August 5, 2024

Jim Jones
Deputy Commissioner for Human Foods
US Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Deputy Commissioner Jones,

The Association of Public Health Laboratories (APHL) is grateful for the close relationship the Association and its members have with the Food and Drug Administration (FDA). Through formal support from the FDA since 2012, collaborative efforts to build an Integrated Food Safety System (IFSS) have fostered communication and trust among APHL, FDA and state laboratory members. Initiated in 2020, the FDA Laboratory Flexible Funding Model (LFFM) cooperative agreement has further cultivated this collaboration while increasing testing capability and capacity at the state laboratories. The LFFM program has had tremendous impacts since its inception; however, state laboratories continue to express concerns regarding FDA review and utilization of state laboratory data—particularly data from testing for chemical contaminants in food. Specific examples and additional details of APHL member concerns are provided in the Issue Brief included with this letter.

State laboratories produce valuable analytical results that can and should be utilized for regulatory purposes at the federal level. FDA's ability to take action on state data was one of the strongest drivers for FDA's investment in state laboratories becoming ISO/IEC 17025 accredited. APHL and its members would like to see this premise realized. We recommend the following actions to improve the efficiency and effectiveness of detecting harmful chemical contaminants in food. If implemented by the FDA, we believe these actions will improve mutual reliance, reduce inconsistencies in regulatory system response and lower the burden on state laboratory workforce and resources.

- Determine and communicate critical information about contaminated samples and evaluate the human health risks associated with such samples before requesting full data packages from state laboratories.
- Determine test result concentrations for analytes of concern (e.g., lead, sulfites, allergens) above which a state data package should be submitted, as well as threshold levels above which one subsample is sufficient for FDA to take regulatory action.
- Develop a checklist of key laboratory data and information that states should include in chemistry data packages, including the necessary elements to prove method equivalency.
- Collect—and make available—metrics on turnaround times for the FDA review of state-submitted chemistry data packages and share information to help state partners better understand FDA review processes.

APHL and our state laboratory members are appreciative of the opportunity to share these concerns and suggestions for improvement and welcome the opportunity to discuss them further with FDA.

For more information or questions related to these comments, please contact Ms. Shari Shea, APHL's director of Food Safety, at 240-485-2777 or shari.shea@aphl.org.

Sincerely,

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories

Megan Crumpler, PhD, HCLD
President and Laboratory Director, Orange County, CA