

Notice calling for suggestions, views, comments etc from stakeholders on the draft Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2017.

F.No. 11/202/LAB REC/QA/FSSAI/2016.-

1. Short title.- (1) These regulations may be called the Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2017.

2. Definitions (1) In these regulations, unless the context otherwise requires, --

- (a) **“act”**-means the Food Safety and Standards Act, 2006 (34 of 2006);
- (b) **“accreditation”** means a third party attestation of the competence of the food laboratories to carry out its functions effectively;
- (c) **“accreditation body”** means an authority that performs accreditation;
- (d) **“adequacy audit”** means the audit conducted to ensure that essential requirements of testing and other related facilities are available in the food laboratory, either done on-site or based on documents;
- (e) **“food analyst”** means an analyst appointed under section 45 of FSS Act, 2006;
- (f) **“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 recognized by the Food Authority under section 43;
- (g) **“initial audit”** means the audit conducted to ensure the overall competency of a laboratory to carry out testing of food items as per Food Safety and Standards Regulations, 2011 at the time of recognition;
- (h) **“notified laboratory”** means a laboratory notified by the Food Authority under sub-sections (1) and (2) of section 43 of the Act;
- (i) **“referral laboratory”** means a laboratory established and/or recognized by the Food Authority by notification under sub section (2) of section 43 of the Act;
- (j) **“reference laboratory”** means those notified and referral laboratories of Food Safety and Standards Authority of India which are accredited as per appropriate ISO/IES standards for method development, method validation, proficiency testing and training by National / International accreditation body signatory to the International Laboratory Accreditation Cooperation (ILAC) or the Asia Pacific Laboratory Accreditation Cooperation (APLAC) or an equivalent accreditation body;
- (k) **“sample”** – means a sample of any article of food taken under the provision of Food Safety and Standards act or any rules and regulations made thereunder.

(2) All other words and expressions used herein and not defined, but defined in the Act, rules or regulations made thereunder, shall have the meanings assigned to the them in the Act, rules or regulations, respectively.

3. Food laboratories and their functions.-

(1) The Food Authority may recognize and notify food laboratories and research institutes as notified laboratory or referral laboratory to carry out the functions entrusted by the Act or any rules and regulations made thereunder.

(2) Notified Laboratory shall carry out the following functions, namely:

- (a) analysis of food samples send by the Food Safety Officer or any other person authorized under this act, Food business operator and purchaser.
- (b) analysis of import food samples send by the Authorized officer or any other person authorized under this act.
- (c) analysis of food sample send for the purpose of surveillance.

(3) Referral Laboratory shall carry out the following functions, namely:

- (a) 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;
- (b) Investigation for the purpose of fixation of standard of any article of food;
- (c) Investigation in collaboration with the laboratories of 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.
- (d) Ensuring that the laboratory follows the scientific protocols laid down for handling/testing the articles of food.
- (e) 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.
- (f) Laying down mechanism for ensuring that personnel of the laboratory adhere to high professional standards and discipline.
- (g) 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.
- (h) As an appellate laboratory in case of any dispute over the results of analysis between two parties (Laboratories/ Food Business Operators) within the ambit of Food Authority,
- (i) Such other functions, as the Food Authority may lay down for Referral Laboratories, from time to time.

(4) The Food Authority may also recognize notified and referral laboratories of Food Authority as reference laboratory for the purpose of method development, method validation, proficiency testing and training. Specifically the reference laboratory shall carry out the following functions, namely:

- (a) Developing country wide standards for routine testing procedures and reliable testing methods.
- (b) Shall be the resource center for provision of information for certified reference materials (CRMs) or reference materials (RMs).
- (c) Provide technical support in the area of competence.
- (d) Evaluate the performance of other notified laboratories.
- (e) Coordinate exchange of information amongst notified laboratories.
- (f) Collaborate for data generation among their network and collate the data related to their specific domain.
- (g) Such other functions, as may be specified by the Food Authority from time to time.

4. Criteria for recognition and notification food laboratories.-

- (1) The food 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.' The applicant laboratory shall have adequate capability and competence for testing of food safety and quality parameters as per the requirements of Food Safety and Standards Act 2006.
- (2) The food laboratory shall have a valid accreditation certificate for the relevant scope against ISO/IEC 17025 by a national / international accreditation agency which is signatory to ILAC or APLAC for carrying out accreditation of laboratories.
- (3) The food laboratory shall have qualified Food Analyst as per Food Safety and Standards Rules 2.1.4 (1) for testing food samples received under Food Safety and Standards Act 2006.
- (4) A private food laboratory recognized by accreditation body, having authorized signatory as designated by the accreditation body in their lab, instead of Food Analyst as per FSS Rules 2.1.4(1), shall also apply for the recognition. The recognition shall be subjected to the condition that the authorized signatory(s) of the laboratory shall clear the food analyst examination within one year of the recognition and notification by the Food Authority or as and when the food analyst examination is conducted by the Food Authority after the recognition and notification by the Food Authority, whichever is earlier.
- (5) The food laboratory shall have all the infrastructure and facilities including equipments required for carrying out the analysis as per the scope applied for.
- (6) The Food Authority reserves the right to recognize and notify or curtail the scope of recognition or suspend or de-recognize a laboratory.

5. Recognition process

(1) Procedure for recognition of laboratories. -

- (a) A laboratory fulfilling the eligibility criteria mentioned at regulation 4 of these regulation shall submit an application form along with the documents as prescribed in Form A of schedule I

respectively along with requisite fees as may be prescribed by the Food Authority from time to time.

- (b) Duly filled application form shall be signed by head or an authorized representative(s) of the Laboratory.
- (c) In case of authorized representative signing the application form, authority letter with name and address of authorized person nominated by Director(s)/partners/proprietor shall be submitted.
- (d) The Food Authority shall scrutinize all applications for recognition for completeness and deficiencies. On scrutiny, deficiencies, if any, shall be informed to applicant within 30 days from the date of receipt of application. The applicant shall provide the information required by the Food Authority within 30 days of the receipt of the communication, failing which the application shall be rejected without any further reference. The fees paid by the applicant for recognition shall not be refunded under any circumstances.
- (e) All applications found to be completed with enlisted documents and other prerequisite shall be registered by assigning a 'Registration Number' which shall be used in all the future correspondence with the laboratory.
- (f) Rejected and closed application shall not be re-opened again. However, laboratory at its discretion may apply afresh with prescribed processing fee etc.
- (g) Adequacy audit/desktop audit (either done on-site or based on documents) of the application and all the documents provided therewith shall be done. Deficiency observed, if any, shall be conveyed to the applicant laboratory for clarification within the given timeframe.
- (h) Food Authority shall decide on the recognition of the applicant Laboratory on the basis of the scope mentioned on the accreditation certificate issued by the accreditation body and the criteria fulfilled by the laboratory as mentioned at regulation 4 of these Regulation
- (i) Food Authority reserves the right to reject an application for the reason (s), to be recorded in writing.
- (j) Execution of Agreement With Food Authority.-

(i) Once the Food Authority decides in-principle to recognize a laboratory, the applicant shall execute an agreement with the Food Authority as prescribed by the Food Authority from time to time. The said Agreement shall come into force from the date of notification of the laboratory in the Gazette of India.

(ii) The laboratory shall follow the terms and conditions and obligations of the agreement strictly, after getting recognition.

(iii) Before signing the Agreement, a private Laboratory shall deposit an interest-free Security Deposit of amount as may be prescribed by the Food Authority from time to time.

(iv) No Security Deposit shall be payable by laboratories owned/promoted/ operated by the statutory bodies, government institutions, government aided or established institutions, research institutions funded by government, UGC/ICMR/ICAR colleges and institutions. But these laboratories shall sign the Agreement with Food Authority as per format prescribed at

schedule II. However, they shall at all times be governed by adherence to the performance standards and ethical practices, and shall be liable for suspension/de-recognition in the event of non-compliance or breach of any of the requirements stated in these regulations.

(2) Notification of Laboratory. -

The Food Authority shall notify the recognized Food Laboratories in the Gazette of India and shall also update the directory of same along with their validity and scope of accreditation on its website.

(3) Audit. -

- (a) If required, initial audit may be carried out by Food Authority or persons or agencies authorized by Food Authority with/without the accreditation bodies.
- (b) Food Authority shall reserve the right to conduct surprise audit, to monitor/review the functioning of laboratory, or investigation, refer any complaint regarding its functioning, at laboratory's premises, as decided by competent authority.
- (c) For routine monitoring / review of the activities of notified laboratories, Food Authority shall reserve the right to conduct scheduled / surveillance audits at a frequency as decided by competent authority.

(4) Validity. -

- (a) The recognition shall be valid for the specific period as indicated by Food Safety and Standards Authority of India, which shall be renewable subject to satisfactory performance based on periodic review/surveillance and assessment for renewal of the food laboratory by Food Safety and Standards Authority of India.
- (b) The recognition of food laboratories shall automatically expire at the end of their validity, unless renewal is sought timely by the concerned food laboratory along with the prescribed fee.
- (c) The recognition of food laboratories shall also expire if the renewal is not agreed to by Food Authority without giving any reason.

(5) Procedure of Renewal of Recognition.-

- (a) Food laboratories, may if so desire make an application for renewal, not later than 60 days prior to the expiry date indicated in the certificate of recognition.
- (b) The Food Authority may consider the application for renewal on the basis that it continues to meet the criteria for recognition as specified in the regulation 4 of these regulations and also based on the performance of the laboratory.

(6) Addition and Deletion in the Scope of the Recognition.-

The Food Authority shall be informed in advance regarding change (addition and/or deletion) in the scope of the laboratory; and also after completion of the process. The laboratory has to submit the fresh accreditation certificate issued by the accreditation body with the changed scope along with the list of documents as given in the Schedule I, if there is any change in the information provided in these documents earlier, once the process involved in change of scope is completed. Food

Authority may carry out audit to the laboratory to ensure the availability of all the requisite requirements for change in the scope.

(7) Procedure for suspension or cancellation of recognition. -

(a) The Food Authority, may suspend the recognition of food laboratory by an order for following conditions:

- (i) The laboratory has made an application to be declared an insolvent;
- (ii) The laboratory has failed to carry out any orders issued by the Food Authority;
- (iii) In case of suspension of accreditation of laboratory by the concerned accrediting agency,
- (iv) Laboratory fails to observe terms & conditions and obligations of the agreement.
- (v) The laboratory has in any other manner become incompetent to continue to be accredited as required under these regulations;
- (vi) Laboratory has failed to provide access to their records and furnish necessary information to the Food Authority to conduct an assessment or investigation on them; if any.
- (vii) In case of expiry of accreditation, the Food Authority notification/recognition of the laboratory would be temporarily suspended till fresh accreditation;
- (viii) Shifting of the laboratory premises;
- (ix) Change in the name, proprietorship/ownership with/without the address of the laboratory;
- (x) Any other reason that the Food Authority deems fit and necessary.

(b) The Food Authority may cancel the recognition of food laboratory by an order for following condition:

- (i) The laboratory has committed a fraudulent act;
- (ii) Cancellation of accreditation of laboratory by the concerned accrediting agency.

(iii) In the event that the food laboratory after suspension still failed to rectify the defects or to comply with the requirements of these regulations or repeated suspension (more than two) during an operative period;

(c) In case of cancellation the security deposit shall be forfeited.

(8) Revocation of Suspension.-The suspension shall be revoked once the laboratory:

- (a) Submits the fresh accreditation certificate(s) from accreditation body, in case of shifting the premises; or
- (b) In the other situations suspension of the food laboratory may be revoked after completion of the suspension period, subject to the submission of relevant clarification or taking suitable corrective action, as deemed fit to the situations referred and accepted by the competent authority.

(9) Cooling Period.- The cooling period for any suspended laboratory (except in cases of shifting or change in name or ownership/ proprietorship) shall be minimum two years which can be extended by the competent authority with valid reasons.]

6. Responsibilities of the Food Laboratory.-

(1) The recognized food laboratory shall perform all the test in the approved premises as per the valid scope of recognition. Sub-contracting is permitted with prior permission of Food Authority for with another Food Authority recognized laboratory with valid scope of recognition.

(2) The recognized laboratory shall not make any change in the Quality Management system, which forms the basis for the grant of the recognition. It shall document all changes made to the Quality Management System and make records of such changes available to Food Authority within a period of 15 days of making the changes. The laboratory shall not carry out sampling or accept any sample for testing, without prior recognition of Food Authority, when there is major change in the Quality Management System, which may affect performance of the testing.

(3) Any change in key personnel in relation to quality assurance, key technical functions or senior management shall be duly intimated to Food Authority within a period of 15 days.

(4) The recognized laboratory shall inform Food Authority, immediately about the major changes/breakdown of equipment with reasons thereof 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).

(5) The recognized laboratory shall inform Food Authority within 5 working days about the suspension/withdrawal of accreditation from relevant accreditation body.

(6) The test report shall be treated as strictly confidential between the testing laboratory and Food Authority. No information regarding the sample or its results shall be divulged to any person including the FBO who may deliver the sample for testing on behalf of Food Authority. 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 Food Authority, the details of testing shall be made available to Food Authority.

(7) The laboratory shall maintain the record of observations and a copy of the test report for a minimum period of three years.

(8) 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.

(9) The recognized laboratory shall permit access to Food Authority officer (s)/teams(s) deputed for the purposes of assessment, surveillance or investigation and access to all relevant records, documents and equipments etc. for the purposes of verifying any details.

(10) Recognized laboratory shall not use its recognition in such a manner s to bring Food Authority into disrepute/dispute and shall not make any statement relevant to its recognition, which Food Authority may consider to be misleading.

(11) Food Authority may at its discretion cancel or suspend recognition, reduce the scope or direct reassessment due to changes in personnel/equipments, 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.

(12) The laboratory shall not use the recognition certification/letter after its validity period is over or in case of cancellation of recognition.

(13) The recognized laboratory shall share all analytical data with Food Authority as and when required and also submit the following statements at the end of every financial year after recognition of the laboratory by Food Authority.

(a) Number of samples received for testing and number of samples tested.

(b) Number of samples failed specifying the parameter/test and other details.

(14) All Food Laboratories recognized by the Food Authority, may mention the same on their stationary, publicity media, communications etc. However, the recognized Laboratory shall ensure that the recognition is not misrepresented and Food Authority is not brought into any disrepute in any manner. Food Authority shall not be responsible of any sort of misdeed by the Laboratory.

7. Dispute Resolution.-

(1) Appeal. - (a) A laboratory aggrieved by the decision/order of Food Authority relating to its recognition/suspension/cancellation may file an appeal to the Chairperson of the Food Authority within a period of thirty days from the date of the decision/order, in the Form-B at schedule II.

(b) Provided that the Chairperson may entertain an appeal after the expiry of the said period, if it is satisfied that the appellant was prevented by sufficient cause from filing in appeal in time.

(c) Chairperson has the authority to curtail or extend the time period of suspension or de-recognize the laboratory.

(2) All correspondence/complaint(s) shall be addressed to CEO, Food Authority

8. Special Situations.-

(1) The recognized laboratory shall ensure that the Food Authority always has up-to-date information about their establishment and shall inform the Food Authority of any modification including change of address, change of name of food laboratory and change of constitution.

(2) In such cases, the recognition and notification shall be deemed to be withdrawn till the receipt of revised accreditation certificate/appropriate communication from relevant accreditation body regarding change of address, change of name of food laboratory and change of constitution, as the case may be.

(3) The food laboratory shall submit the following documents within 15 days, of modification, failing which the laboratory shall be temporarily suspended. However, in case such documents are not submitted within 3 months, the recognition of food laboratory shall be cancelled and security deposit forfeited,-

- (a) Relevant document with respect to change of address, change of name of food laboratory and change of constitution, as the case may be.
- (b) Fresh agreement signed between the authorized person form food laboratory and Food Authority.
- (c) Revised accreditations certificate/appropriate communication from relevant accrediting agency regarding change of address, change of name of food laboratory and change of constitution, as the case may be.

9. Other Laboratories.-

(1) Notwithstanding anything contained in regulation 2(f) above and the requirements prescribed for recognition in these regulations, the Food Authority may recognize fully equipped and functional in house laboratories run by associations or consortia of food business or individual food business, for carrying out the following functions, namely:-

- (a) analysis of surveillance samples;
- (b) analysis of samples submitted by FBOs in fulfillment of requirement detailed in Annexure-3 relating to condition of license of Food Safety and Standards (licensing and Registration of food business) Regulations, 2011.

(2) The recognition of these laboratories shall be as per the conditions and procedure prescribed by Food Authority which may include inspection authorized by FSSAI or State Food Safety Authorities from time to time.

Schedule 1
(See Regulation 5)

FORM-A

APPLICATION FOR RECOGNITION OF LABORATORY

To

The Chief Executive Officer

Food Safety and Standards Authority of India

FDA Bhawan, New Delhi – 110002

Application No.....of 20..... (to be filled by receiving office)		
1.	Name and address of the applicant	
2.	E-mail address	
3.	Telephone No.	
4.	Mobile No.	
5.	Permanent Account Number (PAN)	
6.	Category of Applicant: Govt /Private/ Autonomous body of Govt.	
7.	Name and Address of the Laboratory	
8.	Name and address of the Accreditation Body (Attach certificate of signatory to APLAC/ILAC for accreditation as per ISO/IEC 17025)	

9.	Accreditation Certification number(s) along with date of issue and validity [Attach copy of Accreditation certificate/(s)]	
10.	<p>Details of Accreditation (Enclose the documents in support)</p> <p>a) Categories of food/test</p> <p>b) Specify food articles/test</p> <p>c) Accredited scope of testing</p>	
11.	<p>Details of Laboratory</p> <p>a) Testing facilities available (Enclose list of the food items with testing parameters of products as per relevant FSSR, 2011 as amended from time to time.)</p> <p>b) Infrastructure in terms of land, building, laboratory space etc (Enclose a layout plan of the laboratory with measurements of areas)</p> <p>c) Infrastructure available in terms of equipment and machinery (Enclose list of test equipments with their least count and range against the parameters tested as per relevant FSSR, 2011 as amended from time to time.)</p> <p>d) Infrastructure in terms of manpower to carry out different functions of the laboratory (Enclose a list of employees with their designation, educational qualification and experience in the relevant are of work)</p>	
12.	<p>Details of Food Analysts available in the laboratory (Enclose separate sheet for every Food Analyst)</p> <p>a) Name and Qualification of Food Analyst</p> <p>b) Whether qualified under Rule 2.1.4 of the Food Safety and Standards Rules, 2011(Give details and certificate of Food Analyst)</p> <p>c) Details of Trainings/Specialized trainings</p>	

	attended by Food Analyst	
13.	Details of the Proficiency Testing and Inter Laboratory Comparisons attended and/or organized by the laboratory. (Attach a list of all such programs attended and organized with schedule of next two years)	
14.	Whether the Laboratory was suspended/debarred/black- listed/fined etc by court of law, Central Government/ State Government or any public authorities including Food Authority in the past or such proceedings are pending/contemplated against the laboratory (Give details thereof)	
15.	Capacity of analysis of food samples (Enclose a list of food items to be analyzed in a month)	
16.	Quality Manual (Attach copy of quality manual)	
17.	Particulars of fee deposited for processing of application	
18.	Any other information laboratory wants to provide	
19.	Signature of the applicant with seal	

List of document to be enclosed with the application

- a) Application fee receipt/DD or pay order;
- b) Certificate of accreditation along with copy of scope;
- c) Certificate of signatory to APLAC/ILAC for accreditation as per ISO/IEC 17025;
- d) Copy of quality manual;
- e) Certificate of all Food Analyst;
- f) List of the food items tested in laboratory, with testing parameters of products as per relevant FSSR, 2011 as amended from time to time;
- g) List of test equipments with their least count and range against the parameters tested as per relevant standards;
- h) Capacity of analysis of food samples on weekly basis (Enclose a list);
- i) List of all Proficiency Testing and Inter Laboratory Comparison Programs attended and organized with schedule of next two years;
- j) List of employees with their designation, educational qualification and experience in the relevant are of work;
- k) Layout plan of the laboratory with measurements of areas.

Verification

I _____s/d/o _____do hereby solemnly affirm and verify that to the best of my knowledge and belief the information given in the application and the annexures/ statements accompanying with it, is correct and complete. I clearly understand that the recognition is liable to be cancelled and security deposit forfeited by Food Authority, if any information or data, submitted with the application is found to be incorrect or false at any stage or any condition of recognition granted against this application is violated.

I further declare that I am making this application in my capacity as _____ in (name of the laboratory) and that I am competent to make this application and verify it by virtue of Authorization issue by the competent authority a photo/ attested copy of which is enclosed herewith.

Place:

Date:

Signature
with seal

Note :The application form, including the verification portion and Supplementary Information Form, must be signed in case of an individual, by the individual himself or a person duly authorized by him; in case of Hindu Undivided Family, by the karta; in case of a partnership firm, by the managing partner; in case of a company, by a person duly authorized in the behalf by the Board of Directors; and in any other case, by a person in charge of or responsible for the conduct of the business.

Schedule II

FORM-B

APPEAL

To

The Chairperson
Food Safety and Standards Authority of India
FDA Bhawan, New Delhi – 110002

Appeal No. _____ of 20____ (to be filled by the receiving office)

1. Name and address of the Applicant:
2. Name and address of the Laboratory:
3. Date of order appealed against (also enclosed copy of order):
4. In view of 3 above, whether the appeal is within the limitation period:
(If not, enclose justification for filing the appeal after limitation period)
5. Relief claimed in the appeal:
(Enclose complete statement of facts (with supporting documents) and Grounds for appeal, duly signed by the appellant)
6. Address to which notice may be sent to the applicant:
(Also give E-mail id, Fax Number and Mobile Number of the concerned person)

Signature of Appellant with seal

VERIFICATION

I _____ S/o _____ the appellant, do hereby verify that what is stated above is true to the best of my knowledge and belief:

Date: _____

Place: _____

Signature of Appellant with seal

Note :The form of appeal, ground of appeal and the form of verification must be signed in case of an individual by the individual himself or a person duly authorized by him; in case of Hindu Undivided Family by the karta, in case of a partnership company, by the managing partner; in case of a company, by a person duly authorized by the Board of Directors and in any other case, by the person in-charge or responsible for the conduct of the business.