


# Partnership for Food Protection Information Technology Workgroup (PFP IT WG)

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

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

The PFP IT WG recently caught up with Dr. John Leazer for a coffee talk. The IT WG's goal is to promote data standards to improve the ability to share food safety regulatory data electronically among strategic partners and support timely and accurate decision making. To achieve this goal, the workgroup has undertaken technical projects that are advancing abilities to harmonize a compatible IT environment among all food safety officials.

**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.

**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.**

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 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.

**Data exchange and collaboration are crucial for effective food safety regulation. Could you elaborate on the methods and technologies employed by the NYLHAFL to facilitate data sharing with FDA, states, and other regulatory partners?**

The NYLHAF utilizes numerous technologies and processes to communicate data effectively and efficiently with our public health partners. These FDA technologies include software systems such as Online Reporting Analysis Decision Support System (ORADSS), Compliance Management System (CMS), Field Accomplishments and Compliance Tracking System (FACTS), and Automated Laboratory Information System (ALIS). Additionally, several analysts and managers actively participate in technical advisory groups and harmonization work groups. These serve as cross-cutting forums to discuss current and future needs of the FDA, and the needs of our partner agencies.

**Can you provide a high-level overview of the key responsibilities and objectives of the NYLHAF to ensure the safety of food and feed products, and how it collaborates with partnering organizations?**

The NYLHAF's primary responsibility is to analyze regulatory samples that support the FDA's public health mission. Not only does the lab analyze thousands of samples each year that support various compliance actions, it also analyzes these samples with the highest quality profile and in the most efficient timeline. In both NYLHAF's' chemistry and microbiology programs, our key objective is to provide the best customer service possible to ensure each compliance case has the laboratory data it needs to effectively perform the necessary regulatory action(s). We frequently collaborate with our partners at the Centers, State laboratories, other Federal agencies, and both Domestic and Import operations to ensure the safety of the food and feed products the FDA regulates.

**Share a bit about the types of testing performed in the sections of the NYLHAF.**

NYLHAF is organized into two sections: The Chemistry Branch and the Microbiological Sciences Branch. Testing includes analysis for food additives, colors, elemental analysis (heavy metals), insanitation, decomposition, pesticides, paralytic shellfish poisons, microbial pathogens, bacterial toxin detection, virology, food allergens, whole genome sequencing, and select agents. The laboratory is well-equipped with state-of-the-art instrumentation, but ultimately our greatest strength, is our scientists and experts. They share their expertise internally and externally each day to ensure continuous movement towards a safer global food supply.

**In the context of food safety, what are some of the challenges the NYLHAF faces in developing and implementing effective regulatory methods, and how do you plan to overcome them?**

NYLHAF has a robust method development and validation program across all program areas. Analysts and managers are actively engaged in the Technical Advisory Groups (TAGs) for their respective program areas. During TAG meetings, NYLHAF analysts discuss the research needs of the Agency and assist in validation designs that bring new methods online and update old methods to include new technologies. While our team is well-versed and knowledgeable of method development, our priority is the regulatory sample analyses that support our public health mission. It can be a challenge to balance the timing of completing both our high priority regulatory samples as well as engaging in new method development activities. NYLHAF continues to support engagement in TAG research discussions. We often work with our Center, Headquarters, and Field Laboratory colleagues to support the balance of regular sample work, and research work when analysts need to devote time to research activities.

**Tell us about a success or specific instance where collaboration between the NYLHAF and a regulatory partner resulted in improved food and feed safety outcomes.**

Very recently, the New York State Department of Health (NYSDH) reached out to NYLHAF requesting assistance in testing for *Cyclospora cayetanensis* in several samples they collected from a local restaurant. We received the samples the next day and immediately conducted all appropriate testing. While the samples were all negative for the foodborne parasite, it was an excellent opportunity to collaborate with our state partners toward the shared goal of public health.

**ORA labs are starting to use the FDA's ALIS to improve Office of Regulatory Science's (ORS) ability to conduct Sample Analysis and other laboratory functions. What type of Sample Analysis is performed in the NYLHAF; and what level of detail is captured in ALIS or your Laboratory Information Management System (LIMS) for that analysis?**

ALIS has been a great success for NYLHAF in the areas where it has been rolled out. We have been using the system for pesticide samples for just over a year and have handled about 1000 such samples within that timeframe. Since its roll-out in microbiology two months ago, it has been used on roughly 90% of the branch's samples, equating to about 300 samples completed in the system. ALIS captures all the details needed for our analytical work packages; everything from reagent data, plate reads, instrument graphs and reports, and all the observations made by our regulatory analysts. It bundles all data, attachments, reports, labels, and more into a neat, crisp work package ready for the compliance side of ORA.

**Share a bit more about the great work of the NYLHAF staff and their responsibilities for lab analysis of domestic and imported products.**

The chemists, microbiologists, entomologists, biologists, technicians, and support personnel of NYLHAF are key to the strength of its programs and assignments that accomplish the consumer protection mission of the agency. NYLHAF's key accomplishments include providing the laboratory data that leads to numerous regulatory actions. Additionally, NYLHAF actively participates in validation activities that allow for the use of emerging technologies in the methods utilized in laboratory analysis.

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

Most NYLHAF staff know that I am an avid fly fisherman. I build my own flyrods and tie my own flies. I typically go flyfishing locally at least once a month and always enjoy some type of flyfishing excursion on a yearly basis. I am also a closet musician, with two albums under my belt. I have a soft spot in my heart for animals and I routinely volunteer at my local animal shelter.

The PFP IT WG would like to thank Dr. Leazer for his support, and we look forward to continued collaboration and expanding the PFP IT WG and ORA DX program.

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

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