

File No. 11012/2/2021-QA-FSSAI
भारतीय खाद्य सुरक्षा और मानक प्राधिकरण
Food Safety and Standards Authority of India
(खाद्य सुरक्षा एवं मानक अधिनियम, 2006 के तहत स्थापित एक वैधानिक प्राधिकरण)
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
(गुणवत्ता आश्वासन प्रभाग)
(Quality Assurance Division)
एफडीए भवन, कोटला रोड, नई दिल्ली-110002
FDA Bhawan, Kotla Road, New Delhi – 110002

दिनांक, 28th दिसम्बर, 2022
Dated, the 28th December, 2022

नोटिस/NOTICE

विषय/Subject: Recognition/Approval of accreditation bodies by FSSAI to accredit food testing laboratories.

In pursuance to section 16(2e) in conjunction with section 43 (1&2) of FSS Act, 2006, it has now been decided by the Competent Authority to recognize/approve accreditation bodies for accreditation of food testing laboratories.

2. Interested Accreditation bodies fulfilling the requirements as mentioned in the attached document “*Requirements for Accreditation Bodies for approval by the Food Authority to accredit Food Testing Laboratories*” may submit the application to FSSAI in the prescribed format as mentioned in the above document for approval of the Food Authority.
3. The complete application in all respect shall be submitted in sealed envelope superscribed as “Application for recognition by FSSAI as Accreditation body for food testing laboratories” to Advisor (QA), Food Safety & Standards Authority of India, 3rd Floor, FDA Bhawan, Kotla Road, Near Bal Bhawan, New Delhi-110002.
4. This issues with the approval of the Competent Authority.



(डॉ हरिंदर सिंह ओबरोय)
(Dr. Harinder Singh Oberoi)
सलाहकार (गुणवत्ता आश्वासन)
Advisor (Quality Assurance)

प्रतिलिपि/Copy to: -

IT Division, FSSAI HQ – with a request to upload on official website.

**Requirements for Accreditation Bodies
For
Approval by the Food Authority
To
Accredit Food Testing Laboratories.**

**Food Safety & Standards Authority of India (FSSAI)
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, New Delhi 110 002**

1. Background

1.1. The Food Safety and Standards Authority of India (FSSAI) is established under the provisions of Food Safety and Standards Act, 2006 as a statutory body for laying down science based standards for articles of food and to regulate manufacture, storage, distribution, sale and import of food so as to ensure availability of safe and wholesome food for human consumption.

1.2 Section 16(2e) in conjunction with section 43 (1&2) of FSS Act, 2006 requires Food Authority to frame regulations w.r.t the procedure and guidelines for accreditation of laboratories and notification/recognition of accredited laboratories

1.3 As per section 43 of FSS Act 2006 the Food Authority may notify food laboratories and research institutions **accredited by National Accreditation Board for Testing and Calibration Laboratories or any other accreditation agency** for the purposes of carrying out analysis of samples by the Food Analysts under this Act;’

1.4 FSS Rules 2011 (Rule 2.4.1.10 and 2.4.5) also mentions that the samples have to be sent to **an accredited/NABL accredited/FSSAI Recognized laboratory** for testing.

1.5 FSSAI in 2018 came up with **Food Safety and Standards (Recognition and Notification of Laboratories) Regulation, 2018** laying down criteria for notifying and recognizing food laboratories, procedure for notification of food laboratories, de-notification & de-recognition of laboratories. Sub-regulation 4(2) of the said regulations mentions- *‘For being recognized and notified, every food laboratory shall have accreditation against ISO/IEC 17025 by the National Accreditation Board for Testing and Calibration Laboratories or such other equivalent accreditation agency as may be approved by the Food Authority;’*

1.6 By virtue of the above provisions, FSSAI has been notifying laboratories which are accredited by **National Accreditation Board for Testing and Calibration Laboratories (NABL)** for the purpose of testing.

1.7 Keeping in view of the request received from other accreditation bodies for recognition by FSSAI, It has now been decided to engage **other accreditation agencies for food testing laboratories** which would enable the laboratories to choose the best service provider and bring global expertise into laboratory accreditation program in India. This will also fast-track the accreditation process of laboratories in India to meet the rising demand of food safety requirements.

2. Scope of work:

To provide accreditation services to:

- (a) Testing laboratories in accordance with ISO/ IEC 17025 ‘General Requirements for the Competence of Testing and Calibration Laboratories’
- (b) Calibration laboratories in accordance with ISO/ IEC 17025 ‘General Requirements for the -- Competence of Testing and Calibration Laboratories’
- (c) Proficiency Testing Providers (PTP) in accordance with ISO/IEC 17043 “Conformity assessment — General requirements for proficiency testing” and
- (d) Reference material producers (RMP) in accordance with ISO 17034 “General requirements for the competence of reference material producers”.

3. Eligibility requirements:

An accreditation body seeking recognition must meet all of the following requirements:

- (a) Demonstrates compliance with ISO/IEC 17011:2017(E).
- (b) Demonstrates that it is a full member of the International Laboratory Accreditation Cooperative (ILAC).
- (c) Demonstrates that it is a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC 17011:2017(E) with a scope of "Testing: ISO/IEC 17025."
- (d) Will comply with all additional and specific requirements for accreditation bodies as per FSSAI.

4. Application process:

- **Application form:**

An accreditation body seeking initial recognition or renewal of recognition must submit an application to FSSAI in prescribed Application form (Annexure I) demonstrating that it meets the eligibility requirements.

- **Documents:**

The accreditation body must submit documentation of conformance with ISO/IEC 17011:2017(E) and separate documentation of ILAC membership and ILAC MRA signatory status demonstrating competence to ISO/IEC 17011:2017(E) with a scope of "Testing: ISO/IEC 17025," in meeting the requirements of 3(a) through 3(c). The accreditation body also must submit documentation of its compliance with 3 (d).

- **Application Fee:**

The accreditation body seeking recognition has to pay 2.00 (Two) Lakh Indian Rupees as first time application fee through FSSAI e payment portal.

- **Tenure of Recognition:**

The recognition of the accreditation body will be for tenure of 5 years subject to the condition that the recognized accreditation body will be reviewed for its performance on every 2 years by the Food Authority with nominal fees as decided by Food Authority from time to time. Thereafter, during renewal the body has to pay 2 Lakhs Indian Rupees every 5 years. FSSAI may also conduct additional evaluations of a recognized accreditation body at any time to determine whether the recognized accreditation body complies with the applicable requirements.

- **Signature:**

An application for recognition or renewal of recognition must be signed by an individual authorized to act on behalf of the applicant for purposes of seeking recognition or renewal of recognition.

5. Evaluation of applications for recognition and renewal of recognition:

- **Screening of application:**

The application of accreditation body will be screened for its completeness. Clarification/additional information will be sought from the applicant in case of any insufficiency.

- **Examination of application:**

The complete application will be examined by FSSAI to determine whether the applicant meets the requirements for recognition. In case of renewal of recognition, if final decision on an application is not available before expiry of an accreditation body's recognition, FSSAI may extend the existing term of recognition for a specified period of time or until a final decision on the application for renewal of recognition is taken.

- **Grant and duration of recognition:**

Notification will be sent to the applicant that its application for recognition or renewal of recognition has been approved including any conditions associated with the recognition. This recognition may be granted to an accreditation body for a period not to exceed 5 years from the date of recognition.

- **Rejection of application:**

FSSAI will notify the applicant that its application for recognition or renewal of recognition has been denied and will state the basis for such denial and describe the procedures for requesting reconsideration of the application.

Note: *A separate guidelines will be issued shortly for the other conditions & requirements to be fulfilled by the applicant organization for approval as Accreditation body by FSSAI.*

Application form

- 1. Name and address of the Accreditation Body:**
- 2. Information of the applicant/owner**
 - i. Name of the applicant/owner** - format (First-Middle-last)
 - ii. Designation**
 - iii. Phone Number** (Country/ Area/ Phone Number/ Extension) (the telephone number of the Point of Contact) -
 - iv. Fax Number** (Country/Area/Fax Number) (Optional field) (the fax number of the Point of Contact)-
 - v. E-mail Address** (the e-mail address of the Point of Contact)-
 - vi. Physical Address** (Business) -
- 3. Information of the Point of Contact**
 - i. Name of the Point of Contact-** Format (First-Middle-last)
 - ii. Job Title/Designation** -
 - iii. Web Address** (Optional field) (The URL of the company) -
 - iv. Phone Number** (Country/ Area/ Phone Number/ Extension) (the telephone number of the Point of Contact) -
 - v. Fax Number** (Country/Area/Fax Number) (Optional field) (the fax number of the Point of Contact)-
 - vi. E-mail Address:**
 - vii. Physical Address** (Business) –
- 4. Do you have preferred mailing address other than the physical address mentioned above? If yes, please provide details.**
- 5. Details & document to be provided on the following requirements:**
 - i. Eligibility:** Details & documents (certificates) relevant to demonstrate competence of eligibility requirements mentioned at point **3** of the document “inviting applications from Accreditation Bodies for Recognition by FSSAI.”
 - ii. Competency and Capacity :**
 - a) List of total Manpower (Technical & Non-Technical);
 - b) Details and documentary evidence of recognition as Accreditation body for laboratory accreditation in other countries (specially by Food regulators) across the globe;
 - c) Details with documentary evidence on no of Food testing laboratories assessed and accredited in India and across the globe in the last three years.
Note: Information to be provided separately for testing laboratories, calibration laboratories, proficiency testing providers (PTP) & Reference material producers (RMP).
 - iii. Declaration form for Conflict of Interest** as per the **Annexure II.**
 - iv. Information on whether the Accreditation body is suspended or de-recognised by any government agency across the globe. If Yes, Details, thereof.**
 - v. Declaration on letter head as per Annexure III.**
- 6. Particulars of fee deposited for processing of application :**
- 7. Declaration:**

I hereby declare that the information in the submission is true and accurate and that I am authorized to submit information to FSSAI. Further, I declare that the accreditation body will comply with all the requirements for recognized accreditation bodies as specified by FSSAI.

Name:

Email Address

Contact No.:

Date:

(Signature of the Authorized person)

DECLARATION (ON THE LETTER HEAD) ON CONFLICT OF INTEREST

I, (Name & Designation) solemnly affirm the following on behalf of my company/firm/Institute/Society/Association etc.,:

1. That the officers, employees, or other agents involved in accreditation activities does not own or have a financial interest in, manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) it accredits.
2. That the officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or other item of value from any laboratory the recognized accreditation body accredits or assesses for accreditation.
3. The financial interests of any children younger than 18 years of age or a spouse of a recognized accreditation body's officers, employees, and other agents involved in accreditation activities are considered the financial interests of such officers, employees, and other agents involved in accreditation activities.
4. An accreditation body (and its officers, employees, or other agents involved in accreditation activities) may have an interest in a publicly traded or publicly available investment fund (e.g., a mutual fund), or a widely held pension or similar fund if the accreditation body (and its officers, employees, or other agents involved in accreditation activities) neither exercises control nor has the ability to exercise control over the financial interests held in the fund.

Date:

(Signature) Full name and designation:

(Seal of Organization)

DECLARATION (ON THE LETTER HEAD)

1. I, (Name & Designation) solemnly affirm on behalf of my company/firm/Institute/Society/Association etc., that the information/facts about my company/firm/Institute/Society/Association etc., in the application and annexures are correct and nothing has been concealed. If any information submitted above, is found to be false or fabricated, my company/firm/Institute/Society/Association etc., may be debarred from recognition/empanelment.
2. I permit FSSAI to cross check the above facts from any other source.
3. I or my Single point of Contact, if required by FSSAI, would make a presentation before the duly constituted Committee at my own cost.
4. I will abide by all the decision of FSSAI regarding the application and that will be final.

Date:

(Signature) Full name and designation:

(Seal of Organisation)