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## COFFEE TALK WITH DR. JOHN LEAZER, PH.D.

The PFP IT WG recently had the pleasure of catching up with Dr. John Leazer, Director, New York Human and Animal Food Laboratory (NYLHAF) Office of Regulatory Affairs (ORA), FDA for a coffee talk about the ORA Data Exchange (DX) program. Read about Dr. Leazer's role

Read about Dr. Leazer's role and interesting perspective of the ORA DX program on <u>page 4</u>. The full Coffee Talk article is available on the PFP website.

## ORA DATA EXCHANGE (DX) RELEASE 18.0

Release 18.0 scheduled for March 21, 2024.

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

- retrieve additional Firm History (FH) Data Elements related to Program Risks, Recalls, and Compliance Cases
- learn more about the PFP IT WG via the new Knowledge Article (KA) available on the KA page
- learn more about Firm Search (FS) and FH via the updated FS and FH e-Learning course available on the Training menu
- view additional error messages when submitting Non-Contracted Inspections (NCIs)

### System-to-System (S2S) – Regulatory partners can:

- retrieve the Establishment Type and Industry Code end date via S2S FS capability
- view additional error messages when submitting NCIs

For information regarding current and prior DX releases, read more on the ORAPP About

> page, under the Recent Releases section.

"Be hopeful. Be optimistic. Never lose that sense of hope." – John Lewis

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## Spotlight on PFP Training Workgroup

The **PFP** Training Workgroup's (WG)

goal is to help develop standard curricula and certification programs that will promote consistency and competency among the <u>Integrated Food Safety</u> <u>System</u> (IFSS) workforce.

In partnership with FDA's Office of Training Education and Development (OTED) and the International Food Protection Training Institute (IFPTI), this workgroup is developing a <u>National Curriculum Standard</u> (NCS) for regulatory enforcement professionals. Multiple frameworks have been created representing retail and manufactured food, animal food, and laboratory competencies needed by regulatory professionals to fulfill the duties and tasks of their job. Establishing a NCS gets us one step closer to a competent workforce doing comparable work across all strategic partners.

The PFP, Association of Food and Drug Officials (AFDO), and International Food Protection Training Institute (IFPTI) co-sponsored the first of a series of in-person meetings to complete the buildout of the NCS, which included FDA, state, and local representatives. The NCS is a foundational element of the National Regulatory and Laboratory Training System (NRLTS) for human and animal food regulators. The NCS sets forth the competencies (knowledge, skills, and abilities) needed by regulators for successful job performance across all jurisdictions.

This first meeting, held in Kansas City, focused on the Advanced Level Core area of the NCS, and comprised of a subject matter expert (SME) working group representing FDA, State, and Local regulatory agencies, along with AFDO.



Pictured Above (L to R), NCS Build-out Meeting: Christine Sylvia (NV Local), Sue Brace (IFPTI), Belinda Clifton (Milk & Dairy), Brian Scheuttler (FL MFD), Vianca Philpotts (WA Animal Food), Michael Antee (Shellfish), Nancy Doyle (Remote), Bruce Taylor (Remote), Kathy Taylor (Remote), Jacob Fleig (MO – Animal Food), Kristin Shaw (NH Local Retail), Kevin Klommhaus (FDA), Autumn Schuck (AFDO), Chris Weiss (IES)

The group identified four content areas (Characteristics, Communication Skills, Hazards and Controls, and Inspections and Investigations) at the Advanced Level Core and built out sets of competencies and behavioral anchors (indicators or evidence of competency) for each area.

Similar meetings are planned over the next few months, and will focus on Manufactured Food, Retail Food, Unprocessed Food, Animal Food, and Senior Administration/Management.

To learn more about the PFP Training WG, view their website or email PFP at pfp@pfp-ifss.org.



Scan the QR code to learn more about the PFP Training WG!



**Partnership for Food Protection (PFP)** is a group of dedicated professionals from Federal, State, and Local governments with roles in protecting the food supply and public health. PFP is the structure used to coordinate representatives with expertise in food, feed, epidemiology, laboratory, animal health, environment, and public health to develop and implement an IFSS.

"Hope is being able to see that there is light despite all of the darkness." – Desmond Tutu



**Food Facilities:** Most food-safety inspections are food facility inspections, and these occur at sites such as manufacturers, re-packers, warehouses and distribution hubs, as examples.

**Farms:** Inspections of U.S. farms are generally conducted by states receiving Competition A/B funding under the <u>FDA-State Produce Safety Implementation Cooperative Agreement Program</u>. The FDA conducts farm inspections in states not receiving Competition A/B funding.

**Foreign Food Facilities and Farms:** The FDA seeks to ensure that foods imported by the U.S. meet the same standards as foods produced domestically, and to this end the FDA uses regulatory tools including U.S. importer verification, field examinations, sampling, and foreign inspections. Foreign food facility inspections occur at manufacturers, re-packers, warehouses and distribution hubs, as they do domestically. The FDA also performs inspections of foreign farms, which likewise are comparable to those performed in the U.S.

Source: FDA (2023). Inspections to protect the food supply. *Food Inspection Sites*. Retrieved from Inspections to Protect the Food Supply | FDA



### FDA Inspections Q&A: Does the FDA rely on states to conduct food inspections?

Yes. The FDA <u>contracts</u> with states and territories to conduct inspections of selected food manufacturer/processor facilities to determine compliance with federal laws, state laws, or both. The agency trains the state inspectors who conduct these inspections to ensure consistency in our inspectional approaches.

The agency also provides findings from our inspections to our state counterparts, which aids the states in their understanding of regulated industry and helps create efficiencies with their resources.

Some states also conduct non-contract inspections, which supports the integrated food safety system. States provide the FDA with inspection data via this voluntary program.

Source: FDA (2023). Inspection questions and answers. *Does the FDA rely on states to conduct food inspections*. Retrieved from <u>Inspection Questions and Answers | FDA</u>



"Optimism is the faith that leads to achievement. Nothing can be done without hope and confidence." – Helen Keller



Coffee Talk with Dr. John Leazer, Ph.D.

Director, New York Human and Animal Food Laboratory (NYLHAF), U.S. Food & Drug Administration, FDA

#### Continued from page 1

Hello, Dr. Leazer! Tell us about yourself, and your role and responsibilities as Director of the New York Human and Animal Food Laboratory (NYLHAF).

I am always excited to share information regarding the NYLHAF. As the Laboratory Director, I am responsible for all aspects of lab operations which includes leading the science, guaranteeing the quality of operations, securing appropriate resources (e.g., instrumentation, funding, staffing, etc.), and ensuring the well-being and development of the lab's most valuable

asset, our staff.



KNOW? Dr. Leazer is an avid fly fisherman. He builds his own flyrods and ties his own flies! He typically goes fly fishing locally at least once a month and always enjoys some type of fly fishing excursion on a

**DID YOU** 

### The NYLHAF is one of the FDA's largest regulatory field laboratories. Tell us more about the programs in regulatory methods development and technical training the lab maintains.

yearly basis.

The NYLHAF performs nearly all regulatory analyses completed by ORA Field Laboratories, within the Food and Feed and Medical Products labs. On the Microbiology front, we test foods and feeds for various foodborne pathogens such as Salmonella, Listeria, E. coli, Cronobacter, hepatitis A, norovirus, and many more. The commodities our lab tests range from imported foods around the world, to for-cause foods directly from the domestic marketplace. The NYLHAF also assists with inspectional aspects by analyzing environmental swabs of facilities under inspection, and by testing complex samples, such as Dr. Leazer is a closet musician, with two albums under his belt. He also has a soft spot in his heart for animals and routinely volunteers at his local animal shelter.



irrigation water and soil samples from domestic farms growing the country's fresh produce. Our analysts also participate in several method development and technical training activities within the Chemistry labs. Most recently, the lab hosted courses in the Fundamentals of Regulatory Chemistry, as well as Intermediate Elemental Analysis. The NYLHAF also participates in method development activities across all programs including pesticide residue, elemental analysis, color and food additive, and paralytic shellfish poisoning.

The PFP IT WG would like to thank John for his support of the ORA DX program. For more on John's insight, continue reading the rest of the conversation <u>on the</u> <u>PFP site</u>!



Pictured above (L to R): NYLHAF staff Tyra Cooper, Dominique Stutts, Thomas Herbst, Dr. John Leazer, and FDA staffer, Erin Kendrick-Peabody

"Love recognizes no barriers. It jumps hurdles, leaps fences, penetrates walls to arrive at its destination full of hope." – Maya Angelou

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## Domestic Mutual Reliance

## Advancing Food Safety

Domestic mutual reliance 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 safe national food supply.

The FDA works with our state partners to build and recognize high quality programs using nationally recognized regulatory program standards like <u>Manufactured Food Regulatory</u> <u>Program Standards (MFRPS)</u> and the <u>Animal Feed Regulatory</u> <u>Program Standards (AFRPS)</u>. Such collaboration provides opportunities for the FDA and state partners to lay a quality foundation for sharing information and working together on regulatory services and <u>food protection that industry and</u> <u>consumers can trust</u>.



### Partnership agreements formally document our domestic

mutual reliance relationships to improve foodborne illness prevention, detection, and response in an Integrated Food Safety System (IFSS). Partners collaborate in the following **operational areas** to build a highly trained workforce, coordinate food safety inspection efforts, share data, leverage organizational resources, focus on prevention, and better respond to outbreaks:

- Information Sharing and Public Health Protection through Legal Authority
- Domestic Mutual Reliance Planning and Evaluation
- Leveraging of Resources
- Information Technology
- Training

- Risk-Based Inspection Program
- Compliance and Enforcement
- Industry and Community Relations
- Laboratory Support
- Emergency Response



# WHAT'S NEW!

**January 2024** – The FDA produced a <u>video</u> depicting domestic mutual reliance "in action" among the FDA, states, and other regulatory partners. It focuses on foodborne illness prevention, detection, response activities, and public health impacts.

**December 2023** – The Association of Food and Drug Officials and Quality Assurance Magazine recently published a <u>three-part webinar series</u> on the integrated food safety system featuring, among others, the FDA's Office of Partnerships Director Barbara Cassens (<u>part 2</u>), Assistant Commissioner for Partnerships and Policy Erik Mettler (<u>part 3</u>), and multiple key FDA partners. The series addressed vision, obstacles, and how ORA supports partners to operationalize domestic mutual reliance, including the use of partnership agreements (<u>part 3</u>).

**October 2023** – The FDA signed a <u>partnership agreement</u> with the Guam Department of Public Health and Social Services and the Guam Customs and Quarantine Agency. This agreement formalizes the agencies' shared commitment to public health and consumer protection. It includes activities related to the oversight of imported foods, imported drugs including opioids, medical devices, biological products, tobacco products, and cosmetics to help prevent fraudulent and potentially dangerous products from entering supply chains.

( Article attribution: <u>Domestic Mutual Reliance</u> )

"Where there is no vision, there is no hope." – George Washington Carver

BE GREEN, KEEP IT ON THE SCREEN 🔎



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

## Resources and Useful Information

Contact Us via

ORAPP

**PFP Strategic Plan** 

PFP IT WG Page

**PFP Website** 

**ORA Partners** 

Portal

Question: What Firm History (FH) data categories are available via ORAPP? Answer: There are currently three available data categories: Program Risks, Recalls, and Compliance Cases.

Question: What Firm History (FH) data categories are available via S2S? Answer: There are currently four available data categories: Snapshot, Consumer Complaints, Inspections, and Investigations.

Question: How often are new e-Learning courses published? Answer: New e-Learning courses are published on the <u>e-Learning page</u> via the Training menu on ORAPP, as new features and capabilities are added to the ORA DX systems.

## Question: Can regulatory partners request specific e-Learning courses, instructor-led courses, or Knowledge Articles (KAs)?

**Answer:** Yes, requests for specific training or KA's can be submitted to the ORA DX Training team via the <u>ORAPP Contact Us page</u> for consideration.

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

Check out the ORA DX <u>Training Page</u> to learn more.

## **ORA DX Training Highlights**

The ORA DX Training Team has been busy developing new Knowledge Articles (KAs) and updating current e-Learning courses.

### New KA:

PFP IT WG Overview

### Updated e-Learning Courses:

- Sample Data Sharing:
  - Sample Receipt and Analysis Overview
  - Sample Receipt and Analysis Guidance Materials Overview
  - Sample Receipt and Analysis Submission
  - Sample Receipt and Analysis Errors, Correction, and Resubmission
- Inventory Data Sharing: Firm Search and Firm History

Instructor-led courses are still available on an ad-hoc basis. Be sure to check out the ORA DX <u>Training page</u> to learn more about all <u>e-Learning courses</u> and to catch up on the newest <u>Knowledge Articles</u>.

*"My hope is to leave the world a bit better than when I got here." – Jim Henson* 



## March is National Nutrition Month® Focus: Healthy Habits

Join the U.S. Food and Drug Administration (FDA) in recognizing National Nutrition Month<sup>®</sup> every March by learning how to make informed choices about your food. Start healthy habits this month by using FDA's tools and tips to help you make nutritious choices that last all year long!

Take advantage of available resources to help you start healthy habits and make informed food choices. <u>Resources from FDA</u> and the U.S. Department of Agriculture (USDA) are great tools to help you.

Consider <u>these suggestions</u> to kickstart healthy habits in your own life:

- Plan weekly meals ahead of time by writing out the ingredients you'll need for each meal. This will help you meet all five food groups and can double as a grocery list for easy shopping.
- Use FDA's <u>Nutrition Facts label</u> when grocery shopping to compare ingredients in different food items. Select items that have higher amounts of vitamins, minerals, and dietary fiber and lower amounts of sodium, saturated fat, and added sugars.
- Use <u>MyPlate.gov</u> to create healthy, complete meals that cover all five groups. Check the free <u>MyPlate Kitchen</u> <u>resource</u> for over 1,000 healthy, inexpensive, and tasty recipe ideas.
- Find out how <u>calorie labeling on menus</u> can help you make informed and healthful decisions about meals and snacks.
- Eat smart by monitoring calorie intake and portion sizes using the Nutrition Facts label alongside MyPlate.

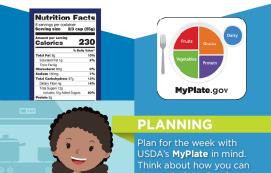
(Check out https://www.fda.gov/food for more information on Food and Nutrition)

## Start using the Nutrition Facts label and MyPlate now!

You may have heard that the Nutrition Facts label is getting an update. The new label is already starting to appear on products nationwide.

> For more information visit www.fda.gov/nutritioneducation and www.myplate.gov

## Eat Healthier With These Tools





### SHOPPING

Find the food that's right for you by comparing different items using the **Nutrition Facts label**. Choose items higher in vitamins, minerals, and fiber and lower in saturated fat, sodium, and added sugar.





Use **MyPlate** to think about how to make your meal as complete as possible. For example, if you are making pasta, add veggies to your dish and cut up fruit for dessert.

COOKING

## EATING

Look at the **Nutrition Facts label** to track calories and use serving information to help you choose the right portion sizes for you.



"Hope is the only bee that makes honey without flowers." - Robert Green Ingersoll