PFP IT WG NEWSLETTER

PARTNERSHIP FOR FOOD PROTECTION INFORMATION TECHNOLOGY WORKGROUP

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Coffee Talk with Erin Woodom-Coleman

The DX team recently had an opportunity to catch-up with Erin Woodom-Coleman who is the Branch Chief of the Laboratory, Medical Products, and Innovation Branch from the Office of Regulatory Affairs (ORA), Office of Partnerships (OP), as part of the DX Coffee Talk series. Erin has been a longstanding member and champion of the PFP IT WG. To see what Erin has to say about the ORA DX program, Read more…

ORA Data Exchange (DX) Program Updates

We are pleased to share that labs from the following state agencies, listed below, are participating in select data sharing capabilities, via either System-to-System services or Enhanced DX Client:

- Alaska Department of Environmental Conservation
- Florida Department of Agriculture and Consumer Services
- Maryland Department of Health Laboratory Administration
- New York Department of Agriculture and Markets
- South Carolina Department of Health and Environmental Control

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

- Iowa Department of Inspections and Appeals
- Missouri Department of Agriculture
- Texas Department of State Health Services

"Life is uncertain. Eat dessert first." - *Ernestine Ulmer*

Meet Your DX Outreach Coordinator!

Omari Fennell

Omari Fennell is the Outreach Coordinator for the ORA DX Program. He supports regulatory partner outreach, onboarding, and other related activities. Omari has been part of the DX program for four years and has a good understanding of program aspects relevant to regulatory partners.

Prior to joining ORA OISM, he served as a project manager and business analyst at GEICO, Booz Allen Hamilton, and Akira Technologies, where he supported various projects. His primary focus throughout his career has been assisting and leading teams dedicated to developing innovative technologies. He has won many awards for technical innovations, collaboration, and marketing. He is very excited about working at the FDA and with our partners on DX-related initiatives!

When not at work, Omari enjoys exploring emerging technologies, listening to a good audiobook, assisting with church projects and spending time with his two kids (Kendrick-7, Kiersten-11) and wife Jocelyn.

Omari Fennell, DX Outreach Coordinator, ORA Office of Information Systems and Management, Food and Drug Administration

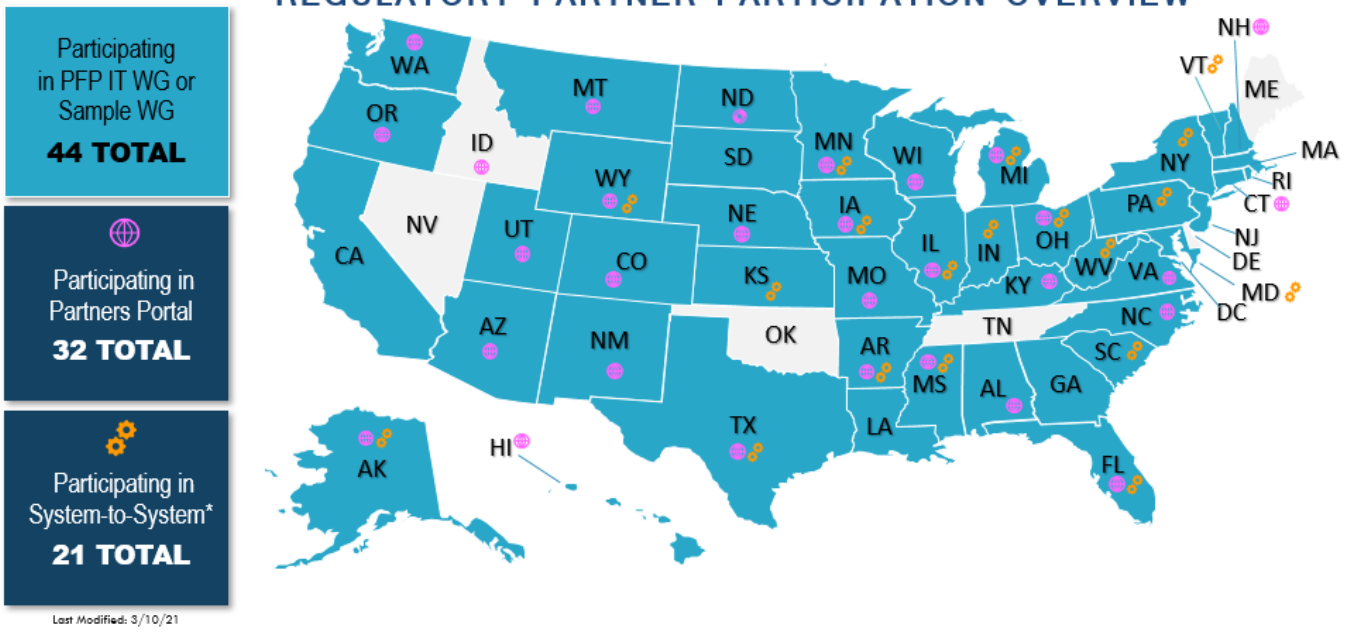
A Message to States, from Omari Fennell

Hello states! Looking back to 2019, we only had a few state participants in the ORA program. Now we have a majority of states participating with more to come! Thank you for your support of the ORA DX program.

February 2020 was the first time I attended the Manufactured Food Regulatory Program Alliance (MFRPA) meeting. I learned so much and finally had a chance to interact with some of you in person. Overall, it was a great experience. I would have never expected the world to change in March 2020 with the COVID-19 pandemic. I hope that your families have stayed safe. For those that have experienced difficult times, my thoughts and prayers are with you. I hope for better days ahead for everyone.

It has been a pleasure working with states and assisting with ORA DX onboarding activities. For those states I have not met yet, I look forward to working with you. Stay safe out there! - Omari

REGULATORY PARTNER PARTICIPATION OVERVIEW



* Includes enhanced DX client participants

"To plant a garden is to believe in tomorrow." - *Audrey Hepburn*

ORA Data Exchange Highlight 2020

In 2020, three ORA DX releases were implemented: 6.0 allowed for the ability to submit Non-Contracted Inspections National Food Safety Data Exchange (NFSDX, a.k.a System-to-System Services); 7.0 enhanced the Sample Data Sharing capability of NFSDX, Enhanced DX Client, and ORA Partners Portal (ORAPP); and 8.0 provided the ability for users to share State Collected Samples Data via NFSDX, Enhanced DX Client, and ORAPP. The following activities were completed in each quarter:

January - March

Submit Non-Contracted Inspection Data to FDA Capability via System-to-System **and Bulk Upload Non-Contracted Inspection Data to FDA Capability** via ORAPP - Requirements and analysis completed; Design and development started.

April – June

Bulk Upload of Non-Contracted Inspection Data to FDA Capability via ORAPP became available to regulatory partners. **Submit Non-Contracted Inspection data to FDA Capability** via System-to-System for availability to regulatory partners.

July - September

Submit Sample Analysis outcomes for FDA collected Samples to FDA Capability via System-to-System, ORAPP, and Enhanced DX Client became available to regulatory partners allowing rapid review of the sample analysis outcomes by avoiding manual sample data entry into Field Action and Office of Compliance Tracking System (FACTS) ORA system.

October – December

Submit State Collected samples data to FDA Capability via System-to-System, ORAPP, and Enhanced DX Client became available to regulatory partners increasing regulatory data sharing between FDA and states.

For additional information, please contact us at:
NFSDX_Info@fda.hhs.gov.

Data Exchange Training

As the ORA DX program evolved over the years, so did the user base. Regulatory partners participation increased across the various data sharing mechanisms (System-to-System, ORAPP, and Enhanced DX Client) to exchange inventory, sample, and inspection data with FDA. With increased partner participation, it became clear that new and current users needed assistance to better understand and use the ORA DX.

ORA DX training need was identified and a training strategy was established. A fiscal year training plan was developed along with the course catalog for various types of training. The first course was offered in August 2020 and it covered the Firm Search/Firm Inventory capability via ORAPP. Since then, the training curriculum has expanded and now includes interactive courses which offers an opportunity for trainees to create and submit simulated data.

The ORA DX training team promotes free courses to existing users, and provides opportunities to register. The upcoming training courses and their schedule is noted below. Contact us for any training related matters at NFSDX_Info@fda.hhs.gov.

ORA DX Training Courses
ORAPP - State Collected Samples Data Sharing (Part 1 - Collections)
ORAPP - State Collected Samples Data Sharing (Part 2 - Receipt and Analysis)
ORAPP - State Collected Samples Data Sharing (Part 3 - Business)
ORAPP - Firm Search and Firm History

"If life is a bowl of cherries, what am I doing in the pits?" - *Erma Bombeck*

Laboratory Flexible Funding Model (LFFM)

What is the Laboratory Flexible Funding Model?

The Laboratory Flexible Funding Model is a 5-year cooperative agreement program that provides support to State, Local, and University food testing laboratories. Under this program, the laboratories increase their ability to detect, prevent, prepare for, respond to, and recover from threats to the country's food supply.

This cooperative agreement is intended to enhance the capacity and capabilities of state human and animal feed testing laboratories in support of an integrated food safety system. Specifically, through sample testing in the areas of microbiology, chemistry, and radiochemistry, and the development of special projects that would support and expand that testing.

Participating laboratories help strengthen and improve FDA's efforts to prevent foodborne illness and minimize foodborne exposures through building a nationally integrated laboratory system. Our partner laboratories are equipped with additional resources that can be employed to build and increase sample throughput capacity within their state.

The data from these samples can be utilized by both the FDA and State partners for tracking and trending, early identification of emerging issues, and evaluation for future sampling initiatives and focus areas. Read more…

What are its goals?

The major goals of this program are to:

- Improve human and animal food testing surveillance programs.
- Enhance the network capacity of state laboratories by using sample testing in the areas of microbiology, chemistry, and radiochemistry, and the development of special projects.
- Expand the national capacity in scientific technology and other areas of interest.
- Accelerate foodborne illness outbreak investigations and reduce foodborne illnesses and deaths.
- Utilize sample data generated by these laboratories to remove adulterated food from commerce and aide regulatory programs in conducting inspections.
- Develop methods for early identification of emerging issues, monitoring and evaluation for future sampling initiatives. Read more..

Who can I contact for more information?

Send specific questions to the appropriate Office of Partnerships' contact within the Division of Partnership Investments and Agreements. General questions can be directed to the Office of Partnerships' general mailbox: op.feedback@fda.hhs.gov.

"If people did not love one another, I really don't see what use there would be in having any spring." -*Victor Hugo*

Information Corner

Contact Us at NFSDX_Info@fda.hhs.gov

Did You Know?

The food supply in the United States is among the safest in the world. However, when certain disease-causing bacteria or pathogens contaminate food, they can cause food poisoning. The Federal government estimates about 48 million cases of foodborne illness annually. Read more…

eSAF Retirement

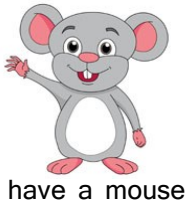
As next steps of the eSAF User Survey, the eSAF transition planning sessions were established to discuss and determine a plan for transition of eSAF capabilities to the ORA DX.

Planning sessions focus on developing a comprehensive and strategic plan for eSAF transition and retirement:

- Iteratively review existing eSAF functionality and its priorities
- Review eSAF User Survey responses
- Discuss related broader DX needs

The Mouse

A mouse can come in many sizes, shapes, colors, and configurations. The selection and placement of a pointer/mouse is a very important factor in creating a safe computer workstation. If you have a mouse issue, consider the following tips:



- Keep the pointer/mouse close to the keyboard.
- Alternate hands with which you operate the pointer/mouse.
- Use keyboard short cuts to reduce extended use.

For more information see OSHA article on pointers.

"The only lasting beauty, is the beauty of the heart." - *Rumi*

ORA DATA EXCHANGE
Frequently Asked Questions

Question: Can any regulatory partner participate in any ORA Data Exchange (DX) Program capability?

Answer: Yes. Any regulatory partner can participate in any ORA Data Exchange (DX) Program capability; however, there could be additional criteria for participation in certain data exchange capabilities. For example, MFRPS conformance is required to participate in non-contracted inspection data exchange capabilities.

Data Exchange Information Resources

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

Question: Will the ORA Data Exchange (DX) Program systems replace Electronic State Access to FACTS (eSAF), and what is the timeline?

Answer: Yes. FDA plans to retire eSAF and migrate selected capabilities into the ORA Data Exchange (DX) Program systems. The timeline for retiring eSAF is still being finalized. FDA expects to announce the timeline in 2021, and the retirement date will be scheduled for 2022 at the earliest.

Question: Is LFFM a requirement for labs to participate in sample data sharing?

Answer: No. LFFM is not a requirement to participate in sample data sharing. However, sample data is submitted to FDA via the ORA Data Exchange (DX) Program for FDA assignments and not for surveillance purposes.

To read additional ORA DX FAQs, click here.

Question: Does System-to-System services support uploading inspection report documents?

Answer: Yes. Currently, System-to-System services supports the uploading and deletion of attachments along with the retrieval of the list of inspection attachments - not to be confused with the actual attachments themselves.

Question: What is the process for regulatory partners to request new ORA Data Exchange (DX) Program accounts?

Answer: Regulatory partners should email the ORA DX Outreach Team at NFSDX_Info@fda.hhs.gov to request new ORA Data Exchange (DX) Program accounts. Information about the users such as first and last name, agency name, email address, and DX capability information should be provided. The request goes through an approval process. Once approved, the FDA will authorize and provide login credentials directly to the user.
System-to-System services is between state and FDA systems. The FDA provides agency-specific system credentials (not individual user) and connection information for approved regulatory partners.

Question: How can I request additional information about DX capabilities?

Answer: Requests for additional information can be sent to NFSDX_Info@fda.hhs.gov or requests can be sent from the contact us page on the ORA Partners Portal (ORAPP).

Drink Tart Cherry Juice and Get More... Z Z Z s

Research shows that drinking tart cherry juice concentrate provides an increase in exogenous melatonin that may be beneficial in improving sleep duration and quality, and might be of benefit in managing disturbed sleep. For more information see Effect of tart cherry juice (Prunus cerasus) on melatonin levels and enhanced sleep quality.

"I cook with wine. Sometimes I even add it to the food." - *W.C. Fields*