

Laboratory Flexible Funding Model Project Briefing

123rd AFDO Annual Educational Conference

June 22, 2019

Erin Woodom-Coleman

Agenda

- What's the Big Picture: Mutual Reliance
- Project Background
- Project Timeline
- LFFM Design
- Communications Strategy
- Next Steps
- Questions & Feedback



Mutual Reliance

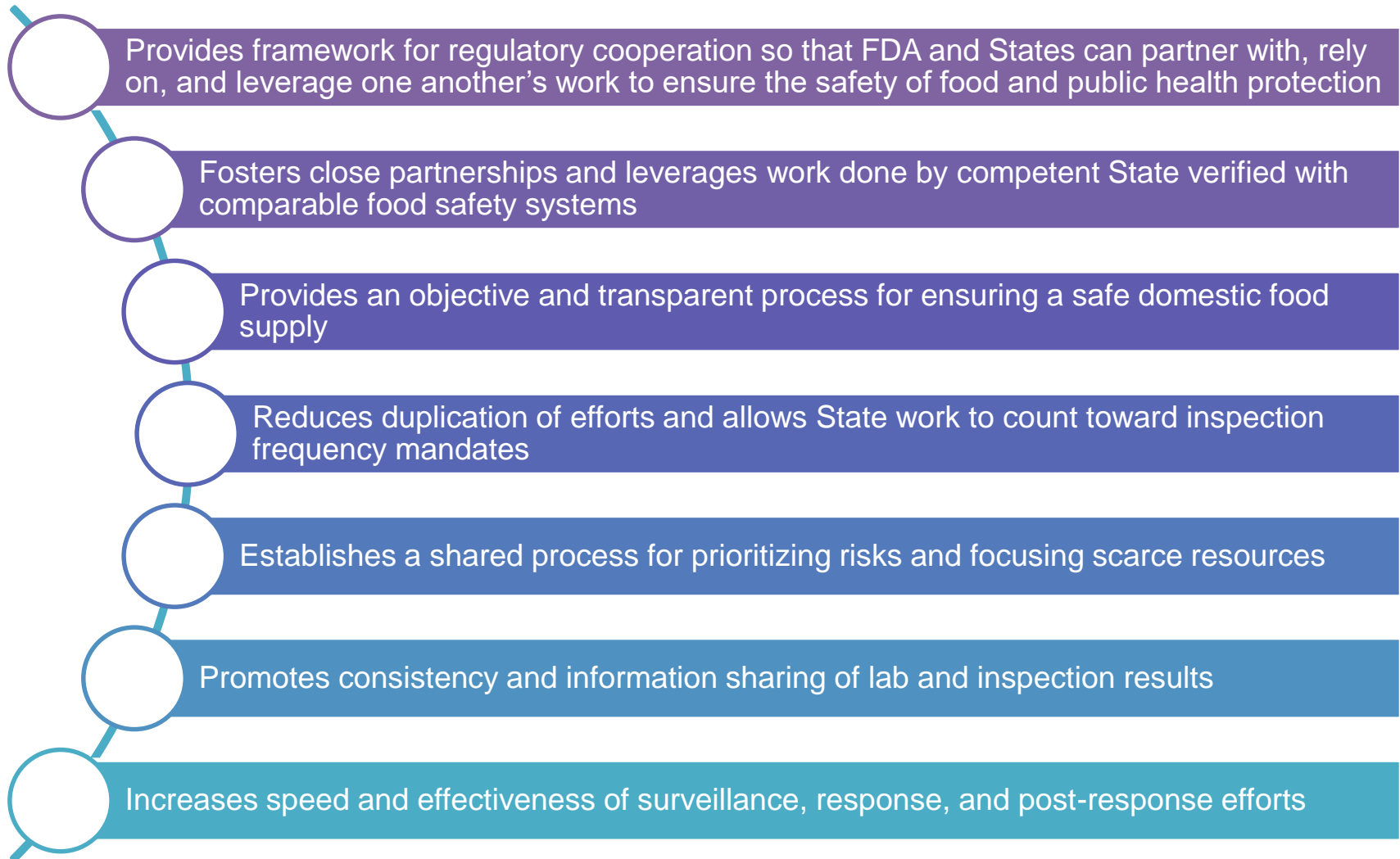
Mutual Reliance is a seamless partnership that enables FDA and States with comparable public health systems to:

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

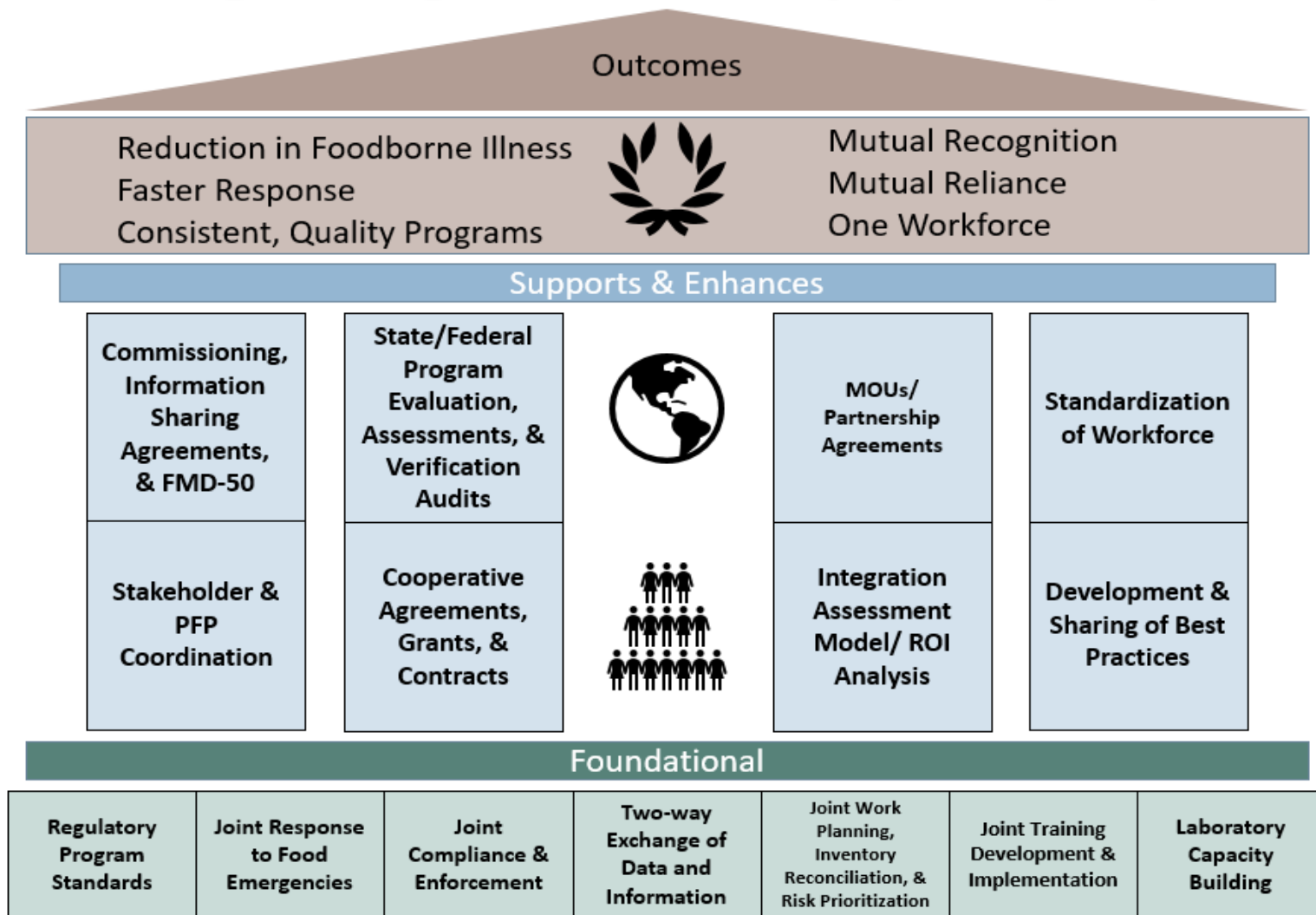
one another's work, data, and actions to achieve the public health goal of a safer national food supply.

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



Achieving an Integrated Food Safety System (IFSS)



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

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 Notice of Intent to Publish (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
	<input type="checkbox"/> Human Food Product and Environmental Samples
	<input type="checkbox"/> Animal Food Product Samples
	<input type="checkbox"/> WGS/Genome Trakr
Discipline	Analytical Track
Chem	<input type="checkbox"/> Food Defense
	<input type="checkbox"/> Human Food
	<input type="checkbox"/> Animal Food
Discipline	Analytical Track
Rad	<input type="checkbox"/> Alpha
	<input type="checkbox"/> Beta
	<input type="checkbox"/> Gamma

For each discipline: Maintenance/Development Options

Maintenance *
Utilizing existing operational capacities and capabilities.
Allow for equipment purchasing.
TBD \$ amt: 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 \$ amt: 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

