Perspectives on FSMA, Lab Testing Standards, and Data Acceptance

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Topics for Today’s Discussion

I. Setting the Stage
   - Why we test/how we test
   - FSMA’s call for partnerships and capacity building
   - The path to leveraging/establishing lab capacity

II. Establishing Laboratory Standards
   - Perspectives:
     - Laboratory partnerships based on mutual reliance
     - Laboratory accreditation – the customer and the provider
   - Laboratory methods, performance standards & fit-for-purpose

III. Key Approaches and What We’ve Learned (thus far)
   - Large scale (future state) sampling paradigm
   - Mutual reliance pilots
   - Laboratory alliance outreach
   - The FVM Science and Compliance Coordination Group
Robust Testing Capabilities Support...

- **Outbreak investigations**
- **Surveillance**
  - Risk-informed targeting of operational resources
  - Emerging issues
  - Baseline/prevalence data for risk analysis/policy decisions
- **Verification**
  - Ensure environmental sampling programs are robust
  - Preventive controls/mitigation strategies/corrective actions effective
  - Import controls are effective: FSVP, Third Party Accreditation, VQIP, Import Certification, Systems Recognition
- **Compliance**
  - Removal of adulterated/misbranded foods from market
  - Environmental assessments / root cause(s)
  - Enforcement actions
Testing to Support Research Needs

- To fill research data gaps,
- Assess newly developed methods for validation suitability
- To acquire data to support risk assessments
- To obtain baseline data on a particular commodity for the purpose of modeling or to support policy development.
Sec. 110: Building Domestic Capacity
- FDA, USDA, and DHS
- Capacity for laboratory analyses
- Recommendations for surveillance, outbreak response and traceability involving fruits and vegetables

Sec. 202. Laboratory Accreditation
- Recognition of Laboratory Accreditation
  - Establish an accreditation program & criteria for recognition of accreditation bodies
  - Recognition of accredited labs
- Model Laboratory Standards (for accreditation)
  - Develop model standards for accreditation
- Testing Procedures
  - By accredited labs
  - Electronic reporting & a process for private lab package reviews by FDA

Sec. 205: Surveillance
- Federal, state, local coordination of hazard/risk-based surveillance systems
- Strategies to leverage and enhance food safety and food defense capacities, i.e. lab resources, capabilities, epidemiological tools
The Benefits of an Integrated Laboratory Science System

- Facilitates the sharing of results between strategic partners.
- Assures comparability of analytical methods and acceptability of laboratory results between partners.
- Recommends processes to leverage laboratory resources to increase information about the food supply chain burden sharing.
- Advances initiatives among strategic partners for the use of best practices to prepare human and animal food testing laboratories for accreditation.
Points to Consider

- Mutual reliance
- Accreditation
- Communication and Consistency
  - FDA labs
  - State and local labs
  - Private labs
- The Lab Path:
  - Define the need
  - Method(s)
    - Fit-for-purpose
  - Performance standards
  - Data acceptance
The Concept of Mutual Reliance

A general perspective:
- The ability of federal and state partners to rely on each other’s food safety work as competent regulatory authorities, work such as inspections, sample collections, outbreak, recall and complaint data, etc.

A laboratory perspective:
- The standardization of laboratory capabilities and competencies to provide confidence in the integrity, scientific validity, and consistency of laboratory analytical data; to provide assurance and trust in the quality of data submitted to the end user.
Accreditation

**DEFINITION**
A rigorous evaluation, conducted by an independent science-based organization to assess the overall capability and competency of a lab and its quality management system; formal recognition of the technical competence of a lab to perform specified methodologies;

*FDA as the “Customer”; the laboratory as the “Provider”*
Accreditation as a baseline level of overall laboratory quality, not a singular guarantee for data acceptance; communication between parties necessary to ensure the laboratory provides the level of services required/needed for the customer to meet its responsibilities as a regulatory authority.
The data received from the laboratory must be accurate, timely and reliable. Prior to entering into an agreement, the laboratory (the provider) must work closely with the food or feed regulatory program (the customer; The FDA) to ensure it provides the needed services (has the capacity and capability) and to encourage (facilitate) data acceptance for regulatory action (by the FDA in a timely manner). This includes the use of test methods which meet the needs of the customer and are appropriate for the tests undertaken (situation at hand)....

†Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories
All laboratories *(accredited or not)* should be operating under a Quality Management System (QMS)

- Governs all activities that directly or indirectly contribute to the quality of testing; **minimum set of standards**;
- May involve additional criteria for food/feed program coordination and alignment

### Minimum Elements to Assess Needed for Regulatory Data Acceptability

**Pre-analytical**
- 1. Program requirements
- 2. Sample collection
- 3. Chain of custody
- 4. Sample receipt

**Laboratory Analyses**

**Post-analytical**
- 1. Reports
- 2. Record keeping
- 3. Data Packages
A Perspective on Accreditation, Analytical Methods & Laboratory Data Acceptance

- Quality Assurance
- Proficiency Testing
- Quality Control Samples
- Analytical Worksheets
- Availability of the raw data
- Staff training and competency assessment

Analytical method(s), validation & verification

- “Fit-for-purpose” and what it means to the provider; to the customer
- Performance standards
- Official/reference method verification
- Validation of non-standard methods
Questions About Analytical Methods: The Answers Will Drive Data Acceptance

- What will the data be used for? Where, along the spectrum of reasons that the FDA tests, does this testing need fit in?
- What are the lab’s (the provider’s) capabilities and capacities and does it match what the customer requires?
  - instrumentation
  - resources for validation, verification, method extension
- Qualitative, quantifiable, screening, confirmatory?
  - Different performance standards will apply
- Harmonization of fed-state method portfolios; FDA reference methods, the easiest path forward.
- How and when are needs defined and realistic capabilities & capacities communicated?
Key Approaches to Lab Capacity Building

Large-Scale Surveillance Sampling

Will require partnerships and resource leveraging for capacity building

- Federal
- State
- Private/contract labs

Collect statistically significant data that can proactively identify public health risks in real time.

Focus surveillance sampling resources on those foods that pose the greatest public health risk.

Establish standardized, transparent, and collaborative processes and communications across the spectrum of stakeholders.
The Steering Committee (made up of FDA Risk Management Groups) prioritizes commodities and practices that pose a risk to public health, taking into account known knowledge gaps, FVM priorities, and other sampling-specific criteria. The Steering Committee proposes annual sampling targets and works with OFVM Leadership, CFSAN Leadership, and ORA Leadership to confirm sampling strategy for a specific year.

The Steering Committee also assesses an assignment’s readiness to begin development to determine how long assignment scoping will take. Depending on the number of gaps for the assignment, the scoping could take up to three years.

Engage stakeholders earlier in the process and validate already determined assignments. Asking for help on how to sample, not what to sample.

Following leadership consensus on sampling priorities, CFSAN and ORA jointly facilitate scoping and developing sampling assignments (how many samples, under what conditions) with input from various offices such as CFSAN OC, CFSAN ORS, CFSAN Program Offices, ORA OFFO, ORA DIO, ORA ORS, and external partners.

Field Sample Collectors execute assignments and send findings to the labs.

Labs perform analysis on samples, and enter data into FACTS, eLexnet or comparable system (includes ORA, state, private and FERN labs).

Project Coordinators monitor sampling and communicates progress to ensure sampling is on schedule, samples are being analyzed and risks are being mitigated. Project Coordinators include representatives from CFSAN OC, CFSAN ORS, ORA OFFO DFFPOI, ORA DIO, and ORA ORS.

Program Office evaluates data and establishes strategies/ further sampling recommendations.

Throughout the iterative process data, findings and recommendations of the Program Offices will be communicated to ORA as well as other risk analytics and research FVM Groups.

The Project Coordinators, in consultation with CFSAN and ORA Headquarters, works with the Program Office to send findings to Steering Committee who will use recommendations and findings to inform the next year’s sampling priorities. Final reports will be communicated with external parties as appropriate.
Large-Scale Surveillance Sampling

- The final phase of development is nearing completion.
- Agency will increasingly rely on its state laboratory partners (particularly FERN laboratories) to conduct such targeted, non-research surveillance of high risk commodities.
- During the piloting phase, the FERN microbiology cooperative agreement program (micro-CAP) laboratories played a key role in one of the initial large-scale surveillance pilots (avocado testing for *Listeria monocytogenes*) in 2014.
- This testing relationship will continue to expand as this new surveillance paradigm is fully implemented.
Mutual Reliance Pilots

Three pilots conducted by the federal-state field staff representing the Eastern, Midwest and Western geographical areas of the country:

1. California Department of Health Services and ORA San Francisco’s and Los Angeles’ District Offices
2. Wisconsin Department of Agriculture and ORA Minneapolis District Office
3. New York Agriculture and Markets and ORA New York District Office
Mutual Reliance Pilots

- All three pilots contained a lab component to test several unique elements of mutual reliance:
  - Utilize the existing egg safety efforts and data in the development of a national integrated food safety system based on mutual reliance.
  - Lab capacity need based on expanded work plan obligations; interchangeability; an adjunct lab of the FDA.
  - Import testing and broadening the use of state-derived data to support FDA actions.
Outreach Activities

- Public health organizations
- Private lab alliances
The FVM Science and Compliance* Coordination Group

- An advisory body of the Science and Research Steering Committee (SRSC).
- Forum to facilitate exchange of compliance-related* information between CFSAN, CVM, ORA and OFVM with regard to laboratory activities and needs to support the regulatory mission.
- Provides cross-center expertise where integration of research; regulatory methodology gaps; methods development and lab implementation, compliance strategies; and, work planning priorities are needed.

*FDA’s activities to evaluate regulated industry’s compliance with the laws FDA enforces, enforcement actions FDA takes to encourage Industry’s compliance, and, the operations that support these activities
The FVM Science and Compliance Coordination Group

Initial Activities:

- Development of data acceptance criteria
- Development of criteria for the release of CRO lab data during outbreak investigations (in coordination with SCORE)
- Development of an integrated communication strategy
Expectations, needs, capabilities, and limitations must be communicated clearly by both the customer and the provider in the early planning phase for laboratory-based mutual reliance efforts to succeed.
THANK YOU
Contact Information

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