The Value of FDA's Investment in Laboratory Accreditation

FDA's Investment

The US Food and Drug Administration (FDA) has invested over $50 million towards the accreditation of state laboratories to the ISO/IEC 17025:2005 standard (ISO 17025). Accreditation is an integral part of mutual reliance and a critical element of an Integrated Food Safety System (IFSS). A fully functioning IFSS allows for acceptance of state data in federal enforcement actions and means FDA and states can act efficiently in the prevention of foodborne illnesses.

In 2012, FDA awarded a cooperative agreement to the Association of Public Health Laboratories (APHL), the Association of Food and Drug Officials (AFDO) and the Association of American Feed Control Officials (AAFCO) to facilitate long-term improvements to the national food and animal feed safety system by strengthening collaboration and supporting laboratories seeking accreditation. That year, FDA also funded 31 laboratories that perform food testing for state regulatory programs to achieve ISO accreditation.

In 2015, six more food laboratories and 20 feed laboratories received ISO funding as part of FDA's program. In 2016, an additional feed laboratory entered FDA's ISO program. In addition to this funding to states, a structured laboratory accreditation support program has been established within the FDA's Office of Partnerships and Office of Regulatory Science to provide guidance and technical assistance to laboratories seeking ISO 17025 accreditation or to enhance the scope of already accredited laboratories.

Achieving Accreditation

As of October 2016, 22 FDA-funded laboratories have either achieved accreditation or expanded their scope of ISO 17025 accreditation. Active monitoring of cooperative agreement deliverables shows that the original FDA-funded food laboratories are on track to achieve or expand their accreditation by August 2017. FDA will actively monitor the remaining food and feed laboratories through their grant periods ending in 2020-21. Additionally, three of 17 laboratories not funded by an FDA ISO cooperative agreement but receiving direct technical assistance through the APHL cooperative agreement achieved accreditation.

Integration and Public Health Protection

Investment in laboratory accreditation helps protect the public's health by ensuring that regulatory agencies, both state and federal, can act quickly on high quality analytical data from accredited laboratories when those laboratories detect a problem in the food supply.

- In June 2014, the accredited New York state agriculture laboratory reported a positive *Salmonella* finding in imported organic sprouted chia seed powder to the FDA New York District Office. FDA swiftly issued an Import Alert within nine days. This successful collaboration and sharing of data prevented adulterated product from entering US commerce.
- In October 2014, the Massachusetts public health laboratory worked with the New York agriculture laboratory on a *Campylobacter* outbreak associated with raw milk. Since New York tested raw milk under their scope of accreditation, regulators in Massachusetts accepted the results and took action to remove implicated product from commerce.
- In October 2014, the accredited Colorado agriculture laboratory detected staphylococcal enterotoxin in breaded chicken nuggets while conducting a surveillance assignment for the Food Emergency Response Network. Officials at the US Department of Agriculture rapidly acted upon the data generated under the laboratory's scope of accreditation.

Routine food product sampling agreements, newly mandated by the FDA ISO Cooperative Agreements, have proven very valuable and effective.

- In February 2015, the South Carolina public health laboratory tested frozen dessert products from a distribution center. They detected *Listeria monocytogenes* in ice cream that was associated with an outbreak in other parts of the country. This testing supported a subsequent product recall.
- Given South Carolina's findings, the Nebraska agriculture laboratory tested frozen dessert products manufactured within the state. In April 2015, they found *L. monocytogenes* in ice cream from a different producer. Immediate recalls prevented anyone from becoming ill from this product.
- In March 2015, the Virginia consolidated laboratory detected *L. monocytogenes* in soybean sprouts. Follow-up testing showed the persistent presence of the pathogen in the facility, leading to two additional recalls in June and August 2015. The manufacturer did not reopen after the August recall.

Association Contributions

The cooperative agreement with APHL, AFDO and AAFCO focuses on several key needs related to accreditation, collaboration and mutual reliance: systematic laboratory training, direct technical assistance, communication among federal, state and local laboratories and with regulatory and public health programs, and expanded proficiency-testing options that meet the ISO 17043 standard for proficiency testing providers. Additional products related to mutual reliance include guidelines in the key areas of electronic sharing of analytical data, obtaining defensible samples, and acceptance of state data for regulatory action. An Executive Summary of specific accomplishments from the associations is available on APHL's Food Laboratory Accreditation web page.

Sustainable Outcomes

With the first FDA funding cycle set to end in August 2017, currently funded laboratories are seeking ways to maintain their accreditation efforts with decreased or no funding from FDA. The commitment to quality shown by ISO 17025 accreditation leads to increased confidence in laboratory data, decreased run-repetition rates, increased customer satisfaction and decreased sample turn-around times. These criteria demonstrate the return on investment of implementing the ISO 17025 standards. Laboratories and their partners will want to sustain these improvements as a permanent aspect of food and feed testing. To this end, the Associations will work with FDA and state laboratories to determine the cost of maintaining and expanding accreditation nationwide.

Given that regulatory testing is an inherent function of governmental laboratories, and accredited laboratories have the infrastructure to generate accurate and defensible results, FDA should fund state laboratories to conduct domestic regulatory testing that falls under their scope of accreditation. Such use of accredited state laboratories strengthens an IFSS and expands the nation's capacity to perform regulatory food testing.

Furthermore, FDA should continue to fund the three Associations to facilitate improvements in the IFSS. Gaps that remain include institutionalizing the concepts of GOODSamples, improving laboratory handling and preparation procedures, upgrading data sharing capabilities through eLEXNET, developing a national laboratory curriculum standard, and further training development and delivery. The associations will also continue to facilitate collaboration among FDA Laboratories, state laboratories and state and federal regulatory partners.

Accreditation of the nation's regulatory food and feed testing laboratories supports the Food Safety Modernization Act's aim of creating a prevention-based food safety system. By facilitating long-term, permanent improvements to our nation's laboratory system, FDA's investment in ISO 17025 accreditation and a leadership structure for state food and feed laboratories will advance public health initiatives and improve the safety of the US food supply.

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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