

# PFP IT WG NEWSLETTER

PARTNERSHIP FOR FOOD PROTECTION INFORMATION TECHNOLOGY WORKGROUP



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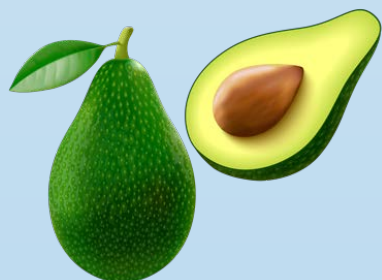
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## Featured Articles

### COFFEE TALK WITH

### JOHN GRIDLEY

The Data Exchange Team recently had the opportunity to catch-up with John Gridley from ORA's Office of Human and Animal Foods Operations (OHAFO), Immediate Office (IO), as part of the DX Coffee Talk series. John is also a member of ORA's Observation and Corrective Action Report (OCAR) workgroup.

Over the last few years, John has been an active participant and champion for the data exchange project and the PFP IT WG, since joining the workgroup in 2015. John was instrumental in developing the data schema used for what is known today as System-to-System services (a.k.a. NFSDX).

To find out what John has to say about the ORA DX Program for states that are considering joining the Program.

[Read more...](#)

## ORA DATA EXCHANGE (DX)

### PROGRAM UPDATES

- Welcome to the following regulatory partners that recently joined or expanded their participation in the ORA DX Program:
  - Arkansas Dept. of Health
  - Colorado Dept. of Health
  - Connecticut Agricultural Experiment Station
  - Florida Dept. of Agriculture
  - Illinois Dept. of Public Health
  - Iowa Dept. of Agriculture
  - Kentucky Dept. of Public Health
  - Nebraska Dept. of Agriculture
  - North Carolina Dept. of Agriculture & Consumer Services
  - North Dakota Dept. of Agriculture
  - Ohio Dept. of Agriculture
  - Wyoming Dept. of Agriculture
  - Washington Department of Agriculture
- The PFP IT WG team attended the 9th Annual Manufactured Food Regulatory Program Alliance (MFRPA) meeting, February 10 - 13, 2020. [Read more...](#)

## Meet Your PFP IT WG PM!

Barbara Thiel has been the PFP IT WG Project Manager for the last five years and is grateful to work with such a dedicated team. Barbara is a member of FDA/ORA's Office of Information Systems Management (OISM), and has actively participated in the development of the National Food Safety Data Exchange (NFSDX) and ORA Partners Portal (ORAPP) since the very beginning, from concept to development - now into production. Barbara appreciates the collaboration and teamwork that was involved in getting such an ambitious initiative established, between Federal, state, and local partners, as well as other PFP WGs. Prior to coming to the FDA, Barbara worked for IBM and PricewaterhouseCoopers.

**Barbara Thiel, PFP IT WG Project Manager and NFSDX/ORAPP, Office of Information Systems Management, Office of Regulatory Affairs, Food and Drug Administration**



### Now, on to the fun details about Barbara

Barbara's work background is in IT system development and management, though she has always reveled in exploring her artistic and creative side. In first grade, Barbara won a statewide art contest (grades K-6) with her imaginative rendering of the Easter Bunny (blue bunny with lots of flowers), she won an orange (her favorite color) AMF Roadmaster bike! Barbara continued her love of art throughout her school years and into college. Barbara lives in Maryland, just outside of Washington, D.C. with her husband Chris and a much-loved rescue dog named Heidi. Barbara enjoys gardening, going to the farmers market, biking and everything in the great outdoors. Barbara is originally from Maryland, though she has lived in several states and has traveled quite a bit, both for pleasure and for her previous jobs. Barbara hopes to someday (soon) have a house at the beach where she rejoices in taking long bike rides and exploring various nature preserves. 🍌

## Information Corner



Contact us at [NFSDX\\_Info@fda.hhs.gov](mailto:NFSDX_Info@fda.hhs.gov)

### Did You Know?



A group of men who willingly consumed dangerous substances, to force the hand of the government into consumer protection, became known as 'The Poison Squad'. They became a pop culture sensation, and their work brought about the 1906 Pure Food and Drug Act, which led to the creation of the FDA. [Read more...](#) 🍌

### FoodSHIELD



FoodSHIELD is a platform created to resolve cross collaboration challenges in the food safety sector. The application is a web-based secure system and collaborative workspace used by public health and food regulatory officials for inter-agency coordination, education, and training. The PFP IT WG monthly meeting minutes and supporting materials used during the PFP IT WG monthly meetings are also uploaded to FoodSHIELD and can be accessed on the site. For information on how to gain access to the monthly PFP IT WG meeting materials on FoodSHIELD. [Read more...](#) 🍌

### eLEXNET Retirement



FDA is scheduled to retire the Electronic Laboratory Exchange Network (a.k.a. eLEXNET) system, on September 30, 2020. The FDA will transition some select capabilities to a more streamlined DX solution, using the ORA Partners Portal. On May 31, 2020, eLEXNET is scheduled to stop accepting select submissions data, legacy surveillance data, voluntary data, and mandatory data. States will stop submitting data to eLEXNET through eLEXNET.gov and via the legacy eLEXNET DX client. For additional information about eLEXNET retirement activities and timeline, read the frequently asked questions ([FAQ's](#)). 🍌

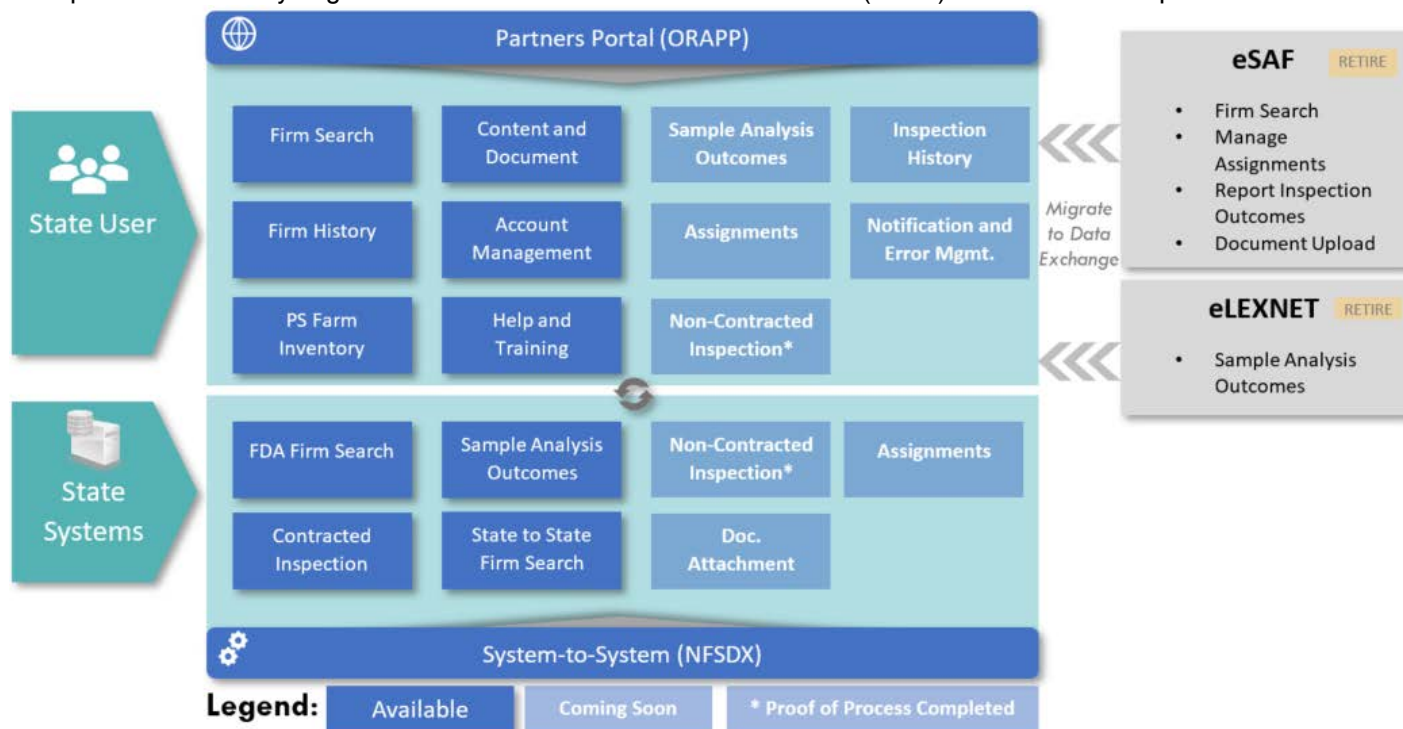
*"Early bird gets the worm. But cookie tastes better than worm. So me sleep in." - Cookie Monster*



# ORA Data Exchange

## Current and Upcoming Capabilities

The ORA Data Exchange (DX) is a unified platform that provides information sharing capabilities and increases operational efficiencies for regulatory partners. Using the DX, information can be shared securely between regulatory partners and FDA. The ORA DX platform enables multiple regulatory information sharing capabilities through the Partners Portal (a.k.a. ORAPP) and the system-to-system services (a.k.a. NFSDX) (as depicted in the graphic below). ORAPP provides regulatory partners with a unified user interface to access and submit relevant regulatory information to/from the FDA. Over the next few years, FDA plans to eventually migrate the Electronic States Access to FACTS (eSAF) and eLEXNET capabilities into ORAPP.



The system-to-system services provides regulatory partners an alternate and more direct data sharing solution that efficiently and seamlessly integrates with the DX capabilities. The ORA DX continues to evolve into a one-stop shop for inventory, inspection, and sample data sharing between FDA and regulatory partners. For more information check out the [Partners Portal](#).

**DX CAPABILITIES - COMING UP NEXT**

*“A party without a cake is really just a meeting.”  
- Julia Child*

### Non - Contracted Inspections

One of the initiatives to support the Mutual Reliance vision is to enable the recognition of non-contract state manufactured food inspections (NCI) to meet FDA FSMA inspection frequency mandates. Supporting and furthering mutual reliance efforts among state and federal agencies is important to reaching our public health protection goals through efficient use of our resources as government agencies. The ORA Data Exchange (DX) systems such as National Food Safety Data Exchange (NFSDX) and ORA Partners Portal (ORAPP) along with regulatory partner’s system will be used to facilitate the NCI data submission.



### Why Should I Submit Non-Contracted Inspections to FDA?

To further strengthen and operationalize the Integrated Food Safety System (IFSS), FDA began a new effort for those states in full-conformance with the Manufactured Foods Regulatory Program Standards (MFRPS). This project involves using non-high risk, non-contract, no action indicated (NAI) inspections from a state that has achieved full conformance with the MFRPS to help the agency to fulfill the FSMA inspection frequency requirement mandated under section 201 of the Act. The impact of this work will help the agency to meet the long-term FSMA inspection frequency mandate by reducing the overall inspection burden to the agency. This approach allows the regulators to direct resources more efficiently towards firms of higher risk.





## ORA Data Exchange (DX) Frequently Asked Questions

### Question: Is the DX Program in pilot phase?

**Answer:** No. The DX Program is currently operational. A few regulatory partners are already participating. Additional partners are in the process of adopting it while few have expressed interest in future participation.

- California grows about 70% of all the asparagus grown in the United States.
- More than 50,000 tons of asparagus are grown in California every year.

### Question: Does a regulatory partner have to conduct a certain number of inspections to participate in DX?

**Answer:** No. There are no minimum or maximum number of inspections that should be conducted by regulatory partners to participate in the DX Program. However, per state contracts, a minimum of ten inspections are expected.

### Question: Can any regulatory partner agency participate in any DX capability?

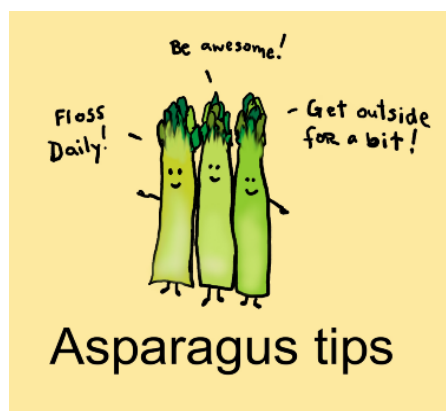
**Answer:** Yes. Any regulatory partner agency can participate in any DX capability. There could be additional participation criteria for certain data exchange capabilities. For example, Manufactured Food Regulatory Program Standards (MFRPS) conformance is required to participate in the non-contracted inspections.

### Question: Is there a checklist for regulatory partners to prepare for System-to-System data exchange?

**Answer:** Yes. A questionnaire is available to capture partner information. A state engagement package is shared during a formal kick-off meeting for onboarding a regulatory partner for data exchange.

### Question: Should a regulatory partner sign any agreements to participate in the ORA DX Program?

**Answer:** Yes. The 20.88 agreements are required to participate in the ORA DX Program. Additional agreements such as Memorandum of Understanding (MOU) and Interconnection Security Agreement (ISA) are required to participate in the system-to-system data exchange.



### Question: Does FDA provide the data exchange specifics and file formats to regulatory partners?

**Answer:** Yes. FDA provides the data fields, formats, message constructs, etc. needed for the data exchange.

### Data Exchange Information Resources

- [PFP Website](#) and [PFP IT WG Page](#)
- [Presentations at 2019 AFDO Conference](#)
- [Presentations at 2020 MFRPA Conferences](#)
  - [Collaborative Data Exchange - Making it happen](#)
  - [Sharing Inventory and Inspection Data Electronically](#)

### Question: Should a regulatory partner be using a specific system to integrate with System to System data exchange?

**Answer:** No. System-to-System data exchange can be integrated with any system that has the ability to integrate with web services.

### Question: What is the difference between FoodSHIELD and System-to-System Services?

**Answer:** FoodSHIELD is a web-based secure system and collaborative workspace for communication, coordination, education, and training among the nation's food and agriculture sectors. System-to-System Services provide a data sharing mechanism and capabilities between regulatory partners and FDA. It is one of two data exchange solutions available via the DX Program.

*"Happiness rarely keeps company with an empty stomach." - Helen Keller*