AGENDA

- Overview of the ORA Data Exchange
- Data Exchange Capabilities (Inventory, Inspection and Sample)
- Data Exchange Vision & Looking Ahead
- What do you need to get on-board?
- Question and Answers
OVERVIEW OF THE ORA DATA EXCHANGE (DX)

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
PFP IT WG AND DX ACCOMPLISHMENTS

- Established bi-weekly data schema definition sessions to capture data element name, format, length, relationship, etc. for Firm, Inspection, and Labs
- Identified scenarios for DX — Inspection Data to FDA, FDA Firm Search, State to State Firm Search
- Released ORA Schema 7 for initial PoC
- Launched National Food Safety Data Exchange (NFSDX) project
- Established PFP IT WG
- Developed Data Integration and Data Elements Harmonization Principles
- Reviewed Pennsylvania Department of Agriculture (PDA) Bovine Spongiform Encephalopathy (BSE) inspection results transfer project lessons learned
- Evaluated Data Elements to develop PFP Data Dictionary (Firm & Inspections data elements) & built Standardized Data Field Document
- Conducted survey with States to understand their data capture and information systems
- Laid foundation for a Data Exchange

- First release of ORA Partners Portal (ORAPP)
- ORAPP capabilities including: content management, technical specifications, Firm Search, Reports, and Account Management
- Initiated discussions on Sample Analysis and Lab data exchange; Evaluated Data Elements for Sample Analysis
- Produce Safety Farm Inventory capabilities (March 2019)
- ORAPP Firm Search and Firm History, Sample Data Exchange via enhanced eLEXNET and NFSDX (December 2019)

- Established NFSDX Initial Operational Capability (IOC)
- Implemented iterative DX processes for the three scenarios
- Established and shared concept of operations and high-level architecture for NFSDX
- Established 20.88 Agreements, State Onboarding Manuals, State Engagement Questionnaire, State Integration Guides, State Integration Plans, etc.
- Onboarded initial participating States for the three scenarios - FL, IL, IA, MN, PA, AR, and TX
- Released ORA information model and information exchange Schema 8.1
- NFSDX Releases 1.0 and 2.0 (Inspection Data to FDA, FDA Firm Search, State to State Firm Search)
OVERVIEW OF DX - REGULATORY PARTNERS SUPPORTING THE DATA EXCHANGE

39 States currently participating in the PFP IT WG

23 PFP States participating in the Data Exchange
DATA EXCHANGE CAPABILITIES

**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.
Seamlessly query and view FDA inventory information using web based and system-to-system solutions

Provides capability for regulatory partners to share Farm Inventory with the FDA to meet Produce Safety goals

High-level Firm Information shared by FDA includes*:

Basic Information:
- FEI, Legal Name and Address, Contact Information, Operational Status, Establishment Type, Business Type, Registration Information, Last Inspection Date, Last Violative Inspection Date etc.

History Information:
- Inspection History, Consumer Complaints, Firm Products Covered, Firm Aliases etc.

Regulatory Partners Using DX Inventory Capabilities:
- Additional regulatory partners are being on boarded

* Certain data elements are redacted/hidden for data privacy and confidentiality purposes
Contracted Inspection capability allows regulatory partners to seamlessly submit inspection outcomes information to the FDA without leaving the states’ inspection management system – reducing double data-entry for investigators.

Non-Contracted Inspection capability allows regulatory partners to share prior inspections with FDA and help realize the vision of Mutual Reliance.

Contracted Inspection capabilities also support additional inspection types e.g., BSE Checklist and Seafood HACCP.

Additional upcoming capabilities (e.g., Bulk Upload of Non-Contracted Inspection, uploading inspection related documents etc.)

Regulatory Partners Using Inspection Capabilities:
- Florida and Illinois
- Additional regulatory partners are being onboarded

**Note: Inspection outcomes attachments are currently not available**
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, MFRPS and AFRPS Cooperative Agreements)

Regulatory Partners Using Sample Capabilities:
- Colorado, Connecticut, Michigan, Nebraska, Ohio, and Virginia
- Additional regulatory partners are being onboarded
ORA Partners Portal Mission

The Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. It authorized the Food and Drug Administration (FDA) to enhance and expand regulations on how foods are grown, harvested, and processed, and directed FDA to develop the Integrated Food Safety System (IFSS) in partnership with state and local regulatory partners.

To improve the efficiency and efficacy of FDA inspections, as well as meet the federally-mandated FSMA requirements, in 2016 FDA sought to develop the IFSS solution with which food safety data can be exchanged, analyzed, and acted upon, across all levels of the regulatory spectrum. Establishing the National Food Safety Data Exchange (NFSDX) in 2017 was the first step in achieving the goal of the IFSS. The NFSDX provides regulatory partners with an investigative tool that will allow sharing and exchange of food safety information, such as inspection findings and facility information, on a national basis.

Data Exchange News and System Updates

Upcoming Events
- Conference for Food Protection, 2020 Biennial Meeting

Newsletter
- PPP IT Workgroup Newsletter (Winter 2019)

Quick Links

New Features
- What’s New in ORA/PFP?

Popular Links
- Conference for Food Protection
- Manufactured Food Regulatory Program Alliance (MFRPA)
- 8th Manufactured Food Regulatory Program Alliance (MFRPA) Meeting
- Food Safety Strategies
- Workshops, Meetings, Webinars on Food and Dietary Supplements
- Food Safety Modernization Act (FSMA)
- FSMA Training
- Food Alliance
- Partnership for Food Protection (PFP)
- FoodSHIELD

Fact Sheets
- NFSDX
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 partners 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.
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
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
  - Ad-hoc meetings

- **Awareness**
  - PFP IT WG Articles and Quarterly Newsletter
  - Updates during monthly PFP IT WG meetings
  - Conferences and Committees meetings
  - PFP WGs collaboration
  - Reach out to State Liaisons
QUESTIONS OR COMMENTS?

▪ Additional Conference Sessions:
  ▪ Speed Dating Session – Collaborative Data Exchange - Making IT Happen
  ▪ ORA DX and the eLEXNET transition

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

▪ Adopt or have question about DX?
  • Contact us at [NFSDX_Info@fda.hhs.gov](mailto:NFSDX_Info@fda.hhs.gov)
APPENDIX — BACK-UP SLIDES
Florida Food Safety

INSPECTOR APPLICATION DEMO
### FIRM SEARCH CAPABILITY

1. Search the FDA Inventory using advanced searching mechanisms including: Name, Address, Operational Status, Establishment Type and FEIs.
2. Search button directly queries the FDA systems to retrieve results based on the search criterion entered by State User.
3. Users are able to view detailed Firm History Information for specific firm by selecting the FEI Number from the results.

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FIRM HISTORY CAPABILITY

Provides regulatory partners a dashboard of historical firm related information including:

- **Firm Details**: Name, Address, Aliases, Establishment Type, Firm Registration etc.
- **Firm Products Covered**
- **Prior Inspections**
- **Consumer Complaints**

FDA is analyzing sharing of additional historical firm information for future releases.