

#### In This Issue

#### **Featured Articles**

Coffee Talk – Barbara Cassens ORA DX Release 15.0 Updates IT WG Spotlight

### **Highlights**

ORA DX Tech Talk
ORA DX State Feed Program
Outreach
Office of Regulatory Science (ORS)
Sample Data Sharing
Coffee Talk – Barbara Cassens
ORA DX Training Highlights
Frequently Asked Questions

#### **Food Safety Tips**

Handling Food Safely While Eating Outdoors



# COFFEE TALK WITH Barbara Cassens



The FDA Office of Regulatory Affairs (ORA) Data Exchange (DX) team recently had the pleasure of catching up with Barbara Cassens, Director of the Office of Partnerships (OP) with the Office of Regulatory Affairs (ORA). With Barbara's leadership the mission of the PFP IT WG has advanced. Read about Barbara's role and interesting perspective of the ORA DX program on page 4. The Coffee Talk article is available on the PFP website.

# ORA DATA EXCHANGE (DX) RELEASE 15.0 UPDATES

# ORA Partners Portal (ORAPP) – Regulatory partners can:

- access updated data elements and list of values in Sample templates
- access the updated Contact Us page
- access the public Training page containing Data Exchange training materials
- leverage the new e-Learning courses about Sample Receipt, Sample Analysis, and System-to-System

# System-to-System – Regulatory partners can:

- submit Food Defense Plan Quick Check (FDPQC) inspection protocol data
- potentially receive establishment type, industry code, and season start/end month fields via Firm Search results



Next PFP IT WG Meeting: June 26, 2023

"Life is like an ice cream cone; you have to lick it one day at a time." — Charles M. Schulz

# Spotlight on the PFP Outreach Workgroup

The PFP Outreach Workgroup (WG) aims to increase visibility, awareness, support, and participation in PFP activities. Through greater awareness, there is an increase in IFSS participation and support, helping further promote PFP's vision for mutual reliance.

The past several years, members of the Outreach WG created a repository of resources and promotional materials, developed a graphics library housed on FoodSHIELD



PFP Outreach WG Leadership Team: Randy Young (AFDO); Jessica Badour (AFDO); Ryan Cates (FDA, ORA); Kimberly Birkin (NY Dept. of Ag.); Brenda Stewart-Munoz (FDA, ORA).

to support communication activities and created and continue to maintain the PFP website.

In the PFP Strategic Plan, the Outreach WG has members liaise with the other workgroups, ensuring coverage and promotion of other groups' activities and products in PFP communications. The Outreach WG also continues to consider ways to develop new content and increase dissemination through a variety of channels, including website, social media, email, stakeholder newsletters, virtual and face-to-face conferences/meetings, etc.

The WG serves as the PFP's primary source to help share success stories about the PFP, IFSS, and examples of mutual reliance by writing, pitching, and publishing information. There is support for graphics and design materials, and key members of the Outreach WG provide ongoing website maintenance and content updates, as well as regular social media posts and engagement on Twitter.

To learn more about the Outreach WG, email PFP at pfp@pfp-ifss.org and follow us on Twitter @pfp-ifss.

### Get to Know AAFCO's Austin Therrell

Austin currently serves as the Executive Director for the Association of American Feed Control Officials (AAFCO). Prior to his current role with AAFCO, he served on the Board of Directors and as the Co-Chair of the AAFCO Feed and Feed Ingredient Manufacturing Committee, as a member of the AAFCO Pet Food Committee, and as a member of the Current Issues and Outreach Committee. Austin previously served as the Animal Feed Program Manager for the South Carolina Department of Agriculture where he oversaw animal food inspection priorities across the state, product registrations, labeling compliance, and a statewide sampling program.

Get to Know AAFCO's Austin Therrell by checking out a recent article published on the American Feed Industry Association (AFIA) Feed Bites Blog.

"Roll out those lazy, hazy, crazy days of summer." — Sam Cooke

Issue 14 June 2023



# ORA DX State Feed Program Outreach with Omari Fennell

Recently, we have been reaching out to state animal food and feed programs to spread the good news about the ORA Data Exchange (DX). Did you know that there are certain ORA DX features that have been developed specifically for state feed programs?

For instance, Bovine Spongiform Encephalopathy (BSE) Checklist results can be submitted to FDA seamlessly and directly from a regulatory system via System-to-System. Additionally, the Firm Inventory Reconciliation and Non-Contracted Inspection data sharing capabilities are also available for state programs.

The ORA Partners Portal (ORAPP) Firm Search and History capability is also available to state agency feed programs that have a Food and Feed 20.88 agreement with FDA. This capability provides over 100+ data elements for firms in



FDA's inventory including inspectional information, that can assist with work planning. Over the past few months, new state feed partners have come onboard for this capability including Georgia Dept. of Agriculture, Illinois Dept. of Agriculture, Maryland Dept. of Agriculture, Ohio Dept. of Agriculture, and Washington State Dept. of Agriculture.

It has been a pleasure interacting with the new partners. Thanks to all the State Liaisons that assisted me with getting connected with them.

If you desire access to an ORA DX capability or have any questions, please reach out to us via the <a href="https://orange.com/ORAPP-Contact-us-page">ORAPP Contact-us-page</a> or via email at <a href="https://orange.com/APPSDesk@fda.hhs.gov">APPSDesk@fda.hhs.gov</a> (put "ORA DX Info" in email subject).

Omari Fennell, ORA DX Outreach Coordinator

Office of Regulatory Sciences (ORS)
Sample Data Sharing

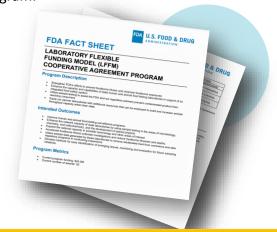


FDA will not require ORA DX as the sample (lab) data reporting mechanism for all Laboratory Flexible Funding Model (LFFM) product testing track in the next Notice of Funding Opportunity (NOFO). The sample data reporting mechanism for LFFM Product Testing Track will remain as quarterly spreadsheet uploads via the Food Emergency Response Network (FERN) Portal.

Questions? Contact LFFM experts Lauren Yeung, and Office of Partnerships (OP), Erin Woodom-Coleman at ORA-LFFM-CAP@fda.hhs.gov.



Select the FDA Fact Sheets below to <u>READ</u> <u>MORE</u> on the LFFM Cooperative Agreement Program.



"Live in the sunshine, swim the sea, drink the wild air." — Ralph Waldo Emerson

Issue 14 June 2023



### **Coffee Talk with Barbara Cassens**

Director, Office of Partnerships (OP)
Office Of Regulatory Affairs (ORA), FDA
& Governing Council Co-Chair,
Partnership for Food Protection (PFP)

#### Continued from page 1

Hello, Barbara! Tell us about your role as director of Office of Partnerships (OP) at FDA.

Of course! OP is currently located in the Office of Regulatory Affairs (ORA) under the Office of Partnerships and Policy (OPP). I direct and oversee the investments in state, local, territorial, and tribal (SLTT) partners and partner associations that cover foods and medical products. This includes a budget of around \$115M to support federal-state initiatives, but it is not just about money. It is supporting and promoting the activities of the regulatory program standards, training, cooperative programs, information sharing and disclosure, laboratory and medical products initiatives and rapid response teams. There are also our coordination efforts with international and federal partners with all FDA offices, and efforts to measure and visualize integration through a series of interactive dashboards. In addition, it involves promoting and advancing Domestic Mutual Reliance (DMR) activities that will get us to One Integrated Workforce under an Integrated Public Health Safety System. I do this successfully through the work of a very talented, forward-leaning, amazing staff in OP. Most days I feel like a coach, mentor, cheerleader, advocate, and conductor all rolled into one person!

What are some of ORA's strategies and plans for achieving DMR, working collaboratively with other ORA offices, FDA centers, and external partners (SLTTs, regulatory/public health associations, and the PFP)?

It really takes everyone — all of FDA, the SLTT and association partners — to make DMR a reality. OP promotes, encourages, and supports partnerships between the state and the field division offices, but it is the states and division offices that do the heavy lift. One of the purposes is sharing resources and mutual support to overall field operations and emergency response activities. A huge part of this is joint work planning and improving the establishment inventory.



Did you know that Barbara loves making jewelry and watch repair? She considers herself an armchair archaeologist and enjoys experiencing new cultures.

Barbara's favorite ice cream is Rum Raisin!

Each partnership is constructed to be unique to the state and FDA field office considering that each relationship is at a different place on the continuum. And, as I mentioned previously, as it all comes together, we will achieve One Integrated Workforce for the greater protection of public health. One of my goals is to achieve a partnership agreement with at least 25 state agencies and corresponding ORA field offices by 2025, present resources allowing. DMR builds on all the foundational elements, i.e., program standards, rapid response teams to reach a state where we work seamlessly together on public health protection. And DMR sells itself. Those state/FDA partners engaged at this close working level sell the idea to other offices.

The PFP IT WG would like to thank Barbara for her support of the ORA DX program and her leadership. For more on Barbara's insight, continue reading the rest of the conversation on the PFP site!

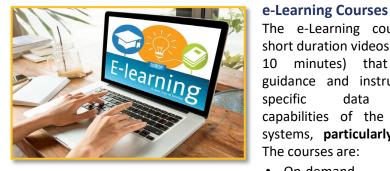
"When all else fails, take a vacation." — Betty Williams

Issue 14 June 2023

## **ORA DX Training Highlights**

ORA DX e-Learning courses are now publicly accessible! You no longer need an account to access and view training materials or videos. Start your training today and access the ORAPP e-Learning page to explore the 16 e-Learning courses today!

Training is focused on ORA DX Systems including ORAPP capabilities. Training is available as e-Learning or Instructor-Led courses. Knowledge Articles are a new addition to the training materials.



#### Instructor Led Courses

The instructor-led courses greatly boost the understanding of the ORA DX systems via instructor and student interactions using structured and focused training materials that are accompanied by a live system demo and practice exercises. The courses are:

- On-demand
- Interactive
- Virtual
- Limited to

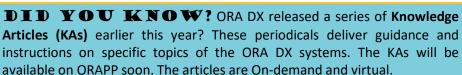


The e-Learning courses are short duration videos (less than 10 minutes) that provide guidance and instruction on specific data sharing capabilities of the ORA DX systems, particularly ORAPP. The courses are:

- On-demand
- Virtual
- Non-interactive
- Accessible by the public via ORAPP



To learn more about the ORA DX Training courses and KAs, Check out the ORAPP Training page



To register for upcoming instructor-led courses, or to find out more information DX on ORA Training, please contact us at APPSdesk@fda.hhs.gov.

"Summer means happy times and good sunshine." — Brian Wilson





## **ORA DX Frequently Asked Questions (FAQs)**

### Resources and Useful Information

- PFP Website and Twitter
- PFP IT WG Page
- PFP Strategic Plan
- ORA Partners Portal
- AFDO Newsletters
- <u>Presentations at MFRPA</u>

**Conferences** 

 Contact Us at AppsDesk@fda.hhs.gov

#### Question: Are FDA firm updates allowed via ORA DX?

Answer: Yes. Currently, the System-to-System allows updates for FDA firm inventory along with the inspection data. The recommended inventory updates are inspection specific and are manually reviewed by FDA State Liaisons or State Contract Monitors in eSAF. Post approval, the changes are propagated to internal FDA systems. Future ORA DX releases shall provide two-way inventory reconciliation between FDA and regulatory partner. FDA firm inventory will be updated using insights from the regulatory partner during planning and inspection phases. Similarly, updates of FDA inventory will be sent to regulatory partner during their planning and pre-inspection preparatory activities.

# Is the Food Defense Plan Quick Check (FDPQC) available for Contracted Inspections in the DX?

Answer: Yes. eSAF and System-to-System are synchronized for FDPQC data from regulatory partners. State partners using eSAF have the same functionality available using System-to-System Contracted Inspection web services. However, the FDPQC functionality cannot yet be used by states as the PAC associated with this functionality has not been turned on in Production.

### For additional ORA DX FAQs read more . . .

 12 pounds of milk are used to produce just 1 gallon of ice cream

 50 is the average number of licks to finish a single scoop of an ice cream cone

 Vanilla is the most popular flavor ice cream, followed by chocolate

Chocolate ice cream was invented before vanilla

On average Americans eat 45.8 pints of ice cream a year



"You are so much sunshine in every square inch." — Walt Whitman

# Food Safety Tips: Handling Food Safely While Eating Outdoors

Picnic and barbecue season offers lots of opportunities for outdoor fun with family and friends. But these warm weather events also present opportunities for foodborne bacteria to thrive. As food heats up in summer temperatures, bacteria multiply rapidly.

To protect yourself, your family, and friends from foodborne illness during warm-weather months, safe food handling when eating outdoors is critical. Read on for simple food safety guidelines for transporting your food to the picnic site and preparing and serving it safely once you've arrived.

Food safety begins with proper hand cleaning — including in outdoor settings.

Before you begin setting out your picnic feast, make sure hands and surfaces are clean.

Utensils and Serving Dishes: Take care to keep all utensils and platters clean when preparing food.



Outdoor Hand
Cleaning: If you don't
have access to
running water, use a
water jug, some soap,
and paper towels. Or
consider using moist
disposable towelettes
for cleaning your
hands.





For more Food Safety Tips, check out the <u>FULL ARTICLE</u> for additional tips on handling **Food Safely While Eating Outdoors**.



"It's always summer somewhere." — Lily Pulitzer