

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 20th March, 2019

Notice

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

FSSAI has framed a policy for adoption of RAFT kit/equipment/method for regulatory purpose (either on field, in laboratory or both).

2. In view of above, the desirous manufacturers/method developers may apply to FSSAI, in prescribed application format, for provisional registration/approval of their RAFT kit/equipment/method. If found suitable then they will be provisionally approved and a conformance certificate, will be issued after the final regulation is in place.
3. The duly filled application form (copy enclosed) shall be sent to the undersigned through e-mail (sp-sampling@fssai.gov.in) and/ or by post.
4. The requisite fee structure and the timelines of the decision making process for RAFT Application are annexed for kind information.



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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	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)
	* Usually panel meetings are held once in 3 months ** Usually the Scientific Committee and Food Authority meetings are held 4 times a year		
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.		