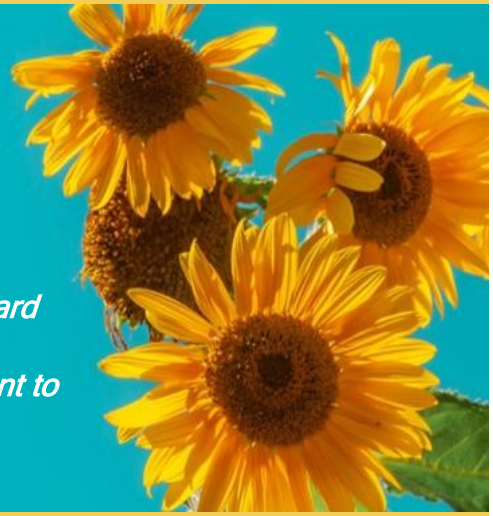
PFP IT WG NEWSLETTER

PARTNERSHIP FOR FOOD PROTECTION INFORMATION TECHNOLOGY WORKGROUP



Thank You!

To all COVID-19 helpers, we say "thank you." Thanks for all the hard work of FDA staff, state and local agencies, and the public health officials across the country. We value your service and commitment to keeping us safe, healthy, and informed as we navigate these uncertain times.

In This Issue

Featured Articles

Coffee Talk with Diane McDaniel

The Data Exchange (DX) team recently had the opportunity to catch-up with Diane McDaniel from the Office of Regulatory Affairs (ORA), Office of Human and Animal Foods Operations (OHAFO), Immediate Office (IO), as part of the DX Coffee Talk series. Diane McDaniel is a state liaison in the Cincinnati District, covering Alabama, Mississippi, Louisiana, Tennessee, Kentucky, and Ohio. These areas house some of the largest food manufacturers in the United States.

Diane's responsibilities as a state liaison include collaborating with several emergency response coordinators and other FDA centers, along with training state, industry, and agency employees.

For more details about what Diane has to say about the DX Program, read more…

FDA Commissioned Corps Officers on the Front Line of COVID-19 Response

FDA Commissioned Corps officers practice fitting of protective items.

Thank you to all who served and continue to protect the country during the COVID-19 pandemic.

The Commissioner of Food and Drugs, Stephen M. Hahn, M.D, also mentioned the hard work and sacrifice put in by the deployed FDA Commissioned Corps officers, in a recently published article. Here is what the Commissioner wrote: "During this difficult time when everyday life is disrupted, classes are cancelled and work hours are cut for many around the country, we are all pulling together to #FlattenTheCurve", read more…

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

Meet Your PFP Chair, Barbara Cassens!

Barbara Cassens is the Director for the Office of Partnerships (OP). Barbara is responsible for the oversight, strategic planning, collaboration, and integration with our federal, state, and local, partners, for manufactured human and animal food safety standards.

Barbara began her career with FDA in 1990 as a field investigator and the Pacific Region Cooperative Programs Director. Eventually, she became San Francisco's District Director. Prior to joining the FDA, she worked in the private sector for Nestlé, Dole Packaged Foods, and John Labatt, LLC.

Ms. Cassens holds a Bachelor of Science from the Iowa State University. She is active in the Western Association of Food and Drug Officials (WAFDO), the Association of Food and Drug Officials (AFDO), the Institute of Food Technologists (IFT), and the International Association for Food Protection (IAFP).

Barbara Cassens, Director, Office of Partnerships, Office of Regulatory Affairs, Food and Drug Administration

Now, onto the fun details about Barbara!

Barbara likes to travel internationally. Her last trip was to the Republic of South Africa, Africa in 2018, where she spent a week with a friend. She then went on to explore the country of Zambia on photo safaris. Once the borders open up again, Barbara's upcoming trips will be to Costa Rica in Central America and Turkey in Western Asia.

Barbara is a little bit of a horologist, she used to repair watches at a local shop in Alameda, California, and dabbles in jewelry making too – a true craftsman.

Barbara enjoys hiking in the beautiful hills of the San Francisco Bay Area, California. She loves thrift store shopping – always on the hunt for a great find, be it jewelry, clothing, furniture, or art.

Information Corner

Contact us at NFSDX_Info@fda.hhs.gov

Did You Know?

One of the books that changed the world is the "Fannie Farmer Cookbook" by **Fannie Merritt Farmer**. The Boston-born Farmer would become the most famous cookbook author in the country. And in the final push for the 1906 Food and Drug Act, as the battle for food safety was really heating up, she would send out a pointed cookbook message of her own. Her publisher was dubious and only agreed to print the book if the author herself paid for the first print run. Within a year, Farmer's 1896 opus had sold close to 400,000 copies, and by the mid-twentieth century, had sold 2,000,000 copies. For a biography on Fannie Farmer, read more…

DX Training Program

The ORA DX training team will be offering online courses to regulatory partners who are current users of ORA DX systems; System-to-System Services (NFSDX) and Partners Portal (ORAPP). Trainees can choose from an instructor-led course or recorded video.

The upcoming instructor-led course is **"ORAPP-Firm Search and Firm History", scheduled for 7/28/2020 and is only available for partners with access to the capability**. To register for this course, or to find out more information, please contact us at NFSDX_Info@fda.hhs.gov.

Why Walk? Why Not?

Walking is a great way to get the physical activity needed to obtain health benefits.

The Physical Activity Guidelines by the Center for Disease Control and Prevention (CDC), recommends that adults get at least 150 minutes of moderate-intensity physical activity or 75 minutes of vigorous-intensity physical activity each week. Children and adolescents are also recommended to be active for at least 60 minutes every day. Following these guidelines can contribute to overall health, and decrease the risk of diseases such as heart disease, cancer, read more…

"A balanced diet is a cookie in each hand." - Barbara Johnson

ORA Data Exchange

Sample DX

The primary goal of the Sample DX is to enable the automated electronic exchange of data between FDA and regulatory partners so that manual data entry is reduced, and FDA can rapidly review sample analysis results which leads to improved efficiencies and timely regulatory decision making. The three available options for Sample DX are: ORA Partners Portal (ORAPP) via an Excel spreadsheet upload, National Food Safety Data Exchange (NFSDX) via a backend system-to-system interface, and DX Client via a desktop application.

Contracted Sample Data Submission

The initial phase of the Sample DX program supports sample submissions under the Food Emergency Response Network (FERN) Cooperative Agreement Program (CAP), where FDA collects samples and sends them to regulatory partners for analysis. The following analysis types are enabled – Elements, Pesticides, Mycotoxins, and Microbiology.

New DX Capability – Coming Up

Support for State Collected Sample DX

The next phase will support data exchange of samples under the Food and Feed Contracts, Manufactured Food Regulatory Program Standards (MFRPS), Animal Feed Regulatory Program Standards (AFRPS), and upcoming Flexible Funding Model (FFM). In each of these programs, regulatory partners collect samples as part of field inspections, analyze samples, and share the outcomes with FDA. The following analysis types will be enabled by Fall 2020: Radionuclides, Filth Analysis for Parasites, Decomposition in Seafood, and Virus. For additional information, please contact us at NFSDX_Info@fda.hhs.gov.

Domestic Mutual Reliance – By Timothy Mueller

Timothy Mueller is the Director of the Division of Integration in the ORA Office of Partnerships (OP). Tim lives by the adage that many hands make light work. Tim came to OP from the Office of Compliance and Enforcement (OCE) in the FDA Center for Tobacco Products (CTP). He believes we must find new ways to collaborate with our partners to address the ever-increasing volume and complexity of the products we regulate in a global world, leading to his passionate work on mutual reliance.

FDA and States Make Progress on Achieving Domestic Mutual Reliance

The domestic mutual reliance concept dates back decades under several initiatives, including the PFP. The current phase of domestic mutual reliance is conducting proofs of process that support a multipronged approach to collaborative regulation, which will require innovative IT solutions. The work being performed by the PFP IT workgroup in developing new and improved data exchanges is a key mechanism in addressing this need. Domestic mutual reliance requires an understanding of both state and FDA needs, goals, and points of collaboration. Read more on the FDA website.

This year, we are renewing our commitment to achieve domestic mutual reliance, a seamless partnership that enables FDA and states with comparable public health systems to rely on, coordinate with, and leverage one another's work, data, and actions to achieve a safer national food supply. Due to many collaborative activities ongoing in the United States and with our foreign regulatory partners, we have chosen to use the term "domestic mutual reliance" when discussing these collaborations with our state, local, tribal, and territorial partners.

We will advance domestic mutual reliance by developing a formalized process in which FDA and states can work as one public health safety net – as trusted partners – to advance efforts already underway to further the Food Safety Modernization Act (FSMA) mandates and work towards achieving a national Integrated Food Safety System (IFSS). Key activities that support domestic mutual reliance include data sharing, work planning, reliance on one another's inspection activities, and increased collaboration on recalls, outbreak response, lab support, and training. Read more on the PFP website.

"Vegetables are a must on a diet. I suggest carrot cake, zucchini bread and pumpkin pie." - Jim Davis

ORA DATA EXCHANGE
Frequently Asked Questions

Question: How does a regulatory partner sign up for a DX capability?

Answer: The partner can request the participation by sending a note to NFSDX_Info@fda.hhs.gov or reach out to their FDA state liaison or field management. In certain instances, FDA reaches out to the state agencies based on various FDA initiatives. The partner participation request is reviewed and approved by FDA.

Data Exchange Information Resources

- PFP Website and PFP IT WG Page
- AFDO June 2020 Newsletter
- Presentations at 2020 MFRPA Conference

Question: Should a regulatory partner choose System-to-System, Partners Portal, or both?

Answer: A regulatory partner can choose to participate in either of the data exchange mechanisms. How a regulatory partner desires to submit and retrieve data from FDA is a driving factor in the choice. System-to-System provides direct electronic data exchange capability between regulatory partner system and FDA system which requires IT resources and effort. The Partners Portal is a web solution for exchanging data with FDA. It does not require any system integration effort by regulatory partner.

Question: Do ORA DX systems integrate with internal FDA systems?

Answer: Yes, ORA DX systems (Partners Portal and System-to-System data exchange mechanisms) integrate with internal FDA systems.

Question: Do ORA DX systems send any data back to regulatory partners?

Answer: Currently, ORA DX systems (System-to-System and Partners Portal) send only acknowledgements of data exchange and error messages back to regulatory partners. However, both systems allow partners to download FDA firm data.

Question: How long does it take for a regulatory partner to enable System-to-System data exchange?

Answer: It will vary depending on multiple factors such as regulatory partner systems, resources, current processes, and availability for integration activities.

Question: Will ORA DX systems replace eLEXNET?

Answer: Yes, by 2020, certain eLEXNET capabilities will be transitioned to the ORA DX. FDA stopped collecting all surveillance, voluntary, or required data via eLEXNET on May 31, 2020 and eLEXNET will be completely retired on September 30, 2020.

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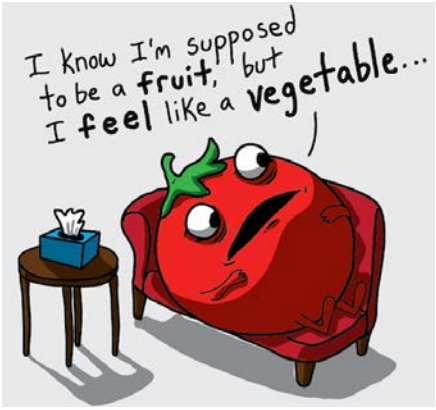
X	F	O	L	R	U	S	E	R	S	Y	A
H	C	B	O	O	R	A	X	N	B	O	R
E	L	X	D	D	T	F	O	B	M	G	T
R	G	O	O	A	S	G	N	M	P	X	N
J	O	H	D	Q	O	A	X	G	J	Z	E
L	R	T	Y	L	O	N	F	L	C	X	R
G	X	C	S	A	M	P	L	E	S	N	S
S	E	C	U	R	I	T	Y	O	T	X	H
I	N	T	E	G	R	A	T	E	D	Y	I
I	N	S	P	E	C	T	I	O	N	S	P
H	P	O	R	T	A	L	A	Y	A	B	D

ORA DX Word Search Puzzle

Data
Food Safety
Inspections
Integrated
Logon
Partnership
Portal
Samples
Security
Users



"It's difficult to think anything but pleasant thoughts while eating a homegrown tomato." - Lewis Grizzard