File No. 11014/06/2021-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 9th January, 2023

Notice

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

This is in supersession of FSSAI notice number 11014/05/2019-QA (part file) dated 12.01.2021 in pursuance with the clause 2.4 of Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011.

2. The desirous manufacturers/method developers may apply to FSSAI in the revised application format (Annexure) and are hereby requested to follow the points mentioned below during submission of the application:

(i) Only the duly filled complete and signed application will be accepted by FSSAI. Incomplete or unsigned applications will be summarily rejected and no fee shall be refunded.

(ii) In case of applications with incomplete or insufficient data on validation and verification the RAFT Secretariat may direct the applicant to submit additional information with supporting documents.

(iii) The applicant shall submit the information sought for within a period of thirty days, failing which the application will be summarily rejected. The applicant may request, for reasons to be recorded in writing to extend the timeline beyond thirty days.

(iv) Validation of the rapid food testing kit/equipment/method in accordance with international guidelines by a third party, such as an authorized FSSAI laboratory or international organizations like AOAC, AFNOR, MICROVAL etc. is mandatory for approval. Validation of a method consist of two phases: 1) a single laboratory validation of all of the parameters viz. scope, Limit of detection (LOD) and Limit of Quantitation (LOQ), trueness, precision, selectivity, sensitivity, efficiency, linear dynamic range and robustness, repeatability, standard deviation, reproducibility standard deviation and 2) a collaborative ring trial (at least 5-7 laboratories), the main outcome of which is a measure of the repeatability and reproducibility together with detailed information on the transfer-ability of methods between laboratories.

(v) FSSAI will only consider the application under RAFT Scheme by commercial manufacturers of the rapid kit/equipment/method and not through the innovator/ researcher/ institute/ organization. However, if the technology is transferred and the kit is manufactured commercially, the manufacturer will have to validate the kit again as per the guidelines and apply to FSSAI.

(vi) Application should be submitted with proper justification for each product individually along with all necessary/ supporting documents (validation certificate in accordance with international guidelines/data and manual/product insert).

(vii) Application for instruments used for analysis of general parameters like pH, density or routine laboratory equipment and accessories etc. will not be accepted. Such applications, if received will be summarily rejected and no fee shall be refunded.

(viii) Any kit capable of detecting a class of antibiotics as per FSSR will be considered by the committee.

(ix) Applicants should submit separate application for each kit/equipment/method and each application should be accompanied by separate application processing fee *(@Rs. 2000/- + GST @18% is for approval of a single rapid food testing kit/equipment/method in a single application form).* **The fee shall be accepted only through online mode.**

3. In case of renewal of RAFT application, declaration form and fees must be sent to FSSAI not less than 60 days prior to the expiration date on the certificate (as per the guidelines of renewal procedure). For more details, please refer https://www.fssai.gov.in/upload/uploadfiles/files/RAFT_Handbook_10_11_2022.pdf (page no. 14).

4. The duly filled application form (copy enclosed) shall be sent to the undersigned through e-mail (raft-approval@fssai.gov.in), **until the online RAFT portal is operational.** The hard copy of the RAFT application will not be accepted.

This issues with the approval of Competent Authority.

(Harinder Singh Oberoi)
Advisor (QA)

To:
IT Division, FSSAI – for uploading on FSSAIs website

Copy to:
(1) PS to Chairperson, FSSAI
(2) PS to CEO, FSSAI

A. Application for (tick whichever is appropriate) ☐ Rapid food testing kit/media ☐ Rapid Equipment ☐ Rapid Method ☐ Rapid food testing kit with equipment ☐ Any other, please specify
B. Details of the kit
(a) Name of the Rapid test kit/media/device/method
(b) Proposed regulatory use (specific product testing/analytical method)
C. General Information
1. Details of Applicant
(a) Name of Principal manufacturer/ Original Equipment 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) GST and PAN no. of the applicant (organisation)
D. Technical Information - Contents to be submitted with the dossier for pre-evaluation by FSSA(I) ***NOTE: The applicant should clearly state which parts of the application are claimed to be confidential/proprietary and provide verifiable justification.***
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 other regulatory bodies/ organizations
(f) If yes, name of regulatory bodies/organizations and validity of approval
(g) Whether 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)
(j) Evidence that manufacturers have a certified Quality Management System or Good Manufacturing Practice (GMP) certification; if applicable
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) Specify Food Category/Matrix as per FSSR (2011) 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/Detection capability
(g) Sensitivity (wherever applicable)
(h) Specificity (including where the studies were performed to generate these values at 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 (minimum three) within India
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) Image/flow-chart of rapid kit/equipment/method
(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. (If the accessories/equipment are proprietary, then provide the validation data).
(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. Fee details: Amount paid (Rs. ……..) Mode of payment (Online Mode only*) Transaction id/UTR No. with date and bank name & account no. Name of the payee with GST no. and account details **payment through cheque mode, demand draft and cash will not be accepted.* The application processing fee of Rs. 2000/- (Rupees two thousand) + GST @18% can 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: BARB0(Zero)NIRDEL The GST No. of FSSAI is 07AAAGF0023K1ZV (0 is Zero).
6. Any additional specific information

Declaration

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. 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 and Seal…….

Contact details……..

To

Chief Executive Officer (CEO), FSSAI