





Partnership for Food Protection Information Technology Workgroup (PFP IT WG) Coffee Talk with Matt Colson Consumer Safety Officer, Auditor Office of Human and Animal Food Operations (OHAFO) Office of Regulatory Affairs (ORA), FDA

The <u>PFP IT WG</u> recently caught up with Matt Colson for a coffee talk about the <u>ORA Data Exchange (DX)</u> <u>program</u>. Before joining FDA, Matt served as the Bureau Chief of Florida's Department of Agriculture and Consumer Services Division of Food Safety.

The ORA DX is a unified platform to securely share information between the FDA and state and local regulatory partners. The mission of the ORA DX is to streamline submission of food safety regulatory data and support timely decision making by providing access to relevant inventory, sample, and inspection information.





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 <u>Manufactured Food Regulatory Program Standards</u> (MFRPS) cooperative agreement. The OHAFO Audit Staff was officially established in 2013 and has since expanded to include the Animal Feed Regulatory Program Standards (AFRPS), the <u>Egg Regulatory Program Standards</u> (ERPS), and the <u>Voluntary Retail Food Regulatory Program Standards</u> (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 <u>Accredited Third-Party Certification Program</u> (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.

## Tell us more about the audits. Are they event driven or are they set up in advance with a schedule or a combination?

Audits are scheduled in advance each year during our work planning period. The audit schedules are based on the state program's enrollment date in the regulatory program standards, and typically occur at the 18, 36, and 60-month mark after enrollment, and then once every 24 months thereafter.



# What are some of the Audit Staff's strategies for promoting the safety and quality of the nation's human and animal foods?

The Audit Staff participates in the development and change processes for the various program standards and offers recommendations to updating those standards based on input received during the audits. The regulatory program standards establish a uniform foundation for regulatory agencies responsible for oversight of food. A goal of the standards is to implement a nationally integrated, risk-based, food safety system focused on protecting public health. The Audit Staff supports the state programs in achieving and maintaining conformance with the program standards which promote the safety and quality of the nation's human and animal foods, solidifying an integrated food safety system, resulting in increased public health protection.



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Share a few examples of Audit Staff recommendations given to ORA and FDA leaders that significantly influenced policy or operations related to the regulation of human and animal food products.

Audit Staff played a key role in establishing the Non-Contract Inspection (NCI) program. Working with FDA leadership, we identified participation criteria for programs who elect to engage in the program, as well as determining criteria for the inspections shared through the program. State programs that have achieved 10/10 conformance with the MFRPS, demonstrating the quality of their inspection program, and who conduct their routine NCI work using equivalent regulations to FDA (21 CFR 117), are eligible to participate, if interested. Here's one example of NCIs in Iowa.

# As a key contributor for ORA DX teams and a liaison between regulatory partners and OHAFO, how does the Audit Staff coordinate with other state agencies and stakeholders to support the PFP objectives and DX program?

Audit Staff have been strong supporters of the PFP IT WG, and the ORA DX from the beginning. Our involvement in the DX dates back to helping facilitate a data exchange pilot project with the Pennsylvania Department of Agriculture in 2012. We participate in PFP IT WG activities, including a State Portal workgroup who facilitate providing state access to various FDA data via ORAPP, as well as other internal and external ORA DX related workgroups. We also work to help increase awareness of ORA DX platforms, and work with the ORA DX team to help onboard new state programs. Our staff also supports <u>Domestic Mutual Reliance</u> (DMR) partnership agreements by helping to facilitate data exchange, and supporting NCI where applicable.

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### As a longtime member of the PFP IT WG and advocate for the ORA DX, are there moments that you think were key to the success of the IT WG and the DX program?

I believe the key to getting us to where we are today is largely attributed to the states and FDA's commitment to investing resources for the DX. FDA standing up the DX program and supporting the PFP IT WG really aided in the forward movement. This momentum continues to push us forward through initiatives including the support of state IT and DX enhancements through our state <u>Cooperative Agreement Programs (CAPs</u>), as well as partnering with organizations such as the <u>Association of Food and Drug Officials</u> (AFDO) and other external stakeholders to continue moving the DX program ahead.



Tell us about your involvement in collaborating with states to initiate their utilization of the NCI capability. Most recently, you were working with Pennsylvania to help them start submitting NCIs via System-to-System (aka National Food Safety Data Exchange).



My experience with the NCI program began in 2018 when I was working for the <u>Florida</u> <u>Department of Agriculture and Consumer Services</u> (FDACS). We were approached by Audit Staff to see if we could help pilot the program by submitting some NCIs via Electronic States Access to FACTS (eSAF). We then began sharing all our NCIs with the Human and Animal Food East Division 4 (HAFE4) bi-weekly, and they shared their inspections with us, so it was a pretty seamless partnership. We were able to use the FDA inspections to offset our inspection frequency at our dually regulated firms. We also used FDA's workplan to help prioritize and reduce duplication of our inspections and resources.

Since joining the FDA I have been able to partner with other states on the NCI project. To date six states have participated (Wisconsin, Florida, Iowa, Utah, Virginia, Pennsylvania), and we recently achieved the milestone of accepting 1,000 NCIs submitted by our state partners. Likewise, FDA has shared inspections with the states to help them meet their inspection frequencies. There is also a group looking into the potential of including animal food into the NCI program.



# What advice would you have for regulatory partners regarding the benefits or advantages of participating in the ORA DX program? What is the best way for the PFP IT WG to communicate this?

The DX is the way of the future. I believe that once we get to a point where there is seamless multi-way electronic transfer of a multitude of food safety data between all stakeholders, we will have truly achieved a fully Integrated Food Safety System (IFSS). Integrating with the DX can streamline processes by reducing dual/manual entry of data, and in the future could assist in a more rapid response to food related incidents by real time sharing of pertinent information. My understanding is that at some point in the future the FDA may be moving away from older software applications such as eSAF, and the DX platforms (ORAPP, and System-to-System) will be the replacement for submitting contract inspection and other data to the FDA. It would benefit programs that have the capacity to participate in the DX program to be ready for that transition. States may be able to take advantage of FDA funding sources such as the MFRPS Flexible Funding Model (FFM) Cooperative Agreement Program, or other Cooperative Agreement Programs, to support enhancements to their IT applications for DX participation, and other IT related needs.



## Finally, is there something fun and interesting about yourself to share with the readers? (Hobbies, interests, vacations, etc.)



These days I'm focusing a lot on health and fitness (mental and physical), and spending time with my friends, family, and loved ones. I hope to be around for a long time and to continue contributing to the food safety community however I can.



The PFP IT WG would like to thank Matt for his support of the ORA DX program and the partnership. We look forward to continued collaboration with Matt and expanding the ORA DX program.

Contact us at <u>appsdesk@fda.hhs.gov</u> if you have any questions or would like additional information.



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