

March 18, 2020

Re: FDA-2019-N-3325

The Association of Public Health Laboratories (APHL) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed rule *Laboratory Accreditation for Analyses of Foods* that aims to ensure the quality and reliability of test results as required by the FDA Food Safety Modernization Act (FSMA). APHL is in favor of a program that will elevate the defensibility of all laboratory data by ensuring both public and private laboratories operate under a robust quality management system.

Only a few public health laboratories that perform shell eggs, sprouts and bottled water testing could be subject to this rule, and due to previous efforts, those laboratories may already operate under several quality management systems including ISO/IEC 17025. APHL and our partners recently created best practice documents aimed at strengthening data defensibility. We suggest FDA use these tools for further development of this important proposed food laboratory accreditation program. Based on the requirements in the ISO/IEC 17025 standard, the [Partnership for Food Protection](#) released [Human and Animal Food Testing Laboratories Best Practices Manual](#), a consensus document for human and animal food laboratories to build confidence among stakeholders in the integrity and scientific validity of laboratory analytical data. For those laboratories that are not accredited or generate data outside of their accreditation scope, [Best Practices for Submission of Actionable Human and Animal Food Testing Data Generated in State and Local Laboratories](#) addresses the minimum elements of an overall quality management system that will help laboratories demonstrate the validity and accuracy of their results.

While the proposed rule does not mandate accreditation for sampling, APHL vehemently supports FDA's stance that "whether a sample is collected and maintained properly is integral to whether analysis of that sample will produce information that is of regulatory significance." The Association of American Feed Control Officials (AAFCO), along with APHL and the Association of Food and Drug Officials, recognizes the importance of sampling processes in ensuring representative data and created two documents, [GOODSamples](#) and [GOOD Test Portions](#), which outline the systematic and scientific approach to develop or evaluate sampling protocols for defensible decisions. APHL recommends that the FDA align any sampling requirements developed under this proposed rule with those outlined in these guidance documents.

The proposed rule states that FDA would rely on the recognized accrediting bodies to review validation and verification studies of laboratory methods during their auditing process. Requiring accrediting bodies to evaluate those validation and verification procedures may require auditors with the expertise needed to evaluate the success of those procedures. We support strengthening the requirements for food laboratory accreditation to the extent that such requirements do not negatively impact the ability of accrediting bodies to effectively fill their mission.

APHL supports the permitting of laboratories to submit abridged laboratory packages to FDA in lieu of full analytical reports once the laboratory meets predetermined requirements. We ask that FDA consider creating a similar pathway for governmental laboratories to submit abridged laboratory packages after meeting predetermined criteria.

Accreditation to the ISO/IEC 17025 standard or an equivalent provides the confidence in laboratory data that is integral to supporting data defensibility and APHL looks forward to working with FDA



and other stakeholders in implementing this vital part of FSMA. For any questions, please contact Robyn Randolph, Senior Specialist, Food Laboratory Accreditation ([robyn.randolph@aphl.org](mailto:robyn.randolph@aphl.org)).

Sincerely,

A handwritten signature in black ink that reads "Scott J. Becker". The signature is written in a cursive style with a small checkmark at the end.

Scott Becker  
Chief Executive Officer

A handwritten signature in black ink that reads "Yvonne Salfinger". The signature is written in a cursive style.

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.*