



**Expressions of Interest (EOI) from Food Testing
Laboratories/Institutions/ Organizations
for declaration as
National Reference Laboratory**

(Last Date for Receiving EOIs : 31.12.2017)

NOVEMBER 2017

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

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(2e) in conjunction with section 43 (1&2) of FSS Act, 2006 prescribes for Recognition and notification of laboratories, research institutions and referral food laboratory. In addition, section 16(2f), mandates the authority to specify the method of sampling, analysis and exchange of information among enforcement authorities.
- 1.2. Under the draft Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2017, the “reference laboratory” means those notified and referral laboratories of Food Safety and Standards Authority of India which are accredited as per appropriate ISO/IEC 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.
- 1.3. Creation of the Reference Laboratory would - (a) enhance reliability of results & continuous adherence to international laboratory practices, (b) results in greater availability of competent laboratories and proficient personnel, (c) allows uniformity in protocols and procedures across the laboratory network, (d) reduces litigations among the stakeholders/ trade partners; and, finally (e) allows effective utilization of existing laboratory infrastructures.
- 1.4. The **vision** of the Reference Laboratory is (i) to ensure that our laboratory system meets the national and international regulatory requirements and obligations; (ii) ensure that the laboratory results on which the regulator(s) make decisions are valid and reliable; (iii) ensure greater availability of competent laboratories with best practices in line with the global trends; and (iv) to provide guidance and flexible but consistent solutions for the different stakeholders.
- 1.5. The **mission** of the Reference Laboratory would be to set up a country wide standard for routine procedures, reliable testing methods & validation of such standard procedure/testing methods, development of new methods and ensuring proficiency in testing across the food laboratories with special reference to the risks or food categories.
- 1.6. With the above mandate, vision and mission for a National Reference Laboratory, FSSAI now invites Expressions of Interest (EOI) from eligible laboratories to be designated as a **National Reference Laboratory (NRL)** and propose to implement a network of such laboratories to be designated as National Reference Laboratory (NRL) Network.

2. Scope of work and incentives

2.1. Tentatively, it is proposed to set up about **14 National Reference Laboratories** on *product basis* (milk & milk products, fish & Fish Products, Meat & Meat Products, Cereal & Cereals Products, Fruit & Vegetables etc.), *analyte basis* (Pesticide residue, Mycotoxins, Veterinary Drug Residues including Antibiotics, Heavy metals etc.) or *combination of both product and analyte* (Veterinary drug residues in fish products, pesticides in a specific agricultural commodity, food contact surfaces, GMO etc). The final decision on the number and functions assigned thereto will be decided by a high level Evaluation Committee to be set up by FSSAI for this purpose.

2.2. The scope of work of a National Reference Laboratory - though not limited to - would be as specified below-

- Shall develop country wide standards for routine testing procedures and reliable testing methods, develop and validate newer methods, provide proficiency testing in selected areas and provide training in the area of competence
- Shall be the resource center for providing certified reference materials (CRMs) or standard reference materials (SRMs) in the specific domain
- Shall provide technical support in the area of competence
- Shall evaluate the performance of other notified laboratories in the area of competence
- Shall coordinate exchange of information amongst notified laboratories
- Shall collaborate and collate data generation for purposes of data banking related to their specific domain
- Shall carry out such other functions, as may be specified by the Food Authority from time to time in the related areas

2.3 (a) Those laboratories chosen as National Reference Laboratory shall be **eligible for an annual grant from FSSAI**, the extent of which will be decided by FSSAI later.

(b) Each of the National Reference Laboratory will **also be provided with grants** for conducting method development, method validation and training, as and when required. This will be **in addition to the annual grant** as mentioned above. Norms for this would also be decided later.

3. Eligibility criteria

3.1. *Applicant Status* - any FSSAI notified food testing laboratories which are single entities fulfilling the laid down eligibility criteria is eligible to apply under this call. Under exceptional circumstances, applicant laboratories which are (i) accredited but not notified by FSSAI or other regulatory bodies, (ii) Centers of Excellence of equipment manufacturer which have separate legal identity and R&D facility and (iii) independent R&D facilities of FBOs will also be considered. The latter categories will be considered purely based on the merit and recommendation of the evaluation committee.

3.2. The *eligibility criteria** - for an applicant to be a National Reference Laboratory is as follows-

- Accreditation as per International Standards (ISO/IEC 17025:2005) 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 technically qualified and well-experienced in-house 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 ideally be a Proficiency Test (PT) provider. If the applicant is not a PT provider, atleast, they should have participated in a minimum of 4 PT programs per year over the last 5 years.
- Should have experience of conducting hands on training facility either in-house or at a third party premises

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

4. 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/institution/organization 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. Documents to accompany EOI

5.1. The application shall accompany the Expression of Interest in **Form I** along with the necessary supporting documents mentioned at **Form II**.

5.2 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.

6. Availability of EOI& Bid processing fee

6.1. The EOI document can be downloaded free of cost from FSSAI's website at (www.fssai.gov.in) and if hard copy is required, it can be obtained from **Joint Director (QA), 3rd floor, FDA Bhawan, Kotla Road, New Delhi – 110002**, on payment of Rs. 1000/- in the form of Demand Draft in favour of "**Senior Accounts Officer, Food Safety and Standards Authority of India**" on or before 15.12.2017, 05:00pm.

6.2. Duly filled EOI applications should accompany with a processing fee of Rs. 5000/- by Demand Draft/ Pay Order payable at New Delhi in favour of "**Senior Accounts Officer, Food Safety and Standards Authority of India**".

7. Submission of Proposal

The proposal complete in all respects shall be submitted in sealed envelope super scribed as "**EOI from Food Testing Laboratories/Institutions/Organizations 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 31.12.2017 by 3.00 P.M.**

8. 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.

9. Evaluation

FSSAI will constitute a high level evaluation committee comprising renowned scientists/ administrators both from National/ International bodies. The committee will be notified in due course. The committee will device criteria for evaluation purpose.

10. Technical Evaluation

The Evaluation committee along with FSSAI officials may visit the facilities to evaluate and/or ask the applicant to make a presentation at the FSSAI HQ, New Delhi.

11. Rejection of EOI

11.1 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 e-mail & not followed/supported by the prescribed documents within the stipulated date.
- e) Proposal received without cost of EOI document if downloaded from website.

Further, applicant is required to furnish a declaration regarding exclusion criteria strictly in the format as given at **Annexure-I**.

12. Disclaimer

12.1 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.

12.2 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

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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 & 4th Floor, FDA Bhawan,
Kotla Road, New Delhi-110 002**

**Ref: Call for Expressions of Interest from Food Testing
Laboratories/Institutions/Organizations 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 *res judicata*;
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 Laboratories/Institutions/Organizations for declaration as National Reference Laboratory

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/Institution/Organization)	
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/Institution/Organization	
5.	Telephone (with STD code)	
6.	Mobile No. of the contact person	
7.	E-mail of the contact person / Website address of the Laboratory/Institution/Organization (if any)	
8.	Fax No. (with STD code)	

3. Documents forming part of EOI – The following documents have been enclosed and serially numbered

Ñ Expressions of Interest in Form – I.

Ñ Complete set of duly numbered documents as listed in the format given at item 5

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.

Thanking you,
 Yours faithfully,

(Signature of the Applicant with seal and date)

Name:

Designation:

Place:

Witnesses:

1. Signature _____

Name :

Address :

Date :

2. _____

Name :

Address:

Date :

1. Details of accreditation & notification/recognition from FSSAI or any other agencies
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. No.	Name & Designation	Educational Qualification	Area of Specialization	Years of Experience	Type of employment (Permanent/Contractual/Temporary)

ii. Details of Infrastructural facilities

1. General Equipment

S. No.	Name	Year & Make

2. Specialized Equipment like HPLC, GC etc.

S. No.	Name	Year & Make

3. High end equipment like LCMSMS, GCMSMS, ICPMS

S. No.	Name	Year & Make

4. Microbiological facility : Provide list of equipments

5. Molecular biology facility : Provide list of equipments

iii. Are above facilities available as centralized facility or different facility in institute

4. Details of testing, R&D and training facility for last 5 years as per below:

i. Testing activities

Year	Product Category	Parameters tested	Number of Samples tested	
			General	Regulatory

ii. Research activity undertaken

Year	Type of Research	Principal Investigator	Salient features

iii. Publications in peer reviewed journals

iv. Hands on or classroom training provided:

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

v. Any other academic activities including student research and training

5. Participation in International collaborations in last 5 years:

i. As project collaboration:

Name of International agency collaborated with	Title of work	Duration

ii. Proficiency Testing:

(a) as PT Provider

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

(b) as PT Participant

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

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)

(b) Training of in-house manpower

Name	Name of training program undergone	Name & address of training provider	Year & Duration	Remarks (Regional/National/In-house/International)

6. Details regarding Building, structure and layout of the building

7. 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.