ORA DATA EXCHANGE AND THE eLEXNET TRANSITION

9th Manufactured Food Regulatory Program Alliance Meeting
Spokane, WA
February 2020
AGENDA

- Overview of the Data Exchange
- Data Exchange Samples Capabilities
- eLEXNET to the Data Exchange
- What do you need to get on-board?
- Question and Answers
OVERVIEW OF THE DATA EXCHANGE

Unified Platform
A bidirectional unified platform to securely share information between regulatory partners and FDA

Regulatory Capabilities
Incrementally building regulatory capabilities enabling regulatory partners to seamlessly access and submit information to and from FDA and other regulatory partners

Collaborative
Built under the Partnership for Food Protection (PFP) initiative and contributes to realizing the vision of Integrated Food Safety System (IFSS)

Increased Efficiencies
Eliminate double data entry and increase timely regulatory decision making by providing access to relevant inventory, sample, and inspection information
ORA DATA EXCHANGE VISION

State User
- Firm Search
- Firm History
- PS Farm Inventory
- FDA Firm Search
- Contracted Inspection
- State to State Firm Search

State Systems
- Content and Document Mgmt.
- Account Management
- Help and Training Resources
- Sample Analysis Outcomes
- Non-Contracted Inspection*
- Sample Analysis Outcomes
- Non-Contracted Inspection*
- Assignments
- Assignments
- Doc. Attachment

Partners Portal
- Inspection History
- Notification and Error Mgmt.

System-to-System

Legend:
- Available
- Coming Soon
- Proof of Process Completed

eSAF
- Firm Search
- Manage Assignments
- Report Inspection Outcomes
- Document Upload

eLEXNET
- Sample Analysis Outcomes

Migrate to Data Exchange

*Proof of Process Completed
ORA DATA EXCHANGE CAPABILITIES

**INVENTORY**
- Firm Search
- Firm History
- State to State Firm Search
- Produce Safety Farm Inventory

**INSPECTION**
- Contracted Inspection
- Non Contracted Inspection
- BSE Checklist and Seafood Inspection

**SAMPLE**
- Sample Analysis Outcomes Sharing for FDA Sample (Elements, Pesticide, Mycotoxins and Microbiology)

**Inventory Data Sharing**
Provides regulatory partners robust inventory related capabilities to search and view FDA’s inventory, share inventory with other regulatory partners and exchange Produce Safety Farm Inventory with FDA.

**Inspection Data Sharing**
Regulatory partners can submit Contracted Inspection outcomes to FDA reducing double data-entry and Non-Contracted Inspection information in support of Mutual Reliance vision.

**Sample Data Sharing**
Provides regulatory partners flexible options to provide Sample Analysis outcomes for multiple analysis types leading to improved information sharing for faster compliance decisions by FDA.
FDA continues to automate and streamline data exchanges and has increased its analytical capacity and expertise in the event of food outbreaks or large scale-food emergencies.

The Food Safety Modernization Act (FSMA) builds a formal system of collaboration with other government agencies. This results in better information sharing and coordination, increased capacity and capability at the state, local, tribal and territorial level. eLEXNET doesn’t contain all the critical information for FDA to take enforcement action, thus it no long meets the increased regulatory requirements.

FDA is consolidating the mechanisms by which food safety agencies and partners share information so that FDA can more easily perform risk assessments analysis and locate problem products and processes. FDA is transitioning to a more streamline data exchange solution via the ORA Data Exchange Sample capabilities.
eLEXNET RETIREMENT ACTIVITIES AND KEY DATES

- **May 31, 2020**: eLEXNET is scheduled to stop accepting legacy surveillance, voluntary and mandatory data
  - States will stop submitting data to eLEXNET via eLEXNET.gov and through the legacy eLEXNET DX client

- eLEXNET is scheduled to be retired by **September 30, 2020**
  - Users will no longer have access to eLEXNET.gov

- However, the recently implemented Sample DX capabilities for **regulatory data** will be transitioned to ORAPP and the newly developed **Enhanced DX Client** will continue to submit regulatory outcomes to FDA
  - Excel upload capability via eLEXNET.gov will transition to ORAPP
Sample Analysis Outcomes for FDA Sample (Elements, Pesticide, Mycotoxins and Microbiology)

- FERN CAP Regulatory partners receiving FDA collected samples can seamlessly submit sample analysis outcomes data using the Sample Data Exchange capabilities
- Multiple DX options available to regulatory partners including: uploading spreadsheets, system-to-system integration and DX client
- Sample DX capability Phase I included support for Elements, Pesticide, Mycotoxins and Microbiology
- Phase II focuses on expanding capability to include additional analysis types: Decomposition, Filth Analysis for Parasites, Radionuclide, and Virus
- Phase II will also enable sharing of Sample Analysis outcomes for State Collected samples (Food & Feed Contracts, MFRPS and AFRPS Cooperative Agreements)

Regulatory Partners Using Sample Capabilities:
- Colorado, Connecticut, Michigan, Nebraska, Ohio, and Virginia
- Additional regulatory partners are being onboarded
SAMPLE DATA EXCHANGE REGULATORY PARTNER ADOPTION OPTIONS

REGULATORY PARTNERS

OPTION 1
Direct Integration with DX

OPTION 2
Enhanced DX Client

OPTION 3
Web Upload

DATA EXCHANGE CAPABILITIES

Samples DX Service

Secured Services

Enhanced Client

Email notifications

ORA Partners Portal*

* Note: Currently being implemented in eLEXNET.gov will be transitioned to ORAPP
WHAT DO YOU NEED TO GET ON-BOARD?

Understand DX Capabilities
- Initial meeting with FDA to understand capabilities and build out an adoption path
- Select relevant DX capabilities that align with regulatory partner needs

Agreements
- 20.88 Agreement
- Memorandum of Understanding (MOU)*
- Interconnection Security Agreement (ISA)*

Adopt & Provide Feedback
- Avail data exchange capabilities to relevant users
- Provide feedback and review upcoming data exchange capabilities

Take the first step... e-mail us today to set-up an initial overview discussion

* Optional Activity/Only if needed
DATA EXCHANGE LOOKING AHEAD

- Expand Firm History (Phase II) to provide additional information (e.g., Recalls, Qualified Facility Registration, FFR Products, Program Risks etc.)
- Evaluating capabilities to match regulatory partner’s firm inventory with FDA’s inventory

- Bulk upload of Non-Contracted Inspection
- Upload of Contracted Inspection spreadsheet
- Upload supporting documents and attachments for Contracted Inspection
- Support additional Inspection Types

- Upload Sample Analysis Outcomes in Portal
- Support additional Sample Analysis Types (Decomposition, Filth Analysis, Radionuclide, and Virus)
- Sample Analysis outcomes sharing for State collected sample

Note: The priorities of the above goals and objectives are periodically updated and subject to change.
QUESTIONS OR COMMENTS?

- **Additional Conference Sessions:**
  - Speed Dating Session – Collaborative Data Exchange - Making *IT* Happen

- **View** [PFP IT WG Newsletter](#) for additional information and background on the DX

- **Have a question about DX?**
  - Contact us at [NFSDX_Info@fda.hhs.gov](mailto:NFSDX_Info@fda.hhs.gov)
AWARENESS, PARTICIPATION & PRIORITIZATION OF FUTURE DX RELEASES

- Regulatory partners participation is important in the prioritization and scope of future releases

- Communications
  - Regulatory partners are informed early and often via collaboration meetings, emails, phone calls, one-to-one meetings, etc.

- Participation
  - Monthly PFP IT WG meeting
  - Monthly Sample Analysis Work Group meeting
  - Touchpoint meetings

- Awareness
  - PFP IT WG Articles
  - PFP IT WG Newsletter
  - Updates during monthly meetings
  - Conferences and Committee meetings
  - PFP WGs collaboration