**APPLICATION FORM FOR ADOPTION OF RAPID ANALYTICAL FOOD TESTING (RAFT) KIT/EQUIPMENT/METHOD BY FSSAI**

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| **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