

Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories

January 24, 2017

Governmental Food and Feed Laboratories Accreditation Meeting

Overview

- Laboratory accreditation has been identified as a critical element for ensuring integrity and accuracy of food and feed testing results
- Food Safety Modernization Act (FSMA)
 - Sec 202: Laboratory Accreditation for Analysis of Foods
 - Seeks to provide an accreditation standard and process for laboratories testing food and feed
 - Governmental laboratories are not specifically listed

Overview

- Partnership for Food Protection (PFP)
 - Food and Feed Testing Laboratories Best Practices Manual (Draft) in December 2013
 - Recognized that other quality systems existed (e.g. CLIA)
 - Provided some options for laboratories to consider
 - State and local laboratories are strongly encouraged to become ISO/IEC 17025 accredited
 - External accreditation demonstrates a commitment to developing and maintaining a QMS

Overview

- However, accreditation may not be feasible in some cases, due to:
 - Not fiscally justifiable due to low volume of testing
 - Testing may be performed only in rare instances
 - Requests for esoteric or situational testing may fall outside of scopes (e.g. melamine, Gulf oil spill, etc)

Background

- In 2014, APHL convened the Data Acceptance Workgroup to further define and clarify gaps for state and local public health laboratories
- Focused on steps that could be taken to encourage data acceptance and use of laboratory data by their partners irrespective of accreditation status

Workgroup

- Individuals representing:
 - State and local laboratories (members of associations)
 - Public Health, Food, and Feed Laboratorians
 - Food and Drug Administration (FDA)
 - United States Department of Agriculture (USDA)
Food Safety and Inspection Services (FSIS)
 - Association of Public Health Laboratories (APHL)
 - Association of Food and Drug Officials (AFDO)
 - Association of American Feed Control Officials (AAFCO)

White Paper

The white paper, published in October 2016, is built out in the following structure:

- Introduction/Purpose
- White Paper Development
- Quality Management System (QMS)
- Requirements of State Cooperative and Regulatory Programs
- Evaluation of Data by Laboratory Customers
- Conclusion
- Appendix A: Checklist
- Appendix B: Example of a Collection Report
- Appendix C: Glossary of Terms
- References

Quality Management Systems

- Includes all activities that contribute, directly or indirectly, to the quality of test results.
- Three major phases of testing: pre-analytical, analytical and post-analytical
- Pre-analytical phase
 - Includes not only sample receipt, but how the sampling is conducted and what tests are needed
 - Communication up front will ensure that all parties understand chain of custody needs and requirements for representative sampling (Sample Quality Criteria and *GOODSamples*)

Quality Management Systems

- Analytical phase
 - Includes but not limited to: Quality Assurance Plan, staff training, demonstration of capability and competency, selection of analytical methods and test method validation and verification, proficiency testing and inter-laboratory comparisons, quality controls for monitoring, documentation of raw data results
- Post-analytical phase
 - Reporting of results according to predetermined customer requirements, record creation and retention, and data packages

Requirements of State Cooperative and Regulatory Programs

- Data received from the laboratory must be accurate, timely and reliable
- Prior to establishing an agreement, the laboratory must work closely with the food and feed programs to ensure providing the service needed and to encourage data acceptance for regulatory action

Requirements of State Cooperative and Regulatory Programs

- Laboratory specific program requirements highlighted in the white paper include:
 - State Manufactured Food Regulatory
 - State Animal Feed Regulatory
 - FDA Grade "A" Milk
 - Retail Food
 - FDA National Shellfish Sanitation

Evaluation of Data by Laboratory Customers

- Customers should evaluate the utility of the data provided.
 - End users may have specific needs and should provide these to the laboratory prior to testing
- Customers should discuss and determine the laboratory's ability and willingness to support the data, including testifying in a legal action

Evaluation of Data by Laboratory Customers

- Communication for test requests
 - The laboratory is responsible for carrying out testing and calibration activities in such a way as to satisfy the customer
 - The customer has an obligation to understand that the laboratory has policies and procedures in place for accepting test requests
 - Any differences should be resolved before work commences
- Understanding the objectives of sampling and the processes used will help to determine if any additional considerations must be discussed

Conclusion

- Accreditation will help labs meet requirements of various customers
- Following these best practices can instill greater confidence in data submitted by a non-accredited laboratories with a QMS in place
- Understand that accreditation or following the best practices does not infer that data will be accepted by the customer

Conclusion

- The white paper does not take the place of any regulatory or customer specific requirements but provides a foundation regarding data acceptability
- Laboratories should focus on achieving ISO/IEC 17025 accreditation when the time and cost can be justified by customer needs
- By working together, laboratories and their partners can achieve a level of quality and efficiency that supports the protection of food and feed products through the sharing of data and information

Additional Tools

- Appendix A: Checklist included that offers laboratories a way to easily review their system against the recommended key elements
- Appendix C: Glossary of terms is provided to ensure uniformity of understanding of the terminology used throughout the white paper

More Information

This white paper is available on the APHL website and through the partnering organizations that helped create the document

Comments and suggested revisions are encouraged and may be sent to

foodsafety@aphl.org

Thank you

**to everyone that contributed
to the white paper**

Kathryn Wangsness, MHA
Arizona State Public Health Laboratory
Kathryn.wangsness@azdhs.gov