PFP IT WG NEWSLETTER

PARTNERSHIP FOR FOOD PROTECTION INFORMATION TECHNOLOGY WORKGROUP

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Featured Articles

Highlights

Coffee Talk with Ellen Buchanan

The FDA Office of Regulatory Affairs (ORA) Data Exchange (DX) team recently had the pleasure of catching up with Ellen Buchanan, Director of Audit Staff at Office of Human and Animal Food Operations (OHAFO), for a Coffee Talk. As one of the initial founding members of the PFP IT WG, she talks about the commitment and vision from the very beginning to how far the DX has matured since. Enjoy reading more about Ellen and the Audit Staff Team as she shares a very interesting and enthusiastic perspective of the ORA DX program. *Continued on page 4…*

ORA DX Program Updates

The following state agencies are joining in select data sharing capabilities:

Via System-to-System (NFSDX):

- Maryland Department of Health Laboratories Administration

Via ORA Partners Portal (ORAPP):

- South Carolina Department of Health and Environmental Control
- 35 State Agencies for Produce Safety Farm Inventory

In addition, six Laboratory Flexible Funding Model (LFFM) Year 2 state labs are participating in the ORA DX:

- California Department of Public Health
- Colorado State Department of Agriculture
- Indiana State Department of Health
- Iowa Department of Agriculture and Land Stewardship
- Rhode Island Department of Health
- Tennessee State Department of Agriculture

"Do not be the proverbial crab in a bucket and make war with those around you! Work together and grow! Love! Live Life!"- Marvin Gaye

Meet the PFP Co-Chair
Patrick (Pat) Kennelly

Pat serves as Governing Council (GC) Co-Chair for the PFP and has been involved with a number of PFP workgroups over the years, including Work Planning, Compliance and Information Technology (IT). As a strong supporter of developing key IT strategies that will allow routine electronic data sharing between states and the FDA, Pat strongly believes that electronic sharing of information is a key cornerstone for a national integrated food safety system.

Pat worked for the California Department of Public Health (CDPH) for 28 years. Prior to his retirement from CDPH in 2017, Pat was Chief of the Food Safety Section and responsible for overseeing the department's statewide food safety operations, which included inspection of processed food manufacturers; investigation of food-borne illness outbreaks, food contamination and tampering events, and food recalls; development and delivery of food safety education to the food processing industry; and oversight of the state's retail food safety program.

When Pat is not protecting our food supply, you will find him working on home improvement remodeling projects or traveling!

Pat joined the Association of Food and Drug Officials (AFDO) in 2017 and has been managing their Manufactured Food Regulatory Program Alliance (MFRPA) Cooperative Agreement with FDA. This has afforded him the opportunity to continue working with states in the development of their manufactured food programs and to provide support to their efforts to conform with Manufactured Food Regulatory Program Standards (MFRPS). Pat also teaches food safety courses periodically, including FD218, FDA's Risk Based Inspections at Retail course.

PATRICK KENNELLY, GOVERNING COUNCIL CO-CHAIR FOR THE PFP

Information Corner

Contact us at NFSDX Info@fda.hhs.gov

Did You Know?

The most often quoted estimate of the number of fish species is 20,000; according to the National Oceanic and Atmospheric Administration (NOAA). The largest fish in the world is actually a shark. The smallest fish is the tiny goby. Scientists can figure out how old a fish is by counting growth rings on its scales or its ear bones (called "otoliths"),

The Orange roughy lives more than 100 years. How long a fish lives depends on its species. Fish would suffocate if they tried to chew their food. For most species, truly fresh fish is almost odorless. To learn more information about fascinating fish, read more...

ORA DX Training

The ORA DX training team offers free online courses to ORAPP users. The available training curriculum includes instructions for creating and submitting simulated data and system demos using ORA DX. Upcoming course schedules are periodically shared on various platforms by the Training Coordinator.

Examples of recent training courses are listed below.

- Firm Search and Firm History
- FDA Collected Samples – Part 1 & Part 2
- State Collected Samples – Part 1 & Part 2
- Non-Contract Inspection (NCI)

Email us at NFSDX_Info@fda.hhs.gov for additional training information.

Strong Passwords

Can you recall all your passwords? we are expected to remember all our passwords, which, in some cases, can be up to 100. Those are a lot of characters to remember. It is understandable why some may think it is okay to create a "strong" new password by changing the sequence of numbers or letters, or even recycling an old password, and using the same password on multiple sites. This does seem risky, but we have too many passwords to remember. To see how hackers crack your passwords and we will show you how to create uniquely strong passwords that you won't forget!
Visit the Cybersecurity and Infrastructure Security Agency Site.

"When you fish for love, bait with your heart, not your brain." **- Mark Twain**

ORA DX Systems and Data Sharing Capabilities

In the Summer/Fall of 2021, four ORA DX releases were implemented: Releases 9.0 and 9.1 (July/August) provided enhancements to the Contracted Inspection (CI) capability for System-to-System (NFSDX), Releases 10.0 and 10.1 (September) enhanced the Samples Receipt and Analysis capability for System-to-System, ORAPP, and Enhanced DX Client. The following enhancements are now available to regulatory partners.

Samples Receipt and Analysis Enhancements (September 2021)

Using System-to-System, ORAPP, and Enhanced DX Client - regulatory partners can:

- Submit Antibiotics (ANT) analysis results to the FDA
- Submit Narrative (NAR) analysis results to the FDA
- Use the new Program Assignment Code (PAC) length for Sample and Non-Contracted Inspections (NCI) submissions
- Download and use the new Sample Receipt and Analysis Excel Template (v 2.3) and the Sample Collection Excel Template (v 1.2) from ORAPP

Contracted Inspection (CI) Enhancements (July/August 2021)

Using System-to-System, regulatory partners can:

- Retrieve a list of point of contacts (POCs) of an FDA firm
- Update FDA firm's POC information including the Top Management Official (TMO) POC designations
- Submit Intentional Adulteration (IA) data to the FDA
- Submit attachment up to size 250 MB to the FDA
- Use the new PAC length for Contracted Inspections (CI)

Connecticut Agricultural Experiment Station (CAES) state laboratory successfully completed its first submission of Sample Analysis Data to the FDA using ORAPP!

Congratulations!

FUN FACT!

The first hamburgers in U.S. were served in New Haven, Connecticut, at Louis' Lunch sandwich shop in 1895. Read more...

For additional information about ORA DX
Contact Us: NFSDX_Info@fda.hhs.gov

"Individually, we are one drop. Together, we are an ocean." – **Ryunosuke Satoro**

Coffee Talk with Ellen Buchanan

Director of Audit Staff
Office of Human and Animal Food Operations (OHAFO)

Interviewed By: Barbara Thiel
Project Manager PFP IT WG, Office of Information System Management (OISM)

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Barbara: Hello Ellen, tell us about yourself and your role and responsibility as Director of Audit Staff at OHAFO/AS. Could you briefly highlight the activities of the Audit Staff and their role at FDA?

Ellen: The role of the Audit Staff originated in 2011 in the Office of Regional Operations (ORO), as part of the Regulatory Program Standards effort for Integration. Senior leaders at the time had a vision for a small, certified team of auditors to work with external stakeholders to evaluate/verify/validate their food safety systems. Domestically we perform assessments with state regulatory programs enrolled in food, animal feed and egg program standards. Internationally we work with Center for Food Safety and Applied Nutrition (CFSAN) International Affairs Staff (IAS) on Systems Recognition with foreign governments. We co-chair the Food Safety Modernization Act (FSMA) Third Party Program with our friends in CFSAN, evaluating Accreditation Bodies and Certification Bodies doing third party assessments of foreign food manufacturing firms. I was lucky enough to be hired as the Audit Staff Director in 2013. Our team of American Society for Quality (ASQ) certified auditors evaluate regulatory foundations, training, inspection protocols, quality assurance programs, emergency response capability, compliance and enforcement, outreach, resource needs and lab capabilities for our external stakeholders in each of the domestic and foreign programs we participate in.

Barbara: Are the audits event driven or are they scheduled in advance or a combination?

Ellen: The domestic Regulatory Program Standards have a requirement for any enrolled state programs to sit for an audit every two years. System Recognition has a five-year audit cycle, and the Third-Party Program provides various audit cycles, depending on how their programs are structured. Each of the external stakeholder programs have an audit component, providing FDA with understanding and confidence in work performed by the programs. This allows FDA to assign our own resources based on risk in areas not covered by these external stakeholder programs.

Barbara: You are a longtime member of the PFP IT WG. Over the years, are there any moments that you think were key to the success of the IT WG and the DX program?

Ellen: I was one of the founding workgroup members of the PFP IT WG. FDA's Caleb Michaud and Drew Polulak (formerly) of Pennsylvania Department of Agriculture were the first co-chairs. Over the past few years, I have delegated this important work to my team members, Clinton Priestley and Matt Colson for scheduling availability and their interest and knowledge of the IT systems, both at the state and with the FDA.

I think the commitment from the very beginning of PFP to recognize the importance of IT and to form the PFP IT WG was wise. From the beginning, the PFP IT WG was involved in the USAFoodSafety System which was built with cooperative agreement funding from the FDA. Their commitment and vision from the very beginning on the details of the data elements collected by FDA and states was an indicator of the variety of systems states use and how we were going to work toward exchanging two-way data in real time.

There was a quick realization this effort would require a long-term commitment and would be achieved incrementally. To me, it was the commitment and the vision, and continual dedicated effort from FDA and the states in the PFP IT WG community. The PFP IT WG has been a stable group over time, with little turnover of work group members. That means that there is interest, people are curious, people are committed, and everybody involved should get a little bit of that credit because as you know, it is no easy task; it is complex.

Barbara: I receive many notes from PFP IT WG members saying, please leave me on even though I cannot join the call, I listen to the recording and I read your meeting notes. I really do think that a lot of people, even if they can't actively participate, are getting a lot of information. And for some, it is the sole source of information about what is going on with the DX. So we are trying to come up with a way to get members more active in our WG meetings. From your feedback, is there something the PFP IT WG could be doing differently or better to get people to be more active again?

Ellen: I am over the moon ecstatic that when you send notes out to state workgroup members they ask to be left on the invite because they read the meeting notes and listen to the recording. At the point when it is feasible for a state to onboard, they will have the knowledge and background needed to move forward. You never know which state is going to be at the moment of ready, so I'm glad they're engaged even if they can't attend the meetings or fully participate. Additionally, there are components in ORA who work closely with our state partners that might be able to provide assistance on when a state might be ready to fully engage with electronic transfer of data (DX). Read more...

"May you always have a shell in your pocket and sand between your toes." - Anonymous

Sample Data Sharing

Maryland Department of Health (MDH) Laboratories Administration, Division of Environmental Sciences

Over the past couple of years, the Office of Regulatory Science (ORS), ORA, FDA, worked with the Office of Information Systems Management (OISM) to build data sharing capabilities to enable state laboratories to submit analytical sample results via the ORA DX systems to the FDA. In January 2021, the first sample data sharing capability related to FDA samples was released for state labs use. ORS plans to open this up to more state labs in the near future.

Recently, the Division of Environmental Sciences at the Maryland Department of Health (MDH) Laboratories Administration signed-up for sample data sharing via System-to-System funded by the Laboratory Flexible Funding Model (LFFM) for year one. The agency completed system integration development in three weeks and is on track to complete testing. The agency successfully implemented their fast-track plan for the development process. Such fast-paced system integration for System-to-System is quite remarkable and groundbreaking. It was a result of a long-standing partnership between the agency and their IT vendor on a series of projects including a large-scale Laboratory Information Management System (LIMS) upgrade that preceded System-to-System integration.

The agency is now close to being operational with System-to-System in Production. The successful strategy was based on a staged approach: in the first stage, lab scientists worked hand-in-glove with their IT programmers to configure their LIMS to encompass all of the data fields required for System-to-System. A cadre of dedicated food sample collectors were deployed in the field to test the new MyLIMS data entry portal. Upon proper configuration and testing of the LIMS, they proceeded with the System-to-System integration development. Having a solid foundation to build upon contributed to a relatively smooth and rapid integration process. The agency is excited to have its food safety testing data available to the FDA in near real-time to enhance data usefulness in protecting public health and looks forward to having additional testing capacity as a result of freeing its dedicated scientists from spending hours on manual data entry.

The agency encourages other state labs to implement ORA DX via System-to-System, and stands ready to offer advice and guidance as requested.

For additional information about MDH Laboratories Administration, Read more…

Seafood HACCP and FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA) is transforming the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it. It enables the FDA to better protect public health by ensuring the safety and security of the food supply. It requires the FDA to promulgate food safety rules that focus on preventing food safety issues rather than relying on detecting issues and reacting to them after they occur. FSMA recognizes that FDA has previously established a preventive control type regulation for fish and fishery products, based on the Hazard Analysis and Critical Control Point (HACCP) principles and plan. The seafood HACCP regulation requires seafood processors to identify food safety hazards that are reasonably likely to occur and develop plans to control the hazards. In addition, the seafood HACCP regulation requires importers of certain seafood products to comply with requirements designed to help ensure that the imported products are processed in accordance with the seafood HACCP regulation. Importantly, several of the regulations that the FDA has issued under FSMA provide exemptions related to the seafood HACCP regulation. This guidance addresses the exemptions, and also provides information about the seafood HACCP regulation in connection with the FSMA regulations. Read more….

***"A smooth sea never made a skilled sailor."* – Franklin D. Roosevelt**

ORA DATA EXCHANGE (DX) Frequently Asked Questions (FAQs)

Question: What is the ORA DX program?

Answer: The ORA DX program enables secure electronic information sharing between regulatory partners and the Food and Drug Administration (FDA). Two IT systems have been implemented to support secure data exchange including: Partners Portal (ORAPP) and System-to-System (NFSDX). The DX systems also include the Enhanced DX Client which supports the submission of sample data only (i.e., collection, receipt and analysis data for FDA and state collected samples) to FDA. Participation provides regulatory partners with the following benefits; increases efficient electronic data exchange between FDA and regulatory partners, it also increases collaboration, and reduces dual data entry in regulatory partner and FDA systems.

Question: How does a regulatory partner sign-up for an ORA DX program?

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, FDA reaches out to the state agencies based on various FDA initiatives. Each partner participation request will be reviewed and approved by the FDA.

For additional ORA DX FAQs,
Read more....

Question: Is participation in the ORA DX program voluntary?

Answer: Yes. It is voluntary to use the ORA DX systems. In the future, with eSAF planned to be retired, regulatory partners will need to use one of the ORA DX systems to submit their data to FDA.

Resources and Useful Information

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

Question: Can any regulatory partner participate in any ORA DX capability?

Answer: Yes. Any regulatory partner can participate in any ORA DX 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 sharing capability.

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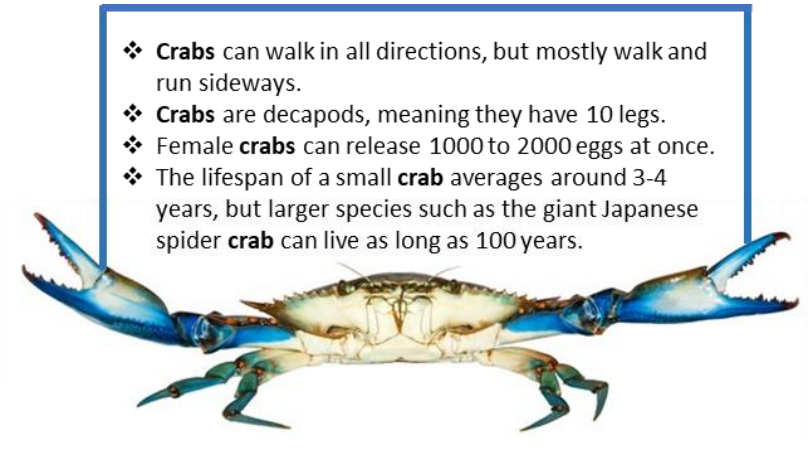
Question: Can inspections with incorrect data be returned to the regulatory partner via the ORA DX program?

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

Question: What is the process for regulatory partners to request new ORA DX system(s) accounts?

Answer: Regulatory partners should email the ORA DX Outreach Team at NFSDX_Info@fda.hhs.gov to request ORA DX systems' 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 FDA approval process. Once approved, the FDA authorizes and provides login credentials directly to the user.

System-to-System services are between state and FDA systems. The FDA provides agency-specific system credentials (not individual user) and connection information for approved regulatory partners.



***"I have a Guinness Book of World Records entry as the most-watched person on television. now I have a new entry as the only man who has a crab named after him."*- David Hasselhoff (aka "Hoff Crab")**