



MODULE 2F

FOOD LABORATORY ACCREDITATION PROGRAM (FOODLAP)

ADDITIONAL REQUIREMENTS

2F.1 SCOPE

The AIHA Laboratory Accreditation Programs, LLC's (AIHA LAP) Food Laboratory Accreditation Program (FoodLAP) is intended for all laboratory, company, government, trade, and independent organizations that perform tests on food products and associated ingredients, including but not limited to, raw agricultural commodities, finished food product, ingredients, in-process samples and associated environmental samples. Food testing laboratories may become accredited for any or all of the Fields of Testing (FoT) in the following testing areas: Chemistry, Microbiology and Residue Chemistry. Laboratory accreditation in this program is based upon a review of the laboratory management systems as defined in Module 2A and this program specific module, and successful participation in appropriate Proficiency Testing as defined in Module 6.

The scope of testing applicable to this accreditation program may include the following areas:

Food Chemistry: Food laboratories performing chemical analyses may perform tests such as fat, protein, salt, vitamin and mineral content, associated with nutritional labeling. Residue chemistry testing laboratories may focus on analysis of halogenated hydrocarbons, pesticides, sulfonamides, nitrosamines, and toxic elements.

Food Microbiology: Food laboratories performing microbiological testing may perform qualitative and/or quantitative analyses for bacteria, yeasts, fungi, protozoa, and viruses. The microbiological procedures may include testing of pathogens such as *Salmonella species*, *Staphylococcus aureus*, *Listeria monocytogenes* and *Bacillus cereus*, *E. coli O157:H7* and other sanitation-related tests (e.g., fecal coliform).

Food Rheology and other Physical Tests: Food laboratories performing testing in this area may perform testing on the characteristics of the material, such as viscosity, elasticity, color or color appearance.

Food Toxicology: Food laboratories performing testing in this area may perform testing to determine the contaminants, chemical attributes or residues of the material.

Functional Testing: Food laboratories perform testing in this area may perform testing to determine the vitamin and mineral content of the material.



Molecular Biology: (including testing for genetically modified organisms): Food laboratories performing testing in this area may perform testing to detect pathogens in the material.

Sensory Testing: Food laboratories performing testing in this area may perform testing of a material to determine the flavor, odor or texture.

The requirements listed here, and in Modules 2A and 6, are not intended to replace or supersede any laboratory requirements specified in other Food Laboratory recognition programs, such as Federal or State programs, that AIHA LAP laboratories may participate in. Such requirements shall remain in effect, in addition to the AIHA LAP program requirements, for those laboratories participating in the AIHA LAP Food Laboratory Accreditation Program and an approved food proficiency testing program, as defined in Module 6.

2F.2 FACILITIES AND EQUIPMENT

The laboratory shall have space, facilities, and equipment adequate for the scope of services to be accredited, and the facility and equipment shall meet all the appropriate requirements.

2F.2.1 Microbiology Laboratories

The most current biosafety level guidelines are defined by the Centers for Disease Control (CDC), the World Health Organization (WHO), and the AIHA LAP. Microbiology laboratories seeking/maintaining accreditation shall have the following, as a minimum:

2F.2.1.1 Procedures addressing laboratory access, ventilation, prohibited practices, and decontamination.

2F.2.1.2 Compound microscopes with low and high power. Microscopes shall be serviced at least annually, and documentation maintained.

2F.2.1.3 Class II biological safety cabinet whose performance has been certified according to NSF Standard 49 (or national equivalent outside the United States). Cabinets shall be certified annually, and documentation maintained.

2F.2.1.4 Proper ventilation of laboratory hoods and instruments, according to current acceptable standards (e.g., ASHRAE).

2F.2.1.5 A steam sterilizer or autoclave with functioning temperature and pressure gauges.



2F.2.1.6 Adequate services, such as electricity, water, vacuum source, hand washing facilities, and appropriate infectious and chemical waste storage, treatment, and disposal procedures.

2F.2.1.7 Proper facilities and equipment for chemical storage and disposal of used containers, chemicals, and refuse.

2F.2.1.8 Incubator(s) with temperature settings appropriate for scope of work performed at the laboratory.

2F.2.2 Chemistry Laboratories, Equipment (See ISO/IEC 17025:2017, Section 6.4)

2F.3 ANALYTICAL METHODS

In addition to the requirements in AIHA LAP Policy Module 2A, the following requirements apply to laboratories seeking FoodLAP accreditation.

2F.3.1 Laboratories shall use methods that are recognized nationally and internationally including, but not limited to, the following sources: EPA, AOAC International Official Methods of Analysis, Compendium of Methods for the Microbiological Examination of Foods (CMMEF), American Public Health Association (APHA), FDA Bacteriological Analytical Manual, U.S. Department of Agriculture (USDA), U.S. Pharmacopeia (USP), and Standard Methods for the Examination of Dairy Products. The laboratory shall obtain customer agreement before using any of these methods for customer samples.

2F.3.2 When a laboratory must use a method that is not recognized nationally or internationally (see Section 2F.3.1), the laboratory shall validate the procedure according to ISO/IEC 17025:2017. The laboratory shall obtain customer agreement before using the method for customer samples.

2F.3.3 Prior to analysis, sample integrity shall be maintained through proper storage and handling conditions. Such conditions shall be documented.

2F.3.4 The laboratory shall have Standard Operating Procedures (SOPs) to address all areas of laboratory responsibility with respect to sample handling and analysis. These responsibilities may include: sampling, transportation, storage, and preparation of test items, QA/QC procedures, and equipment calibrations.

2F.4 QUALITY ASSURANCE / QUALITY CONTROL

Routine QA/QC procedures shall be an integral part of laboratory procedures and functions. These shall include the following in addition to those defined in Module 2A. For qualitative microbiological



determinations, some of the statistical requirements in Module 2A may not fully apply.

- 2F.4.1** The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, damage, or cross contamination of any test item or sample during storage and handling. All necessary environmental conditions, including special security arrangements for sample integrity as needed for some samples, shall be established, maintained, monitored and recorded.
- 2F.4.2** All method specific quality control requirements shall be met. All statistical approaches required by the published method shall be used to verify data acceptability.
- 2F.4.3** The laboratory shall include reference cultures (RC) and/or certified reference cultures (CRC), when available, with all test batches for all microbiological tests. The data obtained from the RC and/or CRC (when available) shall be used to verify the acceptability of the sample media, evaluate laboratory performance, and support the validity of the test procedure(s).
- 2F.4.4** Chemistry laboratories shall include certified reference materials (CRMs), when available, with all test batches. If a CRM is not available, then an internally developed reference material may be used. The data obtained from the CRM or other reference material shall be used to verify the acceptability of the reagents and other supplies, evaluate laboratory performance, and support the validity of the test procedure(s).
- 2F.4.5** The laboratory shall comply with any specific food safety program that requires the use of blind samples to monitor analyst proficiency. Such compliance shall be supported within the SOP for the given procedure and the data shall be documented, including the review and approval process, within the laboratory record keeping system.
- 2F.4.6** Molecular laboratories shall maintain a collection of positive controls (e.g., cultures, DNA extracts, antigen/antibody combinations, etc.) for the molecular tests it provides.
 - 2F.4.6.1** Source and date of acquisition for each shall be documented.
 - 2F.4.6.2** Procedures for maintaining the cultures and/or reagents and using them for training and QC purposes shall be available.

2F.5 SAFETY AND HEALTH

Laboratories participating in the FoodLAP are expected to follow all applicable jurisdictional regulations regarding safety, health, environment, or transportation. Failure to comply with applicable jurisdictional regulations may result in denial, suspension, or withdrawal of FoodLAP accreditation. The assessor shall not perform a safety inspection of the laboratory. However, the



assessor will verify that the laboratory has a safety manual that is reviewed annually, and includes handling and disposal procedures for biological wastes, chemical wastes, toxic materials, and biohazards and addresses spill response procedures.

2F.6 AOAC ADDITIONAL REQUIREMENTS

When applying for FoodLAP accreditation, a laboratory has the option to include the AOAC International requirements (Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals, August 2018). These documents have been identified by the regulators as the type of model that they would utilize in conjunction with the application of the Food Safety Modernization Act (FSMA).

To obtain accreditation, the laboratory shall comply with the General Accreditation requirements defined in ISO/IEC 17025:2017 and relevant AIHA LAP Policy Modules as noted in Section 2F.1.

Laboratories seeking accreditation in this area shall maintain a copy of the AOAC International Requirements in its entirety.

2F.7 FDA LABORATORY ACCREDITATION FOR ANALYSES OF FOODS (LAAF) ADDITIONAL REQUIREMENTS

AIHA LAP is a FDA recognized accreditation body with the ability to accredit laboratories to the standards established in the final rule, [Subpart R](#). LAAF-accredited laboratories are authorized to conduct certain food testing as described in this rule. A LAAF-accredited laboratory will be listed on a publicly available registry on the FDA website, §1.1109. A LAAF-accredited laboratory will have requirements for submitting information to FDA, §1.1110.

To obtain LAAF-accreditation, the laboratory shall comply with the requirements defined in ISO/IEC 17025:2017, relevant AIHA LAP Policy Modules as noted in Section 2F.1, and FDA's LAAF-accreditation requirements. Laboratories seeking accreditation in this area shall maintain a copy of the Final Rule – Subpart R.

General Requirements from [Subpart R](#) - Title 21, Chapter I, Subchapter A, Part 1, Subpart R

§1.1107 When must food testing be conducted under this subpart?

- (a) Food testing must be conducted under this subpart whenever such testing is conducted by or on behalf of an owner or consignee:
 - (1) In response to explicit testing requirements that address an identified or suspected food safety problem, which are contained in the following provisions:
 - (i) *Sprouts*. Section 112.146(a), (c), and (d) of this chapter;



- (ii) *Shell eggs*. Sections 118.4(a)(2)(iii), 118.5(a)(2)(ii) and (b)(2)(ii), and 118.6(a)(2) and (e) of this chapter; and
- (iii) *Bottled drinking water*. Section 129.35(a)(3)(i) of this chapter (for the requirement to test five samples from the same sampling site that originally tested positive for *Escherichia coli*);
- (2) As required by FDA in a directed food laboratory order issued under §1.1108;
- (3) To address an identified or suspected food safety problem and presented to FDA as part of evidence for a hearing under section 423(c) of the Federal Food, Drug, and Cosmetic Act prior to the issuance of a mandatory food recall order, as part of a corrective action plan under section 415(b)(3)(A) of the Federal Food, Drug, and Cosmetic Act submitted after an order suspending the registration of a food facility, or as part of evidence submitted for an appeal of an administrative detention order under section 304(h)(4)(A) of the Federal Food, Drug, and Cosmetic Act.
- (4) In support of admission of an article of food under section 801(a) of the Federal Food, Drug, and Cosmetic Act; and
- (5) To support removal from an import alert through successful consecutive testing.