

February 11, 2021

Re: FSIS–2016–0026

The Association of Public Health Laboratories (APHL) appreciates the opportunity to comment on the Food Safety and Inspection Service’s (FSIS) proposed rule *Changes to Accreditation of Non-Federal Analytical Testing Laboratories*. APHL member laboratories monitor the safety of the U.S. food supply by conducting outbreak and surveillance testing on human and animal food, including FDA and USDA regulated products. FSIS recently increased the possibility of the use of data from public health laboratories through revisions to the *Policy on Use of Results from Non-FSIS Laboratories*, and APHL encourages the utilization of state and local governmental laboratory data whenever appropriate. We support FSIS’ desire to bolster participation in the program and would like to provide comments on the following questions posed by the agency.

1) Comment on how to best manage data associated with an expanded ALP program

While the original role of ALP, providing FSIS with a source of reliable overflow laboratory capacity, remains important, APHL strongly supports the FSIS vision of utilizing ALP to allow regulated establishments to voluntarily submit data to FSIS. Broader data utilization will help monitor foodborne disease trends, inform and evaluate food safety policies, and more efficiently utilize critical federal, state and local resources. Through the Partnership for Food Protection, APHL has contributed to various guidance documents for human and animal food laboratories to build confidence among stakeholders in the integrity and scientific validity of laboratory analytical data. APHL previously offered support for any outreach on ALP programs in comments on the USDA Salmonella Roadmap. We would be happy to provide any assistance and suggest that FSIS include laboratory staff and epidemiology outbreak investigators as an audience to receive communications, as recommended in the 3rd Edition of the Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines¹.

2) Comment on food matrix and analyte pairs in a possible expanded ALP accreditation program

APHL supports the proposed change to make the test menu more flexible, by removing the reference to specific analytes in the regulation. This change will allow the agency to be more responsive to changes in foodborne disease threats. With expansion to microbiological testing, APHL members are interested in seeing the program include accreditation for *E. coli* O157:H7 and STECs in raw meat products, and *Salmonella spp.* and *Listeria monocytogenes* in ready-to-eat meat products. Our members would be happy to discuss any additional chemical or microbiological targets the agency is considering.

3) Comment on whether ISO 17025 accreditation should be a prerequisite to membership in the ALP since it is recognized as providing the general requirements for the competence of testing and calibration laboratories

Accreditation to the ISO/IEC 17025:2017 standard, *General Requirements for the Competence of Testing and Calibration Laboratories*, is considered a best practice for food testing laboratories². As of 12/29/2021, at least 39 non-federal, governmental laboratories were accredited to this standard for regulatory human food testing³. Requiring ISO/IEC 17025 accreditation would provide an additional support for quality results from the ALP program. Requiring accreditation would also provide a potential cost savings for FSIS. ISO/IEC 17025 accreditation would provide a robust quality management system for the laboratories, which could reduce the burden of an FSIS on-site review for certain aspects, above and beyond the required proficiency tests. Those aspects required for ALP laboratories that are covered by accreditation to ISO/IEC 17025 include maintenance and traceability of records, documentation of analysis, equipment maintenance and calibration, and corrective actions.

Food testing laboratories that are not ISO/IEC 17025 accredited should operate under a robust quality management system, or “ISO-like” environment, that follows the recommendations outlined in APHL’s *Best Practices for Submission of Actionable Human and Animal Food Testing Data Generated in State and Local Laboratories*⁴.

4) Comment on ways to incentivize membership in the ALP, to include a possible annual fee reduction for laboratories already ISO 17025 accredited

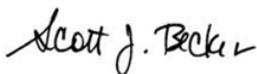
Our member laboratories are not for profit, versus private testing laboratories and face tight, often declining budgets. As accreditation to ISO/IEC 17025 does involve costs to the laboratory, having a reduction to the required annual fee would be an incentive to participate in the ALP program for many state laboratories. Additionally, accreditation to the ISO standard requires participation in an accredited proficiency testing program that offers challenges that are appropriate for the methods under scope. The ALP proficiency testing program should be accredited to the ISO 17043 standard if it is to attract members from the governmental sector. An accredited ALP proficiency testing program would provide a cost-savings to the laboratory, since the proficiency testing would be included in their fees paid to the ALP and additional proficiency testing would not be needed.

Grant opportunities for ALP accredited laboratories to expand to new analytes or matrices through purchase of supplies, equipment, and maintenance could encourage participation in the program. Training and technical support for laboratories that wish to onboard new testing should also be considered.

APHL strongly supports FSIS proposed changes to encourage increased volume and utilization of industry data. While increased program participation by laboratories may increase annual fees provided to FSIS, APHL is concerned that the ALP program may not be able to reach its full potential without additional federal funding allocated to the program. APHL urges USDA to provide any additional needed funding to laboratory programs at FSIS to support this work, in particular Laboratory Quality Assurance Staff (LQAS) and ISO 17043 accredited proficiency testing programs.

Please contact Kirsten Larson, Manager Food Safety (kirsten.larson@aphl.org) with any questions.

Sincerely,



Scott Becker, MS
Chief Executive Officer



Yvonne Salfinger
Co-Chair, Human and Animal Food Subcommittee

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.

¹3rd Edition of the Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines. 2020. [CIFOR-Guidelines-Complete-third-Ed.-FINAL.pdf](#)

²Partnership for Food Protection. Human and Animal Food Testing Laboratories Best Practices Manual. 2018. <https://www.pfp-ifss.org/ifss-resources/human-and-animal-food-testing-laboratories-best-practices-manual-december-2018/>

³Data compiled by the Association of Public Health Laboratories.

⁴Association of Public Health Laboratories. Best Practices for Submission of Actionable Human and Animal Food Testing Data Generated in State and Local Laboratories. 2019. <https://www.aphl.org/aboutAPHL/publications/Documents/FS-2019Jan-Best-Practices-Human-Animal-Food-Data.pdf>