File No. 11014/01/2022-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 31st October, 2023

Notice

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

This is in supersession of FSSAI notice number 11014/06/2021-QA dated 09.01.2023.

2. The desirous manufacturers/method developers may apply to FSSAI in the application format through the Online Portal available at <u>https://raft.fssai.gov.in/</u>. 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. 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 through online RAFT Portal only.

3. In case of renewal of RAFT application, 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.**

This issues with the approval of Competent Authority.

(Dr. Satyen K. Panda) Advisor (QA)

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

Copy to:

- (1) PS to Chairperson, FSSAI
- (2) PS to CEO, FSSAI