WESTERN GROWERS SCIENCE

Primer: Sampling for Optimized Results and Data Analysis

May 16, 2024
Version 0

Primer: Sampling for Optimized Results and Data Analysis

Prepared by: Joelle Mosso M.S., AVP Science Programs and Gustavo Reyes Ph.D., Food Safety Manager

Is sampling that easy?

The act of sampling may be simple, but there are numerous factors related to that sampling that will intentionally and unintentionally influence the sample's result. Careful consideration, documentation and description of these factors should be considered before executing the sampling process, and systems should be put in place for ongoing verification.

This document serves as a primer about the type of quality systems that should be in place to ensure the entire process, from sampling through testing, is executed to plan for a company's food safety and quality strategy.

It is easy to sample a food product since the activity itself just involves grabbing product from the field, carton or processing line; putting it in a sample bag; and sending it off for analysis at your laboratory. Water sampling is something similar: capture some water from your source, bottle it up, and send it off to the lab. While the act of sampling is simple, it is more complex to know what the results of that sample represent once you get the test results. Where within a field do you sample? Are you targeting areas of high risk (i.e., adjacent land to an animal pasture, under an electrical line that birds rest upon)? Alternatively, are you assuming all areas of the field have the same risk? What expected prevalence and concentration is expected to be there (e.g., percent positive and if positive, how many cells/g or mL)? For water samples, do you test at the beginning, middle and end of the distribution system (i.e., at the first, middle and last sprinkler heads in the field) or at the well, pump, or canal?

Build for Result Integrity: Testing & Sampling Programs

Quality management systems and third-party accreditations are important in the food industry where confidence in food safety, consistency and efficacy of systems are critical. Common examples of these programs include schemes managed by the International Organization for Standardization (ISO) such as 9001 for quality, 22000 for food safety and 17025 for testing. The Global Food Safety Initiative (GFSI) also had a set of food quality manufacturing schemes such as Safe Quality Food (SQF)'s, PrimusGFS, FSSC 22000 and British Retail Consortium (BRC) Global Standard. Quality management standards provide structural systems that should ensure comparability amongst producers and address efficiency and consistency so that an operation can

repeatedly deliver high-quality products or services. Accreditation and/or certification by a third-party entity to those standards provides added verification, and thereby instills even greater confidence for clients/consumers in the accuracy of those rendered services or products. These quality systems and accreditations are particularly important in operations where safety and accuracy are critical. Examples of such industries include food production, food testing and medical services.

In the food testing industry, a common quality accreditation is that of ISO 17025. ISO 17025 is an international standard for laboratory testing and calibration. ISO 17025 requires a comprehensive system for sample processing and analysis. This accreditation helps the food industry have confidence that results from their laboratory are accurate and reliable so that they can make decisions with high economic implications, and, more critically, potential public health ramifications. Poor performance in food testing may lead to preventable illnesses and deaths and is therefore of extreme importance. The Food and Drug Administration (FDA)'s Food Safety Modernization Act (FSMA) requires that food testing be performed using validated test methods for the matrix to be tested, and the FDA strongly encourages food companies to utilize laboratories covered by accreditation systems such as ISO 17025. In addition to FDA regulatory language and requirements, there are numerous independent food safety standards and customer requirements that require all testing be performed by ISO 17025-accredited laboratories.

Sample Collection

The accuracy of a test result begins to form long before the sample's submission to the laboratory. Laboratories ensure that the sample will be handled, processed and analyzed per their standard operating procedures and quality systems. However, the laboratory may not have any input or visibility into the sample quality (how the sample itself was collected and prepared). As a result, a laboratory cannot improve the quality of a sample once in their responsibility, they can only ensure that the value of the sample remains the same within their process and analysis.

Food companies preparing samples are encouraged to review or develop quality and verification systems for sampling so that their test results can be correctly interpreted and results from distinct sampling events can be compared and analyzed. The first step in developing a comprehensive testing program should be describing and documenting the overall goal for the testing program (i.e., safety of the lot, surveillance of the area, indicator of quality, etc.). Knowing the goal informs the

necessary design of the sampling program while noting assumptions on the expected prevalence, type of contamination (e.g., uniform, point-source, clustered) and target concentration (e.g., 1 colony forming unit /375g, per 454g, 1 CFU/1500g). Once the goal is established, the sampling procedure should be written and document controlled. Individuals who will be responsible for sampling should be trained on the procedure, and that training should be documented and verified for comprehension. Once the sampling procedure is established, an ongoing verification system should be developed to perform routine quality control monitoring to ensure the standard operating procedure (SOP) for sampling is adhered to. Verification can be achieved through activities such as auditing of sampling activities (announced and unannounced) and implementing technology to track sampling activities and paths to ensure adherence to protocols. The verification system should be documented, controlled and maintained in the food safety plan.

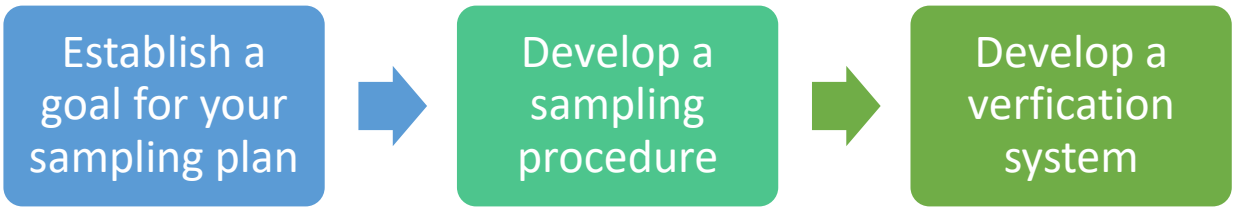

Figure 1: Steps in developing a comprehensive sampling program.

If external groups that are not within the direct control of the food company are performing the sampling, it is a best practice to ensure that the service provider for sampling has the quality systems in place to assure control and consistency of sampling per the client's SOP. Sampling services can be covered with ISO 17025 accreditation regardless of whether the service is associated with an ISO 17025-accredited laboratory or not. If ISO 17025-accredited for sampling services, clients can be confident that the service provider has quality systems and programs in place and that they are verified through third-party auditors and accreditation bodies. If the sampling service provider is not ISO 17025 accredited, the list below identifies some key quality program components to review before utilizing a sampling service. It is a best practice to document this review and file records of the activity in a company's food safety plan to provide supporting evidence for the sampling process and alignment with the testing program's needs.

Key quality program components for sampling service providers:

Program Component	Description
Document Control	Review that procedures are in place to control all documents related to the tests. This includes document creation, approval, distribution and revision.
Review of Contracts	Ensure the service provider has a process in place to review customer requirements, contracts and customer expectation assessments.
Subcontracting of Services	Define guidelines and criteria for subcontracting. If the service provider needs to outsource some of services, determine the process to be used to distribute the work.
Customer Support System	Ensure that there are systems in place to communicate with customers regarding the services offered and to gather feedback to improve service quality.
Complaints	Review that a system is in place to receive, evaluate and make decisions on complaints.
Control of Nonconforming Work	Review the policies of the provider to deal with any non-conforming procedures.
Improvement	Ensure that there is a system for continuous improvement of the management system. This involves improvements in quality policy, objectives, audit results, analysis of data, corrective and preventive actions, and management review.
Corrective Action	Review the type of system used to eliminate the cause of non-conformities to prevent the recurrence of the issue and broader system failures.
Control of Records	Management of records to demonstrate conformity to requirements and the effective operation of the quality management system.
Internal Audits	Verify daily/routine audits are in place to check whether the quality management system is functioning effectively and is compliant with ISO 17025.
Management Reviews	Periodic reviews by top management to ensure the continuing suitability, adequacy and effectiveness of the quality management system.
Personnel	Ensure that all personnel involved in testing activities are competent based on appropriate education, training, skills and experience.
Methods and Method Verification	Employ procedures for the appropriate selection and validation of sampling methods and to ensure that deviations are documented and justified. On-going, routine monitoring of all sampling activities should be in place for review to ensure sampling is performed per SOP.
Handling of Samples	Verify that the provider has procedures for the handling of all samples and that appropriate conditions, equipment and monitoring systems are in place for the handling and transport of samples.

Sampling may be a simple act and an often-overlooked component of a testing program, but sampling design and execution is a critical component of a testing plan that requires thoughtful design and review. It is very important that companies utilizing testing within their food safety plan take careful consideration of their sampling procedures, training or selection of samplers and develop on-going means to audit the activities of sampling. Careful contemplation on design and verification of the testing program is the greatest return on investment for testing dollars and delivers the optimal value and learning possible from testing efforts.

Additional considerations for data analysis

Collection and documentation of samples provide the opportunity to draw meaningful conclusions from datasets that have been created by many iterations of sampling and testing. For the produce industry, effective and high-quality samples can streamline the data collection process but also enhance the accuracy and reliability of assessment when interpreting and getting insights from the data. To conduct insightful analysis, it is essential to establish clear objectives, such as what specific question are you trying to answer. Are you looking to detect contamination? Or are you looking to assess what factor may be related to the detection of contamination?

Below are some considerations to leverage sampling/testing results for data analysis:

- Consider what factors/metadata can supplement your sample collection. If you want to learn from your positives and negatives, gathering information that can be used for further analysis for your sample is important. Information such as proximity to animal operations, recent rainfall, environmental conditions, farming practices, geospatial location, etc. can help you find patterns and build association between your sampling results and the factors collected.
- Use standardized formats for recording and storing your data. This is as simple as having your results in an excel spreadsheet or a database, where each column describes a single aspect of the data.
- Start looking at your data and become familiar with the data you are collecting. Conduct simple analysis, such as calculating your positives in a certain week or month to try to identify patterns.
- Stay curious as you look at your data. You may start to identify patterns and factors associated with your data that provoke questions. This will make you look at your systems

and evaluate if you need to collect new data and identify points of improvement. Continuously monitor key metrics and update your analysis.

6501 Irvine Center Drive, Suite 100, Irvine, CA 92618
949.863.1000 | Fax 949.863.9028 | www.wga.com