

LFFM Project Briefing

MFRPA/Governmental Food and Feed
Laboratory Accreditation Meeting

April 10, 2019

Erin Woodom-Coleman, FDA/OP

Agenda

- Project Background
- Project Timeline
- LFFM Design
- Communications Strategy
- Next Steps
- Questions & Feedback

FDA State Lab Investment

- In the last 10 years, ORA has directly awarded approximately \$172M to over 60 state labs across cooperative programs and contracts.
- Funding vehicles include:
 - The Food Emergency Response Network (FERN);
 - Whole Genome Sequencing cooperative agreements;
 - Manufactured Foods Regulatory Program/ISO cooperative agreements;
 - Animal Feeds Regulatory Program/ISO cooperative agreements;
 - Rapid Response Team cooperative agreement-analytical support; and
 - Contracts for analytical support, including Human (product and environmental testing) and Animal Food.

Project Goals & Deliverables

- Conduct assessment of current State & FDA laboratory portfolio, including various CAPs and FERN. **Completed.**
- Combine multiple state cooperative agreements into one funding vehicle: Laboratory Flexible Funding Model (LFFM). LFFM will ensure more effective monitoring, oversight and accountability of the funds.
- FDA plans to announce this new model in Winter FY20. Funding via this model may begin in Summer 2020.



LFFM Collaboration

- LFFM Workgroup - Consists of staff across FDA:
 - ORA
 - CVM
 - CFSAN
 - OAGS
- LFFM Advisory Stakeholders:
 - Senior FDA leadership
 - State Lab Partners
 - APHL

Milestones and Progress

Milestone	Completion Date	Status
Project kick-off completed	9/29/2017	Complete
State lab portfolio assessment completed	5/30/2018	Complete
LFFM design drafted	6/29/2018	Complete
LFFM design approved	9/28/2018	Complete Approved by: <ul style="list-style-type: none"> • ACRA – 7/20/2018 • FVM Governance Board – 8/9/2018
FOA and NOITP drafted	June 2019 (target)	FOA writing began in September 2018
FOA and NOITP approved & submitted to OAGs	November 2019 (target)	Reviewers and approvers are FDA Sr. Leadership
New awards made	Summer 2020 (target)	

LFFM Design



Disciplines & Analytical Tracks

Discipline	Analytical Track
Micro	<input type="checkbox"/> food defense pathogens/BSL-3
	<input type="checkbox"/> food safety pathogens
	<input type="checkbox"/> Virology
	<input type="checkbox"/> Parasitology
	<input type="checkbox"/> Specialty: (WGS, BSL3)
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Discipline	Analytical Track
Chem	<input type="checkbox"/> LC/MS
	<input type="checkbox"/> GC/MS
	<input type="checkbox"/> ICP/MS
	<input type="checkbox"/> Specialty & Screening Technologies such as XRF, ELISA, Ion Chromatography,
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Discipline	Analytical Track
Rad	<input type="checkbox"/> alpha/beta
	<input type="checkbox"/> gamma
	<input type="checkbox"/> Specialty – Gamma Portable Units

For each track selected must choose: Maintenance or Development Option

Maintenance	
Operations	Equip. Refresh (only available at certain times, per capital investment plan)
TBD \$ amt: costs of analysis for desired number of samples (taking into account personnel, supplies, training)	TBD \$ amt -Cost of new platform
Development	
TBD \$ amt -Cost of platform + costs of analysis for desired number of samples (taking into account personnel, supplies, training). ISO accreditation funding could be an option.	
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Funding level 1
Center of Expertise: Lab applying for and awarded for many analytical tracks within a discipline.

Funding Level 2
Specialty/Surge: Lab applying for and awarded for select analytical tracks within a discipline.

A single agency can apply for as many discipline/analytical track combinations as they qualify for

LFFM Design - Funding process

- Labs apply for as many disciplines/analytical tracks as they are interested in and qualify for
 - FOA: funding priority assigned to labs applying for many analytical tracks (Centers of Expertise) – incentivizes labs to apply broad-based
 - FDA will determine the number of tracks a laboratory needs to be funded for to be considered a Center of Expertise
- FDA pre-determines number of centers/labs to fund (based on capacity needs)
 - Set number of centers per discipline (X micro., X chem., X rad.)
 - Set number of additional labs per analytical track (e.g., X BSL-3, X ICP/MS, etc.)
- Applications are objectively reviewed and scored
 - Award Centers of Expertise first – priority, highest scored applications
 - Award additional analytical tracks (Specialty/Surge Labs) based on FDA need (beyond what is provided by Centers of Expertise) – award in order of score

LFFM Communications Strategy

- Key Messaging
 - LFFM goals and design
- Target Audience
 - State laboratory partners
 - Key national associations (APHL, AAFCO, AFDO, NASDA, etc.)
 - State food emergency response groups/programs (FERN, RRT, FPTF, GenomeTrakr, etc.)
- Communication Vehicles
 - National broadcast message
 - 50-state call
 - Various external stakeholder and national association meetings
- Timeframe
 - January 2019 - January 2020

Next Steps

- Continue developing analytical tracks, work areas and scoring criteria for the FOA, including:
 - Sampling and WGS lab selection process; and ISO support.
- Incorporate FDA's sampling & testing needs, as determined in the outcome-based strategic plan, into the LFFM
 - In development by a cross-center planning workgroup
 - LFFM is the delivery mechanism for work completed by state laboratory partners
 - Includes short and long term needs
 - Separate project team will be charged with overall execution of the strategic plan

