STRATEGIC PLAN FOR STATE HUMAN AND ANIMAL FOOD LABORATORY PARTNERSHIPS

Presented by:
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Background

Assessment of State Lab Cooperative Agreements: 2017 and 2018

Lab Flexible Funding Model: 2018

National Laboratory Network
FDA & States

Strategic Plan: January 2020

Transition to Operations: future
Background

Spring 2018: ORA Lab Assessment

Four sections of analysis and recommendations:
1. FDA’s Laboratory Strategy
2. Laboratory Scope and Capacity
3. Resource Management
4. Operational Support – IT, work planning, etc.
Background

Spring 2018: ORA Lab Assessment

Recommendation 1: Strategic Plan

Scope of an agency-wide strategic approach:

• Mutual Reliance: Strategies to move the FDA towards acceptance and utilization of state laboratory data
• Efficient Operations: Strategies to advance work planning processes and the assignment of sample collections
• Improved Infrastructure: Strategies to better integrate state and FDA data, to streamline the transfer process and sharing of information
Overview

• Provides a roadmap to strengthen FDA’s national laboratory network
  – includes immediate and long-term activities

• Based on ORA Priority 3
  – Leverage and expand ORA’s public health partnerships
Strategic Workplan Elements

Laboratory Strategic Workplan

Top level outcomes, objectives, and activities

Baseline measurement recommendations

Recommendations to update the strategic plan and associated plans
How is the Plan Structured?

Primary Outcome
  Primary Goal
    Laboratory Outcomes
      Laboratory Objective
        Activities & Tactics
Laboratory Outcomes and Objectives

- **Increased Prevention Effectiveness**
  - Develop impactful partnerships by planning work for the efficient collection, analysis, and delivery of public health sample results

- **Increased Detection Capability and Capacity**
  - Support laboratory partners in producing data that support risk assessments, FDA policy development, and enforcement of regulated products

- **Increased Response Capability and Capacity**
  - Ensure state partners meet required analytical capabilities and optimize capacity to support the FDA in addressing food safety, food defense, and other analytical needs in times of emergency and outbreak response
Laboratory Outcome 1 and Supporting Outcomes

- Increase Prevention Effectiveness
  - Execute an expanded work plan
  - Increased sampling efficiency
  - Increased communication efficiency
Laboratory Outcome 2 and Supporting Outcomes

Increase Detection Capability and Capacity

Increase use of system feedback to inform strategic work planning process
Laboratory Outcome 3 and Supporting Outcomes

Increase Response Capability and Capacity

Optimize analytic capabilities and sample capacity of ORA and partner laboratories

Increase assignment execution timeliness
# Baseline Measurement Framework

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Proposed Measures</th>
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<tbody>
<tr>
<td><strong>Increase Prevention Effectiveness</strong></td>
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<tr>
<td>Execute an expanded workplan</td>
<td><em>Expanded workplan = increase in number of completed planned samples AND/OR increase in the number of proposed assignments that end being included in the workplan</em>&lt;br&gt;1. # planned samples analyzed Year over Year (YoY)&lt;br&gt;2. # and % of Center proposed assignments included in workplan (WP) (YoY-proposed assignments)&lt;br&gt;3. #/ % of planned assignments that were issued (YoY)&lt;br&gt;4. # assignments successfully completed for the workplan (YoY-executed assignments)</td>
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<td>Incorporate use of risk-based priorities</td>
<td>5. Out of all proposed assignments, #/ % of assignments based on risk/regulatory action&lt;br&gt;6. Out of all assignments included in the workplan, #/ % of planned assignments based on risk/regulatory action&lt;br&gt;7. Number of assignments based on high-priority hazard/commodity pairs&lt;br&gt;8. Measure number of FDA regulatory assignments issued based upon state data.</td>
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<tr>
<td>Increase efficient sampling</td>
<td>9. #/ % of requested samples collected and delivered to labs on time (per assignment or workplan)</td>
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<tr>
<td>Increase efficiency in assignment process</td>
<td>10. # of assignments issued on time. (delayed from the issue date as stated by Center)</td>
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<td>Efficient sample distribution to labs</td>
<td>11. # of samples to each lab by assignment (% distribution of samples to each state lab by assignment or program area)</td>
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<tr>
<td>Increase efficient communication (getting analytical results to stakeholders)</td>
<td>12. Average # of days between sample completion and communication of results for planned samples sorted by Center (as opposed to program)</td>
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<td>Outcome</td>
<td>Proposed Measures</td>
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<tr>
<td>Increase use of system feedback to inform strategic work planning</td>
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<tr>
<td>process</td>
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<td>Increase usability in analytical data (for compliance actions, research</td>
<td>13. #/% of occurrences where data could not be used for risk assessment or surveillance purposes due to concerns/issues with laboratory findings</td>
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<td>research, tracebacks, etc.)</td>
<td>14. #/% of occurrences where action is not taken/pursued due to concerns/issues with laboratory findings</td>
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<td>• Increase data quality/comparability</td>
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<td>Data Comparability - Increase utilization of non-FDA laboratory data</td>
<td>15. Measure number of state laboratory data packages submitted to the FDA. (Compare those in FFM to those not participating in FFM)</td>
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<td>(i.e. FERN, VET LIRN, etc.) for both food safety and food defense</td>
<td>16. Measure number of FDA regulatory actions taken based upon evidence (i.e. WGS analysis) contained in state laboratory packages.</td>
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<td>• Data Quality – Decrease rejections for quality issues not related to</td>
<td>17. Number of bacterial isolates submitted by states into Genome TrackR (LFFM and non-LFFM).</td>
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<td>data systems integration/interconnectivity</td>
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<td>• Increase effectiveness and efficiency of non-FDA lab package review</td>
<td>18. Number of external/non-FDA packages that require some form of follow-up (regardless of whether the package was accepted/rejected)</td>
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<td>program</td>
<td>19. # of accredited labs to the ISO 17025 standard</td>
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<td>• Data Quality - Increase data systems integration/interconnectivity</td>
<td>20. # of labs that maintained accreditation from previous year</td>
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<td>• Increase laboratory logistics support (PM, supplies, etc.)</td>
<td>21. # of non-FDA lab packages where state evidence was adequate</td>
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<td>22. Timeliness of review of non-FDA packages</td>
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<td>23. Measure the number of states with systems integrated/upgraded with FDA systems (NSFDX).</td>
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<td>24. Actual expenditures vs. projected budget of logistics-related items</td>
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<td><strong>Increase Response Capability and Capacity</strong></td>
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| ➢ Optimize analytic capabilities and sample capacity of ORA and partner laboratories | 25. # of additional samples per assignment that were accomplished based on the additional capabilities provided by partner laboratories.  
26. # of additional samples per assignment that were accomplished based on capacity delta  
27. # and % planned collections that are accomplished and sent to ORA and partner (state) labs |
| ➢ Increase assignment execution timeliness | 28. Time to issue assignment |
Shared Ownership

- CFSAN
- CVM
- ORA
- State Partners

National Laboratory Network
Communication with Stakeholders

- Target Audience
  - FDA/ORA (CFSAN, CVM)
  - State laboratory partners
  - Key national associations
  - State food emergency response groups

- Communications Vehicles
  - Stakeholder meetings
  - Key Messages/FAQs
  - FDA.gov
  - ORA Twitter

- Timeframe
  - November 2019 – 2020
Transition Recommendations

Operations

- Work Planning
- IT Tracking
- Strategic Plan Update Cycle
Strategic Plan Update Cycle

- Stimuli
  - Updated Plan approved
  - Updated priorities, strategies, or outcomes are issued
    - Updates to strategies
    - Updated priorities, strategies, or outcomes are issued
      - Updates to strategies
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      - Updated priorities, strategies, or outcomes are issued
        - Updates to strategies

- Annual review of plan against updates
  - Review/incorporate State stakeholder feedback