

#### In This Issue

Fea	•••	400	1 A	whi		00
F E 6	144	120		100	u	125

Coffee Talk - Matt Colson ORA DX Release 16.0 Updates PFP Lab Science WG Spotlight 2 Lab Flexible Funding Model (LFFM) Spotlight 2

#### **Highlights**

Coffee Talk - Matt Colson Domestic Mutual Reliance (DMR) and Non-Contract Inspections (NCI) in Iowa PFP IT WG Accomplishments via ORA DX 4 **ORA DX Training Highlights** ORA DX Frequently Asked Questions (FAQs)

#### **Food Safety Tips**

September is National Food Safety **Education Month** 



# COFFFF TALK WITH Matt Colson



The PFP IT WG recently had the pleasure of catching up with Matt Colson, Consumer Safety Officer, Auditor with the Office of Human and Animal and Food Operations (OHAFO), Office of Regulatory Affairs (ORA), FDA for a coffee talk about the ORA Data Exchange (DX) program. Read about Matt's role and interesting perspective of the ORA DX program on page 3. The Coffee Talk article is available on the PFP website.

# **ORA DATA EXCHANGE (DX) RELEASE 16.0 UPDATES**

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

- see potential increase in the IR match outcomes due to matching of state Doing Business As (DBA) to the FDA firm legal name
- access improved Sample Analysis templates for DEC analysis data submission
- update **ORAPP** account password to be at least 15characters in length

For information regarding current and prior releases, read more on the ORAPP About page, under Recent Releases.



**Next PFP IT WG Meeting:** 

Sept. 25, 2023

"The more that you read, the more things you will know. The more that you learn, the more places you'll go." - Dr. Seuss

Issue 15 September 2023

# Spotlight on the PFP Laboratory Science Workgroup

The Laboratory Science Workgroup (WG) supports the Partnership for Food Protection's (PFP) vision of mutual reliance for a safer food supply. Comprised of federal, state and association partners, the WG creates resources that build confidence among stakeholders in the integrity and scientific validity of laboratory analytical data and facilitate acceptance of laboratory analytical data by regulatory agencies. The WG:





Promotes use of national lab best practices



Supports efforts to achieve lab accreditation to ISO/IEC 17025 standard



Supports development of a lab science data system for sharing results between strategic partners Pictured PFP Laboratory Science WG Members (left to right): Susan Humphries (FDA); Robyn Randolph, Project Manager (APHL); Kirsten Lawson (APHL); Madhu Chatterjee (NH PHL); Ravinder Reddy (FDA); Amy Bryant (APHL); Sunee Himathongkham (FDA); Stacie Hammack (FDA); Cindi Mangione, Co-Chair (NY Dept. of Ag & Markets); Frank Greene (CT Dept. of Consumer Protection); Megan Young (FDA); Teresa Jarvis (WY Dept. of Ag) Members not pictured: Brian Sauders (NY Dept. of Ag); Christina Chrysogelos (FDA); Christopher Waggener (FDA); Debra Oglesby (NY Dept. of Ag); Dorota Inerowicz (Office of Indiana State Chemist); Guy Delius (FDA); Kirsten Hirneisen, Co-Chair (FDA); Maria Ishida (NY Dept. of Ag); Michael Wichman (FDA); Mike Farrow (FDA); Rachael Yeskey (AZ Dept. of Health Services); Raymond Allum (FL Dept. of Ag); Reagan Converse (NC Dept. of Ag); Ruiqing Pamboukian (FDA), Sally Flowers (KS Dept. of Ag); Shari Shea (APHL); Sherri McGarry (CDC); Sinisa Urban (MD PHL); Terri McConnell (FDA); Tim Tyson (FDA)

The Laboratory Science WG is collaborating with the PFP IT WG to review and enhance the ORA DX program, a PFP initiative that contributes to the development of the Integrated Food Safety System (IFSS) by enabling electronic sharing of food safety information and data between the FDA, states, local health departments, and various regulatory partners. The Laboratory Science WG has produced best practice recommendations to ensure laboratory data defensibility, a checklist to assist in compliance review of laboratory data packages, and a repository of information related to major federal and state laboratory initiatives.

To learn more about the Laboratory Science WG email PFP at <a href="mailto:pfp@pfp-ifss.org">pfp@pfp-ifss.org</a> and follow on Twitter <a href="mailto:opfp-ifss">opfp-ifss</a>.

# Laboratory Flexible Funding Model (LFFM) Spotlight



The FDA Office of Partnerships is pleased to release another informational overview video on an important national cooperative agreement project – the Laboratory Flexible Funding Model (LFFM).

This video provides a brief overview of the FDA's <u>LFFM</u> <u>Cooperative Agreement Program</u>. 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. Watch the LFFM Cooperative Agreement Spotlight Video <sup>1</sup>

 ${\color{red}1} \ (\mathsf{FDA}, \textit{Laboratory Flexible Funding Model Program Cooperative Agreement Spotlight}, \mathsf{FDA}.\mathsf{gov}, \mathsf{July 2023})$ 

"I am a part of everything that I have read." — Theodore Roosevelt



Issue 15 September 2023



# Coffee Talk with Matt Colson

Consumer Safety Officer, Auditor Office of Human and Animal Food Operations (OHAFO) Office Of Regulatory Affairs (ORA), FDA

#### Continued from page 1

Hello, Matt! Tell us about your role and responsibilities as a member of the ORA Office of Human and Animal Food Operations (OHAFO) Audit Staff.

The Audit Program was formed in 2008 to address audit requirements set forth in the Manufactured Food Regulatory Program Standards (MFRPS) cooperative agreement. The OHAFO Audit Staff was officially established in 2013 and has since expanded to include the Animal Feed Regulatory Program

Matt participated in the 1st Coffee Talk - April 16, 2019, while serving with the Florida Dept. of Agriculture.

**DID YOU** KNOW?

CHECK OUT THE ARTICLE

Standards (FRPS), the Egg Regulatory Program Standards (ERPS), and the Voluntary Retail Food Regulatory Program Standards (VNRFRPS) in the domestic portfolio. The Audit Staff also recently participated in the development of the Produce Regulatory Program Standards (PRPS), which should be finalized in late 2024. In addition to the domestic regulatory program standards work, the Audit Staff is also engaged in an international portfolio consisting of the Accredited Third-Party Certification Program (TPP), Systems Recognition, Equivalency determinations with foreign competent authorities, and the Regulatory Partnership Arrangement Program. The Audit Program's primary focus is to meet the agency's increasing responsibility to provide accountability of contractual and non-contractual food safety work products. Confidence of the operational systems used by our partners and/or stakeholders is achieved primarily through an objective assessment of their food safety system programs.

The PFP IT WG would like to thank Matt for his support of the ORA DX program. For more on Matt's insight, continue reading the rest of the Coffee Talk on the PFP site!

These days Matt's focus is health and fitness (mental and physical), and spending time with his family, friends, and loved ones.













**Domestic Mutual Reliance** 



# Domestic Mutual Reliance (DMR) and Non-Contract Inspections (NCI) in Iowa

The FDA worked closely with state regulatory partners in Florida, Iowa, Pennsylvania, Utah, Virginia, and Wisconsin to achieve the major milestone of accepting 1,000 non-contract inspections. Also known as NCIs, these non-high-risk inspections are conducted by the state under its own authority in which no other regulatory action was required. Similarly, these states have been able to leverage a similar number of FDA inspections to support their oversight activities. NCIs greatly increase efficiency and minimize duplication of efforts for both regulators and industry. These efficiencies enable the FDA and state regulatory partners to maximize the impact of millions of dollars in state and federal funding, thereby avoiding additional burden to the American taxpayer and enabling regulators to expand coverage and focus limited resources on areas of highest risk to advance food safety for consumers. Learn more about NCIs in the PFP story.

Check out the FULL STORY HERE.<sup>2</sup>

2 (Krysten Carrera, Domestic Mutual Reliance and Non-Contract Inspections in Iowa, PFP-IFSS.org 2023)

"All I have learned, I learned from books." — Abraham Lincoln

Issue 15 September 2023

# PFP IT WG Accomplishments via ORA DX

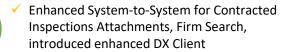
### 2023

- ★ Enhanced ORA Partners Portal (ORAPP), System-to-System, Training, Outreach, and restrategized collaboration with FDA State Liaisons (SLs) and Field Managers (FMs)
- Expanded Sample data sharing capabilities for additional PAFs and managing multiple files submission
- Expanded inspection and inventory data sharing capabilities for Food Defense Plan Quick Check (FDPQC), Contracted Inspection data, Firm Search results, and Inventory Reconciliation matches
- Expanded ORA DX training via e-Learning courses and Knowledge Articles
- ✓ ORAPP modernization Initiated Appian POC



## 2019-22

- Released ORA Partners Portal (ORAPP), rebranded NFSDX project to ORA DX program, enhanced Outreach and Training, and retired eLEXNET
- ✓ ORAPP capabilities included Firm Search, Firm History, Inventory Reconciliation, Non-Contract Inspections, Produce Safety Farm Inventory, Sample Analysis, Sample Collections, e-Learning courses, User Resources such as Frequently Asked Questions (FAQs), Guidance Materials, and Contact Us



 Implemented ORA DX Outreach strategy and expanded ORA DX adoption across states

- Developed 5-year PFP IT WG objectives, restrategized PFP IT WG collaboration, implemented Quarterly Coffee Talk and Newsletters in addition to instructor-led trainings
- Developed draft multi-year plan for eSAF transition to ORA DX
- Initiated ORAPP modernization activities

# 2012-15

- ✓ Established PFP IT WG
- ✓ Successful pilot to transfer Pennsylvania Department of Agriculture (PDA) Bovine Spongiform Encephalopathy (BSE) inspection results to FDA
- Developed data integration and data elements harmonization principles
- Conducted survey with states to understand their data capture and information systems
- ★ Laid foundation for a Data Exchange

## 2016-18

- ✓ Identified scenarios for DX Inspection Data to FDA, FDA Firm Search, State to State Firm Search
- Established 20.88 Agreements, State Onboarding Manuals, State Engagement Questionnaire, State Integration Guides, State Integration Plans, etc.
- Engaged pilot states (AR, FL, IL, IA, MN, PA, and TX) for the three scenarios
- Launched National Food Safety Data Exchange (NFSDX) project and established Initial Operational Capability (IOC)



"When I got [my] library card, that was when my life began." — Rita Mae Brown

Issue 15 September 2023



ORA DX e-Learning

courses are short videos (less than 10 minutes) that provide guidance and instruction on specific data sharing capabilities of the ORA DX systems, particularly ORAPP. Videos can be accessed via the ORAPP e-Learning page. Explore the 18 e-Learning courses today!

Knowledge Articles (KAs) are periodicals that deliver guidance and instructions on specific topics of the ORA DX systems. The KAs for the ORA DX systems are available on the new ORAPP Knowledge Articles page.

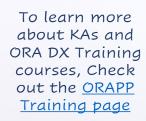
For more information about the ORA DX Program, submit a request via the <u>Contact Us</u> page.

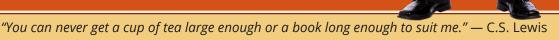
#### **ORA DX Knowledge Articles**

- ORA DX Training Overview An overview of the ORA DX training solutions to assist with the FDA data exchange activities via the ORA DX systems. May 2023
- ORA DX Training Resources Focuses on an overview of ORA DX e-Learning training resources. June 2023
- ORA DX Training FAQs An overview of the two FAQ documents regarding the ORA DX program and related systems. July 2023

#### **Sample Data Sharing Knowledge Articles**

- ORAPP Multi-File Submission for Sample Collections Instructions on how to submit multiple Sample Collections files per single submission via ORAPP. February 2023
- ORAPP Multi-File Submission for Sample Receipt and Analysis Instructions on how to submit multiple Sample Receipt and Analysis files per single submission. February 2023





Issue 15 September 2023

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

Question: What is a Knowledge Article (KA) and how does it differ from e-Learning courses?

Answer: A KA is a periodical (<5 pages) that delivers guidance and instructions on specific topics of the ORA DX systems. KAs are distributed periodically via email to ORA DX participants and will be available on ORAPP soon. KAs focus on a specific feature within a data sharing capability while a set of e-Learning courses focus on an entire ORA DX data sharing capability. The e-Learning courses maintained to be current with the ORA DX systems. KAs are time-based snapshot articles designed to describe a specific feature.

Question: Where are the Knowledge Articles (KAs) located?

Answer: Anyone can access KAs on the new Knowledge Articles page via the Training menu on ORAPP.

# Resources and **Useful Information**

- **PFP Website and Twitter**
- **PFP IT WG Page**
- **PFP Strategic Plan**
- **ORA Partners Portal**
- **AFDO Newsletters**
- **Presentations at MFRPA Conferences**
- **Contact Us via ORAPP Contact Us page**

The FAQs for the ORA DX program may be updated with every ORA DX release. For additional ORA DX FAQs read more . . .

# September is National Food Safety Education Month 2023 is Focusing on People at Higher Risk

Each September for 25 years, in recognition of National Food Safety Education Month, health educators and consumers have focused on the most effective ways to avoid foodborne illness, also known as "food poisoning." The Federal government estimates that there are about 48 million cases of foodborne illness annually - that's about 1 in 6 Americans each year.

Foodborne illness is unpleasant and potentially dangerous for everyone, but you can avoid getting sick by following simple steps - Clean, Separate, Cook, Chill, and if at a higher risk, then possibly avoiding certain foods. FDA has many <u>resources</u> that can help you stay healthy and safe.

This year we want to bring special attention to people who are at higher risk and help them, their family members, and caregivers by highlighting food safety information to avoid foodborne illness. High-risk people include children under 5 (as their immune systems are not fully developed) and those with immune systems weakened by pregnancy, aging, certain chronic diseases or autoimmune disorders, and immunosuppressive treatments.3



For more on Safe Food Handling and FDA Food Safety Resources for People at Higher Risk, check out the FULL ARTICLE here.

3 (National Food Safety Education Month 2023 - People at Higher Risk, FDA.gov, Sept. 2023)

"Classic' – a book which people praise and don't read." — Mark Twain