**Partnership for Food Protection Information Technology Workgroup
(PFP IT WG) Coffee Talk with
John Gridley
Office of Regulatory Affairs (ORA)
Office of Human and Animal Foods Operations (OHAFO)**

The Partnership for Food Protection (PFP) Information Technology Workgroup (IT WG) recently had the opportunity to catch-up with John Gridley, Special Assistant, Office of Human and Animal Foods Operations (OHAFO) Immediate Office (IO), ORA, FDA.

Since joining the workgroup in 2015, John has been an active participant and champion for the ORA data exchange project and the PFP IT WG. John was instrumental in developing the data definitions used for what is now known today as the system-to-system data sharing, also known as National Food Safety Data Exchange (NFSDX).

PFP IT WG Team: Tell us about yourself and your role on the ORA Data Exchange (DX) program.

John: The Observation and Corrective Action Reporting (OCAR) State Portal workgroup joined the PFP IT Workgroup to provide business input into the ORA DX program, which include the IT systems; system-to-System data sharing (NFSDX) and ORA Partners Portal (ORAPP) that exchange data with state partners, which will incrementally replace the double entry needed for the Electronic State Access to FACTS (eSAF) system.

In the past two years, the OCAR State Portal WG has continued in coordination with the PFP IT WG, as well as working within FDA to enhance the use cases for ORA data exchange with state partners. OCAR is a system of systems framework that supports the ORA transition from a regulatory action basis to a broader and more direct public health impact basis under the Food Safety Modernization Act (FSMA), thus, the focus is on inspectional observations and corrective actions taken by firms (including voluntary). A new feature is the Corrective Action Report (CAR) that tracks all inspectional observations, not just those printed on FDA Form 483.

PFP IT WG Team: What are some of the benefits or advantages of the DX program that you would like the states to know?

John: The data exchange program enhances the exchange of information and improves the data burden and manipulation of hard copy mail or email attachments to directly viewing and exchanging selected information through a web and/or system interface. The up side is a significant step forward from snail mail, email attachments, and double entry into eSAF of inspection or lab data.

PFP IT WG Team: Looking ahead, are there any functionalities you would like to see included in the DX?

John: The data elements and various user access roles were identified in 2016 to support all data elements used by states and FDA. Since then, FDA/ORA has expanded the use of its eNSpect electronic inspectional protocol across human and animal food inspections with support for FSMA requirements. Additionally, ORA implemented its Program Alignment in May 2017 so some of the state partner interactions have changed based on the program operations involved. Some things I would like to see states consider:

- *Implementation of systems that capture data elements during inspection*
- *Utilization for work planning (including dynamic features)*
- *Compliance information sharing*
- *Emergency data exchange (include labs)*

PFP IT WG Team: What is your advice for states considering DX?

John: The system to system approach (NFSDX) may be a heavy lift to design the data exchange protocols and conversion elements needed. The web portal (ORAPP) enables enhanced functionality for data sharing prior to establishing the system level data exchange. In its day eSAF was a fit for its needed functionality, the ORA DX is current technology with capability for future expansion and use cases.

PFP IT WG Team: Is there anything unique about your DX experience that you would like to share?

John: I joined PFP IT WG in 2015 as FDA developed the data definitions to be used for what became NFSDX and is the basis for the current ORA DX developments. The current ORA DX is being utilized for a wide range of data sharing use cases. I was involved with an ORA Lab workgroup in 2019 designed to utilize the DX and update its legacy systems. The inclusion of labs will expand data exchange efficiency for better overall public health impact whether emergencies, outbreaks, compliance, or surveillance applications. Traditional contract inspection reporting by states should be viewed as a stepping stone to expanded applications leading to more effective public health. The DX has a key role in support of this functional expansion.

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The PFP IT WG would like to thank John Gridley and his team for their support of the ORA Data Exchange (DX) program and the PFP. We look forward to continued collaboration with OHAFO on the expanding the ORA DX program.

For questions or information about the ORA DX program or the PFP IT WG, contact us at NFSDX_Info@fda.hhs.gov.

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