FDA Laboratory Accreditation for Analyses of Food (LAAF) Program: *Lessons Learned*

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FDA LAAF Program: *Lessons Learned*

- Covered in today's presentation:
  - Background and overview of the FDA LAAF program
  - When will the FDA LAAF program be fully implemented?
  - 5 specific areas of food testing that are covered by the rule
  - FDA LAAF requirements for the laboratory
  - Common pitfalls
  - Questions addressed by FDA

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FDA LAAF Program: *Lessons Learned*

- The final rule, issued by the FDA on December 3, 2021, established the LAAF program and outlined eligibility requirements that accreditation bodies (ABs) and laboratories wishing to participate in the program will need to satisfy.
- The LAAF program is voluntary for ABs and labs, and testing is required only under certain circumstances.

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FDA LAAF Program: *Lessons Learned*

- Approximately 2 years into the program:
  - 8 Accrediting Bodies recognized
  - Over 35 LAAF accredited testing labs
  - The program has not yet been implemented.

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FDA LAAF Program: *Lessons Learned*

- After the FDA LAAF program is fully implemented by the FDA, owners and consignees will use the FDA dashboard to locate a lab and request testing that they need.
- **A non-LAAF accredited laboratory will no longer be receiving request for testing from owners or consignees.**

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Implementation?

FDA has not yet determined that sufficient laboratory capacity has been attained for any of the testing covered by the LAAF final rule. Therefore, use of LAAF-accredited laboratory for food testing is not currently required.

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Once FDA has confirmed sufficient LAAF accredited laboratory capacity for the testing covered by §1.1107, a document will be published in the Federal Register giving owners and consignees **6 months notice** that they will be required to use a LAAF accredited laboratory for such testing.

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Overview of the FDA LAAF Program:

- The FDA LAAF program is an additional, more prescriptive set of requirements to ISO/IEC 17025:2017 standard (ISO being the foundation of the requirements).
- The LAAF program does not apply to all food testing.
- The scope of food testing covered by the LAAF program is limited but may include both product and environmental testing.

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How close is the FDA LAAF program to being implemented?

Very close!

- Possible implementation of the program is projected mid-year 2024.

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FDA LAAF Program: *Lessons Learned*

In addition to ISO/IEC 17025:2017 requirements, laboratories seeking to be accredited to the FDA LAAF requirements or already accredited are assessed to further requirements.

-Eligibility Requirements for LAAF Accredited Laboratories

-Impartiality and Conflict of Interest Requirements

-Sampling Requirements

-Requirements for Analysis of Samples

-Methods of Analysis Requirements

-General Requirements for Submissions to FDA

-Requirements for Submitting Abridged Reports

-Requirements for records as related to the LAAF program

FDA LAAF Program: *Lessons Learned*

The LAAF program:

a) Gathers together some laboratory requirements (validation and verification) beyond those required by ISO/IEC 17025:2017, including certain test method verification and validation, and reporting requirements.

b) Requires the participating lab to obtain information about the training and experience of the sampler as well as sampling plans and sample collection reports.

c) Defines the elements of a full analytical report, the process by which participating labs may be allowed to submit abridged analytical reports *(Labs submit test results to FDA only for the testing that is within the LAAF program.)*

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FDA LAAF Program: *Lessons Learned*

Under which circumstances will owners and consignees be required to use a LAAF accredited lab for testing?

5 specific areas of food testing that are covered by the rule

1) Support **removal of import alert** through successful and consecutive testing
2) To support admission of **imported food** products detained at the border

The LAAF final rule doesn't apply to all imported food, only to those foods that need to be tested that are on import alert or have been detained at the border.

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5 specific areas of food testing that are covered by the rule

3) Follow-up testing required by existing FDA food safety regulations on

-Sprouts. 21 CFR 112.146(a), (c), and (d)

(*Listeria* species and *Listeria monocytogenes* testing)

-Shell eggs. 21 CFR 118.4(a)(2)(iii), 118.5(a)(2)(ii) and (b)(2)(ii), and 118.6(a)(2) and (e)

(*Salmonella Enteritidis* (SE) testing)

-Bottled drinking water. 21 CFR 129.35(a)(3)(i)

(*Escherichia coli* testing)

5 specific areas of food testing that are covered by the rule

4) Certain administrative processes (such as **testing submitted in connection with an appeal** of an administrative detention order)

5) Direct Food Laboratory Order (testing required under Direct Food Laboratory Order if identified or suspected problems are discovered)

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What kind of food testing labs perform this type of testing?

- Labs that perform covered tests of import related foods differ from the labs that perform covered tests of shell eggs, sprouts, and bottled drinking water.
- Labs that test import related food are located close to ports of entry and specialize in testing protocols for foods based on import 35 alerts (automatic detention list).
- Labs that test shell eggs, sprouts, and bottled drinking water are more geographically dispersed to account for proximity as a factor determining lab use.

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Requirements for the laboratories:

- Must be accredited to ISO/IEC 17025:2017.
- Successfully pass PT within the last 12 months or comparison program if no PT available *(results are to be reported to PJLA within 30 days of receipt)*
  - *PJLA will send a memo to the lab after granting accreditation to the LAAF Program instructing the laboratory where to upload PT results. PJLA reviews and tracks PT participation and results.*

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Requirements for the laboratories:

- Use reference materials or quality control samples with each batch of samples tested under LAAF program.
- On-site assessment is required at least once every 2 years.

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Methods:

FDA does not specify which methods labs must use, no defined inventory of methods *(but methods must be fully validated and verified, FDA will confirm)*

- Exceptions: Directed Food Order or for Shell Eggs, Sprouts and Bottled Drinking Water

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Requirements for FDA LAAF program can be found at:

FDA Title 21, Chapter I, Subchapter A, Part1,
Subpart R, Laboratory Accreditation for Analysis of Foods

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Common Pitfalls:

If the lab is following an OMA (without modification) a record of verification is acceptable to submit to the FDA and present to an assessor for review during assessment. However, if a lab has made modifications to a method, or developed an internal method, a full validation is required.

- FDA is seeing a lot of issues with validations and verifications submitted by the labs. They are either incomplete or unorganized.
- FDA reviewers ask that any multiple attachments are labelled appropriately to give an indication of a continuation or an end of a full document. FDA also wants to see raw data in packages.

Common Pitfalls:

- FDA has guidance documents for Microbiological and Chemical methods validations.
- This can be found at **Foods Program Methods Validation Processes and Guidelines** on FDA's website.
- FDA asks that the laboratory references validation guidance that is being followed. (Whether its FDA's guidance or another reputable source)

Common Pitfalls:

- Labs are submitting very large reports and making large files that are being split up and not labelled properly.
  - Ensure that each file is labelled properly
    - (Title and 1 of 3, 2 of 3, 3 of 3, etc.)
  - Upload as few total attachments as possible.
    - (It is time sensitive to open each attachment separately. Do not upload individual attachments, rather large files which are labelled properly)
- Labs cannot use the FDA logo on any materials, reports or webpages.

FDA LAAF Program: *Lessons Learned*

Questions addressed by FDA...

Under the LAAF program, must laboratories collect the samples?

The LAAF rule does not define who collects samples. The LAAF rule requires that the sampler is qualified, both by training and experience to collect the sample. Samples may be collected by a the LAAF accredited lab or third party sampler, or by the owner or consignee. The key is that the sampler is qualified. Lab is responsible by obtaining documentation of qualifications of the sampler, sampling plans and sample collection reports related to the food testing and submitting them with each analytical test report.

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FDA LAAF Program: *Lessons Learned*

Is this program applicable outside of the USA?

Program is open to both, domestic and foreign accreditation bodies and laboratories. Requirements are the same. The only restriction that may impact foreign laboratories is the food testing conducted on food articles offered for import into the US, must be tested after the food article has arrived into the US, unless the owner or consignee has written approval from FDA that a sample taken prior to arrival is or would be representative of the sample offered for import into the US.

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Will FDA audit private laboratories?

The recognized ABs have the responsibility to assess the laboratories. FDA's role is overseeing the accredited laboratories. However, FDA may review the performance of LAAF-accredited laboratories at any time to determine whether the LAAF-accredited laboratory continues to comply with the applicable requirements. FDA may conduct an onsite review of a LAAF-accredited laboratory at any reasonable time, with or without a recognized accreditation body (or its officers, employees, and other agents) present, to review the performance of a LAAF-accredited laboratory under this subpart. Certain review activities may be conducted remotely if it will not aid in the review to conduct them onsite. FDA may report any observations and deficiencies identified during its review of LAAF-accredited laboratory performance under this subpart to the recognized accreditation body. (CFR 1.1159)

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FDA LAAF Program: *Lessons Learned*

Does the LAAF final rule apply to all food testing?

No. Food testing, including environmental testing, is required to be conducted by a LAAF-accredited laboratory only under certain circumstances specified in the rule.

"Food" includes articles used for food or drink for man or animals, as well as articles used for components of food, such as raw materials or other ingredients.

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Does the LAAF program apply to Dietary Supplements?

Yes, if it fell into one of the required testing circumstances, such as a food that is subject DWPE (Detention Without Physical Examination) or import alert.

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FDA LAAF Program: *Lessons Learned*

- Recognized labs and their scopes are identified on the FDA dashboard and is publicly viewable at:

- https://datadashboard.fda.gov/ora/fd/laaf.htm

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Questions?

Feel free to reach out to
lakimenko@pjlabs.com with questions.