FSMA Laboratory Accreditation for Analyses of Foods (LAAF) Program

National Egg Regulatory Officials
Annual Conference
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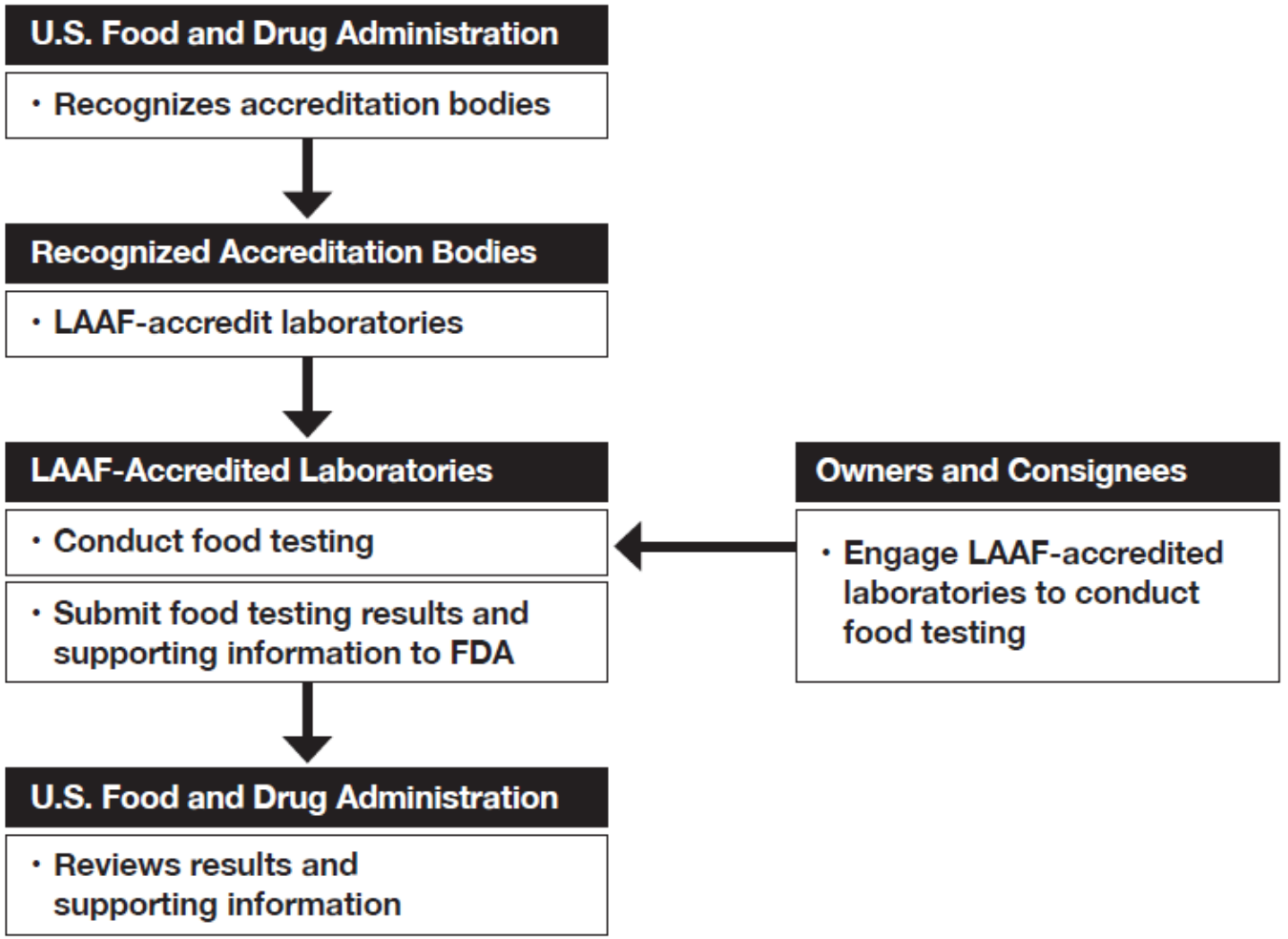
LAAF Program: A Bit of Background

- Is a new program
- Part of the FDA Food Safety Modernization Act (FSMA)
  - Shifting Food Safety focus from response to prevention
- Regulations in 21 CFR sections 1.1101-1200
- Final Rule published December 2021
- Implementation began in 2022 and is ongoing

Overview of the Final Rule

- FSMA § 202(a), FD&C Act § 422
- Voluntary for accreditation bodies (ABs) and laboratories
- FDA management and oversight
- Public registry displaying recognized accreditation bodies and LAAF-accredited laboratories is now live
- Accuracy and reliability of certain food testing

LAAF Program Structure



Testing Covered by the Final Rule

- Scope is limited
- "Food testing" defined to include:
  - Product testing
  - Testing of the production environment (Not applicable to egg testing)
- Related to imports, testing is covered that supports:
  - Removal of a food from an import alert
  - Admission of an imported food detained at the border because it is or appears to be adulterated or misbranded (FD&C Act § 801(a))

Testing Covered by the Final Rule

- Other covered testing:
  - Certain follow-up testing required by existing FDA food safety regulations:
    - Sprouts: 21 CFR 112.146(a), (c), and (d)
    - Shell eggs: 21 CFR 118.4(a)(2)(iii), 118.5(a)(2)(ii) & (b)(2)(ii), and 118.6(a)(2) and (e)

      Note: This applies only to the follow-up egg testing not the environmental testing
    - Bottled drinking water: 21 CFR 129.35(a)(3)(i)
  - Certain administrative processes
  - Directed Food Laboratory Order

Covered Egg Testing Specifics

Egg tests that follow a positive environmental test for *Salmonella enteritidis* (SE) as required by the Egg Safety Rule published in 2009, as follows:

- 21 CFR 118.4(a)(2)(iii) – Egg testing if the pullet environment at 14 to 16 weeks tests positive.
- 21 CFR 118.5(a)(2)(ii) – Unless diverted to treatment, egg testing if the flock environment at 40 to 45 weeks tests positive.
- 21 CFR 118.5(b)(2)(ii) – Unless diverted to treatment, egg testing if the flock environment at 4 to 6 weeks after the end of a molting process tests positive.
- 21 CFR 118.6(a)(2) – Egg testing if there is an SE-positive environmental test any time during the life of the flock and the eggs are not diverted to treatment.
- 21 CFR 118.6(e) – Monthly egg testing if the flock has a positive egg test, the eggs are diverted, and later meet negative test result requirements and return to table egg production
- LAAF FAQ 5b provides information on egg testing methodology

Requirements for Covered Testing

- Food owners/consignees are required to use LAAF-accredited laboratory
- Labs must send test results directly to FDA
  - This includes supporting documentation and sampling information
- There is no cap on the number of laboratories that may participate in the program
- Currently 8 laboratories have become LAAF-accredited

Accreditation Bodies: Requirements for Recognition

- Foundational:
  - ISO/IEC 17011:2017
  - Full member of ILAC (International Laboratory Accreditation Cooperation)
  - Signatory to ILAC's Mutual Recognition Arrangement
  - Assess laboratories for LAAF-accreditation; oversee LAAF-accredited laboratories
  - Other requirements include:
    - Conflict of interest
  - Recognition period is up to 5 years

Laboratories: Requirements for LAAF-Accreditation

- Apply through a Recognized Accreditation Body
- Foundational; for each method:
  - ISO/IEC 17025:2017
  - Successfully passed Proficiency Test (PT) within last 12 months (or comparison program if no PT available or practicable)
    - Report all results to AB within 30 days of receipt
  - Use reference materials or quality control samples with each batch of samples tested under LAAF program
  - Other requirements include:
    - Impartiality and conflict of interest
    - Develop or obtain certain sampling records

AB & FDA Oversight of LAAF-Accredited Laboratories

- Accreditation body oversight
  - ISO/IEC 17025:2017 accreditation
  - Must conduct onsite assessment at least once every two years
- FDA oversight
  - LAAF laboratory analytical reports
- Both accreditation body & FDA
  - Require corrective action
  - Place on suspension (AB)/probation (FDA)
  - Reduce scope or withdraw LAAF-accreditation of laboratory (AB)/Disqualify laboratory from submitting reports under the program (FDA)

Sampling

- FDA oversight of sampling will be accomplished via records:
  - Sampler's qualifications
  - Sampling plans
  - Sample collection report
    - This information will be submitted to FDA with each analytical report

    – 21 CFR 1.1152(c)
    - Laboratory may perform sampling but is not required to do the sampling. If the sampling is done by a third party, the laboratory must collect the sampling documentation and provide it with the analytical package.

Methods

- No defined inventory of possible scopes
- Reference the commodity-specific testing requirements to get an idea of testing that may be needed
  - The methods for egg testing can be found in LAAF FAQ 5b
- Methods within scope of a laboratory's LAAF-accreditation posted on public registry
  - FDA to confirm that methods are fully validated and verified

LAAF Public Registry

Laboratory Accreditation for Analyses of Foods Program

About the Program

The FDA Food Safety Modernization Act (FSMA) final rule on Laboratory Accreditation for Analyses of Foods (LAAF) establishes a laboratory accreditation program for the testing of food in certain circumstances. Under the LAAF program, FDA will recognize accreditation bodies that will accredit laboratories to the standards established in the final rule (referred to as LAAF-Accredited Laboratories).

Important Note:

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 a LAAF-accredited laboratory for food testing is not currently required. 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.

For additional information and guidance, see FSMA Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF).

Tables below identify accreditation bodies that have been recognized and laboratories that have been accredited under the LAAF program. One recognized accreditation body (RAB) may LAAF-accredit many laboratories. A recognized accreditation body may issue one or many certificates of accreditation for any LAAF-accredited laboratory (LAAF-AL) location covering one or multiple laboratory scopes (LS). Separate laboratory locations under common ownership may be LAAF-accredited by different recognized accreditation bodies.

Filters | RAB Table | LAAF-AL Table | LAAF-AL Scopes Table | Download Dataset

LAAF Public Registry Accreditation Bodies

Filters | RAB Table | LAAF-AL Table | LAAF-AL Scopes Table | Download Dataset

Clear All

Recognized Accreditation Bodies

Download RAB Dataset

Active RAB Count: 7 What is an Active RAB?

Recognized Accreditation Body	RAB City	RAB State	RAB Country	RAB Point of Contact	RAB Email	RAB Phone Number	Recogniti... Expiration Date	RAB Type of Change	RAB Effective Date of Change
AIHA LAP, LLC	Falls Church	VA	USA	Lauren Schnack	lschnack@aiha.org	1 (703) 846-0716	06/14/2027	Recognized	06/14/2022
American Association for Laboratory Accreditation	Frederick	MD	USA	Cory Arant	carant@a2la.org	1 (240) 575-7493	05/23/2027	Recognized	05/23/2022
ANSI National Accreditation Board (ANAB)	Fort Wayne	IN	USA	Keith Klemm	kklemm@anab.org	001 (260) 633-5406	06/01/2027	Recognized	06/01/2022
International Accreditation Service, Inc	Brea	CA	USA	Dimitrios Katsieris	dimitriosk@iasonline.org	001 (562) 364-8201	06/14/2027	Recognized	06/14/2022
Mexican Accreditation Entity, a.c.	Mexico City	Mexico City	MX	Martha Mejia	martha.mejia@ema.org.mx	52 (55) 559-14843 Ext 4908	08/16/2027	Recognized	08/16/2022
Perry Johnson Laboratory Accreditation, Inc	Troy	MI	USA	Tracy Szerszen	tszerszen@pjlabs.com	001 (248) 519-	06/17/2027	Recognized	06/17/2022
Standards Council of Canada	Ottawa	Ontario	CA	Synthia Roger	accreditation@scc.ca	1 (613) 238-3222, Ext-331	06/30/2027	Recognized	06/30/2022

LAAF Public Registry LAAF Accredited Labs

LAAF-Accredited Laboratories

Download LAAF-AL Dataset

Active LAAF-AL Count: 7 What is an Active LAAF-AL?

LAAF-Accredited Laboratory	LAAF-AL City	LAAF-AL State	LAAF-AL Country	LAAF-AL Point of Contact	LAAF-AL Email	LAAF-AL Phone Number	Recognized Accreditation Body
ANÁLISIS TÉCNICOS S.A. DE C.V.	Pachuca	Hidalgo C.P.	MX	Carlos Jose Sepulveda Ibarra	cs@agrolab.com.mx	52-771-713-2801	American Association for Laboratory Accreditation
Bureau Veritas Commodities and Trade, Inc.	Olathe	KS	USA	Christine MacDermid	Christine.MacDermid@bereauverita...	905-817-5700 ext. 70	American Association for Laboratory Accreditation
CYCAT LLC.	The Woodlands	TX	USA	Carlos Sepulveda	cs@cycallc.com	346-327-8989	American Association for Laboratory Accreditation
Eurofins Microbiology Laboratories, Inc.	Madison	WI	USA	Kyle McCartney	KyleMcCartney@eurofinsUS.com	608-210-5413	American Association for Laboratory Accreditation
Imperial Private Laboratories, Inc.	Miami	FL	USA	AJ Dellan	info@imperialprivatelabs.com	305-254-1747	ANSI National Accreditation Board (ANAB)
Silliker Inc.	Gainesville	FL	USA	Mamatha Whitwell	Mamatha.Whitwell@mxns.com	817-703-4705	American Association for Laboratory Accreditation
USDA, AMS, Science & Technology National Science Laboratories	Blakely	GA	USA	Michael D Miller	Michael.Miller8@ams.usda.gov	229-723-4570	American Association for Laboratory Accreditation

LAAF Public Registry Scopes

LAAF-Accredited Laboratory Scopes What is an Active LAAF-AL Scope?

Download LAAF-AL Scopes Dataset

LAAF-Accredited Laboratory	Certificate Number	Analyte Group	Specific Analytes	Matrices	Technology	Analytical Method	LS Type of Change
ANÁLISIS TÉCNICOS S.A. DE C.V.	4317.02	Salmonella spp.	Salmonella spp.	Food, Drinking Water and Surfaces	3M Molecular Detection Assay Real Time PCR	AE-SSPP-BM: Detection of Salmonella spp. by AOAC Certified Molecular Techniques (Reference Method Certificate AOAC No. 091501 and Certificate AOAC No. 031001)	Approved Scope
Bureau Veritas Commodities and Trade, Inc.	5254.01	Salmonella	Salmonella	red meat, poultry, eggs, foods, environmentals surface samples, siluriformes, environmental products, and animal feed	Real time PCR	AOAC 2003.09; AOAC RI PTM 100201: BAX System PCR Assay for Salmonella	Approved Scope
CYCAT LLC.	6911.01	Salmonella spp.	Salmonella spp.	Food and environmental samples	3M Molecular Detection Assay	AOAC 2016.01: Salmonella spp. In Select Foods and Environmental Samples	Approved Scope
Silliker Inc.	1307.01	Salmonella	Salmonella	Feed, food, beverages, supplements,	Cultural Confirmation	QA-0010-0113: Salmonella	Approved Scope

LAAF-Accreditation Information

- Laboratories interested in becoming LAAF-accredited must apply to a Recognized Accreditation Body
- Accreditation Bodies perform the LAAF assessments
- Participation in the LAAF program is voluntary
- Laboratories are added to the LAAF Dashboard in the order in which they become LAAF-accredited
- Laboratories are listed in alphabetical order on the LAAF-Dashboard

Foreign Participation in LAAF Program

- Foreign Accreditation Bodies and Laboratories may participate in the LAAF program if they meet all program requirements.
- According to Section 1.1107(c) of the LAAF Final rule:
  - "When must food testing be conducted under this subpart?
  - ***
  - (c) Food testing conducted on articles of food offered for import into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act pursuant to paragraph (a)(4) or (a)(5) of this section may only be conducted after the articles offered for import have arrived in the United States unless the owner or consignee has written approval from FDA that a sample taken prior to arrival is or would be a representative sample of the article offered for import into the United States."
- Commodity-specific follow-up testing of sprouts, shell eggs and bottled water described in 21 CFR 1.1107(a)(1) applies to foreign firms that import those commodities into the United States. This testing occurs prior to sprouts, shell eggs, or bottled drinking water being offered for import, and FDA expects that most of that testing will occur at a location relatively close to the firm in need of the test.

Analytical Reports

- Increased clarity around documentation
- Pathway for labs with positive track record to submit abridged analytical packages
  - Laboratories must request permission to submit abridged reports
    - FDA will notify the laboratory if permission is granted or denied
- Regardless of permission to submit abridged reports, labs must document and maintain testing information and test results to account for the full analytical report (21 CFR 1.1150(d) and 1.1154(a))

Abridged Reports

- All analytical reports (full and abridged) must contain the documentation listed in 21 CFR 1.1152(c)
  - This includes the sampling documentation
    - CR, Sampling Plan, and written documentation of Sampler Qualifications
- Requirements for abridged analytical reports are in 21 CFR 1.1153
- Abridged packages include:
  - All test results and quality control results
  - All information described by ISO/IEC 17025:2017 sections 7.8.2.1 (a)-(p) and 7.8.3.1 (a)-(d)
- FDA may still request full analytical reports per 21 CFR 1.1153(d)

Implementation Steps

- Stepwise approach
- Accreditation body recognition
  - AB application portal opened February 11, 2022
  - Maintain list of recognized ABs on public registry
- Laboratory LAAF-accreditation
  - Announced that laboratories may apply to recognized ABs for LAAF-accreditation on July 12, 2022
  - Maintain list of LAAF-Accredited Laboratories on public registry
    - Includes list of methods on lab's scope

Implementation Steps, cont'd.

- Notice in the *Federal Register* giving 6 months' notice that owners/consignees will be required to use LAAF-accredited laboratory for covered testing.
  - There may be more than one *Federal Register* notice

Resources

- LAAF Program Contact Email Address
  - FDALAAFINQUIRY@fda.hhs.gov
- LAAF Final Rule Website
- LAAF Compliance Guide
- LAAF Final Rule Fact Sheet
- LAAF Application Portal
- LAAF Dashboard
- LAAF final rule (86 FR 68728 (Dec. 3, 2021)) creates LAAF regulations at 21 CFR part 1, subpart R (§§ 1.1101 - 1.1200)

Questions?