

GUIDANCE FOR INDUSTRY:

Submission Of Laboratory Packages By Accredited Laboratories

The American Association for Laboratory Accreditation (A2LA; www.a2la.org) supports the efforts as outlined in the **GUIDANCE FOR INDUSTRY: Submission Of Laboratory Packages By Accredited Laboratories** to provide the FDA with an improved set of tools to address the need to add to its capacity in the analysis of FDA-regulated articles offered for import.

We support approaches that envision the use of accredited laboratories by FDA-recognized accreditation bodies. Since food safety is a global problem, the FDA is fortunate to be able to use the existing recognition infrastructure for accreditation bodies established internationally through the International Laboratory Accreditation Cooperation (ILAC). FDA can participate as a stakeholder member of ILAC to utilize the existing evaluation process on more than 60 accreditation bodies operating around the world. The added benefit is that the cost of accreditation body evaluation and recognition is paid by the accreditation bodies and the cost of accreditation is paid by the testing laboratories. FDA could thereby concentrate its resources to improve surveillance, laboratory capacity and response to prevent and control food borne illness.

Specifically we see as beneficial the following major points:

- **International Recognition:** The accreditation of a testing laboratory would be issued by an accreditation body operating in accordance with ISO/IEC 17011, by a accreditation body who is a signatory to the ILAC MRA.
- **Consensus Guidelines:** The use of ISO/IEC 17025, the guidelines requirements outlined in the AOAC International “Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals” and specific requirements as promulgated by the FDA. These add credibility and acceptance world-wide.
- **Voluntary but with inducements:** The fact that requirement for accreditation is not mandated but serves as an advantage to those that are: Aiding those laboratories that are accredited would be the possibility of making use of abbreviated laboratory packages or full laboratory packages from non-accredited laboratories.
- **Use of a defined scope:** The laboratory must be accredited for the specific test method(s) that they use to generate the data and test results they submit to FDA (not technology or flexible based scope).
- **Sampling activities recognized:** The testing laboratory has control over the sampling activities and collects and process samples in accordance with FDA sampling and chain of custody parameters. An accredited laboratory must be responsible for the integrity of the sample to ensure that it is representative of the lot being tested. We would propose that the sampling organization meet the elements spelled out in TNI’S General Requirements for Field Sampling Measurement Organizations (FMSO v1,) or the applicable compliance program or with the sampling procedures described in FDA’s Investigations Operations Manual, Chapter 4 – Sampling.