ACIL Statement to FDA on Proposed FSMA Final Rule

On July 6, 2020, the American Council of Independent Laboratories Food Sciences’ Section (ACIL) submitted comments on the Food and Drug Administration’s (FDA) proposed rule issued on November 11, 2019 to establish a program for the testing of food by accredited laboratories as required by the FDA Food Safety Modernization Act (FSMA). ACIL applauds the leadership of this section for their decades-long prodigious work in support of accreditation, which is immediately apparent with today's submission regarding this proposed rule.

For many years, ACIL members have worked cooperatively with exporters, importers and FDA by providing dependable inspection and analytical services. As required by FSMA, we believe only accredited independent laboratories should be allowed to sample and analyze laboratory packages related to regulatory actions such as Import Alerts (DWPE). We believe that such recognition of such independent private laboratories accreditation by FDA should allow for expedited review of their laboratory packages for the benefit of importers and their customers. This should allow the FDA to focus its review to the actual sampling and packages provided, and an end to FDA review of the packages for matters covered under accreditation.

Also, we believe that the international accreditation standards under which FDA labs have been accredited, should also apply to all private laboratories and that the only private laboratories authorized should be independent accredited laboratories. If FDA is looking for ‘gold standards’ to emulate for testing and reporting, the standards held by the Consumer 2 Product Safety Commission or ISO 17025, which outline the general requirements for the competence of testing and calibration laboratories, are both successful, efficient examples.

Our services ensure that imported products comply with FDA regulations. ACIL has long advocated for the need to establish uniformity in private laboratory package review and standardize analytical data requirements, upon which FDA may rely, to make better and more efficient imported food, pharmaceutical and cosmetic admissibility decisions. We also believe that a critical component to improving this process is to develop standards that will establish uniformity among FDA district offices and FDA laboratories in reviewing private laboratory data. ACIL has been consistent in urging FDA to adopt and recognize international accreditation standards as a baseline, and national sector specific technical standards as the primary basis for the qualification of laboratories and sampling organizations to sample and submit analytical data to the FDA for any purpose.