

Building a Network of Accredited Governmental Human and Animal Food Laboratories:

A 2017 ISO Cooperative Agreement Metrics Survey Report

Background

The [US Food and Drug Administration](#) (FDA) has identified laboratory accreditation as a critical element for ensuring the integrity of human and animal food testing. Such data integrity is necessary to support mutual reliance, or the interdependence and trust shared between federal and state food safety agencies. Accreditation to a vetted standard, such as ISO/IEC 17025, is one way to demonstrate integrity.

In 2012, FDA provided five-year cooperative agreements to 31 state food testing laboratories to help them attain or enhance their scope of accreditation to the ISO/IEC 17025 standard, with an additional six food testing laboratories added in 2015. Twenty state animal food testing laboratories were also funded in 2015, with an additional animal food laboratory funded in 2016. To assist those laboratories in their efforts, FDA also awarded a five-year cooperative agreement to three associations—the [Association of Public Health Laboratories](#) (APHL), the [Association of Food and Drug Officials](#) (AFDO) and the [Association of American Feed Control Officials](#) (AAFCO) (the Associations Cooperative Agreement). Together, the associations have provided training, resources, guidance and networking opportunities to human and animal food testing laboratories seeking to achieve or enhance their ISO/IEC 17025 accreditation. Over the past five years, the associations have:

- Developed guidelines to help laboratories strengthen their quality management systems, including the APHL white paper *Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories*, *GOODSamples: Guidance on Obtaining Defensible Samples*, and the revised *AAFCO Quality Assurance/Quality Control Guidelines for State Feed Laboratories*;
- Hosted a website of accreditation resources, which includes over 250 documents on accreditation provided by laboratory staff in governmental human and animal food laboratories across the country;
- Provided direct technical assistance via an accreditation consultant to laboratories identified by FDA as having a proven commitment to seeking accreditation but who were not participating in the FDA ISO cooperative agreement program;
- Worked with the [International Food Protection Training Institute](#) (IFPTI) to develop a curriculum framework for governmental regulatory laboratories; and
- Hosted annual Governmental Food and Feed Laboratories Accreditation Meetings, which allow laboratories and regulatory programs to discuss and develop mutually beneficial strategies to address challenges.

Through this work, the associations have committed resources to meet the needs of the laboratory community. Quality managers and technical staff working across the country are helping each other resolve daily challenges using tools provided through the associations. Personnel from both ISO/IEC

17025 accredited and non-accredited laboratories are learning from common challenges and sharing best practices.

Assessment Methods

The associations aimed to assess the utility and success of FDA's efforts to build a network of accredited governmental laboratories, especially those activities supported by the Associations Cooperative Agreement. APHL, AFDO and AAFCO developed a survey tool to determine the laboratories' awareness and use of various resources, as well as measure the effectiveness of the tools and resources provided. In April 2017, the survey was programmed and sent to laboratories involved in the ISO and Animal Food Regulatory Program Standards cooperative agreement programs, unfunded laboratories receiving support through the Associations Cooperative Agreement, and two laboratories identified in a pre-survey assessment as interested in pursuing accreditation but not currently federally-funded for the process.

Of 49 survey recipients, 36 responded (73.4%). Survey results are arranged according to the Associations Cooperative Agreement's specific aims, followed by overarching impact measures.

The Impact of the Cooperative Agreements

Support ISO/IEC 17025:2005 Accreditation of Food and Animal Feed Regulatory Laboratories

The survey sought to determine which laboratories had reached milestones before the cooperative agreements were in place, and as a direct result of the agreements. Milestones included:

- Have a quality manual (19 laboratories before, 19 laboratories after)
- Have a full-time quality manager (17 laboratories before, 19 laboratories after)
- Have a part-time quality manager (four laboratories before, seven laboratories after)
- Have a method for document control (18 laboratories before, 23 laboratories after)
- Conduct internal audits (14 laboratories before, 21 laboratories after)
- Chose an accrediting body (five laboratories before, 23 laboratories after)
- Applied for initial assessment (five laboratories before, 20 laboratories after)

Almost half of the respondents (45.7%) utilized the APHL Food and Feed Testing Accreditation Discussion Board, an online forum for state and local laboratory professionals to exchange information related to ISO/IEC 17025 accreditation. Similarly, 48.5% of respondents utilized APHL's public resources site, which provides general information about the importance of accreditation and stories of laboratory successes in preventing human illness. The members-only document repository—housing standard operating procedures, analytical worksheets and a quality manual—was utilized by 68.5% of respondents. The most popular resources were APHL's training resources (80.0%). When asked how the resources provided by the Associations Cooperative Agreement benefited the laboratory, respondents replied:

- "The document repository and the webinars have been excellent sources of information to get through the accreditation process."
- "Having access to the training documents...[and] both federal and state laboratories/QA managers who have been through the process has greatly assisted us in our preparation for accreditation. This network of resources is of benefit to all as we work together to strengthen the animal feed program."
- "The APHL resources are the first place I go to look for answers to a question."

- “The online trainings have been great for us. We are not able to send everyone to accreditation training workshops but at least they can all see these webinars presented by the experts. It has really helped us with buy-in among nearly all personnel.”

Establish Best Practices for Encouraging Data Acceptance

Released in October 2015, successful marketing efforts of *GOODSamples* resulted in 94.4% of respondents indicating awareness of the document. Through state sampling pilots and workshops, *GOODSamples* practices have been disseminated to the regulatory programs—23.5% of respondents reported working with a regulatory program that adopted sampling practices based on *GOODSamples* theory.

The APHL white paper *Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories*, which was published in October 2016, had been marketed for six months prior to this survey, resulting in an 80.0% awareness rate.

Of those surveyed, 45.7% were aware of AFDO’s Subject Matter Expert (SME) Registry, although none reported utilizing the registry. However, the SME Registry was used to obtain additional commenters on the Laboratory Curriculum Framework by AFDO and IFPTI. Almost half of the respondents (48.5%) were aware of AFDO’s Directory of State and Local Officials (DSLO), with 8.5% utilizing the directory.

Implement a National Framework for Unified Laboratory Response

The associations collaborated with IFPTI to establish a national competency-based curriculum framework for governmental food and feed testing laboratory personnel. Three-quarters of the respondents (75.0%) were aware of the of the Laboratory Curriculum Framework. The course topics that were a high priority for laboratories included Chain of Custody (40.0%), Sample Handling (37.1%) and Quality Management Systems (34.2%).

Improve Communication and Collaboration Between Laboratory and Regulatory Personnel

The associations have worked diligently over the past five years to provide networking opportunities between laboratory personnel and their regulatory programs through various committee and workgroup calls, association annual meetings, and the annual Governmental Food and Feed Testing Laboratories Accreditation meetings. Over three-quarters (77.7%) of respondents agreed that the FDA ISO cooperative agreements improved cooperation between the laboratory and regulatory program staff, with the remainder citing an already-strong relationship with their program prior to the cooperative agreement. Respondents reported that the cooperative agreements have led to:

- “Increased surveillance monitoring of food products...more frequent communications with the regulatory program via conference calls, emails, etc.”
- “Improved sample collection kits and instructions for field sample collection by department sanitarians.”
- “Increased partnerships and understandings regarding issues such as chain of custody, standardization, sampling and sample receipt...increased visibility with senior regulatory leadership regarding the importance of quality assurance, the need and costs of standardization and ISO accreditation”
- “...formalized relationships and set boundaries for each group.”
- “...a more coordinated outbreak response.”

Activities such as laboratory participation in association committee/subcommittee meetings and conference calls, as well as attendance at national meetings, were found to be overwhelmingly helpful. Of the 32 respondents who attended association annual meetings or Governmental Food and Feed Testing Laboratories Accreditation meetings, 100% found them to be helpful for training and networking purposes.

Similarly, 93% of those respondents who participated in subcommittee or committee work found these roles to be helpful for networking with other laboratorians. Respondents commented:

- “These meetings are a great place to meet colleagues from other state agencies performing the same work and collaborate on methods, issues and best practices.”
- “It actually gave us additional opportunities to meet face-to-face with our mentor lab, and were invaluable for problem solving and brainstorming ways to work around roadblocks and other problems.”
- “Yes, these meetings are outstanding. The opportunity to learn from others who are already accredited has been invaluable...The panel presentations/discussions provided an excellent opportunity to ask questions and receive feedback from numerous experts have benefited all attendees.”
- “This is a chance to learn a lot of information in a short period of time without the distraction of being in the lab or office.”
- “It is helpful for networking and being kept updated to trending topics.”

Enhance Scope of Accreditation/Performance Assessment for Laboratory Test Results

AAFCO enlisted members to aid in the revision of the *AAFCO Quality Assurance/Quality Control Guidelines*, released in 2014. Of the animal food testing laboratories surveyed, 29% reported that the guidelines improved or changed their quality assurance/quality control practices. Respondents reported:

- “We began using them to strengthen our quality management system prior to becoming one of the AFRPS cooperative agreement laboratories seeking accreditation.”
- “We are working towards accreditation and are using these guidelines as a reference for some of our quality management documents.”
- “Altered and changed document control and [chain of custody] for regulatory purposes.”
- “We have adopted ISO-like practices with our feed testing division.”

AAFCO also expanded the offerings in their Proficiency Testing Program, to which 91.6% of respondents reportedly subscribe. The Proficiency Testing Program recently achieved ISO/IEC 17043 accreditation through use of Associations Cooperative Agreement resources. Of the animal food testing laboratory respondents, all but one (95.6%) saw the importance of having the Proficiency Testing Program be ISO/IEC 17043 accredited.

Overarching Measures of the FDA ISO Cooperative Agreement

One of the overarching goals of this cooperative agreement targeted data acceptance by increasing the transparency of laboratory processes and ensuring the presence of essential quality elements, leading to increased federal acceptance of state data. Respondents were asked to review their data packet submissions to FDA over the five-year period covering the cooperative agreement.

- Forty-one percent (41.1%) of respondents reported that the number of laboratory data packets submitted to FDA or the US Department of Agriculture (USDA) has increased over the past five years. About half of respondents reported their data packet submissions stayed the same (26.4%) or were unsure (26.4%) if their numbers increased or decreased.
- One third of laboratories reported that the number of data packets accepted by FDA or USDA for regulatory action has increased (35.2%) and none (0.0%) reported a decrease, while one third (38.2%) was unsure and 26.4% reported their acceptance rate stayed the same.

- Finally, 11.7% of respondents reported an increased in the number of import alerts issued based on their laboratory's data, none (0.0%) reported a decrease, one quarter (26.4%) reported level numbers, and 61.7% were unsure if import alerts had increased or decreased over the past five years.

Creating a Lasting Impact on Governmental Laboratories

Through these accreditation activities, FDA's investment in ISO/IEC 17025 accreditation has helped advance public health initiatives and improved the safety of the US food supply. The associations' collaborative efforts with FDA have ensured that the number of accredited governmental human and animal food testing laboratories increased within the five years of the cooperative agreement, and that successful data sharing among agencies will improve. The associations will continue to support and maintain a national network of accredited governmental laboratories to reduce the burden of foodborne illness and enhance the public's health.



Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

Association of Food and Drug Officials

The Association of Food and Drug Officials (AFDO) is a leader in promoting public health, fostering uniformity, and establishing partnerships. AFDO actively works to improve the nation's health and safety by establishing networks for state and local food protection officials and through educational forums designed to advance uniform food, drug and consumer product health and safety regulations.

Association of American Feed Control Officials

The Association of American Feed Control Officials (AAFCO) provides an open forum for discussions of regulatory science in which all stakeholders deliberate to establish model bill, regulations and policy related to feed safety, quality and effectiveness. AAFCO promotes new ideas and innovative procedures and urges their adoption by member agencies for uniformity.

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