FSMA Laboratory Accreditation for Analyses of Foods (LAAF) Program

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Overview of the Final Rule

- Food Safety Modernization Act (FSMA) § 202(a), Food Drug &Cosmetic Act § 422
- Voluntary for accreditation bodies (ABs) and laboratories
- FDA management and oversight
- FDA.gov public registry of participating accreditation bodies and laboratories
- Accuracy and reliability of certain food testing

Section 202 of FSMA
Laboratory Accreditation for Analyses of Foods

202(a) - Recognition of Laboratory Accreditation

202(a)(6) - Model Laboratory Standards

202(b) - Testing Procedures

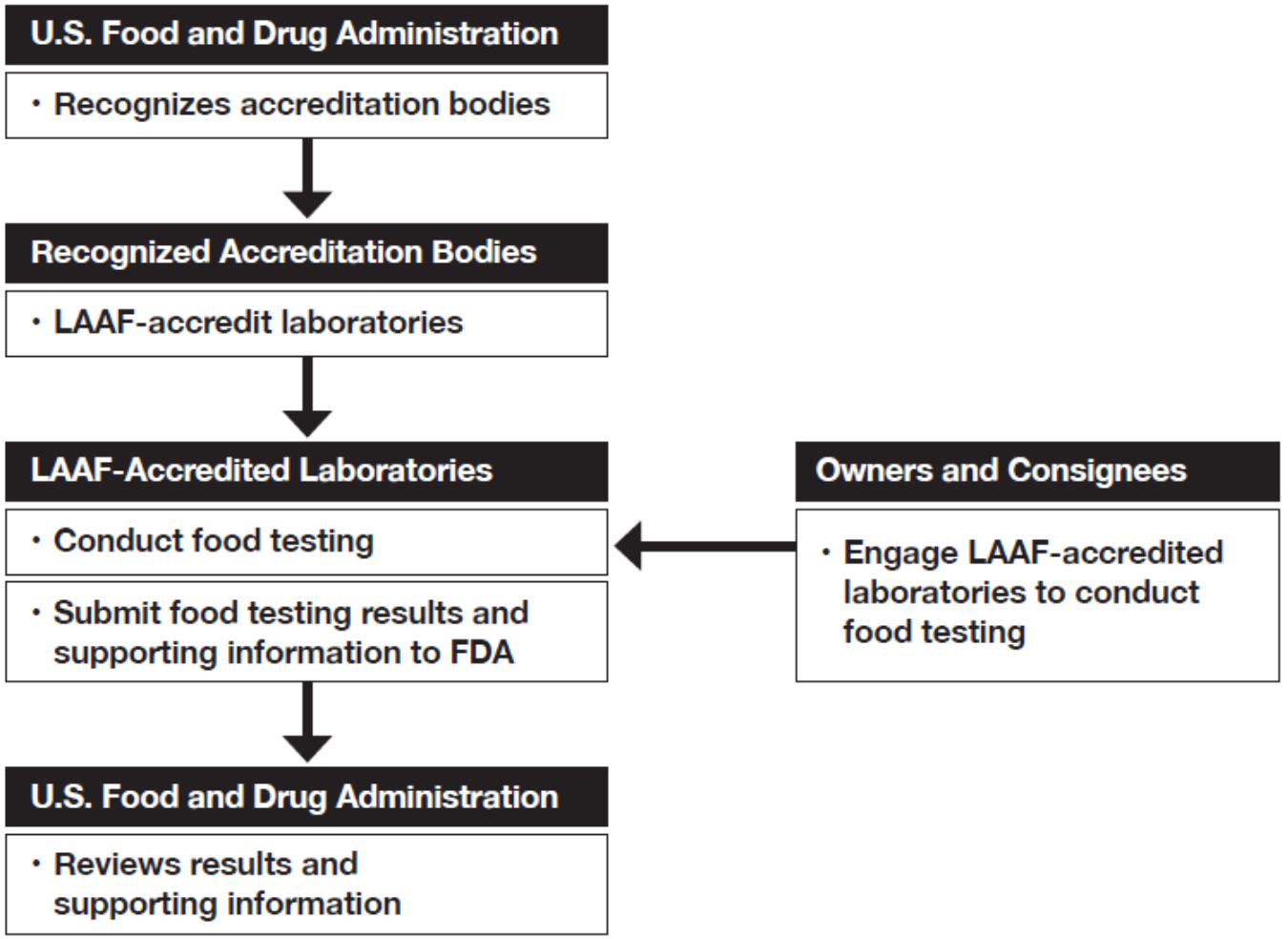
202(c) - Review by Secretary

Section 202 of FSMA
Laboratory Accreditation for Analyses of Foods
Summary

Key Deliverables

- Establish lab accreditation program
  - Develop a process and criteria for recognition and accreditation
  - Develop model standards for testing labs
  - Develop internal database to support program
- Establish public registry of recognized ABs and accredited labs
- Accredited labs to conduct food testing
  - Develop process for electronic submission of data

LAAF Program Structure



Accreditation Bodies: Requirements for Recognition

- Foundational:
  - Meet ISO/IEC 17011:2017
  - Full member of ILAC (International Laboratory Accreditation Cooperative)
  - Evaluate laboratories for LAAF-accreditation; oversee LAAF-accredited laboratories
  - Meet impartiality and conflict of interest requirements
  - Recognition period is up to 5 years

Laboratories: Requirements for LAAF-Accreditation

- Foundational; for each method:
  - Meet ISO/IEC 17025:2017
  - Successfully passed Proficiency Test within 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
  - 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)

Testing Covered by the Final Rule

- Scope is limited
- “Food testing" defined to include:
  - Product testing
  - Testing of the production environment
- 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 under section 801(a) of FD&C Act

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)
    - Bottled drinking water: 21 CFR 129.35(a)(3)(i)
  - Certain administrative processes
  - Directed Food Laboratory Order

Requirements for Covered Testing

- Food owners/consignees are required to use LAAF-accredited laboratory

- Results must be sent by the laboratory directly to FDA
  - Supporting documentation, including sampling information

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)

Methods

- No defined inventory of possible scopes
- Methods within scope of a laboratory's LAAF-accreditation posted on public registry
  - FDA to confirm that methods are fully validated and verified

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)
- 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 request full analytical reports per 21 CFR 1.1153(d)

Implementation Steps

- Stepwise approach
- Accreditation body recognition
  - AB application portal opened Feb. 11, 2022
  - List of seven recognized ABs was posted on the public registry August 16, 2022.
- Laboratory LAAF-accreditation
  - Effective July 12th
    - Laboratories may apply to recognized ABs for LAAF-accreditation

Implementation Steps Cont.

- Once sufficient laboratory capacity is reached
  - Notice in the *Federal Register* notifying owners/consignees that they will be required to use a 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 Fact Sheet
- LAAF final rule (86 FR 68728 (Dec. 3, 2021)) creates LAAF regulations at 21 CFR part 1, subpart R (§§ 1.1101 - 1.1200)

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Questions?