



November 27, 2019

Docket No. FDA-2019-N-4187

The Association of Public Health Laboratories (APHL) appreciates the opportunity to contribute to FDA's blueprint for a New Era of Smarter Food Safety. Our members work at the leading edge of innovative developments in laboratory practice, and thus have valuable perspective on how new technologies and approaches can improve food safety and enhance foodborne disease surveillance and outbreak response.

FDA's continued support for accurate and timely laboratory data, within a modernized regulatory framework is vital. Successfully leveraging new technologies such as whole genome sequencing (WGS) has propelled improvements in surveillance along with outbreak detection, response and risk attribution. However, due to funding shortages, state laboratories are struggling to apply these new technologies to their full potential and provide real time data. Without significant further investment in this space, FDA will find it difficult to realize its vision of a fully integrated food safety system.

The public health data infrastructure is struggling to handle the quantities of data produced by modern testing laboratories, with antiquated, inefficient data entry, transfer and storage systems hindering the flow of information. APHL recommends FDA consider a commitment similar to CDC's nascent public health data modernization initiative, improving infrastructure on a local, state and federal level, from computing hardware and data flow, to the bioinformatics workforce. As one example, we urge FDA to move forward with the laboratory aspects of the National Food Safety Data Exchange platform (NFSDX), moving away from the current inefficient electronic laboratory data exchange platform (eLEXNET).

As agencies advance their own data handling abilities, a commitment to collaborate and improve data exchange between federal food safety partners is imperative. NIH's National Center for Biotechnology Information (NCBI) bears much of the responsibility for storage and curation of WGS data and compatibility. Support for the ongoing functionality of this partner service should be a consideration in any plans. We encourage continued support for coordinated networks for genomic sequencing through the Gen-FS workgroups that target development, coordination and harmonization of PulseNet and GenomeTrackr standardized protocols. These workgroups strengthen federal, state and local laboratory collaboration on the use of WGS in foodborne pathogen analysis and investigation. FDA should consider integrating its regulatory data with the epidemiology and laboratory data in food safety systems such as CDC's System for Enteric Disease Response, Investigation, and Coordination (SEDRIC). Continued investments in the interagency work of National Antimicrobial Resistance Monitoring System (NARMS) is vital to any forward facing food safety plan. Likewise, improved infrastructure will assist the work of the Food Emergency Response Network (FERN), however emphasis on improving the coordination between the agencies involved is critical to effective response.

As the FDA works towards strengthening mutual reliance between state and federal partners, we recommend that FDA continue to support the development of the National Curriculum Standard (NCS) Laboratory Curriculum Framework (LCF) and its accompanying training courses. We recommend harmonization across federal agencies of public health laboratory competency statements, promoting equal work performed by an equal workforce in support of a prevention-based Integrated Food Safety System.

APHL strongly supports the breadth of advances FDA is considering, but even the most ambitious plan will fail if there are foundational needs left unfulfilled. For example, many states do not have the resources they need for testing under the National Shellfish Sanitation Program and the Interstate Milk Safety Program. FDA efforts to better support these critical food safety programs in the areas of validation and personnel certification are necessary to not leave weak links in critical parts of the food safety system.

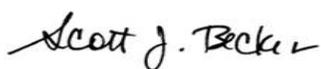
The Food Safety Modernization Act's (FSMA) Agricultural Water Rule strives to maintain a difficult balance between safety and practicality. The safety and risk issues are complex, testing needs vary, and laboratory capacity needs improvement across the country. To ensure the successful application of the rule FDA should direct outreach and education to not only the covered industry, but also allied sectors such as laboratories to enhance understanding, and to help foster a culture of food safety among partners.

APHL applauds the publication of the laboratory accreditation rule and plans to submit comment. While the rule focuses on the use of private laboratories, APHL appreciates the significant financial investment FDA has made over the past decade to support ISO/IEC 17025 accreditation in non-federal governmental human and animal food testing laboratories. APHL encourages FDA to continue supporting ISO/IEC 17025 accreditation in these laboratories, which strengthens laboratory capability and enhances the Integrated Food Safety System. These non-federal governmental laboratories have the capability and infrastructure necessary to conduct domestic regulatory testing for FDA, and APHL supports FDA's use of these laboratories whenever possible.

Addressing systemic improvements in the food safety system is an ambitious undertaking. APHL commends FDA for beginning the conversation and looks forward to working together to make the food supply safer through strong science, data analysis, modeling and smart regulation.

For any questions, please contact Kirsten Larson, Manager Food Safety Program ([Kirsten.Larson@APHL.org](mailto:Kirsten.Larson@APHL.org)),

Sincerely,



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*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.*