Integrated Food Safety System Update

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Agenda

• FDA Office of Partnerships Today

• Partnership For Food Protection (PFP)

• Mutual Reliance

• Data Acceptance
OFFICE OF PARTNERSHIPS AND OPERATIONAL POLICY
OFFICE OF PARTNERSHIPS

OFFICE OF THE DIRECTOR

DIVISION OF PARTNERSHIP INVESTMENTS AND AGREEMENTS
DIVISION OF INTEGRATION
DIVISION OF STANDARDS IMPLEMENTATION
Food Safety Modernization Act and Integrated Food Safety System

• Building the national Integrated Food Safety System (IFSS) is mandated by the Food Safety Modernization Act (FSMA)

• The IFSS is an interagency partnership

• Partnership for Food Protection (PFP) contributes to the development of the IFSS
Partnership for Food Protection (PFP)

• The Partnership was established in 2009 to help implement the recommendations from the 2008 50 State Workshop

• PFP is comprised of 7 work groups whose members are experts in human and animal food safety, epidemiology, laboratory science, animal health, environment and public health

• PFP contributes to the development and implementation of an Integrated Food Safety System
PFP Structure

• Governing Council comprised of federal, state, local governments and food safety associations providing strategic direction

• 7 workgroups
  • Compliance and Enforcement
  • Information Technology
  • Laboratory Science
  • Outreach
  • Surveillance Response and Post Response
  • Training and Certification
  • Work Planning and Inspections
PFP Work Towards Supporting Integration

- Development of best practices
- Compliance, inspection and work planning tools
- Information exchange model/pilot
- Training work shops
PFP Compliance and Enforcement Workgroup

Focus: Roles of partner agencies in compliance and enforcement actions
PFP Information Technology Workgroup

Focus:

– Seven states piloting a National Food Safety Data Exchange (NFSDX) to share data electronically: Arkansas, Florida, Illinois, Iowa, Minnesota, Pennsylvania, and Texas

– Completed development and testing efforts for National Food Safety Data Exchange Release 1.0 and on track for production release on 5/9/2017 of Initial Operating Capability (IOC) Use Cases

– Developed initial standard architecture and data definitions for the common data and business services for ORA internal and States data sharing purposes

– Initiated internal FDA discussions on supporting Preventive Controls State inspections and Produce Safety Farm Inventory initiative
PFP Information Technology Workgroup

Upcoming Milestones:

– Start developing the National Food Safety Data Exchange Release 2.0 capabilities and work with pilot States to start integration testing

– Evaluating future Full Operating Capability (FoC) use cases and scenarios for the National Food Safety Data Exchange

– Complete the development of the standard data architecture and framework for a subset of the Common Data Services and Business Services
PFP Laboratory Science Workgroup

Focus: Major laboratory initiatives affecting integration and “PFP Food/Feed Testing Laboratory Draft Best Practices Manual”
Mutual Reliance

FDA’s vision for an Integrated Food Safety System
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.
Mutual Reliance Pilots

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

  – California Department of Health Services and ORA San Francisco’s and Los Angeles’ District Offices
  – Wisconsin Department of Agriculture and ORA Minneapolis District Office
  – 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.
Integrating Work Planning

Number of Firms with Independent Routine Inspections by Both WDATCP and FDA

- Fiscal Year
- Calendar Year

MIN-DO began providing copies of all food EIRs for inspections conducted within Wisconsin

Initiation of Mutual Reliance Pilot – duplication reduction efforts beginning FY16 (data through 5/17/2016)
Data Acceptance – 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
Data Acceptance – 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.
Data Acceptance – Accreditation

• Data received from laboratory must be accurate, timely and reliable.
• Prior to entering into an agreement, laboratory (the provider) must work closely with human/animal food regulatory program (the customer aka FDA) to ensure it provides needed services (has the capacity and capability) and to encourage data acceptance for regulatory action by the FDA in a timely manner.
  – includes use of test methods which meet the needs of the customer and are appropriate for the tests undertaken (situation at hand)....
Data Acceptance – Minimum Elements

• 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
Data Acceptance – 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?
• 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?
Data Acceptance

• 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 and data acceptance efforts to succeed
Data Acceptance – Next Steps

- Pilot Evaluation/Lessons Learned
- Data Acceptance Process Development
- Stakeholder Collaboration and Communication
Contact Information

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Questions?