# PFP IT WG NEWSLETTER

PARTNERSHIP FOR FOOD PROTECTION INFORMATION TECHNOLOGY WORKGROUP


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### Featured Articles



### Highlights



## Coffee Talk with Steven Honn

The Data Exchange team recently had an opportunity to catch-up with Steven Honn, who works as an Environmental Health Specialist, FDA Contract Coordinator for the Illinois Department of Public Health, for a Coffee Talk about the ORA Data Exchange.

Given that Illinois was the first state to integrate with the DX, it has been a few years since their first Coffee Talk, and now Steven shares an updated perspective of participating in the ORA DX program. Read more...

## ORA Data Exchange (DX) Program Updates

The following state agencies are joining in select data sharing capabilities via System-to-System Services (NFSDX):

- Alaska Department of Environmental Conservation
- Georgia Department of Agriculture
- Iowa Department of Inspections & Appeals
- Mississippi State University

The state agencies listed below are joining in select data sharing capabilities via ORA Partners Portal (ORAPP):

- Michigan Department of Agriculture
- Pennsylvania Department of Agriculture
- Utah Department of Agriculture & Food
- Virginia Department of Agriculture and Consumer Services

*"I believe in the forest, and in the meadow, and in the night in which the corn grows."* – Henry David Thoreau

# Partnership for Food Protection (PFP) Strategic Plan 2021 to 2026

The Partnership for Food Protection (PFP) is comprised of dedicated professionals from strategic partners with roles in protecting the food supply and public health. The PFP is the structure used to coordinate representatives from these institutions with expertise in food, feed, epidemiology, laboratory, animal health, environment, and public health to develop and implement an Integrated Food Safety System (IFSS).

The PFP is not a policy setting organization. The function of the PFP is to promote communication and integration between all jurisdictions and provide resources, risk-informed insight, and best practices to improve the system that partners can utilize to inform and enhance their work to protect public health.

The PFP Governing Council sees the PFP as a unique resource to strategic partners for obtaining the tools and knowledge available to support integration. The Strategic Plan focuses primarily on integrating functions related to manufactured human and animal food. The Strategic Plan recognizes the importance of the collaborative efforts of both regulatory and non-regulatory strategic partners to achieve an IFSS.

## PFP Strategic Goals

- Strengthen communication and collaboration among PFP members and stakeholders
- Develop regulatory capacity and standards
- Champion consistent inspections and compliance best practices among regulators
- Promote coordinated and effective outbreak responses

Inherent within the Strategic Plan are the activities that support the advancement of domestic mutual reliance (DMR). DMR is a seamless partnership that enables the FDA and states with comparable regulatory public health systems, as trusted partners, to rely on, coordinate with, and leverage one another's work, data, and actions to meet the public health goal of a safer national food supply. The purpose of this partnership is to improve industry compliance, avoid duplication of effort, drive efficiencies, and prevent or reduce human and animal foodborne illness outbreaks.

DMR is a key component of the New Era of Smarter Food Safety, an FDA initiative that represents a new approach to food safety, leveraging technology and other tools to create a more digital, more traceable, and safer food system.

The Strategic Plan supports concepts identified within the New Era Blueprint, which advances strategic partners toward an IFSS. This plan will be reviewed every two years to allow for adjustments based on recent accomplishments and changes in the regulatory landscape.

For more information, read the Partnership for Food Protection Strategic Plan.

# Welcome to the New Era of Smarter Food Safety

The world around us is changing rapidly; many believe we will see more changes in the food system over the next 10 years than we have in decades. Foods are being reformulated; there are new foods, new production methods, and new delivery methods; and the system is becoming increasingly digitized.

To keep pace with this evolution, the FDA is taking a new approach to food safety, leveraging technology and other tools to create a safer and more digital, traceable food system.

Smarter food safety is about more than just technology. It's also about simpler, more effective, and modern approaches and processes. It's about leadership, creativity, and culture. The ultimate goal is to bend the curve of foodborne illness in this country by reducing the number of illnesses. For more information, read about the New Era of Smarter Food Safety at FDA.

*"This corn will teach to you, should you peel away the husk, and be willing to open your ears."* – Anthony Liccione

# Meet Your ORA DX Program Manager! Mark Siegal

Mark Siegal is the Program Manager for the ORA DX, including the systems ORA Partners Portal (ORAPP) and the National Food Safety Data Exchange (NFSDX or System-to-System). Mark joined FDA/ORA's Office of Information Systems Management in January 2020. Mark serves as the program lead for ORA DX activities, coordinates across the significant number of staff and teams supporting the ORA DX, and prioritizes program initiatives, systems releases and features based on input from regulatory partners and other stakeholders. In February 2020, he attended the Manufactured Food Regulatory Program Alliance (MFRPA) conference and appreciated having the chance to meet many of you, and Mark is looking forward to more collaboration opportunities in the future.

Before working at FDA, Mark led website redesign and management efforts at other agencies within the Department of Health and Human Services.

**Mark Siegal, ORA Data Exchange Program Manager, Office of Information Systems Management, Office of Regulatory Affairs, Food and Drug Administration**

## *Now, onto the fun facts about Mark!*

Mark lives in Maryland and enjoys reading, listening to audiobooks and tech podcasts, and relaxing with his wife and two sons, one of whom is a rising second grader and hard to believe the other about to start middle school.

Mark's favorite food is sushi. And the first time Mark flew in an airplane, it was to go skydiving…*so far just once!*

## Information Corner

Contact us at NFSDX_Info@fda.hhs.gov

### Did You Know?

It's time for picnics, barbecues, and outdoor fun with family and friends. Warm weather events also present opportunities for foodborne bacteria to thrive. As food heats up in summer temperatures, bacteria multiply rapidly.

To protect yourself, family, and friends from foodborne illness during warm-weather months, safe food handling when eating outdoors is critical.

For simple food safety guidelines for transporting, preparing, and serving it safely to all your friends and family once you've arrived, read more...

### DX Training Program

The ORA DX training team offers free online courses to regulatory partners who are current users of the Partners Portal (ORAPP).

The training curriculum includes interactive courses which offers an opportunity for trainees to create and submit simulated data. The upcoming training courses are noted below.

Contact us for any training related matters at NFSDX_Info@fda.hhs.gov.

- Firm Search and Firm History
- State Collected Samples – Part 1
- State Collected Samples – Part 2
- Non-Contracted Inspections (NCI)

### Enjoy the Ride!

Bike riding is a lot of fun and great exercise, but when a crash occurs between a vehicle and a bike, it's the cyclist who will most likely be injured. So before you put your feet on the pedals, learn the bicycle tips and rules of the road, from a properly fitting helmet to driving defensively and predictably. At the link below find education material, resources for your community and learn how to prevent injuries and deaths.

A large percentage of crashes can be avoided if motorists and cyclists follow the rules of the road and watch out for each other. For more information to stay safe, read more... *Let the good times roll!*

*"She's sittin' on the back steps just shuckin' that corn, that gal's been grinnin' since the day she was born."* – John Prine

# ORA Data Exchange

## Sample Submissions from State Labs

Over the last year, the Office of Regulatory Science (ORS) has been working with Office of Regulatory Affairs (ORA) Information Technology (IT) staff to build procedures and processes allowing state laboratories to submit analytical sample results through the ORA DX to FDA. In January 2021, ORA/ORS initiated the first production usage of the system with FDA import samples and had requested ORA/Office of Enforcement and Import Operations (OEIO) collect 10 official import samples (5 microbiological samples and 5 pesticide samples). These samples were collected by Division of West Coast Imports (DWCI) staff using the routine sample collection process, submitted in Operational and Administrative System for Import Support (OASIS), and routed to the **Connecticut Agricultural Experiment Station**, and **Michigan Department of Agriculture and Rural Development** for analysis. The Sample Analysis Results were electronically returned to FDA via the ORA DX and reviewed by ORS.

***Sample Submissions Capability - Moving Forward***

ORS is currently working on having more regulatory partners share their data through the ORA DX. More information to come!

# All Aboard the ORA Data Exchange

Ahoy regulatory partners and welcome aboard! We may not be the Love Boat, but we do have some *exciting and new* capabilities!

You may be wondering, how can my state agency come onboard? The ORA Data Exchange (DX) partner onboarding process is a series of activities for a regulatory partner to become a DX user. The onboarding activities start once a regulatory partner decides to participate in any ORA DX capability. From there, the ORA DX Team assists with the signing of DX agreements, providing technical guidance, distributing credentials, etc., until the partner is fully onboard.

*Set a course for adventure* with two IT solutions that support secure data exchange: Partners Portal (ORAPP) and System-to-System Services (aka NFSDX). Both DX systems offer flexibility for regulatory partners to be selective in data exchange capability participation. However, the FDA does approve participation and certain capabilities have prerequisites.

**Partners Portal (ORAPP) Onboarding:** The onboarding process for the Partners Portal is straightforward since no IT development is required by regulatory partners to utilize it. Once a short approval process is completed, login information is shared with individual DX users. The following graphic shows the general steps for onboarding.


**System-to-System Services (NFSDX) Onboarding:** The onboarding for System-to-System Services is extensive due to IT system integration activities. Activities start with meetings between FDA and partner, followed by planning, development, and testing activities by the partner. Onboarding activities wrap up with production roll-out. The below graphic shows the high-level onboarding process. Once integration is in place, data can be transmitted and received seamlessly between state and FDA systems.


*Come onboard, we are expecting you!* Reach out to us at NFSDX_Info@fda.hhs.gov to learn more and to set up a DX Overview meeting.

*"The corn is as high as an elephant's eye, An' it looks like it's climbin' clear up to the sky."* – Oscar Hammerstein II

# ORA DATA EXCHANGE
## Frequently Asked Questions

**Question: How does the ORA Data Exchange (DX) Program help the regulatory partner?**

**Answer:** Participation in the ORA Data Exchange (DX) Program provides the regulatory partner with improved information sharing capabilities with the FDA. At a minimum, it eliminates dual data entry in the state's system and FDA's system and any challenges associated with data updates. The Partners Portal is envisioned to be the centralized and comprehensive portal for all the electronic data exchange between regulatory partners and the FDA. Additional FDA data that will benefit regulatory partner will be made available to partners in the future.

**Question: Is ORA DX Program participation voluntary?**

**Answer:** It is voluntary to use the ORA DX. In the future, regulatory partners will need to use one of the ORA Data Exchange (DX) Program systems to submit their data, as DX will eventually replace eSAF which is retiring.

**Question: Do the DX Partners Portal and the System-to-System services mechanisms interact?**

**Answer:** The ORA DX Partners Portal and the System-to-System services mechanisms are integrated within FDA's IT framework.

**Question: Can inspections with incorrect data be returned to the regulatory partner via ORA Data Exchange (DX) Program?**

**Answer:** Error messages are sent back for any submissions with incorrect data. Also, any corrections or updates to inspection data can be submitted via the System-to-System services.

### Resources and Useful Information

- PFP Website and PFP IT WG Page
- PFP IT WG Newsletters
- AFDO Newsletters
- Presentations at 2021 MFRPA Conference

**Question: How does a regulatory partner sign-up for an ORA DX Program capability?**

**Answer:** A regulatory partner could either email NFSDX_Info@fda.hhs.gov or contact their FDA state liaison or field management indicating their interest to participate in the ORA DX Program. In certain instances, the FDA reaches out to the state agencies based on various agency initiatives. Each regulatory partner participation request is reviewed and approved by the FDA.

**Question: Are there similar ORA DX programs being envisioned for drug manufacturing facilities in the future?**

**Answer:** Although the ORA Data Exchange (DX) Program started out with food and feed programs, it could potentially be expanded to exchange different commodities and other types of data.

**Question: What is the main difference between DX System-to-System services and FoodSHIELD?**

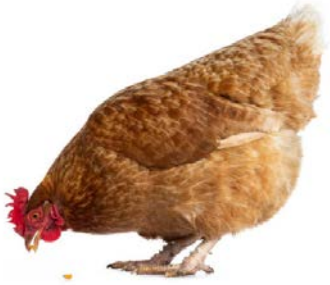
**Answer:** System-to-System services enables electronic data transfer from regulatory partner's system into FDA systems of record. It also enables a regulatory partner to search FDA systems of record for certain data.

FoodSHIELD is a secure web-based system and collaborative workspace for communication, coordination, education, and training among the nation's food and agriculture sector professionals. It serves as a comprehensive federal-state-local infrastructure enabling the planning and implementation of an online Integrated Food Safety System.

Read additional ORA DX FAQs, click here.

### *Lend Me Your Ears for Corn Facts!*

- Corn is America's number one field crop
- Corn leads all other crops in value and volume of production
- A pound of corn consists of approximately 1,300 kernels
- An ear of corn averages 800 kernels in 16 rows
- 1 acre of corn removes 8 tons of harmful greenhouse gases (more than produced by the average car annually)
- Niblets, popped or on-the-cob…*Corn is a-maize-ing!*



*"It's true that I did get the girl, but then my grandfather always said, 'Even a blind chicken finds a few grains of corn now and then.' "* – Lyle Lovett