ORA Data Exchange - Sample Data Sharing by Lauren Yeung

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ORA DX is a critical part of our long-term strategy for integrated data sharing between the FDA and states. Data sharing capability is essential for both emergency situations, and for supporting large scale national surveillance testing programs, like LFFM. These successful data submissions, both for FDA-collected samples and state-collected samples, are critical milestones that reflect significant progress. We greatly appreciate participating state partners who have helped pave the way for others to follow.

The first successful sample submissions via ORA DX were for FDA-collected import samples collected as part of ORA DX Pilot OEIO Assignment #20-D06 in spring 2021. Ten samples were collected and sent to the Michigan Dept. of Agriculture and Rural Development and Connecticut Agriculture Experiment Station for microbiology and chemistry analysis.

In 2022, we wanted to continue and build upon the successes of the initial pilot, and the stars aligned when the opportunity presented itself during the *Cronobacter sakazakii* powdered infant formula recall. FDA leveraged LFFM laboratory capacity to help meet a national demand for product testing from states that lacked capability to test for *Cronobacter*. Some of these samples were collected by FDA and sent to LFFM laboratories. One of those laboratories (Maryland Dept. of Health) was able to utilize ORA DX to submit the lab receipt and analysis data for the FDA-collected samples. This instance built upon the successes of the Michigan Dept of Agriculture and Rural Development and the Connecticut Agriculture Experiment Station during the spring 2021 ORA DX pilot for FDA import samples. It was also unique and notable in that the Maryland Dept. of Health is the first lab to complete an NFSDX (system-to-system) integration.

Maryland's involvement went even further than submission of lab receipt and analysis data for FDA-collected samples. The Maryland Dept of Health mentioned that they were collecting and analyzing large numbers of powdered infant formula, presenting a unique and valuable opportunity – sample data on powdered infant formula was indeed of high interest, and it was the same analysis that FDA and state staff had already worked out specifics on for the FDA-collected samples, which made the scope expansion more manageable. Maryland Dept. of Health was able to successfully submit 73 samples of state-collected powdered infant formula for *Cronobacter* and *Salmonella* testing via the DX.

Submitting sample collection data presents some unique and additional challenges. Required fields include FDA Product Codes (a standardized product description), FEI numbers (FDA unique identifier for a firm), and other fields that require some training and/or resources to complete. While state-collected sample data submission is more resource intensive, it also represents the overwhelming majority of future use cases for ORA DX. This makes the successful sample data submissions by Maryland ground-breaking and a very exciting milestone.

ORA DX sample data sharing exists to allow state sample data to be submitted and integrated into FDA data systems. There are two potential uses/needs for ORA DX capability:

State-Collected Samples: States collect and analyze samples as part of an FDA surveillance testing program (such as the LFFM Product Testing Tracks for Micro/Chem Human and Animal Food). In Year 2 of the LFFM, laboratories are analyzing approximately 20,000 samples. In these situations, the state must submit sample collection, lab receipt, and analysis data. The ability to submit state-collected samples to the FDA data system is an important capability for receiving large scale surveillance data and integrating state data with FDA data for data mining, analysis, risk assessment, etc. LFFM represents a significant resource that can be tapped into to accomplish and support many goals for the agency, delivering on the true potential of this analytical resource requires integration of the data with the larger FDA dataset. Our goal is for all 40 of our LFFM Product Testing Track laboratories to be ready and able to submit data via ORA DX by 2025.

FDA-Collected Samples: FDA collects a sample and sends to a state lab for analysis; the state lab uses ORA DX to submit results. In these situations, the state only has to submit lab receipt and analysis data, because the sample collection record was completed by FDA and is already in the FDA data system. The ability for states to submit analytical data that can be associated with an FDA sample collection record is an important capability for surge capacity/large scale emergencies (where FDA may be inundated with huge numbers of samples and a bottleneck in FDA laboratory capabilities or capacity).