LFFM Project Briefing

APHL Annual Meeting
June 4, 2019
Abe Brown
Agenda

• What’s the Big Picture: Mutual Reliance
• Project Background
• Project Timeline
• LFFM Design
• Communications Strategy
• Next Steps
• Questions & Feedback
Mutual Reliance is a seamless partnership that enables FDA and States with comparable public health systems to:

- fully rely on,
- coordinate with, and
- leverage

one another’s work, data, and actions to achieve the public health goal of a safer national food supply.

We all benefit from Mutual Reliance by leveraging partner agencies to improve industry compliance with a goal of reducing food borne illness outbreaks and increasing public health protection in our integrated Food Safety System.
Mutual Reliance Benefits

- Provides framework for regulatory cooperation so that FDA and States can partner with, rely on, and leverage one another’s work to ensure the safety of food and public health protection.

- Fosters close partnerships and leverages work done by competent State verified with comparable food safety systems.

- Provides an objective and transparent process for ensuring a safe domestic food supply.

- Reduces duplication of efforts and allows State work to count toward inspection frequency mandates.

- Establishes a shared process for prioritizing risks and focusing scarce resources.

- Promotes consistency and information sharing of lab and inspection results.

- Increases speed and effectiveness of surveillance, response, and post-response efforts.
Achieving an Integrated Food Safety System (IFSS)

Outcomes

- Reduction in Foodborne Illness
- Faster Response
- Consistent, Quality Programs
- Mutual Recognition
- Mutual Reliance
- One Workforce

Supports & Enhances

- Commissioning, Information Sharing Agreements, & FMD-50
- Stakeholder & PFP Coordination
- State/Federal Program Evaluation, Assessments, & Verification Audits
- Cooperative Agreements, Grants, & Contracts
- MOUs/Partnership Agreements
- Integration Assessment Model/ROI Analysis
- Standardization of Workforce
- Development & Sharing of Best Practices

Foundational

- Regulatory Program Standards
- Joint Response to Food Emergencies
- Joint Compliance & Enforcement
- Two-way Exchange of Data and Information
- Joint Work Planning, Inventory Reconciliation, & Risk Prioritization
- Joint Training Development & Implementation
- Laboratory Capacity Building
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:
  - Office of Regulatory Affairs (ORA)
  - Center for Veterinary Medicine (CVM)
  - Center for Food Safety and Applied Nutrition (CFSAN)
  - Office of Acquisition and Grants Services (OAGS)

- LFFM Advisory Stakeholders:
  - Senior FDA leadership
  - State Lab Partners
  - APHL
## Milestones and Progress

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<tr>
<th>Milestone</th>
<th>Completion Date</th>
<th>Status</th>
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<tbody>
<tr>
<td>Project kick-off completed</td>
<td>9/29/2017</td>
<td>Complete</td>
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<tr>
<td>State lab portfolio assessment completed</td>
<td>5/30/2018</td>
<td>Complete</td>
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<tr>
<td>LFFM design drafted</td>
<td>6/29/2018</td>
<td>Complete</td>
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<tr>
<td>LFFM design approved</td>
<td>9/28/2018</td>
<td>Complete Approved by:</td>
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<td>• ACRA – 7/20/2018</td>
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<td>• FVM Governance Board – 8/9/2018</td>
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<tr>
<td>FOA and Notice of Intent to Publish (NOITP) drafted</td>
<td>June 2019 (target)</td>
<td>FOA writing began in September 2018</td>
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<td>FOA and NOITP approved &amp; submitted to OAGs</td>
<td>November 2019 (target)</td>
<td>Reviewers and approvers are FDA Sr. Leadership</td>
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<td>New awards made</td>
<td>Summer 2020 (target)</td>
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### Disciplines & Analytical Tracks

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<td>Food Defense/BSL-3</td>
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<td>Human Food and Environmental Samples</td>
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<td>Whole Genome Sequencing/Genome Trakr</td>
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<td>Chem</td>
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### For each discipline: Maintenance/Development Options

#### Maintenance *
- Utilizing existing operational capacities and capabilities.
- Allow for equipment purchasing.
- TBD $ amount: costs of analysis for desired number of samples (taking into account personnel, supplies, training); equipment purchase; small scale method validations and method extensions.

#### Development *
- Develop new analytical capability
- TBD $ amount: Cost of platform + costs of analysis for desired number of samples (taking into account personnel, supplies, training).

### Special Projects Track *
- Priorities could include: Sample Collections, IT Upgrades, and Method Development

*A single agency can apply for as many discipline/analytical track combinations of which they qualify.*

* Using grant funds for ISO accreditation may be possible under special circumstances.
LFFM Design - Funding process

• Labs apply for as many disciplines/analytical tracks as they are interested in and for which they qualify
  – FOA: structured to incentivize labs to apply broad-based
  – State labs could apply individually or in collaboration with other labs in the same state

• Applications are objectively reviewed and scored

• Awards are made based on determined FDA capability and capacity needs
  – Selects a number of broad-based labs per discipline (X micro., X chem., X rad.) – highest scored applications
  – Selects additional labs per analytical track needed beyond the capacities/capabilities of broad-based labs (e.g., X food defense, X human food and environmental sampling, etc.) – 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, Rapid Response Teams, Food Protection Task Force, 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