

Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed

Dare Akingbade ^a, Ron Klein ^b, Cynthia Mangione ^c, Tom Philips ^d, Yvonne Salfinger ^{a,b}, Sharon Shea ^{*a}, Nancy Thiex ^e

^a Association of Public Health Laboratories, Silver Spring, MD

^b Association of Food and Drug Officials, York, PA

^c New York State Department of Agriculture and Markets, Albany, NY

^d Maryland Department of Agriculture, Annapolis, MD

^e Association of American Feed Control Officials, Champaign, IL

ARTICLE INFORMATION

Article History:

Received April 8 2014

Received in revised form

July 21 2014

Accepted July 23 2014

Keywords:

ISO 17025

Accreditation

Laboratory

Associations

Food

Feed

ABSTRACT

The Food Safety Modernization Act (FSMA) provides the US Food and Drug Administration (FDA) with structures to achieve better public health protection and improve the food safety system. The Partnership for Food Protection (PFP) was created to ensure collaboration among federal, state and local entities and to formulate standards that can be used nationally to ensure uniformity of inspection and laboratory procedures and expand foodborne outbreak response capacity. Resulting national standards together with laboratory accreditation are expected to allow the seamless use of laboratory analytical data across federal, state and local jurisdictions and the rapid acceptance of such data for regulatory actions.

In 2012, FDA funded three national organizations (Association of Public Health Laboratories, Association of Food and Drug Officials, and Association of American Feed Control Officials) to prepare government food and feed regulatory testing laboratories seeking to achieve, maintain, and enhance accreditation to the ISO/IEC 17025:2005 standard. These associations strengthen multi-disciplinary laboratory collaboration, develop training and mentoring programs, improve direct electronic sharing of analytical data, and build a framework for unified laboratory response. Their efforts will increase the number of accredited governmental food and feed testing laboratories within five years and enhance the safety of the national food supply.

1. Introduction

The Food Safety Modernization Act (FSMA), signed into law by President Barack Obama on January 4, 2011, provides the United States Food and Drug Administration (FDA) with a framework to strengthen the food safety system and better protect public health. The Act gave greater powers

to FDA to protect the nation's food supply of both domestic and foreign source to reduce foodborne illness (Coffman et. al., 2014). According to the CDC, an estimated 48 million people are sickened resulting in 128,000 hospitalizations and 3,000 deaths each year in the United States due to foodborne illness (CDC, 2011). The primary

* Corresponding authors. Association of Public Health Laboratories, 8515 Georgia Avenue, Ste. 700, Silver Spring, MD 20910 Tel: (240) 485 - 2745; fax: (240) 485-2700 E-mail: shari.shea@aphl.org (S. Shea)

purpose of the Act is to ensure the safety of the US food supply by shifting focus from response to prevention of food and animal feed contamination through enhanced partnerships and integration among federal, state, local, tribal and territorial partners.

The Partnership for Food Protection (PFP), created to facilitate collaboration among agency partners of federal, state and local governments, has been working to develop an integrated food safety system with strengthened inspection, laboratory, and response capacity. PFP workgroups, agency members, and association partners continue to work closely with state, local, tribal, and territorial partners to develop and implement the Integrated Food Safety System (IFSS). Examples of current activities include efforts to standardize training and expertise levels of inspectors and develop national standards for federal, state, and local laboratories. These national standards together with laboratory accreditation are expected to facilitate the rapid acceptance of laboratory analytical data across federal, state and local jurisdictions and improve response to outbreaks. (FDA, 2013)

The Association of Food and Drug Officials (AFDO), the Association of American Feed Control Officials (AAFCO), and the Association of Public Health Laboratories (APHL) continue to work towards meeting the goals of a Cooperative Agreement with FDA, with a maximum award of \$7.5 million dollars over a period of 5 years to support food and animal feed testing laboratories seeking to achieve, maintain, and enhance their accreditation to the ISO/IEC 17025:2005 standard (ISO, 2005). To date, 14 Association-led groups worked on nine specific aims of this Cooperative Agreement. Participation in workgroups is voluntary yet very robust, with over 70 individuals actively contributing. Members are committed to the work and share a common goal of creating a unified food and animal feed laboratory system in the United States.

ISO/IEC 17025 (ISO, 2005) is an international quality management standard that was first released in 1999 and revised in 2005 to address the general requirements for the competence of testing and calibration laboratories (Kohl, 1998). Accreditation to this standard is conducted by a third party accrediting body and confers several benefits to the laboratory accredited to such standards. Some of the benefits include acceptance of ISO/IEC 17025 accredited laboratory data in the international

community (Kohl, 1998); the ability to more readily and systematically identify issues with testing methods, personnel or equipment; and, with continuous improvement through corrective and preventive action procedures and audits, enhanced reliability of test results, demonstrated technical competence of staff, and improved customer satisfaction. (Honsa and McIntyre, 2003; Abdel-Fattah, 2010). Guzel and Guner (2009) reported an increase in the number of staff who believed that quality of test results improved one year after accreditation to the ISO 15189 standard (ISO, 2012) in a medical laboratory.

The objectives of the nine specific aims of the Associations cooperative agreement are to: 1) provide support programs for food and animal feed testing laboratories that seek to achieve, maintain and enhance ISO/IEC 17025:2005 accreditation; 2) establish data acceptance criteria among federal, state and local testing laboratories; 3) establish national models that will encourage rapid sharing of state and local laboratory test result data for regulatory purposes; 4) implement a unified response system to food and animal feed safety emergencies; 5) improve collaboration between laboratories and regulatory agencies; 6) provide educational and mentoring opportunities; 7) achieve national consensus on the acceptance of laboratory test data; 8) use association infrastructure to achieve conformance with applicable program standards; and 9) ensure rapid submission of clinical isolates related to foodborne illnesses to the public health laboratory system.

2. Methods

Fourteen groups of committed members from the three associations and assigned FDA leads and association staff were convened to work on nine specific aims of the cooperative agreement. These groups deliberated on issues relevant to meeting the deliverables of the cooperative agreement via regularly scheduled teleconference calls and/or in-person meetings. Other tools used to accomplish the work included webinars, a SharePoint site, FoodSHIELD, a discussion board, accreditation web pages (both public and restricted-access), training needs assessments, infrastructure of the three associations, and contractual agreements. Some of these tools are discussed in greater details in succeeding sections.

Each of the specific aims has activities and some use workgroups to achieve the above stated cooperative agreement objectives.

3. Results and Discussion

In this paper, we highlight some of the twelve groups' successes and how they have helped APHL, AFDO and AAFCO achieve the deliverables of the cooperative agreement:

A Food and Animal Feed Laboratory Accreditation Discussion Board was developed and is currently hosted by APHL. The discussion board is an on-line forum for the exchange of information related to becoming accredited to the ISO/IEC 17025:2005 standard. It provides laboratorians and quality managers a tool to collectively address issues confronted as they strive for accreditation. As of June 2014, there are 65 registered participants on the discussion board with approximately 70 topics posted for discussion and clarification among laboratory professionals.

Web pages were created to support Food and Animal Feed Testing Laboratories seeking accreditation including a repository of ISO/IEC 17025:2005 resources such as best practices, standard procedures, and work plans. The resource webpages went live in August 2013 and are located on the website of APHL's Food Safety Program (<http://www.aphl.org/aphlprograms/food/laboratory-accreditation/pages/default.aspx>). AFDO and AAFCO both have links to the APHL site from their websites. Apart from additional publicly available documents, as of June 2014, 226 documents under 14 ISO categories have been posted, an increase of approximately 30% from the previous six months.

A Training Needs Assessment was conducted, and a prioritized list of training topics was developed. A spreadsheet of currently available ISO/IEC 17025:2005 training is located at the APHL resource site. To ensure training efforts are not duplicated, FDA and the Associations are diligently working together to identify training needs, determine if training is currently available, and if not, to develop new training to meet the identified needs. A pre-recorded webinar "ISO/IEC 17025 Road to Accreditation: Where to Start and What to Consider" (APHL et. al., 2013) was released in August 2013, and a second webinar titled "ISO/IEC 17025 Road to Accreditation: The Journey Continues..." (APHL et. al., 2014) based on questions received from the first presentation was developed and made available on April 3, 2014.

Eighty participants have registered and viewed the first webinar as of July 10, 2014; 26 have registered for the second webinar.

In addition, a live webinar "Key Elements of a Laboratory Quality Manual for U.S. Food and Feed Laboratories" was developed and archived for later viewing on June 12, 2014. A two part live webinar on the mentoring process was developed and archived for later viewing on June 19 and 20, 2014. Lastly, an in-person workshop was conducted on 'Developing a Quality Manual' on June 24, 2014 and a Mentoring Toolbox development workshop occurred on June 25, 2014, both in Denver, CO.

Three live webinars were coordinated by APHL to demonstrate commercially available tools that may be of value to laboratories seeking accreditation to the ISO/IEC 17025:2005 standard. Two of these webinars focused on document control software while the third was about compliance management software. APHL also offered free registration for a webinar series on ISO/IEC 17025:2005 management requirements to all food and animal feed testing laboratories. Of 39 evaluations received, almost 100% of respondents agreed the 13 stated objectives were met; 95% agreed the material presented will help them perform their job better; 79% agreed that they will recommend changes based on the information presented; and 95% agreed the course was worth the time spent to take it.

A discovery report (APHL, 2013) on data exchange among food and animal feed testing laboratories and FDA's eLEXNET was developed. The discovery report identified gaps in the current landscape and suggests the next steps to improve the food and animal feed data exchange. This discovery report is a product of information gathered from interviews, existing reports and data exchange manuals and from those with expertise in food and animal feed data exchange between state laboratories and FDA. The report has been reviewed by FDA and is currently posted on APHL's website.

A Subject Matter Expert (SME) Registry hosted on the AFDO website (<http://www.afdo.org/sme>) was expanded to include food and animal feed laboratory professionals. As of June 28, 2014, the registry included 56 Food Laboratory SME's (an increase from 20 prior to the time the cooperative agreement was put in place). In addition, other categories of expertise have also increased. New categories include Pet Food Testing, Animal Feed Testing, Laboratory Accreditation, and Sampling. The SME database supports the Manufactured Food

Regulatory Program Alliance's mission of community building, information exchange and a national food safety system. The SME registry provides a source of experts who can be called upon to help with the accreditation process and answer questions posed by laboratories seeking/enhancing accreditation, as well as provide technical expertise for testing issues.

A curriculum framework to identify career-spanning training for food and animal feed laboratory professionals is currently under development with the assistance of the International Food Protection Training Institute (IFPTI). Progress has been made on a curriculum framework diagram which depicts the professional development content areas that food and animal feed laboratory professionals should undergo during their careers. This curriculum is similar to the IFPTI Food Protection Curriculum Framework for regulatory food protection professionals (Kaml, 2013). The process for developing the competency framework for food and feed testing personnel is described in Kaml et al., 2014.

National standards are being established for the collection and handling of food and animal feed materials as a critical component of ensuring equivalency of data from federal, state and local laboratories. A nationwide survey of state sampling personnel sought feedback on issues with sampling processes, state-based conference calls captured sampling needs and "spend a day with an inspector/sampler" visits to various states captured day-to-day challenges. Work is underway on a guidance document, *GOODSamples* (Guidance on Obtaining Defensible Samples) based on the Theory of Sampling (Gy, 1998; Pitard, 1993). A publication describing these efforts was published in TOS Forum (Ramsey and Thiex, 2014). A laboratory study was conducted to evaluate inter-laboratory sample preparation error. Awareness training/sampling seminars that have occurred in 2014 include the AAFCO Midyear Meeting, the AAFCO Feed Seminar, Manufactured Food Regulatory Program Alliance (MFRPA), AFDO Annual Meeting and the AOAC International Annual Meeting. Venues scheduled for 2015 currently include the AAFCO Midyear Meeting, Manufactured Food Regulatory Program Alliance and State Food and Feed Laboratory Accreditation Meetings, APHL Annual Meeting and the Journal of the AOAC International.

The AAFCO Quality Assurance Quality Control Guidelines (Guidelines) for State Feed Laboratories (Ogden and Snodgrass, Eds., 2014) was revised to serve as a supplement to the ISO/IEC 17025:2005 Standard for animal feed laboratories. The Guidelines were released in February 2014 as three volumes and include a copy of the ISO/IEC 17025:2005 standard (ISO, 2005) and additional requirements beyond ISO/IEC 17025:2005 for feed laboratories as well as guidance for meeting these requirements; and examples of documents and forms. They are available for purchase at https://secure.fass.org/AAFCO_2014_QAQC_Guidelines_Order_Form.asp.

AAFCO manages proficiency-testing (PT) programs for analytical laboratories testing animal feed (AAFCO, 2014). The programs are administered by the AAFCO Collaborative Check Sample Committee (CCSC) and managed by the Committee Chairperson, a voluntary position. Progress has been achieved towards accreditation to the ISO/IEC 17043:2010 (ISO, 2010) proficiency testing standard for the AAFCO Collaborative Check Sample Program (CCSP) and extension of the scope of the CCSP to include pet food, mineral contaminants, mycotoxin contaminants, and veterinary drug residues. The Pet Food Program, which provides quarterly shipments of pet food ingredients, was successfully initiated in 2013. 2013 and 2014 subscriptions were 63 and 72 laboratories and an additional 118 analysts, (subscriptions total 180, however only results from 72 unique laboratories were included in statistics). The Mycotoxin Contaminants Program provides quarterly shipments of animal feed and pet food that have been contaminated with naturally occurring aflatoxins, fumonisins, deoxynivalenol, zeralenone, ochratoxin A and T-2 toxin. Thirty laboratories have enrolled for 2014.

A Laboratory Managers Steering Committee was established by AFDO to provide leadership on enhancing the program standards, implementing accreditation, improving integration, and promoting the standards and accreditation in jurisdictions where they are yet to be employed. Steering Committee subject matter experts are developing the Laboratory Curriculum Framework with IFPTI. The steering committee actively works with the MFRPA to address issues related to manufactured food program – laboratory collaboration and Manufactured Food Regulatory Program Standard Ten i.e. Laboratory Support (FDA, 2014).

A Clinical Isolate Submission report was developed to outline successful partnerships that improve clinical foodborne isolate submission to the public health system. The report describes ongoing challenges and proposes a pilot project to assist states in implementing successful programs.

The collaborative efforts funded under this cooperative agreement are enhancing and improving partnership, improving communication, and eliminating redundancies among all three associations, their members, staff from laboratories seeking accreditation, and FDA. This will accelerate progress towards the creation of a unified laboratory system which will ensure that food and animal feed laboratory test results from state and local laboratories are acceptable for regulatory, enforcement and compliance purposes.

Some of the immediate impacts from the cooperative agreement are the commitment of members to help one another resolve daily challenges that are faced by food and animal feed testing laboratories and the creation of an atmosphere for personnel from both ISO/IEC 17025:2005 accredited and non-accredited laboratories and regulatory food programs to interact and learn from one another regarding challenges, best practices, operating procedures and other common issues.

4. Conclusion

Good progress has been made by APHL, AFDO, and AAFCO to meeting the goals of this Cooperative Agreement to assist public health laboratories that seek to achieve, maintain or enhance accreditation to the ISO/IEC 17025:2005 standard. The associations' collaborative efforts with FDA will ensure that the number of accredited governmental food and animal feed testing laboratories will increase within five years and that successful data sharing among agencies will improve. The three associations are uniquely qualified to perform this work because their common mission is to assist the multi-disciplinary laboratories that perform food and animal feed testing in support of regulatory programs, surveillance efforts and outbreak investigations.

By working with FDA and facilitating long-term, permanent improvements to the national food and animal feed safety system, the work completed through this Cooperative Agreement will advance public health initiatives beyond the five-year funding cycle and improve the safety of the US food supply

by providing effective and efficient solutions to stakeholder laboratories to ensure food and animal feed safety.

5. Acknowledgements

The authors would like to acknowledge APHL, AAFCO and AFDO and all the workgroups, committees and subcommittee involved in this effort. We also acknowledge all the FDA leads and thank our reviewers for their helpful suggestions and editing.

This publication was supported by the Association of Public Health Laboratories ("APHL") and by Grant No. 1U18FD004710 from the Food and Drug Administration ("FDA") of the U.S. Department of Health and Human Services. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of APHL or FDA. This project was 100% funded with federal funds from a federal program of \$750,000.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

References

- Abdel-Fattah, H.T.M. (2010). ISO/IEC 17025 Accreditation: Between the Desired Gains and the Reality. *The Quality Assurance Journal*, 13, 21-27.
- Association of American Feed Control Officials (AAFCO) Proficiency Testing Programs. (2014) Retrieved from : <http://www.aafco.org/Laboratory/Proficiency-Testing-Programs>.
- Association of Public Health Laboratories (APHL). (2013). Discovery Document: Data Exchange among Food and Feed-Testing Laboratories and FDA's eLEXNET. Retrieved from: <http://www.aphl.org/Pages/default.aspx>.
- Association of Public Health Laboratories (APHL), Association of Food and Drug Officials (AFDO), Association of American Feed Control Officials (AAFCO) and Food and Drug Administration (FDA). (2014). ISO/IEC 17025 Road to Accreditation: Road to Accreditation: The Journey Continues... Retrieved from: <http://www.aphl.org/Pages/default.aspx>
- Association of Public Health Laboratories (APHL), Association of Food and Drug Officials (AFDO), Association of American Feed Control Officials (AAFCO) and Food and Drug Administration (FDA). (2013). ISO/IEC 17025 Road to Accreditation: Where to Start and What to Consider. Retrieved from: <http://www.aphl.org/Pages/default.aspx>

- Centers for Disease Control and Prevention (CDC). (2011). CDC Estimates of Foodborne illness in the United States. Retrieved from: <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>
- Coffman, V., Plunket, D. W., Wilson, G. and Warren, W. (2014). The Food Safety Modernization Act – A Series on What is Essential for a Food Professional to Know. Article 7. Laboratory Accreditation. *Food Protection Trends*, 34(1), 44-48.
- Food and Drug Administration (FDA). (2013). Federal/State Integration. Retrieved from <http://www.fda.gov/Food/GuidanceRegulation/FMA/ucm257981.htm>
- Food and Drug Administration (FDA). (2014). Manufactured Food Regulatory Program Standards (MFRPS). Retrieved from: <http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/Overview/>
- Guzel, O., and Guner, E. I. (2009). ISO 15189 Accreditation: Requirements for quality and competence of medical laboratories, experience of laboratory I. *Clinical Biochemistry*, 42, 274-278.
- Gy, P. (1998). *Sampling for Analytical Purposes*. Chichester: John Wiley & Sons Limited.
- Honsa, J. D., and McIntyre, D. A. (2003). ISO 17025: Practical Benefits of Implementing a Quality System. *Journal of AOAC International*, 86, 1038-1044.
- ISO 15189:2012. *Medical laboratories – Requirements for quality and competence*. International Standards Organization, Geneva, Switzerland.
- ISO 17025:2005. *General requirements for the competence and testing and calibration laboratories*. International Standards Organization, Geneva, Switzerland.
- ISO/IEC 17043:2010. *Conformity assessment - General requirements for proficiency testing*. International Standards Organization, Geneva, Switzerland.
- Kaml, C., Fogarty K.J., Wojtala G., Dardick W., Bateson A., Bradsher J.E., Weiss C.C. The development of a standards-based national curriculum framework for regulatory food safety training in the United States. *The Journal of Environmental Health*, 76, 38-42.
- Kaml, C., Weiss, C. C., Dezendorf, P., Ishida, M., Rice, D., Klein, R., Salfinger, Y. (2014). Developing a competency framework for U. S. state food and feed testing laboratory personnel, *Journal of AOAC International*, 97, 768-772.
- Kohl, H. (1998). The new ISO 17025 – basic idea. *Accreditation and Quality Assurance*, 3, 422-425.
- Ogden, L. R. and Snodgrass, B. Editors (2014). *AAFCO Quality Assurance / Quality Control Guidelines for Feed Laboratories*, Association of American Feed Control Officials (AAFCO), Champaign, IL.
- Pitard, F. F. (1993). *Pierre Gy's Sampling Theory and Sampling Practice*. Heterogeneity, Sampling Correctness, and Statistical Process Control. (2nd Ed.). Boca Raton, FL: CRC Press.
- Ramsey, C. and Thiex, N. (2014). Improved Food and Feed Safety through Systematic Planning and the Theory of Sampling (TOS): An Introduction to “GOODSamples”. *TOS Forum*, 1-2, 8-11. IM Publications, Chichester, UK.