

GUIDELINES FOR RECOGNITION
OF
FOOD TESTING LABORATORIES



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1. INTRODUCTION

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.

Ministry of Health & Family Welfare, Government of India is the Administrative Ministry for the implementation of Food Safety and Standards Act (FSSA). FSSAI has been mandated by the Food Safety and Standards Act, 2006 for performing the various functions related to Food Quality and Safety. These functions in addition to others include “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 technically competent which are implementing Laboratory Quality Management System as per International Standard ISO 17025.

2. SCOPE

This document lays down the guidelines for general as well as the technical criteria for recognition, terms and conditions of recognition, withdrawal / cancellation of recognition and financial aspects of the Laboratory Recognition.

- 2.1.** The recognition scheme is applicable to laboratories, which are functioning independently irrespective of being an in-house laboratory or linked directly or indirectly to any of the manufacturing / processing unit /organization/ Institution to the satisfaction of FSSAI provided the laboratory demonstrates that there is no conflict of interest.
- 2.2.** 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 premises, 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.

2.3. These criteria shall be applicable to **Level 1- Food Laboratory, Level 2- Food Laboratory** and **Referral Food Laboratory** which are defined below:

2.3.1 Level 1 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”.

2.3.2 Level 2 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”.

2.3.3 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”. In addition the Referral laboratory must have the competence to meet the following requirements :

2.3.3.1 R & D Capabilities: For investigation for the purpose of fixation of standard of any article of food and standardizing methods of analysis. The preference will be given to the Laboratories having documentary evidence for carrying out R&D in food sector.

2.3.3.2 Training Facilities: The laboratory should have training center for Capacity building by way of organizing professional training, workshops and seminars for the Food. The preference will be given to the Laboratories having documentary evidence for conducting trainings / workshops / seminars in food sector.

2.3.3.3 Other Facilities : The laboratory should have all the other required facilities for performing the functions of Referral Food Laboratory as defined in the Act and reproduced below:

- 2.3.3.3.1.** 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;
- 2.3.3.3.2.** Investigation for the purpose of fixation of standard of any article of food;
- 2.3.3.3.3.** 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.
- 2.3.3.3.4.** Ensuring that the laboratory follows the scientific protocols laid down for handling/testing the articles of food.
- 2.3.3.3.5.** 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.
- 2.3.3.3.6.** Laying down mechanism for ensuring that personnel of the laboratory adhere to high professional standards and discipline.
- 2.3.3.3.7.** Such other conditions, as the Authority may lay down for Referral Laboratories such as coordinating proficiency testing programmes in the country etc.

3 CRITERIA FOR RECOGNITION

3.1 The laboratories seeking recognition shall have implemented and maintained Quality Management System in accordance with the latest version of ISO / IEC 17025 'General requirements for the competence of Testing and Calibration laboratories' and concerned NABL guidelines The applicant laboratory shall have adequate capability and competence for testing of food

safety and quality parameters as per the requirements of Food Safety & Standards Act 2006.

3.2 The applicant laboratory must be NABL accredited Or accredited by other accrediting agency

3.3 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:

3.3.1 Qualifications : 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 programmes specified by the Food Authority periodically.

3.3.2 Duties: The Food Analyst shall analyze or cause to be analyzed the article of food sent to him for analysis. In analyzing the article of food, the Food Analyst shall follow such instructions and shall adhere to such procedure as adopted by the Food Authority from time to time. The report of analysis shall be signed by the Food Analyst. After completion of analysis of article of food, the Food Analyst shall send his report to

the Designated Officer, or the Purchaser of article of food, as the case may be.

3.3.3 Authorized signatory may be different person other than the person who is analyzing the samples.

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

3.5 Equipment: The Applicant Laboratory for recognition as Level-1, Level-2 and Referral Laboratories should have all the equipment required for testing under their scope of recognition. In addition to the basic requirement, the Referral Laboratory must have at least one LCMSMS, GCMSMS, AAS / ICPOES / ICPMS, HPLC, GC and ELISA Reader & Washer.

4 PROCEDURE FOR OBTAINING RECOGNITION

4.1 APPLICATION

4.1.1 Interested Laboratory shall apply to the FSSAI office **in duplicate** in the prescribed proforma as per format at **Annexure-I** along with copy of its Quality Manual and application fee, as prescribed from time to time. The application fee is non- refundable. The Schedule of Fee is given in Clause No. 12. Application fee shall be applicable separately for each of the scope given below:

- **Scope 1:** Parameters covered under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 as updated on FSSAI's website from time to time.
- **Scope 2:** Parameters covered under the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 as updated on FSSAI's website from time to time

The Product Categories for scope of recognition should be defined under the titles given at **Annexure-II**:

4.1.2 The applicant laboratory shall ensure the following:

4.1.2.1 The scope shall not be amended /changed; however, it may be reduced, but, shall not be appended, till on-site assessment is completed once application is submitted.

- 4.1.2.2** The scope for recognition shall not include any test by sub-contracting. Sub-contracting is permitted with prior permission of FSSAI / the customer from another FSSAI recognized laboratory with valid scope of recognition. Sub-contracting is not permitted from the laboratory, which is not recognized by FSSAI.
- 4.1.3** The application shall be signed by the proprietor/partner or the Managing Director/Chief Executive Officer (CEO) of the laboratory or any other person duly authorized for the purpose. The authorization shall be supported with the Resolution or a letter, as applicable under companies act/rules by Governing Council/ Governing Board/Board of Directors of the company. The name and designation of the person signing the application must be recorded legibly in a space set apart for the purpose in the application form.
- 4.1.4** The laboratory shall have adequate infrastructure, equipment facilities and resources to perform the tests under the scope for recognition, which shall be verified during the on-site assessment.
- 4.1.5** If necessary, FSSAI shall seek further information from the applicant in order to facilitate processing of the application.
- 4.1.6** FSSAI reserves the right to **reject an application** for one or more of the following reasons:
- 4.1.6.1** The laboratory does not have adequate facilities for the scope applied for as given in its application;
 - 4.1.6.2** Application fee as applicable for each scope for recognition and adequacy audit fee as applicable has not been submitted;
 - 4.1.6.3** Application form is not completely filled;
 - 4.1.6.4** Quality Manual has not been submitted along with the application and not addressing the scope applied for, adequately;
 - 4.1.6.5** In case of renewal of recognition, performance of the laboratory is not satisfactory during its earlier recognition;
 - 4.1.6.6** The laboratory is sub-contracting any test under the scope for recognition.

4.1.6.7 The Laboratory not meeting any of the criteria for recognition as per Clause-3.

4.1.6.8 FSSAI reserves the right to reject the application, without giving any reason.

4.2 ADEQUACY AUDIT

After acceptance of the application, adequacy audit of the Quality Management System shall be conducted by Assessor/ any other person deputed by FSSAI based on the Quality Manual submitted by the laboratory. The laboratory shall pay adequacy audit fee as per Clause No. 10. Any deficiencies observed in the Quality Manual shall be communicated to the applicant within 01 month of the receipt of Quality Manual in FSSAI, for taking suitable corrective actions. The laboratory would resubmit the Quality Manual after review and revision along with applicable adequacy audit fee for further adequacy audit within 15 days of the dispatch of Non Conformances (NCs) from FSSAI.

The adequacy audit of Quality Manual may not be carried out at the time of renewal, in case it is not a new revised issue.

4.3 ASSESSMENT

4.3.1 FSSAI shall process the application for on-site assessment only after adjudging the suitability of management system by adequacy audit. A team of assessors as per scope applied by the laboratory shall be deputed by FSSAI to ascertain compliance to the documented Quality Management System, equipment facilities/ infrastructure and technical competence. The laboratory shall make arrangements for travel and stay of the assessors and provide the facilities required for on-site assessment as per the auditing principles.

4.3.2 The on-site assessment shall have the following steps:

4.3.2.1 Opening Meeting - This meeting will be conducted by the assessment team leader (Lead Assessor) in which the Chief/Head of the laboratory, the Quality Manager (QM) and the technical heads of all the divisions being audited are

expected to be present. During this meeting, the team leader will explain the scope and extent of the assessment as well as the proposed plan for assessment. The scope for recognition shall not be changed during the opening meeting. Permission to take photocopy or photograph of documents relevant to substantiate the audit findings shall be complied with by the laboratory. The laboratory shall ensure that necessary infrastructure facilities and documentary evidences are provided promptly to complete the assessment in scheduled time. The laboratory shall primarily be responsible for completing the assessment in scheduled time.

4.3.2.2 Conducting Assessment - The assessment shall be conducted as per the assessment plan agreed to during the opening meeting, and shall cover areas of the relevance to the scope of recognition of the laboratory. Evaluation shall include verification of test facilities, accommodation and environment, examination of documents and records, assessment of competence of laboratory personnel in conducting laboratory analysis/ testing, performance in witness tests, documentary evidence of participation in International Proficiency testing programs for relevant analyses and matrices and compliance to its Annual Plan for participation in such programs etc. A laboratory official, conversant with the activities of the division(s) being audited, should accompany each assessor. The non-conformances (NCs) identified by the assessment team shall be briefed and submitted to the auditee for necessary corrective action(s).

4.3.2.3 Closing meeting - The assessment shall conclude with a closing meeting during which the assessment team shall present its findings to the laboratory. All the members present in the opening meeting should preferably be present in the closing meeting. The non-conformance reports shall be acknowledged by QM or authorized signatory, as a token of acceptance and time frame for the corrective action(s) will be

agreed to. No NC shall be closed either during the assessment or at the time of closing meeting.

4.4 The Assessment team shall recommend for recognition of the laboratory for the specific scope in case there is no major or minor NC.

4.4.1 Major NCs shall cover the following :

4.4.1.1 Absence of a procedure required by ISO/IEC 17025

4.4.1.2 Significant failure to implement a procedure

4.4.1.3 Direct effect on the quality of test results.

4.4.2 All NCs other than listed under 4.4.1 qualify as minor NCs

4.5 The scope recommended shall not include the parameters that are sub-contracted by the laboratory. The lead assessor and the corresponding technical assessor shall duly sign on the recommended scope with appropriate recommendations.

4.6 In case NC has been raised by the team of assessors, the scope can be recommended subject to verification of the actions taken for closure of the NCs. Assessor shall not carry out any verification of the closure of NC, raised during the current assessment. No NC shall be closed at the end of the assessment. The laboratory shall ensure the closure of NC(s) within stipulated time period of **not more than two months**. The minor NC closure may not require on-site verification. However, closure of major NC may require on-site verification. In case of non-closure of the NCs within the stipulated time period, the laboratory shall have to apply a fresh after satisfying itself about the closure of the NCs and ensuring compliance to the requirements.

4.7 The Lead Assessor shall send Assessment Report to FSSAI within five (05) days after completion of the assessment of the laboratory.

4.8 ASSESSMENT FEE

The applicant laboratory shall bear assessment fee, as estimated by FSSAI, for the number of assessors and man-days deputed for assessment, based on the scope applied for and arrangement for travel/stay etc. as per Clause No. 12 .

4.9 RESPONSIBILITIES OF APPLICANT DURING THE ASSESSMENT

The laboratory is expected to provide the following assistance to the assessment team during the visit:

- 4.9.1** Arrangements for stay, local guidance, travel etc.
- 4.9.2** A representative of laboratory to accompany the team during the assessment.
- 4.9.3** A suitable room where members of the team can meet and discuss during the day and at the end of the day to exchange their notes and findings.
- 4.9.4** Secretarial and other office assistance like photocopying, etc.
- 4.9.5** Free accessibility to the records, test facilities as is deemed relevant by the assessors

4.10 ON-SITE VERIFICATION ASSESSMENT

The laboratory shall take necessary corrective actions within the stipulated time period of not more than two months for the closure of the NC's, brought on record by the assessment team, which will have to be verified by the corresponding assessor before considering it for grant of recognition. On-site verification assessment by the corresponding assessor may be required for closure of major NCs. This follow up visit, for full or partial assessment, may be carried out as above. The applicant Laboratory shall make all the arrangements as per Clause No. 4.9 and bear the assessment fee.

4.11 GRANT OF RECOGNITION

- 4.11.1** Based on the recommendation of the assessment team, FSSAI shall consider for grant of recognition to the laboratory. The laboratory will be issued a Certificate of recognition annexed with the scope of recognition. The decision of the FSSAI for granting the recognition or otherwise shall be final.

4.11.2 The recognition granted shall be valid for a period of three (03) years from the date of recognition. The renewal of recognition shall also be for three (03) years at a time. It shall be binding for the recognized laboratory to comply with the directions/any modification in the scheme, issued by FSSAI from time to time. The FSSAI recognized laboratory shall bound with the terms and conditions given under Clause No. 8.

4.12 CONSIDERATION FOR NABL ACCREDITATION

Laboratories having NABL accreditation shall be given due weightage depending upon the scope of accreditation, but, not binding to FSSAI for consideration.

5 SURVEILLANCE

- 5.1** The recognized laboratory shall be subjected to surveillance audit **at the end of the 1st year of recognition** to verify the continued compliance and maintenance of competency and the implementation of quality system established by the laboratory. The laboratory shall be subjected to verification audit in case of any complaints in sampling, testing and test reports or any other reasons.
- 5.2** During the validity of recognition, if the laboratory is found violating the terms and conditions of recognition, its recognition is liable to be suspended and may call for verification visits, for which the laboratory is liable to pay visit charges, as set out in Schedule of Fee given in Clause No. 12

6 EXTENSION OF SCOPE

The recognized laboratory can request for extension of its scope of recognition to cover additional products/matrices and test parameters of the interest to FSSAI by following the procedure as given in Clause No.4. The laboratory shall apply in the prescribed format by filling in the relevant information applicable to the extension of scope along with supporting documents and application fee prescribed in Clause no.12. In case the Quality Manual is revised, Current Quality Manual shall also be submitted for scrutiny along with adequacy audit

fee prescribed in Clause No. 10. On-site assessment shall be conducted for the applied scope for extension as per the procedure given in Clause No. 4. Assessment fee shall be applicable as per Clause no. 12.

7 RENEWAL OF RECOGNITION

- 7.1** Any recognition granted automatically expires at the end of the period of its recognition. The recognized laboratory shall apply to FSSAI **at least six months before the date of expiry of its recognition**. Application for renewal of recognition shall be rejected if application does not reach to FSSAI before six months of expiry of its current recognition.
- 7.2** The laboratory shall submit the application for renewal of its recognition as per Clause No. 4. Assessment for renewal of recognition shall be carried out similar to the initial assessment.
- 7.3** It shall be ensured during renewal assessment that the terms and conditions for recognition were not breached during the validity of recognition.
- 7.4** In case there is a impediment in renewal of recognition, the laboratory shall undertake to maintain the integrity of already received samples by providing appropriate storage conditions and return to the client in its original condition so that the same can be analyzed in another laboratory. No test report shall be issued by the laboratory when it has no valid recognition of FSSAI. The laboratory shall restrict itself from entertaining any sampling and/or testing for the commodities or product within the purview of FSSAI, 2006, when it has no valid recognition of FSSAI.

8 TERMS AND CONDITIONS OF RECOGNITION

- 8.1** The recognition shall be granted for a period of three (03) years, which shall be renewable for maximum period of three years at a time subject to satisfactory performance based on periodic review/ surveillance and assessment for renewal of the laboratory by FSSAI. The laboratory shall apply for its renewal at least six months before expiry of recognition.
- 8.2** The recognized laboratory shall perform all the tests in its approved premises as per the valid scope of recognition. Sub-contracting is permitted with prior permission of FSSAI / the customer in another FSSAI recognized

laboratory with valid scope of recognition. Sub-contracting is not permitted from the laboratory, which is not recognized by FSSAI.

- 8.3** The recognized laboratory shall not make any change in the Quality Management System, which forms the basis for the grant of the recognition and which prevents its compliance to the Scheme without prior recognition of FSSAI. It shall document all changes made to the Quality Management System and make records of such changes available to FSSAI within a period of 15 days of making the changes.
- 8.4** Any change in key personnel in relation to quality assurance, key technical functions or senior management shall be duly intimated to FSSAI within a period of 15 days.
- 8.5** The recognized laboratory shall inform FSSAI, immediately about the major changes/breakdown of equipment with reasons thereof etc. effecting testing of the relevant products/compliance to this laboratory scheme. The laboratory shall not carry out sampling or accept any sample for testing, when there is breakdown of the equipment to be required for performing the test(s). The laboratory shall not carry out sampling or accept any sample for testing, without prior recognition of FSSAI, when there is major change in the Quality Management System, which may affect performance of the testing.
- 8.6** The recognized laboratory shall inform FSSAI within 5 working days about the suspension / withdrawal of accreditation from NABL.
- 8.7** 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:
 - 8.7.1** Sample shall always be accompanied by a test request specifying the parameters and purpose.
 - 8.7.2** Whenever required, the recognized laboratory shall draw samples only by its own trained Sample Collecting Officers.
 - 8.7.2.1** 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.

- 8.7.2.2** The Sample Collecting Officer shall also ensure drawl of true representative sample of complete Assortment/ Batch/ Lot as the case may be.
- 8.7.3** The laboratory shall ensure, while accepting the samples / sample containers sealed by Food Safety Inspector / authorized representatives of laboratory, that the seal is intact with the details of the sealing indicated in the test request. A statement / record to this effect shall be made on receipt of sample and in the test report by the concerned laboratory.
- 8.7.4** The laboratory is liable to maintain confidentiality of samples and information thereof.
- 8.7.5 Test Methods:** 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.
- 8.7.6 Test Report :** 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.
- 8.7.6.1** The test report shall clearly indicate who has drawn the sample and the reference method.
- 8.7.6.2** 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.

- 8.7.6.3** The Test report/Certificate shall include information as per the details given in Form A/ Form B of FSSAI. Additionally the information shall be in compliance with the ISO/IEC 17025 requirements.
- 8.7.7 Sample Retention :** The laboratory shall keep the remnants of the sample after testing for a minimum period of **one month** except for perishable items, under stipulated storage conditions as given in Test Request by the customer or as deemed fit by the laboratory before they are disposed off or returned to the customer.
- 8.7.8** 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 the Food Business Operator (FBO) 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.
- 8.7.9** 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.
- 8.7.10 Record Retention:** The laboratory shall maintain the record of observations and a copy of the test report for a minimum period of **three years**.
- 8.7.10.1** 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.
- 8.7.11** The recognized laboratory shall participate in Proficiency Testing / Inter-Laboratory Test Comparison programmes organized by national and international bodies of repute for demonstrating technical competence of the laboratory personnel, at its own cost.
- 8.8** The recognized laboratory shall permit access to FSSAI officer(s)/team(s) deputed for the purposes of assessment, surveillance or investigation. It

shall give access to all relevant records, documents and equipment etc. for the purpose of verifying any details.

8.9 A recognized testing laboratory shall not use its recognition in such a manner as to bring FSSAI into disrepute/dispute and shall not make any statement relevant to its recognition, which FSSAI may consider to be misleading.

8.9.1 The recognized laboratory may make a public claim regarding its recognition. However, such claim shall be strictly based on the scope of its recognition. It shall discontinue claiming FSSAI recognition and withdraw all promotional and advertising material upon expiry / suspension or cancellation of its recognition.

8.9.2 The recognized laboratory shall furnish either a Performance Bank Guarantee (PBG) of `One Lakh or the payment of ` One Lakh (refundable) by way of Demand Draft/ Pay order drawn in favor of FSSAI before grant of recognition. This guarantee/ payment made can be invoked only with the due recognition of the CEO FSSAI, by his nominated official for breach of any of the terms & conditions of FSSAI. The referral laboratory need not submit any PBG. The PBG shall be forfeited under following circumstances :

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

8.9.2.2 If the laboratory is found indulging in unethical practices

8.9.3 The laboratory shall be issued a show cause for time bound reply and reasons furnished thereof shall be adjudged by the nominated official of FSSAI before any action for invocation of its bank guarantee/ payment is initiated

8.10 A laboratory may relinquish recognition by giving three month's notice in writing to FSSAI. It shall however either complete testing of all samples pending with it or return the pending samples along with the test requests. It shall not be entitled to any refund of recognition fee.

8.11 FSSAI may at its discretion cancel or suspend recognition, reduce the scope or direct reassessment due to changes in personnel/equipment, break-down of equipment, and/or if a complaint or any other information

is received which indicates and is proved that the technical competence and integrity/ confidentiality of the laboratory is not satisfactory.

8.12 The laboratory shall not use the recognition certificate/letter after its validity period is over or in case of cancellation of recognition.

8.13 The recognized laboratory shall not handle any sample of the client for testing when the laboratory fails to demonstrate satisfactorily to FSSAI that its direct/indirect trade association has no consequence/ bearing on its test results.

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

8.14.1 Number of samples received for testing and number of samples tested.

8.14.2 Number of samples failed specifying the parameter/test and other details.

9 EXPIRY/SUSPENSION AND CANCELLATION OF RECOGNITION

9.1 The recognition of laboratories shall automatically expire at the end of their validity, unless renewal is sought timely by the concerned laboratory along with the prescribed fee.

9.2 The recognition of laboratories shall also expire if the renewal is not agreed to by FSSAI without giving any reason.

9.3 The recognition of laboratories may also be suspended / cancelled any time during the recognition period for any and or the reasons given below:

9.3.1 If FSSAI feels that no useful purpose is being served by the continuation of the recognition of the laboratory.

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

9.3.3 If the laboratory is unable to maintain the Criteria for Recognition.

9.3.4 NABL suspends accreditation

9.3.5 If the laboratory is found indulging in unethical practices

9.4 FSSAI shall issue a show cause notice in case it intends to suspend / cancel recognition of a laboratory, as per clause 8.9 after due investigation,

if required. The concerned laboratory shall be given an opportunity to explain its view point before any action is taken against the laboratory.

9.5 The laboratory may apply afresh not earlier than one year from the date of cancellation / withdrawal / non-renewal of recognition.

9.6 The laboratory shall return the pending sample(s) in appropriate conditions to the customer for onward transmission to another recognized laboratory and undertake to retain records as per requirements of Clause 8.7.10 on cancellation / withdrawal / non-renewal / expiry of recognition.

10 APPEALS AGAINST REFUSAL/ CANCELLATION OF RECOGNITION

The Laboratories can appeal to FSSAI in case of refusal to grant and cancellation of existing recognition.

10.1 In case of appeal against refusal recognition, FSSAI will consider the application on merit basis and in case found necessary may order re-assessment of the laboratory, during which time the NCs pointed out by the assessment team should be rectified by the laboratory.

10.2 In case of appeal against the cancellation of recognition, the original certificate for the award of recognition must be submitted alongwith the appeal.

11 COMPLAINTS

Any complaints received regarding laboratory recognition shall be handled as per complaint handling procedure of FSSAI

12 SCHEDULE OF FEE

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

S no.	Purpose	Fee
1.	Application Fee: (Recognition / renewal of recognition for each scope as specified under Clause No. 4.1.1)	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 (for each as specified under Clause No. 4.1.1)	Rs.10,000/- per scope + Assessment Fee as defined at Sr. No. 3 above

12.2 The laboratory shall make these payments in the form of Demand Draft / Pay Order drawn in favor of "The Senior Accounts Officer, Food Safety & Standards Authority of India, payable at New Delhi.

13 RELAXATION IN CRITERIA

13.1.1 In case of need for specialized laboratory, the compliance to Criteria for Recognition as per Clause No. 3 may be relaxed at the discretion of FSSAI and laboratory may be recognized based on technical competence only.

13.1.2 Anything not covered under this recognition scheme shall be dealt on case to case basis under the provisions of FSSAI rules & regulations in force.

APPLICATION FOR LABORATORY RECOGNITION / RENEWAL OF RECOGNITION

(Under the FSSAI Laboratory Recognition Scheme)

A)	Type of Laboratory (please tick)	Level 1 / Level 2 / Referral Lab
B)	Type of Recognition (Please tick)	Fresh / Renewal
C)	Laboratory Details	
1.	Name of the Applicant Laboratory	
2.	Address of location for which recognition is sought?	
3.	Phone, Fax and e- mail	
4.	Address of Head office (if different from 2.)	
5.	Phone, Fax and e- mail (if different from 3)	
6.	Type of Organization (Govt./Semi Govt./Private/Educational Institution/Other)	
7.	Legal status and date of establishment (Please give registration number and name of the authority who granted the registration with all documentary proof) Attach documentary Proof.	
8.	Laboratory Premises/Layout	
8.1	Total space available (Sq Feet)	
8.2	Layout plan of the laboratory indicating testing areas, seating plans, receipt and storage of samples, administration and other facilities(Attach Layout Plan)	
9.	Other Accreditations / Recognitions / Approvals (Attach List)	
D)	Organization Details	
1.	Manpower details	

2.	Name and designation of the person responsible for technical operation/ Technical Manager(s).	
3.	Name and designation of the person responsible for Quality Management Systems/ Quality Manager.	
4.	Total No. of personnel	
5.	Senior management (No.)	
6.	Testing personnel (No.)	
7.	Details of professionally qualified staff with qualification (Enclose details as per format given at Appendix I)	
8.	Authorized signatories for issuance of test reports (enclose details as per format given at Appendix II)	
9.	Authorized Sample Collecting Officers (enclose details as per format given at Appendix III)	
E)	Technical information	
1.	Scope for recognition proposed (in case of Fresh Recognition) or Recognized scope by FSSAI (in case of renewal of recognition). (Please attach in the format as per Appendix IV)	
2.	Date of validity of recognition (in case of renewal of recognition)	
3.	Has the laboratory implemented Quality Management System (QMS) as per	

	guidelines of ISO/IEC 17025: latest version?	
4.	Does the QMS cover the scope for recognition as required by FSSAI	
5.	Whether accredited by NABL as per ISO/IEC 17025 latest version?	
6.	If yes, does the scope of accreditation cover the scope applied for FSSAI recognition ? (please attach certificate and scope of accreditation along with a separate comparison sheet at)	
7.	List of equipment with laboratory (Attach at Appendix V in the format given)	
8.	List of Standard/ Certified reference materials (SRM/CRM) available for use: (Attach at Appendix VI in the format given)	
9.	Internal Audit and Management Review:	
10.	Date of last Internal Audit, its findings and corrective actions taken (Attach copies)	
11.	Whether all requirements of ISO/ IEC 17025: 2005 covering all activities of laboratory have been audited at least once in last one year	
12.	Date of last Management review (Attach copy of Agenda and Minutes of Management Review)	
13.	Details of subcontracting, if any	
14.	Proficiency Testing: Participation in International and National PT programme : (Attach details as per format at Appendix VII)	
15.	Total Turnover (in terms of Test reports issued for last 3 years as per the scope)	

16.	For domestic samples	
17.	For imported Samples, if any.	
18.	Any complaints/disputes in last three years pertaining to laboratory testing activities (Please attach details)	
F)	Details of Fee:	
1.	Application Fee in the form of Demand Draft / Pay Order payable to FSSAI (No and Date)	

G). Declaration by The Laboratory:

I / We declare that

- a) We have read & understood the terms and conditions of the FSSAI Laboratory Recognition Scheme and are willing to abide by them
- b) We agree to comply fully with ISO/IEC 17025: latest version for the recognition of testing laboratory.
- c) We agree to comply with recognition procedures, pay all costs for assessment, verification visit (if any), surveillance and reassessment irrespective of the result.
- d) We agree to co-operate with the assessment team appointed by FSSAI for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of recognition.
- e) We satisfy all national, regional and local regulatory requirements for operating a laboratory.
- f) In case of breach of any of the terms and conditions of FSSAI Laboratory recognition scheme, the decision to invoke action/ Bank guarantee/ payment made, by FSSAI is final and binding on us.
- g) All information provided in this application is true to the best of our knowledge.

Date:

Signature of Authorized Signatory

Place:

Name

Designation

Stamp

Appendix I

Details of Technical Staff

S.No	Name	Designation	Academic and Professional Qualifications	Relevant Trainings	Experience related to present work (in years)

Appendix II

Details of Authorized Signatories

S. No	Laboratory/ Department/ Section	Name & Designation of Signatory	Qualification with Specialization	Experience in years related to present work	Relevant Training	Authorized for which specific area of testing	Specimen Signature

Appendix III

Details of Authorized Sample Collecting Officers

S. No	Name	Designation	Academic and Professional Qualifications	Experience related to present work (in years)

Appendix IV

Scope for Recognition

Sl no	Group of products, materials or items tested	Specific tests or types of tests performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	MU (±)

Note . Laboratories performing site testing shall clearly identify the specific tests on product(s)/ material performed at permanent laboratory and/ or at site.

Appendix V

Details of Equipment

S.No.	Name of equipment	Make/Model/year of make	Receipt date & date placed in service	Range and accuracy	Purpose / scope of the equipment	Maintenance (In house/ outside)	Date of last calibration	Calibration due on	Calibrated by

Appendix VI

Details of Reference Material/Culture

S.No.	Name of reference material/ strain/ culture	Source	Date of expiry/ validity	Traceability

Appendix VII

**Details of participation in Inter Laboratory Comparison (ILC) /
Proficiency Testing (PT) Programmes**

Sl. no.	Product/ Material	Details of Test(s)	Date of Testing	Nodal Laboratory	Performanc e in terms of Z score	Corrective action taken (If any)
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Annexure II

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

FORM A
(Refer regulation 2.2.2)
CERTIFICATE OF ANALYSIS BY THE REFERRAL FOOD LABORATORY

Certificate No.

Certificate that the sample, bearing numberpurporting to be a sample/of
 Was received on with Memorandum No. Dated From
 [Name of the Court] for analysis. The condition of seals on the container and the
 outer covering on the receipt was as follows:

.....

I (Name of the Director)_ found the sample to be
 (Category of food sample) falling under Regulation No.
 of Food Safety and Standards(Food Products and Food Additive) Regulations,
 2011. The sample was in a condition fit for analysis and has been analyzed on
 (Give date of starting and completion of analysis)..... and the result of its
 analysis is given below /*was not in a condition fit for analysis for the reasons given
 below:—

Reason:—

.....

Analysis Report:—

(i) Sample Description:—

.....

(ii) Physical Appearance:—

.....

(iii) Label: —

S.No.	Quality Characteristics	Name of the Method of the test used	Results	Prescribed Standards as per:-
				(a) As per Food Safety and Standards (Food Products and Food Additive) Regulations, 2011 (b) As per label declaration or proprietary foods (c) As per the provisions of the Act and Regulations, for both above

Opinion **

Place:

(Signature)

Date:

Director Referral Food Laboratory

(Seal)

* Strike out whichever is not applicable

** When opinion and interpretation are included, document the basis upon which the opinions/interpretations have been made.

Format for Test Report

FORM B
Report of the Food Analyst
(Refer Regulation (ii) of 2.3.1)

Report No. _____.

Certified that I _____ (name of the Food Analyst) duly appointed under the provisions of Food Safety and Standards Act, 2006 (34 of 2006), for _____ (name of the local area) received from _____* a sample of _____, bearing Code number and Serial Number _____ of Designated Officer of _____ area* on _____ (date of receipt of sample) for analysis.

The condition of seals on the container and the outer covering on receipt was as follows:

I found the sample to be (category of the sample) falling under Regulation No. _____ of Food Safety and Standards (Food Products and Food additive)Regulations, 2011. The sample **was in a condition fit for analysis and has been analysed on _____ (give date of starting and completion of analysis) and the result of its analysis is given below/

** was not in a condition fit for analysis for the reason given below:

Reasons:

.....

Analysis report

(i) Sample Description

.....

(ii) Physical Appearance

.....

(iii) Label

.....

S.No.	Quality Characteristics	Name of the Method of the test used	Results	Prescribed Standards as per (a) Food Safety and Standards (Food Products and Food additive) Regulations, 2011 (b) As per label declaration for proprietary food (c) As per provisions of the Act, rules and regulations for both the above.

Opinion***

Signed this _____ day of _____ 20

(Sd/-) Food Analyst.

Address: * Give the details of the senders

** Strike out whichever is not applicable

*** When opinion and interpretation are included, document the basis upon which the opinions/interpretations have been made.