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.

(Shailender Kumar)
Assistant Director (QA)
Email: sp-sampling@fssai.gov.in
Ph: 011-23237417

To:

IT Division, FSSAI – for uploading on FSSAIs website

Brief of the process

<table>
<tr><td>Objective</td><td>To recognize the rapid test kits or equipments or method of analysis</td></tr>
<tr><td>Fees</td><td>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, New Delhi by Demand Draft.
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.
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.
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.
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.</td></tr>
<tr><td>Timeline for scrutiny of application</td><td>
<table>
<tr><th>S. No.</th><th>Activity</th><th>Timeline</th></tr>
<tr><td>1.</td><td>Scrutinization of RAFT application</td><td>3 working days from date of receipt of application by the Secretariat</td></tr>
<tr><td>2.</td><td>Desktop audit of technical components of the application and subsequent recommendation to the Sc. Panel on Methods of Sampling & Analysis (SPMSA)</td><td>By the Methods Review Group (MRG) [4-6 weeks]</td></tr>
<tr><td>3.</td><td>Endorsement of the recommendation of MRG by the SPMSA</td><td>First available meeting*</td></tr>
<tr><td>4.</td><td>Endorsement of the recommendation of SPMSA by the Scientific Committee</td><td rowspan="2">First available meeting**</td></tr>
<tr><td>5.</td><td>Approval of the recommendation of the Scientific Committee by the Food Authority</td></tr>
<tr><td>6.</td><td>Issuance of Conformance Certificate</td><td>5 working days from the date of approval by the Food Authority (only after finalization of minutes of the meeting)</td></tr>
<tr><td colspan="3">* Usually panel meetings are held once in 3 months
**Usually the Scientific Committee and Food Authority meetings are held 4 times a year</td></tr>
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</td></tr>
<tr><td>Validity of Conformance Certificate</td><td>The Conformance Certificate will be valid for three years from the date of issuance</td></tr>
<tr><td>Withdrawal of Conformance Certificate</td><td>FSSAI may withdraw or suspend the Conformance Certificate issued to applicant on the basis of its own investigation or complaint received in this regard.</td></tr>
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APPLICATION FORM FOR ADOPTION OF RAPID ANALYTICAL FOOD TESTING (RAFT) KIT/EQUIPMENT/METHOD BY FSSAI

A. Application for (tick whichever is appropriate) ☐ Rapid food testing kit/media ☐ Rapid Equipment ☐ Rapid Method ☐ Any other, please specify
B. General Information
1. Details of Applicant
(a) Name of Applicant
(b) Name of authorized person
(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) ***NOTE: The applicant should mark any proprietary information***
1. Product Information
(a) Market name and product name
(b) Names and corporate addresses of manufacturers
(c) Address(es) of manufacturing site(s)
(d) Whether approved/verified by regulatory bodies/ organizations

(e) If yes, name of regulatory bodies/organizations and validity of approval
(f) If validated by international bodies (e.g. ISO/AOAC etc.)
(g) If yes, attach documents/certificates/approvals etc.
(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 (*this list is only indicative all necessary information to support and strengthen the application must be submitted)*
(a) The principle and detailed methodology
(b) Applicable to Type(s) of food and food product categories (e.g. unprocessed/low fat)
(c) Test procedure, including the time needed to run the test
(d) Sensitivity and specificity (including where the studies where performed to generate these values and 95% confidence intervals with supporting documents)
(e) Reproducibility across multiple test kit lots (e.g. including number of samples, type of food, number of different lots/devices)
(f) Robustness of the kit/method
(g) Details of inter-laboratory validation of method/multiple users of device
(h) Demonstration of stability throughout the shelf life of the product under recommended storage conditions(not applicable to devices and methods)
(i) If device, warranty period, availability of maintenance service/ spare parts etc
(j) Evidence of satisfactory test performance for kits from userswithin India (not applicable to devices and methods)
4. Operational characteristics for kits/devices
(a) Number of steps
(b) Total run time

(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)
(i) Number of Individual tests/package
(j) Required accessories necessary for operation that are not provided
(k) Availability of Certified Reference Material/Standard Reference Material
(l) Advantages and disadvantages over the conventional technique/method/device
(m) Amount and type of waste generated (e.g. chemical/biological hazard)
(n) 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