ACIL’s FSMA FDA LAAF Approved Recommendations

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). On December 3, 2021, the FDA announced the FSMA final rule on Laboratory Accreditation for Analyses of Foods (LAAF) establishing a laboratory accreditation program for the testing of food in certain circumstances. Under the LAAF program, FDA will recognize accreditation bodies (ABs) that will accredit laboratories to the standards established in the final rule (referred to as LAAF-accredited laboratories).

As required by FSMA, ACIL supports “only accredited independent laboratories should be allowed to sample, analyze, and submit laboratory report packages related to regulatory actions such as Import Alerts (DWPE).” We support that such recognition of independent private laboratories accredited by FDA should allow for expedited review of their laboratory report packages for the benefit of importers, their customers, and commerce. This should allow the FDA to focus its review to the actual sampling and report packages provided, and an end to FDA review of the report packages for matters covered under accreditation.

We support that 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 standards to emulate for testing and reporting, the standards held by the Consumer Product Safety Commission or ISO 17025, which outline the general requirements for the competence of testing and calibration laboratories, are both successful and efficient examples. Additionally, 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.

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 contend 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.

Based upon the above and buttressed by the leadership of this section for their decades-long prodigious work in support of accreditation, along with our cooperative work with exporters, importers and the FDA, ACIL is pleased to inform you that our recommendations to the FDA’s proposed rule were included in the LAAF program, including:

- Accreditation to mean accredited by a Recognized Accrediting Body not by FDA, and a laboratory that wants to be LAAF Accredited must apply to a recognized AB;
- A directed food laboratory order will require testing by an LAAF Accredited lab for food and food product environment. The order will state whether the LAAF Accredited Lab may be owned by the owner or consignee;
- ABs must be signatory to ILAC and accredited to ISO/IEC 17011:2017, with FDA recognition for 5 years;
- Laboratories applying for LAAF Accreditation, if assessed within last 2 years onsite, can be assessed remotely, and must only demonstrate capability for applicable scope methods: successful PT for those methods within last 12 months, and meet impartiality (conflict of interest requirements) of ISO/IEC 17025:2017;
- LAAF Accredited Lab may appeal to an AB regarding a suspension, scope reduction, or decision to withdraw or deny LAAF Accreditation by an AB;
- If the AB is no longer recognized by FDA, the LAAF Accredited lab will have 1 year or before its ISO accreditation lapses (whichever is sooner) to become LAAF accredited by another recognized AB;
- A LAAF Accredited lab may submit a written request to FDA requesting permission to use a method outside of its LAAF scope, when a new method has been developed or in response to a food emergency; and
- All records pertaining to LAAF Accreditation, assessments, food testing, associated correspondence, change in management, internal investigations, corrective action, internal audits, suspension etc., must be retained for 5 years, and may be electronic.