (HF) Product Testing	25	9,150 *Unique analyses*	**Chem – Human Food (HF) Product Testing**	26	7,400 *Unique analyses*
Micro – Animal Food (AF) Product Testing	18	3,300 *Unique analyses*	**Chem – Animal Food (AF) Product Testing**	15	3,000 *Unique analyses*
Micro – Whole Genome Sequencing (WGS)	31	7,300 *Isolates*	**Chem - Development**	9	
Micro - Development	18	n/a	**Rad – Food Defense**	18	n/a
Sample Collection	31	n/a	**Rad - Development**	Not open in YR4	
Method Development / Validation Studies	23	n/a	**Data Exchange Implementation (New development)**	1	n/a

Planning the Product Testing Tracks

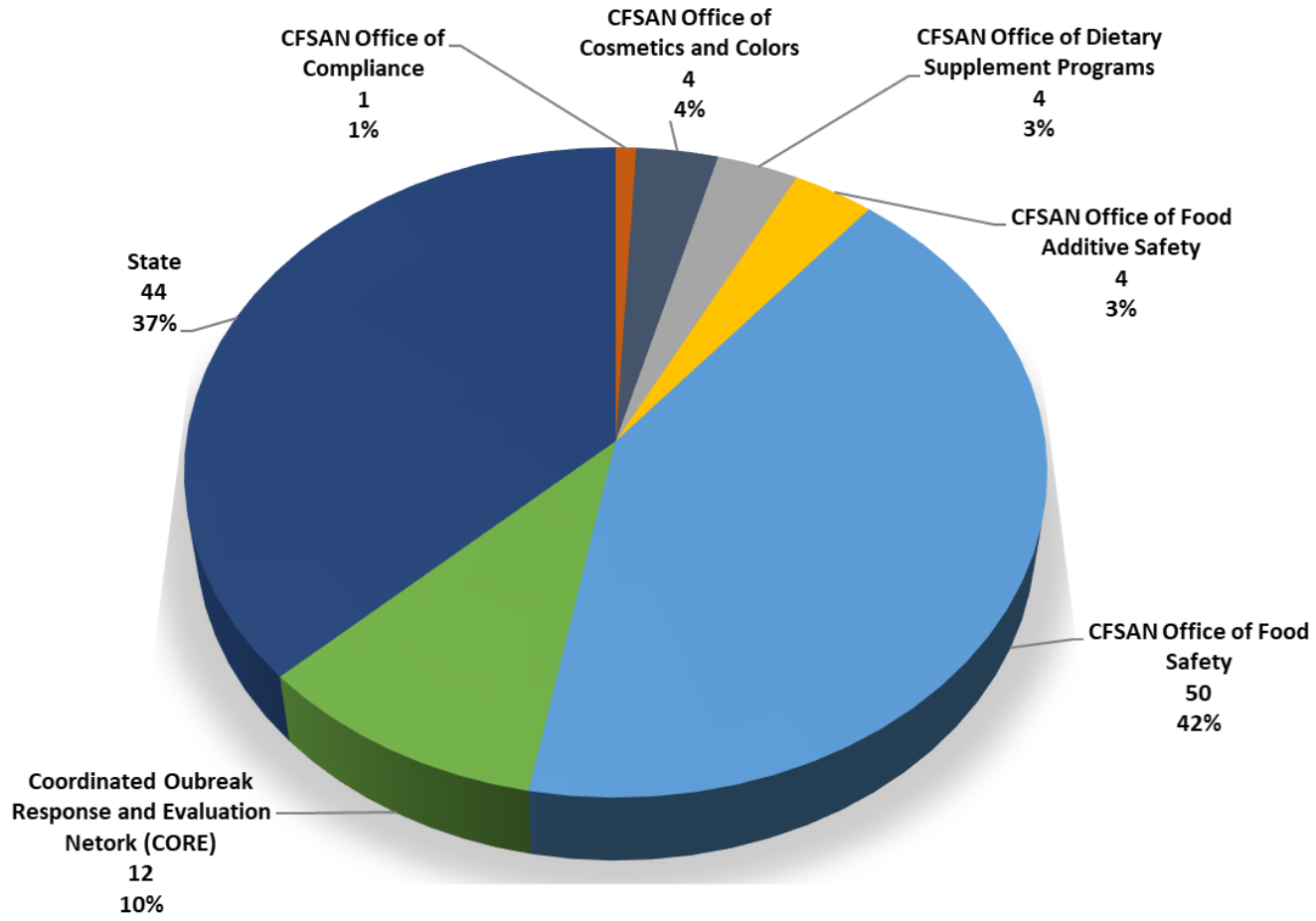
- LFFM provides a list of options (commodity/hazard pairs)
- Lab works with state regulatory program partners to develop sample plan proposal
  - SRP-lab agreement submitted (SRP agrees to lead follow-up)
- Review & approval of Sample Plans
- Process document: LFFM Sample Guide



CFSAN Objectives for Year 4

1. Fully integrate LFFM into CFSAN Work Planning Prioritization process
2. Include sampling options across CFSAN programs.
3. Sample for both microbiological and chemical hazards.
4. Consider signals detection vs. regulatory surveillance.
5. Encourage internal and external stakeholders to submit priorities

CFSAN Work Planning Prioritization Request FY 24 Participation by Office



Year 4 Micro Human Food Surveillance

Product/commodity	Pathogen	Est. planned # of samples
Artisanal Ice Cream	*Salmonella, Listeria monocytogenes*	~500
Dietary Supplements (containing mushroom ingredients)	*Salmonella*	~150
Enoki Mushroom	*Listeria monocytogenes*	~250
Green Onions (whole)	*Salmonella*	<50
Soft Queso Fresco-type Cheese	*Listeria monocytogenes*	~1,000
Leafy Greens - Controlled Environment Agriculture (Hydroponic, Aquaponic)	*Salmonella, Listeria monocytogenes, EHEC/STEC*	~350
Leafy Greens, including spinach – Bagged	*Salmonella, Listeria monocytogenes, EHEC/STEC*	~1,000
Melon - Cantaloupe, Fresh, Whole	*Salmonella*	<50
Onions (whole)	*Salmonella*	<50
Raw Milk Cheese	*Salmonella, Listeria monocytogenes*	~300
Smoked Fish	*Salmonella, Listeria monocytogenes*	~500
Soft Cheese	*Listeria monocytogenes*	~500
Sprouts	*Listeria monocytogenes*	~800
Tomatoes (whole, raw)	*Salmonella*	<50
Wood Ear Mushroom	*Salmonella*	~100
Misc. products of local interest (state-proposed)	*Salmonella, Listeria monocytogenes*	~200

Who collects these samples and from what facilities?

- Year 2 Micro Human Food Surveillance Data

	Human Food	Animal Food
Total Samples Collected & Analyzed	7,728	3,058
Collecting Organization		
State Laboratory	1,855 (24%)	582 (19%)
State Regulatory Program	5,757 (74%)	2,476 (81%)
FDA	30 (0.4%)	--
Third Party (e.g., contract with IEH Laboratories)	86 (1%)	--
Collection Location (Facility Type)		
Retail	6,998 (91%)	2,529 (83%)
Distributor, Manufacturer or Grower	730 (9%)	529 (17%)

What happens if a sample is positive?

- The State Regulatory Program (SRP) with jurisdiction has primary responsibility for follow-up
  - SRP will share information, coordinate with FDA throughout the investigation/follow-up
- 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 (e.g., detection of *Listeria innocua*)
- Follow-up activities may include:
  - Referring the sample to another SRP if it was produced out of state (most samples are collected at retail)
  - Document collection/traceback from retailer, distributor, and/or manufacturer levels
  - Notifying the responsible firm
  - Discussing preventive measures and corrective actions with the firm
  - Conducting an investigation at the facility
  - Collecting additional samples
  - Adding firms to import alert (FDA)
- Process document provided to labs and SRPs: LFFM Sample Guide

LFFM support of GenomeTrakr

- In year 1, we established WGS capabilities in 6 new labs
- Currently fund 31 labs annually to maintain WGS capability and sequence isolates
- LFFM labs sequence and submit thousands of isolates per year
  - All pathogens isolated from LFFM surveillance testing are sequenced
  - Labs also develop partnerships with academic and sometimes international partners to access and sequence historical caches of isolates
  - Data goes into NCBI and is critical resource during outbreak investigations
- In Year 2-3, labs also worked on Wastewater Surveillance for SARS-CoV-2 Variants
- GenomeTrakr Network | FDA

Year 3 Method & Capacity Development

- Implemented a harmonized method for pesticide testing
- Implemented methods for detection of sesame allergen
- Implementing a method for testing Salmonella from agricultural water (in progress)
- Supporting a Multi-lab Validation for ICP-OES analysis of nutrient elements (in progress)
- Extended a glyphosate method to new matrices (foods)
- Developed a new method for quantification of aflatoxins in pelleted animal feeds
- Developing a method for Arsenic speciation in seafood using LC/ICP-MS
- Supported a Multi-lab Validation for Salmonella qPCR (update to BAM Ch5)
- Extended Loop-Mediated Isothermal Amplification (LAMP) screening method for Salmonella to new matrices (foods)

Accomplishments – Product Testing Track

Track	Year 1	Year 2	Year 3
Micro – Human Food Product Testing	25 labs Planned: 5,938 samples* Analyzed: 5,919 samples (100%)	25 labs Planned: 7,070 samples* Analyzed: 7,728 samples (109%)	25 labs Planned: 9,150 analyses Data in progress
Micro – Animal Food Product Testing	21 labs Planned: 4,163 samples* Analyzed: 4,545 samples (109%)	16 labs Planned: 3,250 samples Analyzed: 3,058 samples (94%)	19 labs Planned: 3,550 analyses Data in progress
Chem – Human Food Product Testing	26 labs Planned: 5,025 samples* Analyzed: 3,923 samples (78%)	26 labs Planned: 6,068 samples* Analyzed: 6,134 samples (101%)	26 labs Planned: 7,400 analyses Data in progress
Chem – Animal Food Product Testing	21 labs Planned: 4,213 samples* Analyzed: 4,305 samples (102%)	15 labs Planned: 3,300 samples Analyzed: 3,200 samples (97%)	15 labs Planned: 3,000 analyses Data in progress
Total	**18,692 samples analyzed**	**20,120 samples analyzed**	**23,100 analyses planned**

**Planned sample accomplishments prorated due to delays in approval to start sampling for the year*

Track	Year 1	Year 2	Year 3
WGS	28 labs Planned: 7,900 isolates Analyzed: 3,566 isolates (45%)	31 labs Planned: 8,050 isolates Sequenced: 5,824 isolates (72%)	31 labs Planned: 7,900 isolates Data in progress

Where can I find more information?

[Laboratory Flexible Funding Model Cooperative Agreement Program | FDA]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LFFM Year 1 Accomplishments

Capacity & Capability Expansion

- 12 labs stood up BAM Ch19b for Cyclospora: Doubled national Cyclospora testing (critical for recurring outbreaks)
- 9 labs stood up Luminex MAGPIX for Allergen testing
- 14 labs developed or expanded alpha, beta, and gamma detection capabilities in food (radiochemistry)
- 6 labs stood up Whole Genome Sequencing (WGS) capability
- 27 laboratories conducted method development/validation activities – looking at new methods/technologies

1st Annual LFFM Meeting

- Virtual format, held 5/24-5/27/21
- 13 general sessions and breakout sessions; 44 presentations
- 329 registered attendees and 67 speakers

Surge Capacity & Notable Projects

- Toxin screen & pentobarbital testing on samples linked to consumer complaint (pet deaths)
- Melamine testing of pea protein (live import entry) when FDA servicing lab equipment was down
- Proof of Concept for ORA DX - Import sample pilot (2 labs); 15 labs funded to begin ORA DX connection

Product Testing Tracks: Recalled Products

Pathogen	Products	Action
Salmonella	Tahini, Sesame Oil, Halva, Pet Food, Dog Food, Raw Pet Food*, Poultry Treats	Recall (6) Consumer Advisory (1)
Inorganic Arsenic	Infant Rice Cereal	Recall
Aflatoxin	Dog Food	Recall
Sulfites	Dried Fruit	Recall
Cyclospora	Basil	Recall
E. coli & S. aureus	Cheese	Consumer Advisory

**Raw Pet Food recalled for Salmonella and Listeria*

Lessons Learned from Year 1

- LFFM provides resources to states to maintain, build, and enhance capabilities/capacities in their state, and to protect consumers in their state through surveillance testing
- LFFM labs provide valuable data about hazards in FDA regulated products; aligned with FDA's public health mission
- **There is great value and opportunity in LFFM capacity and data, despite growing pains**

LFFM Year 2 Accomplishments

Surge Capacity Support & Notable Projects

- Provided surge capacity testing for Cronobacter PIF recall
- 2 LFFM M-FD labs provided surge capacity testing for a *Legionella* investigation involving domestic cruise ships.
- Supported pivoting of LFFM planned samples allow states to test products associated with ongoing illness investigations
- LFFM labs participated in FDA RTE Cereal 3rd party collection pilot (*Salmonella* testing, IEH collections, 116 samples, YR1-2)

LFFM Webinar

- In lieu of Annual meeting, held 2 virtual webinars
- 3/23/22 – Grants Management, ~125 attendees
- 4/20/22 – LFFM Case Studies (presenters from FDA and states) – enokis/LM, asparagus/pesticide, ~150 attendees

ORA Data Exchange (ORA DX)

- 6 laboratories began implementation of ORA DX – either NFSDX, DX Client, or ORAPP
- First successful transmission of state-collected, state-analyzed samples into ORA DX (MD Dept of Health)

Capacity & Capability Expansion

- EHEC/DEUF testing capability developed; Cyclo is paused (14 labs, M-C/C Track)
- Salmonella qPCR MLV (9 labs, MDV Track)
- Verification and subtyping of *Listeria monocytogenes* using qPCR MLV (9 labs, MDV Track)
- Gamma spectrometry exercise – fresh romaine (18 labs, R-FD Track)
- Chain of custody and data package training (all FD Tracks)
- Training and support for labs standing up LM enumeration capabilities (M-HF Track)
- Harmonize toxic element and iAs speciation testing - lowering LOD/LOQs, duplicate analysis (C-HF Track)

Reflections on Year 2

- LFFM provides resources to states to maintain, build, and enhance capabilities/capacities in their state, and to protect consumers in their state through surveillance testing
- LFFM labs provide valuable data about hazards in FDA regulated products; aligned with FDA's public health mission
- **Recipe for success: the right strategic inputs + a strong written framework + a focus on mutual benefit (FDA/state)**