PFP IT WG NEWSLETTER

PARTNERSHIP FOR FOOD PROTECTION INFORMATION TECHNOLOGY WORKGROUP

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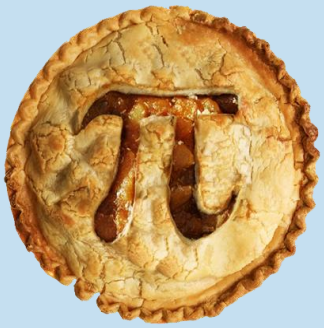


Coffee Talk with Jennifer Pierquet

The FDA Office of Regulatory Affairs (ORA) Data Exchange (DX) team recently had the pleasure of catching up with Jennifer Pierquet, Project Manager at the Association of Food and Drug Officials (AFDO) 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. Enjoy reading Jennifer's very interesting and enthusiastic perspective of the ORA DX program *on page 4.*

This article is also available on the *PFP site*.

AFDO and PFP

AFDO works with food and medical product professionals, representing a host of disciplines, including industry, government, academia, and consumer groups. AFDO has been a key partner of PFP, and has worked in almost every area of the PFP. Major activities include:

- Help support initiatives through communication and recruitment
- Serve on workgroups including outreach, training and credentialing, and information technology
- Offer support for the 2022 in-person PFP meeting
- Assist and develop guidance materials and best practices that support PFP

To read about Steve Mandernach, Executive Director of AFDO, *go to page 2.*

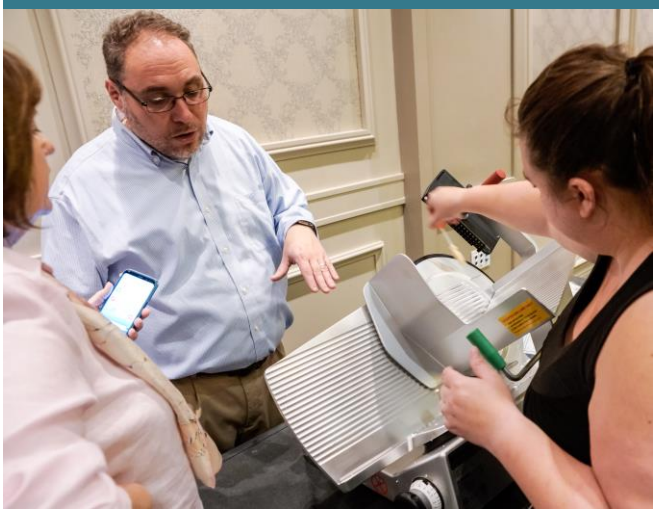
"Pie makes everybody happy"
Laurie Halse Anderson

***"Good apple pies are a considerable part of our domestic happiness."* - Jane Austen**

Meet Steven Mandernach! (*Mawn-dur-knock*)

Executive Director, Association of Food and Drug Officials

Steven Mandernach is the executive director of AFDO. AFDO unites high-level regulatory officials, industry representatives, trade associations, academia, and consumer organizations to improve food safety and public health around the world. AFDO members strive to foster uniformity in the adoption and enforcement of science-based food, drug, medical device, and cosmetic products safety laws and regulation to protect public health and safety.



More about Steve

Prior to becoming executive director in 2018, Mandernach was the bureau chief for food and consumer safety at the Iowa Department of Inspections & Appeals. Mandernach is a past president of AFDO and current co-chair of the Association's Laws and Regulations committee. He also served as the chair and co-chair for the Manufactured Food Regulatory Program Alliance (MFRPA). He is a past president of the Mid-Continental Association of Food and Drug Officials (MCAFDO).

Mandernach has a J.D. from Drake University Law School. He has completed graduate work in Food Safety at Michigan State University.

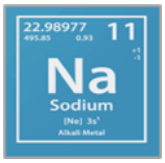
Now on to the fun stuff!

I'm a farm kid from very rural South Dakota (my graduating class was 24 students including two foreign exchange students). I'm an attorney by training and have worked in the government and regulatory field for over 20 years. Throughout my career, I've led information technology development and implementations. In my spare time, I love arts in general – theater, music, film, and playing with my fur family – basset hound Roosevelt, standard poodle Carter, and cat Truman. In 2019, we moved from Iowa to Philadelphia for the AFDO Executive Director position and I am missing smoked brisket from Iowa/KC areas.

Information Corner

Contact us at APPSDesk@fda.hhs.gov

SODIUM IN YOUR DIET



You have probably heard that most Americans eat too much sodium. Your body needs a small amount of sodium to work properly, But too much sodium can be bad for your health. Diets higher in sodium are associated with an increased risk of developing high blood pressure, which is a major cause of stroke and heart disease. *Read more…*

LISTERIA

In 1929, A. Nyfeldt reported the first confirmed cases of listeriosis in people. But *Listeria monocytogenes* wasn't identified as a major cause of foodborne illness in people until the 1980s when several large outbreaks occurred. You've probably heard of Salmonella and are familiar with the symptoms of salmonellosis. But you may not have heard much about the lesser known foodborne illness listeriosis caused by the germ *L. monocytogenes*. *Read more…*

ENHANCED DX CLIENT

Enhanced DX Client is a desktop application of ORA DX that enables a regulatory partner to securely share samples collection, receipt, and analysis data with FDA. A regulatory partner can create/generate xml data files from their laboratory systems and drop them in the pre-configured DX Client directory. The application has a scheduler that periodically scans a pre-configured directory for data files to be transferred to the FDA. *Learn more…*

***"This must be where pies go when they die."* - FBI Special Agent Dale Cooper, Twin Peaks**

ORA DX Participation

On July 27, 2021, the FDA announced that awards were issued to 47 state grantees of FDA's Produce Safety (PS) Cooperative Agreement Program (CAP). This funding advances efforts for a national Integrated Food Safety System (IFSS) by supporting state and territorial PS program efforts. The best part is the ORA Partners Portal PS Farm Inventory capability is being used by most grantees and FDA to exchange PS information. During the summer and fall of 2021, the ORA DX Team assisted state grantees with obtaining access.

Produce Safety on Partners Portal – New Participating State Agencies

We Would Like to Welcome:

- Alabama Department of Agriculture & Industries
- Arkansas Department of Agriculture
- California Department of Food and Agriculture
- Colorado Department of Agriculture
- Connecticut Department of Agriculture
- Delaware Department of Agriculture
- Florida Department of Agriculture and Consumer Services
- Georgia Department of Agriculture
- Indiana State Department of Health
- Kentucky Department of Agriculture
- Louisiana Department of Agriculture and Forestry
- Maine Department of Agriculture, Conservation, and Forestry
- Massachusetts Department of Agricultural Resources
- Michigan Department of Agriculture and Rural Development
- Minnesota Department of Agriculture
- Missouri Department of Agriculture
- Nebraska Department of Agriculture
- Nevada Department of Agriculture
- New Jersey Department of Agriculture
- New Mexico Department of Agriculture
- New York Department of Agriculture and Markets
- North Carolina Department of Agriculture and Consumer Services
- Oklahoma Department of Agriculture, Food and Forestry
- Pennsylvania Department of Agriculture
- Rhode Island Department of Environmental Management
- South Carolina Department of Agriculture
- Tennessee Department of Agriculture
- Utah Department of Agriculture and Food
- Vermont Agency of Agriculture Food and Markets
- Virginia Department of Agriculture and Consumer Services
- Washington State Department of Agriculture
- West Virginia Department of Agriculture
- Wisconsin Department of Agriculture, Trade and Consumer Protection

"You like pie? I like Pie." – **Barack Obama**

Coffee Talk with Jennifer Pierquet

(Part A)

Project Manager, Association of Food and Drug Officials

Continued from page 1.

Hello Jennifer, tell us about yourself and your role on the ORA DX project.

My title is Project Manager with my focus being the USAPlants and USAFoodSafety systems – the state inspectional systems that currently support 20 states that use one or both applications. The two systems encompass milk, animal food, retail, manufacturing, produce, and other inspectional programs.

Included in my oversight is working with the two vendors that currently support the existing USAPlants and USAFoodSafety systems, the current user communities, and the governing council that oversees the maintenance and support of the existing systems while working toward a long-term plan to replace these systems with modern technology. The most exciting part of my work is to help define future needs for current and potentials users that will open the doors for additional food safety integration.

One important facet of my work is helping the current USAFoodSafety states work within the evolving parameters of the exchange of inspectional data with U.S. Food and Drug Administration (FDA) via the System-to-System (National Food Safety Data Exchange - NFSDX) of the ORA DX.

I work with the triad of stakeholders including states, current vendors, and the FDA data exchange team. My goal is to represent the states in translating what data currently is collected and what really happens in the field so that FDA and the USAFoodSafety vendor are developing to meet all needs.

What do you think are some of the benefits or advantages of participating in the ORA DX that you would like to share with the states you support at AFDO?

Really the benefits boil down to the ability to have an automated transfer of inspectional data in real time. The goal is ultimately to replace duplicative work being done at the state level. Currently, most states complete two inspection reports: 1) state inspection report; 2) FDA contract inspection report. The System-to-System replaces the need for states to login to FDA's eSAF to enter inspectional data. In lieu of manual data entry, state collected FDA information is sent from USAFoodSafety to eSAF by the click of a Submit button. The result is time savings for both the state inspector and FDA State Liaison reviewing state reports. A bonus is state inspection results are available in real time.

The DX allows for searching of FDA firms and also sharing firm information between states via State-to-State Firm Search if states permit. This search capability allows for states to look-up their state specific FDA inventory as well as search other state's firm inventory. As more products cross state lines, sharing information and issues becomes increasingly valuable for states and FDA. This sharing is critical to problems being identified and corrected quicker ultimately protecting the public.

Looking ahead, are there particular functionalities you would like to see in ORA DX for state(s) you support?

The ORA DX is being developed to be a two-way communication channel for regulatory partners and FDA. Initial functionality of the ORA DX was focused on state to FDA data sharing. Recent efforts have expanded that functionality to be more two-way-focused, while including all stakeholders in the food safety ecosystem to include state laboratories. This would allow the FDA to provide consistent and timely communication and data to the whole state food safety community. ***Editor's Note:*** *FDA is actively working on expanding shared data sets with regulatory partners (states).*

Another project on the forefront is the Inventory Reconciliation which will look to harmonizing firm inventory data between a state and their FDA Division. The completion of this project will streamline the annual work planning process by creating a single inventory for a state and FDA Division eliminating duplicate and inactive firms.

FDA and the states are challenged to meet their own data goals while supporting each other's systems through integration due to the myriad of state technologies or lack thereof. Within FDA, this is a huge undertaking due to the breadth of internal systems currently in place. For states, understanding what FDA will require and provide in the future will be critical as a new state platform is developed.

Read more…

"Cut my pie into four pieces, I don't think I could eat eight."
– Yogi Berra

"If you want to make an apple pie from scratch, you must first create the universe." - Carl Edward Sagan

ORA 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: ORA 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 by regulatory partners increases efficient electronic data exchange between FDA and regulatory partners, increases collaboration, and reduces dual data entry in regulatory partner and FDA systems.

Question: Which technical components are used in the System-to-System?

Answer: The System-to-System services uses technical components such as XML schema definition, Java, and SOAP Web Services.

Question: How does participation in the ORA DX program help a regulatory partner?

Answer: Participation in the ORA DX program provides regulatory partners with improved information sharing capabilities with FDA. At a minimum, it eliminates dual data entry in the state's system and FDA's system and any challenges associated with the related data updates.

Resources and Useful Information

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

The Partners Portal is envisioned to be the centralized and comprehensive portal for all the electronic data exchange between regulatory partners and FDA. Additional FDA data that will benefit regulatory partners may be available to partners in the future.

Question: Should a regulatory partner participate in both of the ORA DX systems (System-to-System and Partners Portal)?

Answer: May be. A regulatory partner could choose to participate in either of the ORA DX systems, or both. The System-to-System services (NFSDX) provides direct electronic data exchange between regulatory partner and FDA systems, which requires IT resources and effort by the regulatory partner. The Partners Portal (ORAPP) is a website for a regulatory partner to exchange data with FDA. It does not require any system integration effort by a regulatory partner.

Question: Does a regulatory partner require agreements to participate in the ORA DX program?

Answer: Yes. The Food and Feed 20.88 agreement is required to participate in the ORA DX program. Additionally, a Memorandum of Understanding (MOU) and an Interconnection Security Agreement (ISA) are required to participate in the System-to-System services, along with a Non-Disclosure Agreement (NDA) for uploading attachments.

For additional ORA DX FAQs, *read more...*

When asked what dessert Americans prefer a friend or family member bring to their house for a holiday dinner, pie was the winner with 29 percent, followed by cake (17 percent) and cookies (15 percent). *Yes, please!*

"Things that really matter are the things that gold can't buy, so let's have another cup o' coffee and let's have another piece o' pie." **- Irving Berlin**