Food Safety & Standards Authority of India Ministry of Health & family Welfare, Government of India FDA Bhawan, Kotla Road, New Delhi-110 002

No. 11/202/LAB REC/QA/FSSAI/2014

Dated: 1.05.2014

NOTICE

"Inviting applications for Recognition / Authorisation/ Notification of NABL accredited food testing laboratories for analysis of sample under FSSA".

Under the provision of Section 43 of FSS Act, 2006, Food Safety and Standards Authority of India (FSSAI) intends to notify NABL accredited food testing laboratories where the sample drawn by authorised person, including the part to be tested at the request of the Food Business Operator can be tested for parameters as per the Food Safety and Standards (Food Products and Standards) Regulations, 2011 or otherwise specified.

The food testing laboratory(s) shall conduct test as per requirement of Food Safety and Standards (Food Products and Standards) Regulations, 2011. The laboratory(s) is also expected to have NABL accreditation for the test parameters as per the Food Safety Regulation 2011.

Applications are invited from interested parties/laboratories in the prescribed format for recognition under FSSAI and are requested to supply the information (along with the valid documentary proof) to FSSAI in the prescribed format attached alongside.

The stated procedure of recognition/authorisation of Laboratories under FSSAI is an open and continuous process to be pursued until any further amendment/orders by FSSAI.

In this regard detailed information may be obtained from FSSAI's website http://fssai.gov.in.

(Dr. Sandhya Kabra) Director (QA), FSSAI

PROCEDURE

1 PURPOSE

- 1.1 FSSAI is mandated under Section 43 of the FSSA to recognise by notification, 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.
- **1.2** This document describes the procedure for recognition and notification of the Food testing Laboratories by FSSAI.

2 SCOPE

- 2.1 This document describes the process that the Food Testing Laboratories are expected to follow for obtaining recognition from FSSAI for undertaking testing of food products for FSSAI or having their test results/reports accepted by FSSAI as demonstration of compliance to its regulations.
- **2.2** The stated procedure of recognition/authorisation of Laboratories under FSSAI is an open and continuous process to be pursued until any further amendment/orders by FSSAI.

3 ELIGIBILITY FOR RECOGNITION

- **3.1** NABL accreditation to ISO 17025 for the relevant scope is a prerequisite for applying for recognition and notification by FSSAI.
- **3.2** NABL scope of accreditation in different food parameter.
- **3.3** Merely being assessed and found competent by NABL would not entitle any laboratory to FSSAI recognition. FSSAI reserves the right to assess need for labs and recognise labs only, if needed. It also reserves the right to recognise labs with a restricted scope than for which the Food Laboratory has been accredited by NABL.

4 RECOGNITION PROCESS

4.1 Once the Food Laboratory has obtained accreditation from NABL against ISO17025 and has been satisfactorily assessed by FSSAI for recognition, it should follow the following process for obtaining FSSAI recognition and notification.

- **4.1.1** The Food Laboratory seeking FSSAI recognition and notification is required to apply in the prescribed application proforma at Annexure 1.
- **4.1.2** The Food Laboratory shall submit the application form duly filled and signed by head of the laboratory or an authorized representative/s of the Food Laboratory, along with the required documents and prescribed fee.

The following documents are mandatory to be submitted along with the application form:-

- 1. NABL Accreditation Certificates
- 2. Scope of testing with facilities
- 3. Quality manual

The application processing fee of Rs. 1000/- as DD in favor of "The Senior Accounts Officer, Food Safety & Standards Authority of India, payable at New Delhi" is to be submitted along with the duly filled application form and with the above documents.

- **4.1.3** Applications in any other format are not accepted by the FSSAI. Incomplete applications shall not be processed and the deficiencies shall be communicated to the applicant Laboratory for providing missing information. The Laboratory should provide information within 30 days failing which the application shall be rejected without any further reference.
- **4.1.4** FSSAI shall on the basis of the scope and criteria mentioned on the NABL Accreditation Certificate decide upon the recognition of the applicant Food Laboratory. The decision of the FSSAI shall be communicated to the applicant Food Laboratory, within 60 days of the receipt of complete application.
- **4.1.5** The FSSAI recognition of Food Laboratory shall be maintained on the following conditions;
 - a) The Food Laboratory continues to maintain the NABL accreditation (against ISO/IEC 17025 and the FSSAI criteria) for the relevant scope;

- b) There are no adverse reports/information/complaint with the FSSAI about the Food Laboratory regarding the testing activities performed by the laboratory which are found valid by FSSAI.
- c) The FSSAI recognition of the Food lab is valid subject to:
 - i. Validity of NABL accreditation for the relevant scope;
 - ii. the specific period as indicated by FSSAI; and
 - iii. maintains integrity in its operations at all times
- d) In case of NABL accreditation cancellation, FSSAI authorisation will automatically stand cancelled.
- **4.1.6** FSSAI shall reserve the right to call for any information from the recognized Food Laboratory, conduct an audit or investigation at its premises, refer any complaint regarding its functioning to NABL and seek any reports from NABL.
- **4.1.7** FSSAI may suspend/withdraw recognition in case its own investigations/audits reveal any adverse findings with due notice to the lab.
- **4.1.8** In the event of suspension/withdrawal of the NABL accreditation of the Food Laboratory, the FSSAI recognition of the lab shall automatically stand suspended/withdrawn from the same date.
- **4.1.9** Following withdrawal of FSSAI recognition, the Food Laboratory shall be eligible to seek fresh recognition from FSSAI as a new applicant subject to conformance as per requirement of FSSAI.
- **4.1.10** The Food Laboratory recognized by FSSAI for the purpose of checking compliance to its regulations, shall sign a legally enforceable agreement for provision of testing services to FSSAI as given in Annexure 2.

An Agreement/MoU will be signed between the FSSAI and the Laboratory, defining the terms and condition of laboratory recognition criterion by FSSAI & the procedure for undertaking testing for the purposes of carrying out analysis of samples by the Food

Analysts under the FSS Act. The agreement/ MoU will be established with the Laboratory after satisfactorily assessment of the need of the laboratory by FSSAI, and after receiving duly filled application form, with the prescribed fee along with the above said documents.

While signing the Agreement/ MoU the food Laboratory will deposit a sum of Rs. 1 Lakh (only applicable for private laboratories) as Security Deposit to FSSAI and which may be issued in favor of "The Senior Accounts Officer, Food Safety & Standards Authority of India, payable at New Delhi"

- **4.1.11** All Food Laboratories that are recognized by FSSAI are permitted to mention the same on their stationary, publicity media, communications etc. However, it shall be the responsibility of the recognized Food Laboratory that the recognition is not misrepresented and FSSAI is not brought into disrepute in any manner.
- **4.1.12** FSSAI shall maintain and update the directory of Food Laboratories recognized by it with specific scope of work on its website.

Annexure 1

Application Proforma

To

Director, Food Safety and Standards Authority of India, FDA Bhawan, Kotla Road, New Delhi-110 002

Sub: Application for notification of NABL accredited food testing laboratories for analysis of sample taken during sampling of food articles by Authorised person-reg

Sir.

The undersigned having read the details for getting notification of NABL accredited food testing laboratories for analysis of sample taken during sampling of food articles by Authorised person do hereby submit the following details (alongwith the relevant documents).

Name & Address of Laboratory	NABL Accreditation No. (with Certificate)	Date of validity of Accreditation	NABL Accreditation			Average charges for a particular package
			Categorie s of Food/test	Specific food Articles/ test	NABL Accredited Scope of Testing (Supported with	

2. Documents forming part of application;

We have enclosed the followings:

- Application form
- NABL Accreditation Certificate alongwith the scope of food testing.
- Testing facilities available
- Infrastructure and the scientific competence.
- Food sample handling capacity on daily basis
- Location and outreach
- Any other information as deemed suitable.

4. I/ We hereby declare that the information contained is true and correct to the best my/ our knowledge and belief.	t of
Thanking you,	
Yours faithfully,	
(Signature of the Applicant) Name: Designation: Seal: Date: Place:	
Witness: Signature Name Address Date	

3. Contact person and contact details:

Annexure 2

Agreement for Recognition of Food Testing Laboratories by FSSAI To be executed on a stamp paper of Rs. 50/-

AGREEMENT FOR THE RECOGNITION OF FOOD TESTING LABORATORIES

This ag	greement is	s made between	the "Food \$	Safety and	Standards .	Authority of	India",
having	it principa	I office at New De	elhi, India,	hereinafter	referred to	as "FSSAI"	" which
expres	sion shall i	nclude its success	or and assi	gnees and	the	(N	lame of
the	Food	Laboratory)	having	its	principal	office	at
				(Ad	dress) here	inafter refe	rred to
as the	"Food Lab"	which expression	shall include	de its succe	essors and a	assignees.	

1. INTRODUCTION

- 1.1 FSSAI is mandated under Section 43 of the FSSA to recognize by notification, food laboratories and research institutions accredited by National Accreditation Board for Testing ad Calibration Laboratories or any other accreditation agency for the proposes of carrying out analysis of samples by the Foods Analysts under this Act.
- 1.2 This Agreement sets out the relationship between FSSAI and the recognized Food Laboratories undertaking testing for the purposes of carrying out analysis of samples by the Food Analysts under this Act.
- 1.3 The Food Laboratories applying for recognition are expected to comply with the requirements for recognition stipulated by FSSAI. The term Food Lab is therefore deemed to cover also applicant Food Laboratories for the purposes for this agreement.
- 1.4 The Food Laboratories are expected to abide by the letter, spirit and intent of this Agreement.

2. RECOGNITION OF FOOD LABORATORIES

- 2.1 A Food lab applying for recognition will have to be accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) to ISO/IEC17025 as applicable, with the relevant scope. In case the NABL accreditation is suspended/ withdrawn at any time, the FSSAI recognition shall also be deemed to the suspended/ withdraw with immediate effect.
- 2.2 The FSSAI recognition of the Food Lab is valid subject to:
 - a) validity of NABL accreditation for the relevant scope;
 - b) the specific period as indicated by FSSAI;

c) maintains integrity in its operations at all times;

automatically stands cancelled.

- d) no adverse reports/information/complaint against the laboratory is received by the FSSAI and established to be true/valid, regarding its testing activities carried out by the laboratory system with reference to the FSS Regulations, 2011; and e) In case of NABL accreditation cancellation, FSSAI authorization
- 2.3 FSSAI may monitor the continuing conformity with the relevant requirements prescribed by FSSAI for recognition of food labs and reserves the right to carry out additional or unscheduled assessments or investigations over and above the NABL assessments.
- 2.4 FSSAI reserves the right to call for any information from the Food lab, conduct an audit or investigation at its premises, refer ay complaint regarding its functioning to NABL and seek any reports from NABL.
- 2.5 If a Food Lab fails to comply with the terms of this Agreement, or any undertaking given to FSSAI, or the relevant recognition criteria, or in case FSSAI's own investigations/assessments reveal any adverse findings, FSSAI may suspend or with draw recognition, reduce the scope of recognition, require an assessment either directly or through NABL or impose other sanctions as appropriate after giving due notice to the lab.
- 2.6 All information obtained by FSSAI and its staff in dealing with the Food Lab, other than information available in the public domain, will be treated as confidential and will not, subject to the law of the land, be divulged without prior written consent of the Food Lab.

3. CONDITIONS TO BE MET BY THE FOOD LAB

3.1 The FSSAI recognized Food Lab shall offer FSSAI and its representatives such reasonable access and co-operation as necessary to enable FSSAI to monitor conformity with this Agreement and the relevant standard(s)/requirements.

3.2 The Food Lab shall:

- (a) Have Qualified Food Analyst as per FSSAI Rules 2.1.4(1) for testing food samples received under FSS Act, 2006.
- (b) At all times comply with the terms of this Agreement and with the relevant recognition criteria;
- (c) Only claim that it is recognized in respect of those activities which are the subject of this Agreement issued to it by FSSAI from time to time and which are carried out in accordance with this Agreement and the relevant standards(s);

- (d) Pay any fee/deposit that FSSAI may prescribe from time to time.
- (e) Not use this recognition in such a manner as to bring FSSAI into disrepute, and take appropriate steps to correct any statement or expression, which FSSAI considers to be misleading:
- (f) Upon the suspension/withdrawal of FSSAI recognition, however determined, discontinue forthwith its use of any reference to Recognition, withdraw all advertising matter which contains any reference, thereto, discontinue issue of test reports under this Agreement, and take such action with respect to test reports already issued as FSSAI may require.
- (g) Ensure that the FSSAI recognition shall not be used by itself for promotional or publicity purposes in any way that FSSAI considers to be misleading or inappropriate, and take such immediate steps as FSSAI may require to correct any such misleading/inappropriate use.
- (h) The Food lab will deposit sum of Rs. 1 lakh as security deposit to FSSAI, and the draft may be issued in favour of Senior Accounts Officer, FSSAI New Delhi -110002.
- 3.3 The Food lab may use in documents, brochures or advertising media, without variation, the phrases "a FSSAI recognized food laboratory listed under registration number....... " and "listed in the FSSAI Register of Recognized Food Laboratories under registration number.........".
- 3.4 The Food lab wishing to relinquish its FSSAI recognition shall give at least ninety days written notice to FSSAI of its intent.
- 3.5 Any notice or other communication given or sent by FSSAI to a food lab in connection with, or under, this Agreement, shall be deemed to be duly given or sent if dispatched by registered post to the address of the accredited laboratory last known to FSSAI and shall be deemed to be given at the time when the same would have been delivered in the ordinary course of post.
- 3.6 Fees prescribed by FSSAI for a particular test parameter/set of test parameters will be final and the recognized laboratory shall not charge other than the prescribed fees.

4. APPEALS

4.1 Appeals will be considered only against a decision relating to the recognition made by FSSAI. A decision is a decision by FSSAI to grant or not grant, curtail, suspend or withdraw recognition or when FSSAI grants, or denies, an extension to scope. Such a decision by FSSAI shall stand pending disposal of the appeal, if any.

4.2 Appeals in writing against a decision by FSSAI shall be made to the Chairpersons, FSSAI who, if he is satisfied that there is a prima facie case for consideration, may set up an independent 3 member appeals panel to look into the appeal and advise him.

5. COMPLAINTS

Any complaint should be addressed to the CEO, FSSAI in writing.

6. ASSIGNMENT

Except as otherwise agreed by the parties in writing, recognition shall not be assigned.

7 LIABILITY

No representation, promise or warranty, express or implied, is or will be made or given as to the accuracy or completeness of any information, review, audit, or advice supplied, made or given by NABL (or any of its directors, employees or agents) in the course of providing services pursuant to this Agreement and no director, employee or agent of NBAL is authorized (nor shall any such person be deemed to have been given any such authority) to make or give any such representation, promise or warranty, and any such representation, promise or warranty purported to be so made or given shall not be relied upon by the accredited food laboratory.

8. LAW

This Agreement shall in all respects be construed and operate as an Agreement made in India and in conformity with Indian Law and the construction and validity shall be governed by the Indian Laws and is subject to the exclusive jurisdiction of the Delhi Courts.

9. TERMINATION

These arrangements shall continue in force unless and until terminated;

- a) By either party upon 90 days written notice to the other:
- b) By withdrawal of recognition by FSSAI.
- c) By completion of the recognition validity period as indicated by FSSAI.

On the date of termination, the FSSAI recognition shall immediately cease to be valid but the Food Lab will remain bound by the relevant conditions of this Agreement in respect of work performed under this Agreement.

10. THE PARTIES TO THE AGREEMENT

For the Food Lab	For FSSAI
Name:	Address
Address	FDA Bhawan, Kotla Road,
	New Delhi- 110 002
Signed	Signed
Designation	Designation
Name (BLOCK Capitals)	Name (BLOCK Capitals)
Date	Date

No. 1/PLR/FSSAI/2011

Food Safety & Standards Authority of India Ministry of Health & family Welfare, Government of India FDA Bhawan, Kotla Road, New Delhi-110 002

<u>Terms and Condition for Notification of Food Testing Laboratories under Section</u> <u>43(1) of FSS Act, 2006.</u>

- 1. Food testing laboratory(s) shall conduct test as per requirement of Food Safety Regulation 2011.
- 2. The laboratory(s) should have NABL accreditation for the test parameters as per the Food Safety Regulation 2011.
- 3. Laboratory is required to indicate the package/ blanket average charges for a particular package/set of tests/parameters.
- 4. The laboratory(s) will be liable for sharing the data of testing of regulatory samples with FSSAI for any further scientific analysis as and when required and will be willing to put the same online once a network is established.
- 5. Each test will be accompanied by a certificate that there is no conflict of interest of the laboratory with the FBO whose sample has been tested.

I/ We hereby declare that I will abide by the above terms and condition.

Yours faithfully,
(Signature of the Applicant) Name: Designation: Seal: Date: Place:
Witness: Signature Name Address
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