

**OFFICE OF
REGULATORY
AFFAIRS
(ORA)**

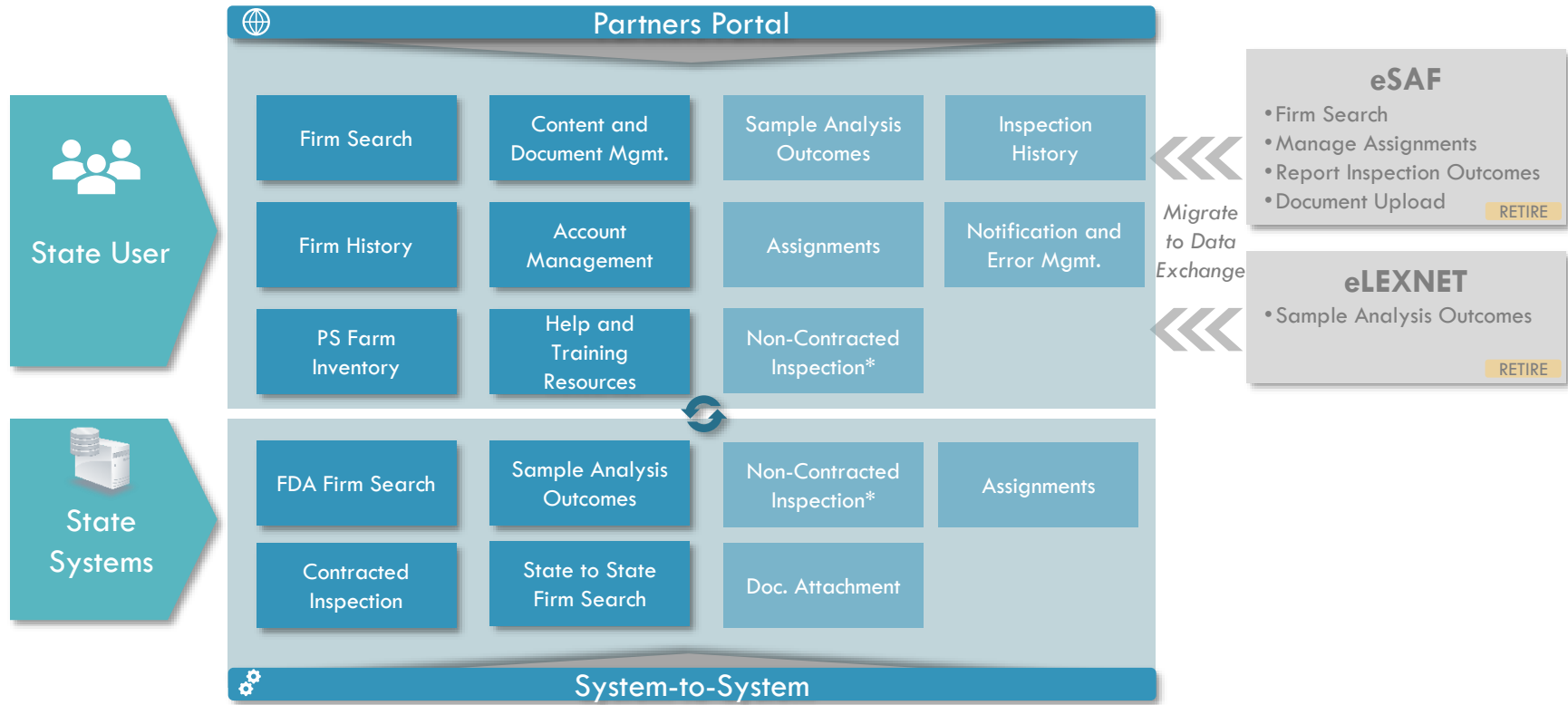


**COLLABORATIVE DATA EXCHANGE —
MAKING IT HAPPEN**

**9th Manufactured Food
Regulatory Program Alliance
Meeting**

Spokane, WA
February 2020

DATA EXCHANGE (DX) – VISION



Legend:

Available

Coming Soon

* Proof of Process Completed

DX — CAPABILITIES





INVENTORY

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

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

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

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

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

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.

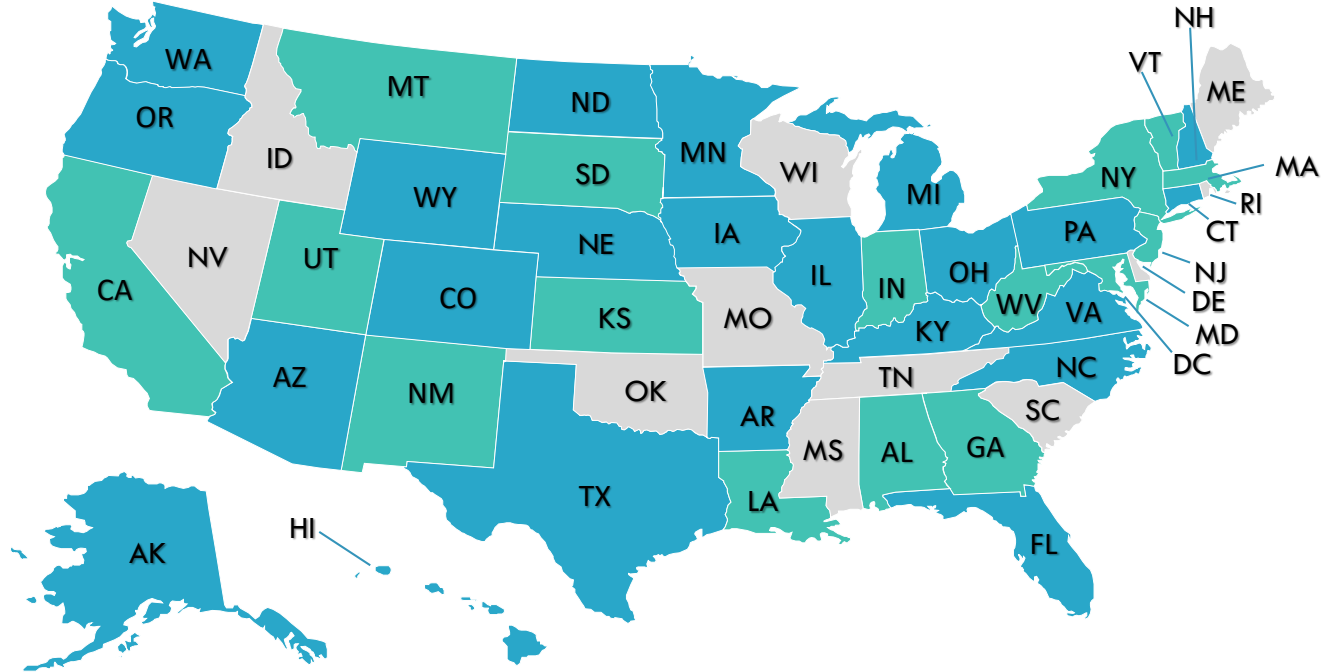
DX – PARTICIPATION

39

States currently participating in the PFP IT WG

23

PPF States participating in the Data Exchange



DX DEMO VIDEO – INSPECTION RESULTS SUBMISSION



Florida Food Safety

INSPECTOR APPLICATION DEMO

KIKODA

DX DEMO VIDEO – FDA FIRM SEARCH & HISTORY

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FDA U.S. FOOD & DRUG ADMINISTRATION **ORA Partners Portal** [Login](#)

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What's New in NFSDX?

[Learn More](#)

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.

[More](#)

Data Exchange News and System Updates

Upcoming Events

- Conference for Food Protection, 2020 Biennial Meeting

Newsletter

- PFP IT Workgroup Newsletter (Winter 2019)

Quick Links

New Features

- What's New in DRAPP?

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

FDA U.S. FOOD & DRUG ADMINISTRATION [FDA.gov](#) [FoodSHIELD](#) [FSMA](#) [Contact Us](#)
[Sitemap](#) [PFP](#) [AFDO](#)

DX – LOOKING AHEAD

INVENTORY



- 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

INSPECTION



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

SAMPLE



- 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

QUESTIONS OR COMMENTS?

- [Email us](#) if you need additional information about the DX beyond this session



APPENDIX | DX — RESOURCES

- [PFP IT WG Newsletter](#)
- [FoodSHIELD - PFP IT WG Workspace](#)
- [PFP Website](#)
 - [PFP IT WG Page](#)
- [ORAPP](#)
- [AFDO Conference Presentation](#)