

***MANUAL FOR RECOGNITION***  
***OF***  
***FOOD TESTING LABORATORIES***



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## 1. INTRODUCTION

Ministry of Health & Family Welfare, Government of India is the Administrative Ministry for the implementation of Food Safety and Standards Act (FSSA). **The Food Safety and Standards Authority of India (FSSAI)** has been established under Food Safety and Standards Act, 2006 which consolidates various acts & orders that have hitherto handled food related issues in various Ministries and Departments. FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

Food testing laboratories plays a vital role in Food Safety and Standards Act, 2006. FSSAI has been mandated by the FSS Act 2006 for performing the various functions. One of the function is related to lab which states “Laying down procedure and guidelines for recognition of laboratories and notification of the accredited laboratories”

Keeping this in view these guidelines have been prepared for recognition of laboratories which are technically competent and implementing Laboratory Quality Management System as per International Standard ISO 17025. This document will help laboratories seeking recognition a clear understanding of the complete process

Recognition is the evaluation process by FSSAI for conformity against recognised standards to carry out specific analysis of food and food products and ensuring their competence. This document provides guidelines for food testing laboratories. As per Act “Food Laboratory“ means any food laboratory or institute established by the central or a state government or any other agency and accredited by National Accreditation Board for testing and Calibration Laboratories or an equivalent accreditation agency and recognised by the Food Authority under section 43.

Laboratory should comply with these relevant statutory or legislative requirements for recognition by FSSAI, New Delhi.

## 2. SCOPE

This document describes specific requirements that a laboratory should meet before recognition by FSSAI.

- 2.1 To harmonize the laboratories standards in India through inspection and recognition.
- 2.2 Analysis of samples sent by Authorized Officer/ Food Safety Officer/ Food business operator/ Consumer to the laboratory.
- 2.3 The laboratory shall follow the scientific protocols laid down for handling/testing the food samples.
- 2.4 Maintaining high standards of accuracy, reliability and credibility in the operation of the laboratory and achieving and maintaining the required levels of reliability.
- 2.5 Laying down mechanism for ensuring that personnel of the laboratory adhere to high professional standards and discipline.
- 2.6 Laboratory will gain International/ National recognition for its commitment to quality, competency and reliable results. It will help to assure customer that the laboratory has technical competence to provide reliable and accurate test or calibration results.
- 2.7 It will assure that the recognized laboratories are operating in accordance with its efficient management system.

## 3. DEFINITIONS FROM ACT

For the purpose of the recognition, the relevant definitions given in FSS Act, 2006 applies and are reproduced below:-

**“Adulterant”** means any material which is or could be employed for making the food unsafe or substandard or mis-branded or containing extraneous matter.

**“Contaminant”** means any substance, whether or not added to food, but which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry or veterinary medicine), manufacture,

processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination and does not include insect fragments, rodent hairs and other extraneous matter.

**“Extraneous matter”** means any matter contained in an article of food which may be carried from the raw materials, packaging material or process systems used for its manufacture or which is added to it, but such matter does not render such article of food unsafe.

**“Food”** means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zk), genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water , alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances.

**“Food Additive”** means any substance not normally consumed as a food by itself or used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food but does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities.

**“Food Safety”** means assurance that food is acceptable for human consumption according to its intended use.

**“Hazard”** means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

**“Ingredient”** means any substance, including a food additive used in the manufacture or preparation of food and present in the final product, possibly in a modified form.

**“Sample”** means a sample of any article of food taken under the provision of this act or any rules and regulations made there under.

**“Standard”** means standards notified by food authority.

**“Unsafe food”** means an article of food whose nature, substance or quality is so affected as to render it injurious to health.

#### **4. TYPES OF LABORATORY**

Recognition shall be accorded to a laboratory for single premises only where actual testing is carried out. If the laboratory carries out testing activities in more than one premise, separate recognition for each premise will have to be obtained with a clear demarcation of scope of recognition. However, if the laboratory establishes field / satellite laboratories for preliminary / screening tests near / at the place of the primary production of the food, the facilities can be considered as part of the central / main laboratory of the establishment, with additional scope, where conformity tests can be carried out for the presence of the particular substance(s), provided such arrangements are addressed in the Quality Manual of the Laboratory.

**4.1 Main Laboratory-** A laboratory that maintain a single location whose address is denoted in the application form for recognition.

**4.2 Multi- location laboratory-** Multi-location laboratories refer to the two or more laboratories owned by the same organization and may or may not utilize same management system. Such laboratories need separate recognition for each location.

**4.3 Satellite laboratory-** A laboratory that is branch of main laboratory and is allowed to carry out testing in the main laboratory’s scope with the following conditions-:

**4.3.1** Specifying location in recognition application.

**4.3.2** Reference of main laboratory will be written in test report as footnote/header.

**4.3.3** Satellite laboratory shall perform test in the same field of testing for as per the recognized scope of main laboratory.

4.3.4 Operated by the management system of main laboratory.

4.3.5 Not performing any other activities other than testing such as forming standards policy formulation procedure development.

4.3.6 Scope of testing will be added in the main laboratory scope of testing and can be listed in different section.

4.3.7 The recognition will be granted on auditing of main laboratory and satellite laboratory in single visit.

4.3.8 Satellite laboratory will be addressed in the quality manual of main laboratory. If there is more than one satellite laboratory then the scope will be listed for each separate satellite location.

**4.4 Field laboratory**:- The laboratory which carry analysis at customer's premises/ outside the laboratory premises with following condition:-

4.4.1 Satisfying the conditions of testing mentioned in scope and quality manual.

4.4.2 Field testing shall be carried out by the food analyst/ staff of main laboratory.

4.4.3 Field testing is preferred for in-situ testing i.e. testing at the place of origin / processing.

4.4.4 Testing is part of standard/ approved test procedure.

4.4.5 Field laboratory is assessed as part of main laboratory and mentioned in main laboratory's Scope of recognition.

**4.5 Mobile laboratory**: - A laboratory that undergo transportable testing and is capable of testing under controlled environmental conditions.

A mobile laboratory shall fulfill following conditions:-

4.5.1 The laboratory shall be self-contained and fully equipped for applied scope of testing.

4.5.2 The laboratory shall follow standard procedures.

4.5.3 A mobile laboratory may be an independent laboratory with fixed business address or may be branch of main laboratory with fixed premises.

4.5.4 A laboratory needs to apply separately for different mobile units until the technical capabilities are within scope of recognition. However number of mobile units shall be mentioned in application form.

4.5.5 The recognition process shall be applicable to **Level 1- Food Laboratory**, **Level 2- Food Laboratory** and **Referral Food Laboratory** which are defined below:

**4.5.5.1 Level 1- Food Laboratory:** - The laboratory which is competent to carry out the complete analysis as per “The Food Safety and Standards (Food Products Standards and Food Additives-Part-I & II) Regulations, 2011” for 18 categories of Food covered in Food code. The level 1 laboratory will carry out the following analysis:-

- a) Physical analysis
- b) Chemical analysis
- c) Microbiological analysis
- d) Rheological analysis
- e) Functional testing
- f) Basic nutrient analysis such as fat, protein, calorific value
- g) Sensory analysis

**4.5.5.2 Level 2- Food Laboratory:** - The laboratory which is competent to carry out the complete analysis as per “The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011” and “Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011” for 18 categories of Food covered in Food code. The level 2 laboratory will carry out the analysis covered in Level 1 Food Laboratory as well as the following analysis:-

- a) Contaminants (chemical, microbiological)
- b) Toxic substances
- c) Pesticides residues
- d) Antibiotics and pharmaco logically active substances
- e) Irradiation of food
- f) Detailed nutrient analysis
- g) Molecular analysis (genetically modified food)

**4.5.5.3 Referral Food Laboratory:-** The Laboratory having competence to carry out the analysis as per “The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011” and “Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011” i.e Level 1- Food laboratory and Level 2- Food laboratory.

## 5. SCOPE OF RECOGNITION

Scope of Recognition refers to the official listing of the various tests, type of test, specific test methods of the tests that the laboratory is been competent to perform. The scope will also identify the food categories out of listed categories in Food code of FSS act, 2006 for which the recognition is applied. The Food code is available on FSSAI website. Format of scope of recognition is mentioned in application form. The laboratories will apply as per the following scope.

### Product Categories for Scope I & II

#### Scope I

Dairy Products And Analogues	Cereal & Cereal Products
Fats, Oils And Fat Emulsions	Meat & Meat Products
Fruits & Vegetable Products	Fish & Fish Products
Sweets & Confectionery	Other Food Product and Ingredients
Sweetening Agents including Honey	Food Additives
Salt, spices, Condiments & Related Products	Beverages,(Other than Dairy & Fruits & Vegetables based)

#### Scope II

Metal Contaminants
Pesticide Residues
Antibiotic and other Pharma-cologically Active Substances
Crop contaminants and naturally occurring toxic substances
Proprietary Food
Irradiation Of Food

## 6. FUNCTIONS OF REFERRAL LABORATORY/ FOOD LABORATORY

The Referral Laboratory/Food laboratory shall carry out the following functions, namely:

- 6.1 Analysis of samples of food sent by any officer or authority authorized by the Food Authority for the purpose and submission of the certificate of analysis to the authorities concerned.



- 6.2** Investigation for the purpose of fixation of standard of any article of food.
- 6.3** Investigation in collaboration with the laboratories of Food analysts in the various States and such other laboratories and institutions which the Food Authority may approve on its behalf, for the purpose of standardizing methods of analysis.
- 6.4** Ensuring that the laboratory follows the scientific protocols laid down for handling/testing the articles of food.
- 6.5** Maintaining high standards of accuracy, reliability and credibility in the operation of the laboratory and achieving and maintaining the required levels of accreditation and reliability.
- 6.6** Laying down mechanism for ensuring that personnel of the laboratory adhere to high professional standards and discipline.
- 6.7** Such other conditions, as the Authority may lay down for Referral Laboratories.
- 6.8** Capacity building by way of organizing professional training, workshops and seminars for the Food analyst, laboratory personnel in the states specified by the Food authority.
- 6.9** The laboratory should have R&D Capabilities for the purpose of developing standards for any article of food and standardizing methods of analysis.
- 6.10** The laboratory should have training centre for capacity building by way of organizing professional training, workshops and seminars for the food.

## **7. TECHNICAL REQUIREMENT**

### **7.1. PERSONNEL**

The laboratory should have sufficient qualified, trained and experienced staff to handle the testing jobs under scope. The laboratories recognized under scheme, shall have to have at least one qualified Food Analyst (must have cleared food analyst exam conducted by FSSAI), within a period of two (02) years of the recognition of the Laboratories. The laboratories already having

qualified food analyst shall be given preference. The qualifications and experience of the food analyst as defined in the act are reproduced below:

#### **7.1.1. Qualifications**

**Food Analyst :** A person shall not be qualified for appointment as Food Analyst under the Act unless she/he holds a Master's degree in Chemistry or Biochemistry or Microbiology or Dairy Chemistry or Food Technology, Food and Nutrition or holds Bachelor of Technology in Dairy/Oil or holds degree in Veterinary Sciences from a university established in India by law or is an associate of the Institution of Chemists (India) by examination in the section of Food Analysts conducted by the Institution of Chemists (India) or any other equivalent qualification recognized and notified by the Central government for such purposes and has not less than three years' experience in the analysis of food; and Has been declared qualified for appointment as a Food Analyst by a board appointed and notified by the Authority. A person appointed as Food Analyst shall undergo all specialized training programs specified by the Food Authority periodically.

**Lab Analyst/ Chemist:** - A person shall be qualified as Analyst/ Chemist shall hold Master's degree in Chemistry or Biochemistry or Microbiology or Dairy Chemistry or Food Technology, Food and Nutrition or holds Bachelor of Technology in Food/Dairy/Oil or holds degree in Veterinary Sciences or equivalent degree from a university established in India by law.

#### **Duties: -**

- The Food Analyst/ Analyst shall analyze the food samples sent to him for analysis.
- The Analyst shall follow the standard procedures, instructions and shall adopt the amendments and new procedure as adopted by the Food Authority from time to time.

- The report of analysis shall be signed by the Authorized Signatory who may be the different person other than the person who is analyzing the sample.
- The Food Analyst/ Analyst shall send his report to the concerned Authority/officer/ person.

**7.2. Support staff:** - The laboratory technicians/ helpers shall have minimum qualification of Bachelor degree in science. They shall have undergone training in relevant field.

## **8. INFRASTRUCTURE**

The Applicant Laboratory must have all the infrastructure and facilities required for carrying out the analysis as per the scope applied for.

- 8.1** Food laboratories shall be designed to meet the testing requirements. The layout of laboratory shall be arranged in such a way that test procedures can be carried out in sequential manner and risk of contamination can be reduced.
- 8.2** The space shall be managed with respect to specialized activities such as separate space for wet analysis and dry analysis.
- 8.3** The laboratory layout shall meet the instructions of equipment's and instruments handling.
- 8.4** Special provisions / rooms shall be available for weighing balance, sensitive instruments, radioactive material, media preparation, storage (samples and chemicals) and washing of glassware.
- 8.5** Provision of water (potable & distilled/Millipore), cupboards, sinks, dustbins, reagent shelves, glassware, fume cupboards and power.
- 8.6** Ventilators and fume cupboard shall be placed carefully such as to maintain the dust free environmental conditions in laboratory and to avoid risk of contamination of test samples/ chemicals.

- 8.7 Work place shall be smooth, easy to clean and shall be made of material according to the test requirements so as to prevent hazard to laboratory staff.
- 8.8 Appropriate environmental monitoring programme shall be carried out such as temperature and humidity control. Their daily record shall be maintained. If required positive pressure and laminar flow can be provided.
- 8.9 Laboratory shall have at least 300 lux light intensity for working places except particular conditions mentioned in test methods.
- 8.10 Laboratory shall be prohibited from eating, drinking and smoking. Visitors shall be restricted in laboratory especially in contamination prone areas.
- 8.11 Appropriate system/device shall be used to control environmental contamination.
- 8.12 Staff shall be aware of Contamination prone areas. They shall be trained to take appropriate measures for safety and security. Analyst shall wear lab coat, gloves, mask and eye shield/goggles while working in lab.
- 8.13 Laboratory shall follow good housekeeping activities such as floor and wall cleaning, washrooms, dustbins, fume heads, freezers, refrigerators, air conditioners, air filters, flies killer lamp.
- 8.14 The laboratory shall be liable to maintain safety measures and pest control measures.

## **9. EQUIPMENTS AND THEIR CALIBRATION**

- 9.1. **Equipment:** - The Applicant Laboratory for recognition as Level-1 Food Laboratory, Level-2 Food Laboratory and Referral Laboratories should have all the equipment required for testing under their scope of recognition.

**List of equipment which can be used in food analysis is as followed:-**

- Any other equipment as per requirement
- Autoclave
- Centrifuge
- Chromatography assembly/ analyzer
- Colony counter
- Crude fiber assembly
- Deep freezer
- Distillation assembly
- ELISA Reader & Washer
- Falling number apparatus
- Homogenizer
- Hunter color lab
- Incubator
- Kjeldahl apparatus
- Laboratory hoods
- Laboratory pumps
- Laboratory sterilization equipment
- Laminar flow
- LCMSMS, GCMSMS, AAS / ICPOES/ ICPMS, HPLC, GC
- Lux meter
- Microscope
- Milk fat analyzer
- Mixer Grinder
- Moisture Analyzer
- Muffle furnace
- NIR (Near Infrared Analyzer)
- Oven
- PCR system
- PH Meter
- Polarimeter
- Rapid Visco analyzer
- Refractometer (Abbe, Portable etc)
- Refrigerator

- Rheometer
- Rotary Evaporator
- Shaking Incubator
- Sonicator
- Soxhlet apparatus
- Texture analyzer
- Titration assembly
- UV-Vis Spectrophotometer
- Viscoanalyzer
- Viscometer
- Water activity meter
- Weighing Balance (sensitivity according to the requirements)

**9.2. Calibration:** - Laboratories can get their equipment calibrated from national metrology laboratory in the knowledge that the calibration is internationally traceable. Calibration certificates shall be maintained for volumetric and mass measuring equipment's. Calibration shall be performed using reference material and results shall be verified from standards and documented. The records shall mention the date of calibration, reference standard used, next due date of calibration and periodicity of calibration.

## **10. MANAGEMENT RESPONSIBILITIES**

**10.1. Filing Application-** The management shall follow the recognition Guidelines and Manual before filing the application form for fresh recognition and renewal. The Criteria of recognition and terms and conditions shall be read and followed. The management shall help the laboratory authorized signatory in preparing scope of testing and quality manual.

**10.2. Filing projects/contracts/ tenders –** Management shall be updated with the state of present contracts/ tenders and their renewal dates. They shall be aware of the new projects/ contracts/tenders that can be applied.

**10.3. Management review meeting-** Management shall undergo periodic management review meeting which shall be reported in documents and can be presented at the time of recognition.

**10.4. Documents-** All the documents shall be properly maintained and updated in the state that it can be reproduced at any time if required.

**10.5. Amendments-** Management team shall be updated with the BIS/ IS/ ISO/ Codex/ recognizing agencies for amendments from time to time.

**10.6. Upgradation of laboratory-** Management shall consider the various ways to upgrade the laboratory without violating the law. New recommended testing technologies/ equipment can be incorporated for more efficient work.

**10.7. Non conformities-** In case any major/ minor Non Conformities has been raised during assessment, management shall take care to close the NC's within stipulated time. If the closure of Major NC's require re onsite assessment than that shall be managed by the management team.

**10.8. Any other corrective action-** management shall take necessary steps to take corrective action whenever required.

## 11. SAMPLING

**11.1.** The adequate quantity of sample of food to be sent to the Food analyst/ Director of referral lab for analysis shall be as specified in FSSRs (Laboratory and sample analysis) clause 2.3.1.

### 11.2. Packaging

**11.2.1** The quantity of sample of food packaging material to be sent to the Food analyst/ Director of referral lab for analysis shall be as specified below:-

S.No.	Name of food packaging material	Approximate quantity/surface area to be supplied
1	Food packaging material when sample is taken from manufacturer	8 x 1000 x 9 sq.cm. surface area.
2	When sample is taken from small consumer packages.	Complete packaging material used for one

		container
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**11.2.2** Foods sold in packaged condition (sealed container or package) shall be sent for analysis in its original condition without opening the package as far as practicable, to constitute approximate quantity along with original label. In case of bulk packages, wherever preservatives are to be added as per the requirement under these rules, the sample shall be taken after opening sealed container or package in the presence of the Food Business Operator or in case of his refusal, in the presence of one or more witnesses and the contents of the original label shall also be sent along with the sample for analysis. However, such samples shall not be used for microbiological analysis.

**11.2.3** Sample of article of Food for the purpose of analysis shall be taken in clean dry bottles or jars or in other suitable containers which shall be closed to prevent leakage, evaporation or to avoid entrance of moisture in case of dry substance and shall be carefully sealed. Provided, if a sealed package marketed by the manufacturer/Food Business Operator is taken as sample, further sealing in separate containers will not be required.

**11.2.4** All bottles or jars or other containers containing the samples for analysis shall be properly labelled and the parcel shall be properly addressed. The label on any sample of food sent for analysis shall bear:-

- a. Code number of the sample
- b. Name of the sender with his official designation
- c. Date and place of collection
- d. Nature of articles being sent for analysis
- e. Nature and quantity of preservative, if any, added to the sample.

## **12. Preservative**

The Food Safety Officer or the Authorized Officer, while taking sample for the purpose of analysis under the provisions of the Act except in the case where the sample is meant for microbiological testing/ analysis, may add to the sample, a preservative as may be prescribed from time to time in the regulations for the



purpose of maintaining it in a condition suitable for analysis. Whenever any preservative is added to a sample, the nature and quantity of the preservative added shall be clearly noted on the label to be affixed to the container.

The preservative used in the case of samples of any milk (including toned, separated and skimmed milk), standardized milk chhana, skimmed milk chhana, cream, ice-candy, dahi, khoa or khoa based and Paneer based sweets, such as Kalakand and Burfi, Chutney and prepared foods, gur prepared coffee and tea in liquid or semi- liquid form shall be the liquid commonly known as “formalin”, that is to say, liquid containing about 40 per cent of formaldehyde in aqueous solution in the proportion of 0.1 ml. (two drops) for 25 ml. or 25 grams. Provided that in case of samples of ice-cream and mixed ice-cream, the preservative used shall be liquid commonly known as formalin, that is to say, a liquid containing about 40 percent of formaldehyde in aqueous solution in the proportion of 0.6 ml. for 100 ml. or 100 g. Provided further that in case of the unspecified products, the quantity drawn shall be determined in consultation with the Food Analyst.

### **13. TEST METHODS**

**13.1** The Manual of the Methods of Analysis (FSSAI Manual), as amended/adopted by FSSAI from time to time including AOAC /ISO /Pearsons /Jacob/IUPAC/Food Chemicals Codex /BIS /Woodmen /Winton-Winton /Joslyn shall be used for analyzing the samples of food articles. However, in case the method for analyzing any parameter is not available in these manuals, a validated method of analysis prescribed by internationally recognized Analytical/Regulatory agencies, shall be adopted.

**13.2** If a laboratory wish to recognize its own method then they must provide the following information to the auditors before assessment:-

- a. Origin/reason of method
- b. Comparison with the standard method
- c. Reasons for changes in standard methods
- d. Validation of data

## **14. TESTING OF SAMPLES**

The following instructions shall be followed by the recognized laboratory for testing the samples sent by FSSAI or Food Business Operator or consumer for the purpose of monitoring / certification:

- 14.1** Sample shall always be accompanied by a test request specifying the parameters and purpose.
- 14.2** Whenever required, the recognized laboratory shall draw samples only by its own trained Sample Collecting Officers.
  - 14.2.1** The Sample Collecting Officer shall strictly adhere to the sampling procedure and provide sampling details as per FSSAI requirements. The sample shall be drawn only from the complete Assortment / Batch / Lot as the case may be having uniform characteristic in the form of source / production conditions / processing conditions.
  - 14.2.2** The Sample Collecting Officer shall also ensure drawl of true representative sample of complete Assortment/ Batch/ Lot as the case may be.
- 14.3** The FBO shall not be allowed to witness the test or to come in contact with the testing personnel without prior recognition of FSSAI. Any assistance or intervention required from the FBO for testing the sample shall be duly indicated by FSSAI in the test request and shall be reported in the test report.

### **14.4 Functions Of Food Analyst**

- 14.4.1** On receipt of the package containing a sample of food for analysis, the Food Analyst or an officer authorized by him shall compare the seals on the container and the outer cover with specimen impression of seal received separately. A statement / record to this effect shall be made on receipt of sample and in the test report by the concerned laboratory.
- 14.4.2** If the sample container received by the Food Analyst is found to be in broken condition or unfit for analysis, he shall, within a period of seven days from the date of receipt of such sample,

inform the Designated Officer/ Food business operator/ consumer about the same and request him to send the second part of the sample for analysis.

**14.4.3** On receipt of the sample, the Food Analyst shall analyse the sample and send the analysis report mentioning the method of analysis. The analysis report shall be signed by the Food Analyst and such report shall be sent within fourteen days of the receipt of the sample by the Food Analyst. In case the sample cannot be analysed within fourteen days of its receipt, the Food Analyst shall inform the Designated Officer and the Commissioner of Food Safety/ Food Business Operator/ consumer giving reasons and specifying the time to be taken for analysis.

**14.4.4** The laboratory is liable to maintain confidentiality of samples and information thereof.

## **15. TEST REPORT**

**15.1** The test report duly sealed in confidential cover unless the report is sought by any other means in the format as per Form A (for Level-I & Level II Laboratories) / Form B (For Referral Laboratories) of FSSA (**Annexure-III A & B**) shall be sent to the officer / Food Business Operator/Consumer, who has sent the sample and requested the testing.

**15.2** The test report shall clearly indicate who has drawn the sample and the reference method.

**15.3** The laboratory shall issue the test reports immediately after completion of the tests and not later than a maximum period of 14 days from the date of receipt of sample or as defined by FSSAI from time to time.

**15.4** The analysis report shall be as per **Form VII A** and four copies of the same shall be sent to the Designated Officer under whose jurisdiction the Food Safety Officer functions or the purchaser of article of food. The analysis report shall be signed by the Food Analyst and such report shall be sent within fourteen days of the receipt of the sample by the Food Analyst. The Designated Officer shall keep two copies of analysis report

for further action, one copy shall be sent to Food Safety Officer for record and one copy to Food business Operator from whom the sample was taken.

**15.5** The analysis report of the sample sent by the food business operator/ consumer shall be as per form.... And consist of 2 copies. One copy shall be sent to the food business operator/ consumer and the second shall be kept in laboratory record.

**15.6** The test report shall be treated as strictly confidential between the testing laboratory and FSSAI. No information regarding the sample or its results shall be divulged to any person including food business operator/ consumer who may deliver the sample for testing on behalf of FSSAI. However, in case sample is submitted by the FBO/Consumer for testing within the scope of recognition for the purpose of self-monitoring or for monitoring / certification by FSSAI, the details of testing shall be made available to FSSAI.

**15.7** An appeal against the report of Food Analyst shall lie before the Designated Officer who shall, if he so decides, refer the matter to the referral food laboratory as notified by the Food Authority for opinion.

## **16. SAMPLE RETENTION**

The laboratory shall keep the remaining sample after complete required analysis for a minimum period of **one month** in the desired storage conditions as required by the test procedure. Exceptions can be made for perishable items where the remaining sample can be discarded after acceptance of report by the Authorised officer/ consumer/ food business operator. Discard time period of perishable samples can be mentioned in the test report to avoid claims.

## **17. RECORD RETENTION**

**17.1.** The laboratory shall maintain the record of observations and a copy of the test report for a minimum period of **three years**.

**17.2.** In case of withdrawal / cancellation of recognition, the laboratory shall give an undertaking to make available of the records of FSSAI related testing of three years.

Duplicate issue of report shall be issued only with a valid reason in written which shall be approved by the authorized person.

## **18. ANNUAL REPORT**

The recognized laboratory shall submit the following statements at the end of every financial year after recognition of the laboratory by FSSAI.

**18.1.** Number of samples received for testing and number of samples tested.

The report shall give detail about the number of samples sent by the FSSAI Food sampling officer/ Consumer/ Food business operator.

**18.2.** Number of samples failed specifying the parameter/test.

**18.3.** Number of samples whose condition does not comply with the test conditions.

**18.4.** Other relevant details as required.

## **19. FEE STRUCTURE**

**19.1. Application Fee:** - The fee that has to be paid along with application form to proceed the process which include examination of application form, Quality manual and other related documents, plan of assessment schedule etc. The application fee is Rs. 50,000 per scope i.e. if the applicant is applying for Scope 1 and Scope 2 then the applicant has to pay Rs1, 00,000

**19.2. Assessment Fee:** - The laboratory has to pay Rs. 5,000 per manday plus expenses for travel and stay of assessors during recognition visit, renewal visit, surveillance visit and special visit of assessors/ team of assessors.

**19.3. Recognition Fee:-** Rs. 50,000 has to be paid by applicant laboratory as recognition fee along with application form in advance in order to carry out all the related matter after recognition of lab for 3 years. In case the lab is not fit for recognition then this amount will be refunded by the authority.

**19.4. Enhancement fee:** Applicant laboratory has to pay Rs. 10,000 per scope for enhancement along with the assessment fee as specified above.

**19.5. Security deposit-** The laboratory has to pay Rs. 1, 00,000 as Performance Bank guarantee (PBG)/ Security fee. This fee shall be forfeited under following circumstances:-

**19.6.** If the laboratory is found violating the terms and conditions of recognition.

**19.7.** If the laboratory is found indulging in unethical practices

**19.8.** The applicant laboratory has to make these payments on separate demand drafts /Pay order in favour of “The Senior Accounts Officer, Food Safety & Standards Authority of India, payable at New Delhi”.

**19.9.** The following shall be the fee payable by applicant/ recognized laboratory.

<b>S no.</b>	<b>Purpose</b>	<b>Fee</b>
1.	Application Fee: (Recognition / renewal of recognition for each scope)	Rs.50,000/- per scope
2.	Assessment Fee / Surveillance Fee / Special visit charges	Rs.5000/- per man-day plus expenses for travel and stay of assessors at actual
3.	Recognition Fee (to be paid in advance on consideration for recognition)	Rs.50,000/-
4.	Enhancement of Scope	Rs.10,000/- per scope + Assessment Fee as defined at Sr. No. 3 above
5.	Security deposit	Rs. 1,00,000