

Expressions of Interest (EOI) from FSSAI recognized Food Testing Laboratories (notified primary and/or referral laboratories) for declaration as

National Reference Laboratory

(Last Date for Receiving EOIs : 15.09.2022)

JULY 2022

Food Safety & Standards Authority of India (FSSAI)
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, New Delhi 110002

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. Section 16(2) (e) in conjunction with section 43 (1) & (2) of FSS Act, 2006 prescribes provisions for Recognition and notification of laboratories, research institutions and referral food laboratory. In addition, section 16 (2) (f), mandates the authority to specify the method of sampling, analysis and exchange of information among enforcement authorities.
- 1.2. As per the Sub-Regulation 3 of Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2018, the Food Authority may recognize any notified food laboratory or referral food laboratory as "**reference laboratory**" for the purpose of developing methods of testing, validation, proficiency testing and training.
- 1.3. With the above mandate, FSSAI now invites Expressions of Interest (EOI) from eligible laboratories to be designated as a **National Reference Laboratory (NRL).**

2. SCOPE OF WORK

2.1 National Reference Laboratories will be recognized based on the expertise for particular food product category such as Dairy Products and Analogues; Fats, Oils and Fat Emulsions; Fruit & Vegetable Products; Cereals and Cereal Products; Meat and Meat Products; Fish and Fish Products; Sweets & Confectionery; Sweetening Agents Including Honey; Salt, Spices, Condiments and Related Products; Beverages (Other than Dairy and Fruits & Vegetables based); Foods for infant nutrition; Alcoholic Beverages; Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food; Organic food, GM Foods etc., In addition, NRL may also be recognized based on the a*nalyte basis* (i.e Pesticide residue, Mycotoxins, Veterinary Drug Residues including Antibiotics, Heavy metals etc.). The final decision on the number of NRL will be decided by an 'Evaluation Committee for NRL' to be constituted by FSSAI for this purpose.

3. FUNCTIONS OF REFERENCE LABORATORIES:

- 3.1 As per the Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2018, following are the functions to be carried out by a national reference laboratory:
 - a) be a resource center for provision of information for certified reference materials and reference materials:
 - b) develop standards for routine testing procedures and reliable testing methods;
 - c) provide technical support in the area of competence;
 - d) evaluate the performance of other notified laboratories;
 - e) coordinate exchange of information amongst notified food laboratories;
 - f) collaborate for data generation among the network of notified food laboratories and referral food laboratories and collate the data related to their specific domain; and
 - g) such other functions as may be specified by the Food Authority from time to time.
- 3.2 Following are the additional roles of the National Reference Laboratories i.e Functions apart from those specified in the FSS (Recognition & Notification of Laboratories), Regulation, 2018:
 - Ensure availability of adequate technical infrastructure and competent staff, especially in case of food safety incidents;

- collaborate with national/international bodies
- organize annual event/conference for all the NRLs, primary and referral testing laboratories in the area of chosen expertise (out of turn by each NRL)
- acknowledge FSSAI Manuals of Methods of Analysis and publish methods in association with AOAC;
- support FSSAI in surveillance activities and risk assessment in the specific areas of expertise of NRL
- hand hold State Food Testing Laboratories including capacity building.

4. ELIGIBILITY CRITERIA & SUBMISSION OF EOI FOR NRL

4.1 Eligibility criteria

Any FSSAI notified food testing laboratories which are single entities fulfilling the laid down eligibility criteria is eligible to apply under this call. The *eligibility criteria** - for an applicant to be a National Reference Laboratory is as follows-

- Accreditation as per International Standards (ISO/IEC 17025:2017) under FSSAI-NABL
 Integrated Assessment is mandatory. Any additional accreditation in the laboratory related
 area (e.g. PT provider, training etc.) or notification/ recognition by other regulatory agencies
 will attract additional weightage during evaluation.
- Should have qualified food analysts and Director as Authorized signatory in case of referral laboratory and well-experienced in-house technical manpower.
- Should have sufficient in house infrastructure and laboratory equipment to carry out the tests, method development and research activities in the area specified.
- Should have a strong research background as evidenced by publications in peer reviewed journals in specified area.
- Should desirably be a Proficiency Test (PT) provider under NABL in the area of choosen expertise. Besides, the laboratories should have participated in a minimum of 4 PT programs per year over the last 5 years.
- Should have experience and facility to impart hands on training.

Note: *Documentary evidences should be provided for fulfilling each condition as part of application.

4.2 Submission of proposal

• The proposal complete in all respects shall be submitted in sealed envelope super scribed as "EOI from Food Testing Laboratories for declaration as National Reference Laboratory" to Advisor (QA),Food Safety and Standards Authority of India, Ministry of Health & Family Welfare, Govt. of India, 3rd Floor, FDA Bhawan, Kotla Road, New Delhi-110002 on or before 15.09.2022 by 3.00 P.M).

• Documents to accompany EOI

The application shall accompany the Expression of Interest in **Form I** along with the necessary supporting documents mentioned at **Form II**. Every sheet and all forms shall be complete in all respects and duly numbered. The Power (s) of Attorney supporting/authorizing of the signatory shall be enclosed with the offer. Any / all corrections made in the proposal shall be duly authenticated by the signature of the Authorized Signatory.

• Authorized Signatory

The 'Applicant' mentioned in the EOI document shall mean the one who has signed the EOI document forms. The applicant should be the Head of laboratory/ or a duly Authorized Representative, for which a Certificate of Authority shall be submitted. All certificates and documents (including any clarifications sought and any subsequent correspondence) submitted thereby, as far as possible, shall be furnished and signed by the Authorized Representative. Whosoever signs the application, he/she shall be the contact nodal point for future communications in reference to National Reference Laboratory, if selected.

5. EOI DETAILS & BID PROCESSING FEE

5.1 Availability of EOI & Bid processing fee

The EOI document can be downloaded free of cost from InFolNet 2.0 portal (https://infolnet.fssai.gov.in/#/) through FSSAI website at (www.fssai.gov.in). Duly filled EOI applications should accompany with a processing fee of Rs. 5000/- + 18% G.S.T to be paid through the online e-payment portal of FSSAI under the heading 'NRLP' in the link (https://fssai.gov.in/cms/epayment.php). The receipt of the online transaction (mentioning details such as date, transaction number etc) shall be submitted along with the application.

5.2 Amendment to EOI

At any time prior to the last date for receipt of proposals, the Food Authority, may for any reason, whether at its own initiative or in response to a clarification requested by a prospective applicant, modify the EOI document by an amendment. In order to provide prospective applicants reasonable time in which to take the amendment into account in preparing their proposals, the Food Authority may, at its discretion, extend the last date for the receipt of proposals and/or make other changes in the requirements set out in the EOI.

5.3 Rejection of EOI

The application is liable to be rejected if:

- a) Not in prescribed form and not containing all required details
- b) Not signed by the signing authority
- c) Received after the last date of submission
- d) Offer is received by fax, telegram or email & not followed/supported by the prescribed documents within the stipulated date.
- e) Proposal received without the processing fee. Further, applicant is required to furnish a declaration regarding exclusion criteria strictly in the format as given at **Annexure-I.**

6. EVALUATION OF BIDS

- i. FSSAI will constitute an 'Evaluation Committee for NRL' comprising renowned scientists and administrators. The evaluation committee will be notified in due course.
- ii. Technical Evaluation: The 'Evaluation Committee for NRL' along with FSSAI officials will

visit the facilities to evaluate and also ask the applicant laboratory to make a presentation before the Committee. The Committee will device criteria for evaluation purpose.

7. EVALUATION OF RECOGNIZED NRLS

- The recognized laboratories (NRLs) shall have to submit the proposals for the expected work along with the estimated expenditure and timeline annually as per the format prescribed by FSSAI within the initial 1 month of the beginning of the financial year. The timeline for proposal/ work should be maximum of one year.
- The proposals submitted by the NRLs will be evaluated by an 'Evaluation committee for NRL'. NRL shall initiate the activities only after their proposal get approved from the Evaluation Committee.
- In addition to the work specified for NRLs under 'Section 3-Functions of reference laboratories' of this document', the Scientific Committee/ Scientific Panel/ Expert Committee etc., of FSSAI may request NRLs for additional work related to their specific area of expertise. The work assigned will be evaluated by the committee constituted.
- Laboratories shall acknowledge FSSAI for any publications or patents made as part of work done under functions of 'Reference laboratory'.
- Laboratories shall have to submit progress report of all the activities under NRL on quarterly and annually basis as per the format prescribed by FSSAI. The progress of the work done by NRLs will be evaluated and monitored by the 'Evaluation Committee for NRL' quarterly and/or annually basis. The meeting of the committee shall be done quarterly/ annually/ as required by FSSAI.

8. FINANCIAL GRANT FOR NRLs

- 8.1 The recognized **National Reference Laboratory** shall be **eligible for an annual grant up to Rupees Twenty Five Lakhs (including G.S.T) from FSSAI.** The annual grant may be decided by FSSAI from time to time (if required). Fund will only be released for those activities which is either assigned or approved by FSSAI. In addition, FSSAI may also consider an additional grant, wherever required.
- 8.2 The terms of references for financial grant are as follows:
 - This grant will be used under following heads of expenditure:
 - i. Manpower (for salary of maximum of two person including fellowships to post graduate trainees)
 - ii. Method Development & Validation
 - iii. Training activities and Annual event/Conference
 - iv. Proficiency Testing
 - v. Data Generation and Surveillance activities
 - **Schedule of Grant Release**: Annual grant will be released to NRLs in two installments in the following manner:

Installment	Month
First	April-May
Second	October- November

- For the first year, after the recognition of NRL, the first installment will be released in the month of October. Subsequent, installment will be released accordingly.
- The release of second installment will be done subject to submission of half yearly SoE (Submission of Expenditure) and progress report; followed by recommendation of 'Evaluation Committee for NRL'.
- The release of grant for next Financial Year (FY) will be done only after submission of annual report, utilization certificate (UC) & SoE by the recognized NRL in the month of March of previous FY. The grant will be released only after receiving the technical and financial approval from the Evaluation Committee.
- Interest earned, if any, on the grant is to be returned to FSSAI along with submission of UC.
- If the approved amount is not utilized by the NRL for the said Financial Year, the Food Authority may request the NRL to return the unutilized amount of previous Financial Year and fresh grant will be released after reviewing the documents submitted.

9. DISCLAIMER

The Food Authority shall not be responsible for any late receipt for any reasons whatsoever. The applications received late will not be considered and returned unopened to the applicant. The Food Authority reserves the right

- To relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the Food Authority without assigning any reasons thereof
- To include any other item in the Scope of work at any time after consultation with applicants or otherwise
- To cancel EOI in part or in full without assigning any reasons thereof.



APPLICANT'S DECLARATION REGARDING THE EXCLUSION CRITERIA

To be completed and signed by the applicant and to be included in the EOI application

To Advisor (QA) Food Safety and Standards Authority of India Ministry of Health & Family Welfare, Govt. of India, 3rd&4thFloor,FDA Bhawan, Kotla Road, New Delhi-110002

Ref: Call for Expressions of Interest from Food Testing Laboratories for declaration as National Reference Laboratory

I/we understand that our application shall be excluded from participation in the call for EOI to be a National Reference Laboratory, if-

- 1. I/We are bankrupt or being wound up, having our affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matter, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- 2. I/We have been convicted for an offence concerning our professional conduct by judgment which has the force of *resjudicata*;
- 3. I/We have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
- 4. I/We have not fulfilled obligations in respect of payment of social security contribution or the payment of taxes in accordance with the legal provisions of the country in which established or with those of the country of the contracting authority or those of the country where the contract is performed;
- 5. I/We have been the subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organization or any other illegal activity detrimental to the communities' financial interests;
- 6. I/We have received grants from Governmental organizations or from community budget and found to be in serious breach of contract for failure to comply with the award conditions of such grant In response to your call for expression of interest, I/We hereby declare that I/we:
- (a) Am/are not in any of the situations excluding me/us from participation contracts (and will produce the corresponding certificates if so requested)
- (b) Agree to abide by the highest ethical standards in the profession and, in particular, have no potential conflict of interest;
- (c) Will inform the Authority immediately if there is any change in the above circumstances at any stage during the tender procedure or during the implementation of the project;
- (d) Fully recognize and accept that any inaccurate or incomplete information deliberately provided in this tender may result in my/our exclusion from this or other contracts funded by the Authority

(Signature of the applicant/ authorized representative along with Office seal & date)

EOI Letter Proforma

To Advisor(QA), Food Safety and Standards Authority of India, Ministry of Health & Family Welfare, Govt. of India, FDA Bhawan, Kotla Road, New Delhi-110 002

Sub: Call	for	Expressions	of	Interest	from	Food	Testing
Labora	tories for	declaration as Na	tional R	eference Labo	ratory		

Sir,

The undersigned having read and examined in detail all the EOI documents pertaining to the proposals for National Reference Laboratory, do hereby express the interest to do the work as specified in the scope of work.

2. Correspondence details:

1.	Name of the applicant
	(Laboratory/)
2.	Address
3.	If notified/accredited by any National/International body. If Yes, please enclose documentary evidence
4.	Name, designation & address of the person to whom all references shall be made in case of applicant on behalf of the Laboratory/
5.	Telephone (with STD code)
6.	Mobile No. of the contact person
7.	E-mail of the contact person/ Website address of The Laboratory(if any)
8.	Fax No.(with STD code)

- 3. Documents forming part of EOI The following documents have been enclosed and serially numbered
 - Expressions of Interest in Form– I.
 - Complete set of duly numbered documents as listed in the format given at item 3.2
- 4. I/We hereby declare that my/our EOI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Γhanking you,	Yours faithfully,
	(Signature of the Applicant with seal and date)
	Name:
	Designation:
Witnesses:	Place:
1.Signature	
Name:	Name:
Address:	Address:
Date :	Date :

- 1. Details of FSSAI notification/recognition (Provide the details of Gazette notification)
- 2. Scope of accreditation as per certificate(s) issued by the Accreditation Body (provide complete details and documents in support)
- 3. Details of manpower and equipment as per the formats below
 - i. Details of qualified technical manpower

S.	Name &	Educational	Area of	Years of	Type of
No.	Designation	Qualification	Specialization	Experience	employment
					(Permanent/
					Contractual/
					Temporary)

ii. Details of Infrastructural facilities

A. For chemical analysis

1. High End Equipment like LC-MSMS, GC-MSMS, ICP-MS, IRMS, HRMS etc.

S. No.	Name	Year & Make

2. Specialized Equipment like HPLC, GC, AAS, ICP-OES etc.

S.No.	Name	Year &Make

3. General Equipment

S.No.	Name	Year &Make

B. For Microbiological Analysis

S. No.	Name	Year& Make

C. For Molecular biology facility

S. No.	Name	Year & Make

D. Any Other facility (Please specify for e.g.: Radiation, R material testing etc.)

S. No.	Name	Year & Make

- iii. Are above facilities available as centralized facility or different facility in institute/laboratory
- 4. Details of testing, R&D, surveillance activity and training conducted for last 5 years as per below:

i.Testing activities

FORM-II

Year	Food	Parameters	Number of Samples tested	
	Product	tested	General	Regulatory
	Category			

ii.Project/Research activity undertaken related to food (in reference to FSSAI)

Year	Type of Research	Principal Investigator	Salient
			features

iii. Any method developed, validated, verified and published in association with AOAC

Year	Details of the	Developed	Verified	Publication of the
	method	& validated		method (if any)

iv. Details of surveillance done in association with FSSAI

Month	Details of Food	Number of sample	Remarks (if any)
&Year	Product/ Food	analyzed	
	category		

- v. Publications in peer reviewed journals in the specified areas
- vi. .Hands on or classroom training provided to laboratories:

Year	Title of	No. of participants	Brief description of
	training		Training program
	program		

- **5.** Participation in National/International collaborations in last 5 years:
 - *i.As project collaboration:*

Name of	Title of work	Duration
National/International		
agency		
Collaborated with		

ii.Proficiency Testing:

(a) As PT Provider (provide complete details and documents in support of ISO/IEC 17043 accreditation)

Name of	Year	No. of	Spread of participants
PT	&	participants	(National or
activity	Duration		International or both)

(b) As PT Participant

Name &	Product	Name of	Year	Z Score
Address of		PT		
PT		parameter		
provider				

iii.Human Resource Development other than 4(iv) above

(a) Academic training programs related to testing and analysis

Program	No.of participants	Nature of training	
		(Classroom/Hands	
		on/virtual)	

(b) Training of in-house manpower

Name	Name	Name &	Year &	Remarks
	of	address of	Duratio	(Regional/Natio
	training	training	n	nal/In-
	progra	provider		house/Internatio
	m			nal)
	undergone			

- 6. Details regarding Building, structure and layout of the building
- 7. Types of premises (Owned/ Rented)
- 8. Area of laboratory (in Sq. Ft)
- 9. Any additional/separate facility available for training
- 10. Any other information in support of the application relevant to scope of work

Note: Every sheet and all forms shall be complete in all respects and duly numbered. The Power (s) of Attorney supporting/authorizing of the signatory shall be enclosed with the offer. Any/all corrections made in the proposal shall be duly authenticated by the signature of the Authorized Signatory.