National Food Safety Data Exchange Pilot (NFSDX)

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Agenda

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### Drivers

- FDA seeks to establish a risk-driven Integrated Food/Feed Safety System.
- FSMA mandates FDA to implement comprehensive new programs supporting new regulatory authorities (i.e. preventive controls and produce safety).
- FDA, States, and local health departments have no automated way to share data among their disparate systems to support the new mandates.

### Solution

- Increase sharing of accurate, timely, complete, and relevant food safety data to fulfill FDA’s mandate.
- Create a data exchange to automate data transfers from State to FDA, FDA to State, and State to State.

### Benefits

- Reduce state and FDA administrative effort for completing contracted inspections.
- Improve efficiency and efficacy of FDA monitoring and regulatory activities.
- Provide secure and immediate access to relevant information for operational activities.
- Define a common data format for exchanging food safety data.
Building Upon Prior Data Exchange Success

• PFP IT Workgroup 2012: BSE
  – Successful pilot to transfer BSE (Bovine Spongiform Encephalopathy) Inspection data from Pennsylvania Department of Agriculture (PDA) to FDA

• PFP IT Workgroup 2016: NFSDX Project
  – Established standard and vocabulary for data sharing among food regulatory partners
  – Collaborated with PFP IT WG members to document their state system data to evaluate data fit for pilot
  – Analyzed States system data and map to data exchange model

• PFP IT Workgroup 2017
  – Deliver the business capability to receive contracted inspection data from states
  – Establish a data exchange for sharing and moving any food safety data across disparate systems and political boundaries
  – Establish plan to support future initiatives such as produce safety
NFSDX Architecture

State Systems
(Inspection Data, Firm Data, Sample Analysis)

Other Federal and Partner Regulatory Agencies
(Inspection Data)

National Food Safety Data Exchange (NFSDX)

3rd Party / Industry Partners
(Recall Audit Checks, etc.)

FDA

Business Service
(Business Rules for Validation)

Notification Service

Attachment Service

FDA Data Repositories

eSAF

Firm Data

Legend:
State to State Data Sharing
State to FDA and FDA to State Data Sharing
Data Sharing with other agencies/systems
1. State to FDA Electronic Transmission: Submitting Contracted Inspection Results

2. FDA to State Electronic Transmission: Receiving Firm Data
   States Participating: Arkansas, Illinois, Iowa, Minnesota, and Pennsylvania

3. State to State Electronic Transmission: Requesting, Receiving, and Sending Firm Data
   States Participating: Arkansas, Illinois, and Iowa
NFSDX State Outreach Timeline

2016
Oct Nov Dec

1: Due Diligence

2017
Jan Feb Mar Apr May Jun Jul Aug Sep

1. Due Diligence
2. Identify Interested States & Assess Readiness
3. Recommend Select IOC States
4. Develop IOC State Integration Plans
5. Execute State Integration Plans
6. Maintain State Liaison throughout IOC implementation

Sprint 0
Sprint 1
Sprint 2
Sprint 3
UAT

Requirements Definition
Concept of Operations

Release 1
Release 2

Identified Pilot State Participants
Start Integration Testing
System Changes Made and Integration Tests Completed
Completed all testing and successfully deployed to Production on 5/10, as planned

Key Accomplishments of Release 1.0:

- Delivery of the business capability to automate receipt of Contracted Inspection data from states
- Provision of infrastructure foundation for NFSDX to support future business capabilities in data sharing
- Implementation of core technical components that are common and extensible for future NFSDX releases
- Collaboration with pilot States to define a standard process for future State Expansion including State Integration Plan and legal framework for data sharing
Forward Plan

• Start developing the National Food Safety Data Exchange Release 2.0 capabilities and work with pilot States to start integration testing
• Complete the development of the standard data architecture and framework for a subset of the Common Data Services and Business Services
• Expand to future states for continued information sharing
• Evaluate future Full Operating Capability (FOC) use cases and scenarios for the National Food Safety Data Exchange, e.g., state requests data objects such as Firm History Products, Lab Results, Operations Data, etc.
Standardize State Engagement

• The State Engagement Package will be provided to all States joining the pilot now and in the future
  – State Onboarding Handbook
  – Kick-Off Presentation
  – Questionnaire
  – MOU Templates/20.88 Agreement (WIP)
  – State Integration Guide
  – State Integration Plan (to be tailored to meet individual state’s needs)
  – NFSDX Operations Manual (WIP)
Program Challenges

- **FOIA Laws and Data Protection**
  - Sharing with States, local governments, and other federal agencies has to comply with current or new 20.88 agreements

- **Governance Framework**
  - MOUs/20.88s
  - Participation Policies
• For PFP IT WG membership and POC enrollment please contact:
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