

File No. 11014/05/2019-QA
Food Safety and Standards Authority of India
(A statutory Authority established under the Food Safety and Standards Act, 2006)
(Quality Assurance Division)
FDA Bhawan, Kotla Road, New Delhi – 110002

Dated, the 18th September, 2019

Notice

Subject: Approval of Rapid Analytical Food Testing (RAFT) Kit/Equipment/ Method by FSSAI – reg.

In suppression of FSSAI notice of even number dated 20.03.2019, FSSAI has revised the guidelines for approval of Rapid Analytical Food Testing Kit/ Equipment/Method for the purpose of testing of food.

2. In view of above, the desirous manufacturers/method developers may apply to FSSAI, in the revised application format. The desirous applicants are hereby requested to follow the below mentioned points while submission of the application-

- (i) Duly filled complete and signed application will only be accepted by FSSAI. Incomplete or unsigned applications will be summarily rejected and no fee shall be refunded.
- (ii) Applicants should submit separate application for each kit/equipment/method and each application should be accompanied by separate application processing fee. This shall be applicable to the applications which have already been scrutinized.
- (iii) Application should be submitted with proper justification for each of the product separately along with all necessary/ supporting documents (validation certificate/data and manual/product insert).
- (iv) No application for general parameters like pH, density or routine laboratory equipments and accessories etc. will be accepted. Such applications, if received will be summarily rejected and payment received will be forfeited by FSSAI.
- (v) Applicant to ensure that their kit/equipment/method should be able to test the parameter(s) mentioned in Food Safety and Standard Regulations (FSSR).

4. The duly filled application form (copy enclosed) shall be sent to the undersigned through e-mail (dinesh.k@fssai.gov.in and sp-sampling@fssai.gov.in) and also by post in 2 sets.

5. The requisite fee structure and the decision making process for RAFT Application are annexed for kind information.


18/9/19

(Dr. Dinesh Kumar)

Assistant Director (QA)

Email: dinesh.k@fssai.gov.in

Ph: 011-23218231

To:

IT Division, FSSAI – for uploading on FSSAI's website

Brief of the process

Objective	To recognize the rapid test kits or equipments or method of analysis		
Fees	<p>a) Common requirements- (i) Duly filled application in the prescribed format; (ii) Application processing fee of Rs. 2,000 (not included in the fees prescribed against each category) per application/product in favour of Sr. Accounts Officer, FSSAI payable at New Delhi by Demand Draft.</p> <p>b) For hand held or portable equipments- (i) At least 20 instruments – can be taken back by the manufacturer after the trials; (ii) Details of method / technology on which the equipment is based; (iii) Validation/scrutiny fee of Rs. 10,000 per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p>c) For test kit(s)- (i) At least 25 kits with clear details of instruction; (ii) Details of method/technology on which the kit is based; (iii) Validation/scrutiny fee of Rs. 25,000 per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p>d) For method(s)/protocols- (i) Binded copies of methods clearly specifying different steps involved; (ii) Details of relevant conventional method(s)/protocol(s) for which the rapid method is alternative; and, sources of reference materials; (iii) Validation/scrutiny fee of Rs. 2.5 to 5.0 lakhs depending on the chemicals involved per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p>e) For issuance of certificate by FSSAI (i) The manufacturer/method developer shall pay a fee of Rs. 25,000 for the issuance of the Conformance Certificate (CC); (ii) Subsequent renewal, if recommended by MRG & SPMSA and approved by the competent authority, will attract a renewal fee of Rs. 10,000.</p>		
Timeline for scrutiny of application	S. No.	Activity	Timeline
	1.	Scrutinization of RAFT application	3 working days from date of receipt of application by the Secretariat
	2.	Desktop audit of technical components of the application and subsequent recommendation to the Sc. Panel on Methods of Sampling & Analysis (SPMSA)	By the Methods Review Group (MRG) [4-6 weeks]
	3.	Endorsement of the recommendation of MRG by the SPMSA	Either electronically or in First available meeting*
	4.	Approval of the recommendation of the Scientific Panel by the Food Authority	First available meeting**
	5.	Issuance of Provisional Conformance Certificate and/ or Conformance Certificate	5 working days from the date of approval by the Food Authority (only after finalization of minutes of the meeting)
	<i>* Usually panel meetings are held once in 3 months ** Usually the Scientific Committee and Food Authority meetings are held 4 times a year</i>		
Validity of Conformance Certificate	The Conformance Certificate will be valid for three years from the date of issuance		
Withdrawal of Conformance Certificate	FSSAI may withdraw or suspend the Conformance Certificate issued to applicant on the basis of its own investigation or complaint received in this regard.		

Brief of the process

Objective	To recognize the rapid test kits or equipments or method of analysis		
Fees	<p>a) Common requirements- (i) Duly filled application in the prescribed format; (ii) Application processing fee of Rs. 2,000 (not included in the fees prescribed against each category) per application/product in favour of Sr. Accounts Officer, FSSAI payable at New Delhi by Demand Draft.</p> <p>b) For hand held or portable equipments- (i) At least 20 instruments – can be taken back by the manufacturer after the trials; (ii) Details of method / technology on which the equipment is based; (iii) Validation/scrutiny fee of Rs. 10,000 per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p>c) For test kit(s)- (i) At least 25 kits with clear details of instruction; (ii) Details of method/technology on which the kit is based; (iii) Validation/scrutiny fee of Rs. 25,000 per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p>d) For method(s)/protocols- (i) Binded copies of methods clearly specifying different steps involved; (ii) Details of relevant conventional method(s)/protocol(s) for which the rapid method is alternative; and, sources of reference materials; (iii) Validation/scrutiny fee of Rs. 2.5 to 5.0 lakhs depending on the chemicals involved per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p>e) For issuance of certificate by FSSAI (i) The manufacturer/method developer shall pay a fee of Rs. 25,000 for the issuance of the Conformance Certificate (CC); (ii) Subsequent renewal, if recommended by MRG & SPMSA and approved by the competent authority, will attract a renewal fee of Rs. 10,000.</p>		
Timeline for scrutiny of application	S. No.	Activity	Timeline
	1.	Scrutinization of RAFT application	3 working days from date of receipt of application by the Secretariat
	2.	Desktop audit of technical components of the application and subsequent recommendation to the Sc. Panel on Methods of Sampling & Analysis (SPMSA)	By the Methods Review Group (MRG) [4-6 weeks]
	3.	Endorsement of the recommendation of MRG by the SPMSA	First available meeting*
	4.	Endorsement of the recommendation of SPMSA by the Scientific Committee	First available meeting**
	5.	Approval of the recommendation of the Scientific Committee by the Food Authority	
	6.	Issuance of Conformance Certificate	5 working days from the date of approval by the Food Authority (only after finalization of minutes of the meeting)
	<i>* Usually panel meetings are held once in 3 months</i>		
	<i>** Usually the Scientific Committee and Food Authority meetings are held 4 times a year</i>		
Validity of Conformance Certificate	The Conformance Certificate will be valid for three years from the date of issuance		
Withdrawal of Conformance Certificate	FSSAI may withdraw or suspend the Conformance Certificate issued to applicant on the basis of its own investigation or complaint received in this regard.		

**APPLICATION FORM FOR APPROVAL OF RAPID ANALYTICAL FOOD TESTING (RAFT)
KIT/EQUIPMENT/METHOD BY FSSAI**

A. Application for (tick whichever is appropriate) <input type="checkbox"/> Rapid food testing kit/media <input type="checkbox"/> Rapid Equipment <input type="checkbox"/> Rapid Method <input type="checkbox"/> Any other, please specify
B. General Information
1. Details of Applicant
(a) Name of Principal manufacturer/ OEM
(b) Name of authorized person/ dealer in India (attach Authorization letter from principal manufacturer)
(c) Mobile No/Phone No
(d) Email (all communication will be through provided email/phone number)
(e) Name of the organization/manufacturer
(f) Address of the organization/registered office
(g) Manufacturing License number in India if any
(h) Name of the Rapid test kit/media/device/method
(i) Proposed regulatory use (specific product testing/analytical method)
C. Technical Information - Contents to be submitted with the Dossier for pre-evaluation by FSSA(I) <i>NOTE: The applicant should mark any proprietary information</i>
1. Product Information
(a) Market name, product name and product code
(b) Names and corporate addresses of manufacturers
(c) Country of Origin
(d) Address(es) of manufacturing site(s)

(e) Whether approved/verified by regulatory bodies/ organizations
(f) If yes, name of regulatory bodies/organizations and validity of approval
(g) If validated by international bodies (e.g. ISO/AOAC etc.)
(h) If yes, attach documents/certificates/approvals etc.
(i) Bar code scanner, power source, data storage capacity (if applicable)
(h) Evidence that manufacturers have a certified quality management system or Good Manufacturing Practice (GMP) certification
2. Provide details of the conventional method/equipment/test kit with which the said product should be compared with
3. Technical Specifications on rapid testing kits/device/method <i>(this list is only indicative all necessary information to support and strengthen the application must be submitted)</i>
(a) The principle and detailed methodology
(b) Specify Food Category/Matrix for which approval is sought
(c) Test procedure, including the time needed to run the test
(d) Qualitative/ Semi Quantitative/Quantitative
(e) Range and Reporting Units (if applicable)
(f) LOD/LOQ
(g) Sensitivity (wherever applicable)
(h) Specificity (including where the studies were performed to generate these values and 95% confidence intervals with supporting documents)
(i) Reproducibility across multiple test kit lots (e.g. including number of samples, type of food, number of different lots/devices)
(j) Inclusivity/ exclusivity (applicable for microbiology kits/methods/device etc.)
(k) Robustness of the kit/method
(l) Details of inter-laboratory validation of method/multiple users of device

(m) Demonstration of stability throughout the shelf life of the product under recommended storage conditions(not applicable to devices and methods)
(n) If device, warranty period, availability of maintenance service/ spare parts etc
(o) Evidence of satisfactory test performance for kits from users within India (not applicable to devices and methods)
4. Operational characteristics for kits/devices
(a) Number of steps (from starting to results)
(b) Total run time (sample preparation to final result)
(c) Ease of data interpretation
(d) Overall ease of use
(e) Training requirements
(f) Recommended storage conditions
(g) Shelf life of kit
(h) Kit size/Device (hand-held/table top/portable/non-portable)
(i) Minimum quantity of sample required for one analysis
(j) Number of Individual tests/package
(k) Required accessories necessary for operation that are not provided
(l) Availability of Certified Reference Material/Standard Reference Material/Quality Control material provided
(m) Advantages and disadvantages over the conventional technique/method/device
(n) Amount and type of waste generated (e.g. chemical/biological hazard)
(o) Cost/Kit and Cost/Test, cost/device
5. Any additional specific information

I/ We understand that incomplete submissions, submission not conforming to the prescribed format, and applications containing excessive errors will be summarily rejected. I/ We undertake that requisite material/ content will be submitted to FSSAI as desired in case the pre-evaluation document is approved by FSSAI and FSSAI will provide the applicant with instructions for further action. If the documentation is not approved, FSSAI will notify the applicant with reasons.

Name of the authorized personnel

Signature.....

Contact details.....

To
Advisor, Quality Assurance Division

File No. 11014/05/2019-QA
Food Safety and Standards Authority of India
(A statutory Authority established under the Food Safety and Standards Act, 2006)
(Quality Assurance Division)
FDA Bhawan, Kotla Road, New Delhi - 110002

Dated, the ¹⁴29 March, 2019

CORRIGENDUM

**Subject: Application for Rapid Analytical Food Testing (RAFT) Kit/
Equipment/ Method - reg.**

In continuation to this office Notice no. 11014/05/2019-QA dated 20.03.2019 on the subject cited above, it is informed that the application processing fee of Rs. 2000/- (Rupees two thousand) can also be paid through online mode, in the bank account mentioned below-

Name: **Senior Accounts Officer, FSSAI, New Delhi**
Bank: **Bank of Baroda, Nirman Bhawan**
Account No: **26030100008653**
IFSC Code: **BARBON1RDEL**
↓
(Zero)


(Shailender Kumar)
Assistant Director (QA)
Ph: 011-23237417