11014/RAFT01/2023-QA I/26085/2025

# File No. 11014/RAFT01/2023-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 28 February, 2025

### **Notice**

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

This is in supersession of FSSAI notice number 11014/06/2021-QA dated 31.10.2023.

- 2. The desirous manufacturers/method developers may apply to FSSAI in the application format through the Online Portal available at https://raft.fssai.gov.in/. Applicants are hereby requested to follow the points mentioned below during submission of the application:
  - i. FSSAI shall accept the duly filled, complete and signed application received on the online RAFT Portal only. **Any other mode of application shall not be accepted.**
  - ii. In case of applications with incomplete or insufficient data, the RAFT Secretariat may direct the applicant to submit additional information with supporting documents. The applicant shall be granted 02 chances for submission of the required data or any rectifications/clarifications in the application.
  - iii. The applicant shall submit the information sought for within a period of thirty days for technical queries e.g. validation data and seven days for non-technical/administrative queries, failing which the application will be summarily rejected. The applicant may request, for reasons to be recorded in writing to extend the timeline beyond the stipulated time period.
  - iv. Validation of the rapid food testing kit/equipment/method in accordance with national/international guidelines by a third party, such as an authorized FSSAI laboratory or international organizations like AOAC, AFNOR, MICROVAL, ILVO, USFDA, NORDVAL etc. is mandatory for approval. Validation of a method consist of two phases: 1) a single laboratory validation of all of the parameters viz. measurement range, accuracy, measurement uncertainty of the results, limit of detection (LOD), limit of quantification (LOQ), selectivity/specificity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias; and 2) a collaborative ring trial (at least 5-7 laboratories) conducted by host/expert laboratory.
  - 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

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- have to validate the kit again as per the guidelines and apply to FSSAI.
- vi. International manufacturers are encouraged to directly apply to FSSAI for RAFT approval. In case the application is submitted through Indian importer/distributor/vendor, it shall be accompanied by authorization letter as mentioned in FSSAI Notice No. File No. 11014/06/2021-QA-Part(1) (E 7948) dated 2<sup>nd</sup> December, 2024.
- vii. In case of the overseas manufacturers having an Indian subsidiary, the RAFT Application will be accepted from Indian subsidiary only. In such cases, the RAFT application if received from any other dealer/vendor/distributor shall be rejected.
- viii. Application should be submitted with proper justification for each product individually along with all necessary/ supporting documents
- ix. 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.
- x. Only the applications based on the parameters specified in Food Safety and Standards Regulations shall be considered for approval.
- xi. 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% for single rapid food testing kit/equipment/method in a single application form). The fee shall be accepted through online RAFT Portal only.
- xii. In case of renewal of RAFT Certificate, the applicants must apply for renewal on the **online RAFT Portal** not less than 60 days prior to the expiration date on the certificate (as per the guidelines of renewal procedure). **Any other mode of renewal application shall not be accepted.**

(Dr. Satyen Kumar Panda) Advisor (Quality Assurance)

To:

IT Division, FSSAI - for uploading on FSSAIs website

### Copy to:

- 1. PS to Chairperson, FSSAI
- 2. PS to CEO, FSSAI