



APHL Position Statement

FDA and the Use of Governmental Food and Feed Testing Laboratories

A. Statement of Position

The Association of Public Health Laboratories (APHL) recommends that the Food and Drug Administration (FDA) give preference to state and local food and feed testing laboratories for domestic regulatory testing.

B. Implementation

1. APHL will expand communication with FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Office of Regulatory Affairs (ORA) around FDA's testing needs in relation to state and local laboratory capabilities with a goal of better understanding FDA's impetus for using private 3rd party laboratories for regulatory testing.
2. APHL will collaborate with the National Association of State Departments of Agriculture (NASDA) and the Association of Food and Drug Officials (AFDO) to develop profiles of state and local food and feed laboratories' testing capabilities, using survey tools to fill gaps in knowledge when necessary.
3. APHL will assist state and local laboratories as they strengthen their capabilities for food and feed testing to meet evolving regulatory needs through training, guidelines, best practices, advocacy and technical assistance. The Association will work across FDA to procure federal resources to help strengthen state and local capabilities.

C. Background/Data Supporting Position

APHL supports the use of state and local food and feed testing laboratories for regulatory testing of domestic food products because:

- FDA has invested millions of dollars over the past decade to support governmental food and feed testing laboratories. The investment helps laboratories achieve or expand their accreditation to the ISO/IEC 17025:2005 standard, thereby enabling governmental laboratories to generate defensible results. This investment also allows Food Emergency Response Network (FERN) laboratories to perform large-scale surveillance testing and engage during emergency events, demonstrating their capability and efficiency in testing domestic and imported products.
- Using accredited state and local laboratories strengthens an Integrated Food Safety System (IFSS) to ensure the safety of the food supply and increase public health protections. The impact of integration is evident in the finding of *Listeria monocytogenes* by a state laboratory performing surveillance testing for the FDA. This finding helped change the FDA's guidance on frozen desserts and led to an understanding of potential consumer health hazards. As another example, in June 2014, the New York State Department of Agriculture and Markets, which has been ISO/IEC 17025 accredited since 2008, reported a *Salmonella*-positive imported

organic sprouted chia seed powder product to FDA's New York District Office. This product was linked to a multistate outbreak with 31 infected persons from 16 states. An Import Alert was issued nine days after the initial report of analysis. This successful collaboration between the state and FDA resulted in prevention of future adulterated product from entering US commerce.

- Regulatory testing is an inherent function of state and local governmental laboratories that work in tandem with the federal government to ensure the safety of the food supply. Many governmental food and feed testing laboratories have the capability and infrastructure necessary to conduct domestic regulatory testing for FDA. In addition, the governmental laboratory system represents a viable, rapid and accurate partner for the FDA laboratory system when a food-related outbreak exceeds the capacity of the FDA laboratory in a region. These laboratories are regionally situated, ISO-accredited, well staffed and have the capability and capacity to aid in these outbreaks so that rapid laboratory results can be utilized to remediate the situation.
- Governmental laboratories should be developed and respected as the most fundamentally capable and legally credible analytical resource for laboratory-based regulatory evidence. The absence of standardization or accreditation in some domestic private sector third-party laboratories could raise legal questions in regulatory actions and product recalls. Using non-governmental entities for governmental work may have adverse effects on public trust and consumer confidence, including issues around conflict of interest. APHL recommends that FDA reexamine its authority in regards to establishing appropriate requirements for standards and quality management systems for domestic private sector third-party laboratories and programs.

APHL stands behind AFDO's resolution [1] and NASDA's Action Item [2] that question FDA's use of private sector laboratories for domestic regulatory testing. All three associations stand behind the capabilities of state and local food and feed testing laboratories and support preferentially engaging the services of these laboratories whenever possible. Governmental laboratories have trained and qualified personnel, instrumentation and proof of proficiency due to public health emergency preparedness requirements. FDA stresses the importance of an IFSS, which has an ultimate goal of preventing foodborne illness and protecting the nation's food supply. This goal relies heavily on communication and mutual reliance between federal, state and local partners. The infrastructure for these communications already exist in governmental laboratories

D. References

1. Association of Food and Drug Officials (2016, June). *FDA's Use of Private Laboratories*. Retrieved September 28, 2016 from <http://www.afdo.org/resources/Documents/4-news-and-events/Resolutions%202016/AFDO%20Resolution%202016-1%20-%20FDA's%20use%20of%20Private%20Laboratories.pdf>
2. National Association of State Departments of Agriculture (2016, January). *FDA's Use of Private Laboratories*. Retrieved October 12, 2016 from <http://www.nasda.org/File.aspx?id=40367>

E. Resources

1. US Food and Drug Administration (2016). *FSMA Final Rule on Accredited Third-Party Certification*. Retrieved December 22, 2016 from <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm>
2. Centers for Disease Control and Prevention (2014, August). *Multistate Outbreak of Salmonella Infections Linked to Organic Sprouted Chia Powder*. Retrieved October 20, 2016 from <http://www.cdc.gov/salmonella/newport-05-14/index.html>
3. Food Emergency Response Network. *FERN IMPACTS—FERN's Impact on Recent Outbreaks and Public Health Events*. Retrieved December 22, 2016 from <https://www.fernlab.org/fern-in-action/>

Recommended by: The Food Safety Committee, Approved by Board of Directors for Interim Use: January 2017, Approved by Membership: March 2017, Sunset Date: March 2022

Contact: Celia Hagan, Senior Specialist, Public Policy
240.485.2758, celia.hagan@aphl.org.