



Guidelines for Accreditation of FSMS Assessment Agencies

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Table of Contents

Policy on accreditation.....	3
Procedure for Selection of Agencies	5
Eligibility Criteria	
Registration Process	
Initial Evaluation	
Surveillance	
Recertification	
Monitoring of accredited agencies	
Records to be maintained by accredited agencies	
Procedure for Assessor Competency.....	12
Assessor Education Requirements	
Assessor Competence Criteria	
Assessor Qualification Process	
Management of Impartiality	
Conformity Assessment and Training Provision Requirements for FSMS Certification	17
Responsibility of Accredited Agencies	
Certification Process to be followed by Accredited Agencies	
Initial Evaluation	
Grant of Certification	
Management of Impartiality	
Annexure.....	23
Assessment Report Format	
Certificate Format	
Code of Conduct for Accredited Agencies	



Accreditation Policy

1. The agencies that are willing to undertake the certification or inspection for FSMS assessment shall have an accreditation from FSSAI.
2. An Agency that wishes to have an accreditation shall undergo all four steps of accreditation process as per this guidance document.
 - Preliminary investigation
 - Initial investigation
 - Accreditation decision
 - Annual Surveillance assessment
3. The accreditation reassessment shall be done every three years.
4. The agencies shall update FSSAI on the certification status on monthly basis as per the stipulated information.
5. The Agency shall maintain the stipulated records of inspections & required records to demonstrate the competencies of inspectors.
6. FSSAI has rights to ask for additional information from the accredited Agency as & when required.
7. FSSAI has rights to delist/withdraw accreditation if the Agency fails to comply with the requirements.
8. FSSAI allocates FBOs to individual agencies for FSMS certification.
9. An Agency conducting audit may not conduct training for the FBO during the period of certification – assessors are not prohibited from providing improvement methods as part of an assessment.



SCOPE OF THIS DOCUMENT

Section 16(2)(c), of the FSS Act, 2006 provides for the Mechanism for accreditation of certification bodies for Food Safety Management Systems and Section 44 of FSS Act provides for Recognition of organisation or Agency for food safety audit and checking compliance with Food Safety Management System required under the Act or the rules and regulation made thereunder.

This document explains the process of approval of certification / inspection bodies and the requirements that should be followed in order to obtain, operate and maintain the accreditation.



PROCEDURE FOR SELECTION OF AGENCIES:

1.0 INTRODUCTION

- 1.1 One of the functions of FSSAI is to establish the mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management systems for food businesses.
- 1.2 Each applicant Agency provides information to FSSAI on its activities, organization and staff.
- 1.3 Assessment of the competence of a certification / inspection Agency is carried out using document review, and may include an on-site assessment of the Agency's central location or key regional sites.
Continued conformance will be monitored through post assessment reviews of certificated FBO.
- 1.4 All information obtained before, during or after assessment, including the fact that a particular Agency has applied for accreditation, or that an application has been deferred or rejected, will be treated as strictly confidential by FSSAI staff and assessors.
- 1.5 This document outlines how FSSAI plans and conducts assessment, surveillance and re-assessment visits to certification bodies working to the Standard on a three year cycle. It also refers to the assessment techniques normally used.
 - 1.5.1 Every organisation is unique and the assessment plan must recognise this. However, a structure is needed within which judgments are made. By outlining the minimum requirements this document provides such a structure.
 - 1.5.2 All circumstances cannot be anticipated and it may necessary to deviate from these requirements, in order to conduct an effective assessment. FSSAI will provide the reason for the use of any alternative approach.

2.0 DEFINITIONS

Act means the Food Safety and Standards Act, 2006 (Act 34 of 2006)

Food safety means assurance that food is acceptable for human consumption according to its intended use;

Food safety audit means a systematic and functionally independent examination of food safety measures adopted by manufacturing units to determine whether such measures and related results meet with objectives of food safety and the claims made in that behalf;

Food Safety Management System (FSMS) means the adoption Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business;

Food Business Operator in relation to food business means a person by whom the business is carried on or owned and is responsible for ensuring the compliance of the Act, rules and regulations made thereunder

Assessor means an individual who is an employee or agent of an accredited certification / inspection Agency and, although not individually accredited, is qualified to conduct food safety audits and consultancy on behalf of an accredited Agency.



Certification / Inspection Agency (Agency) means an Agency that is accredited under the International Accreditation Forum (IAF) for delivering FSMS Audits and considered for approval by the authority to conduct food safety audits to certify that FBOs meet the applicable regulations.

Assessment Manager means an employee of FSSAI nominated by the authority for the review and assessment of applications received from certification / inspection agencies.

3.0 ELIGIBILITY CRITERIA

The proposals will be screened on the basis of the following essential eligibility criteria: -

Level 1 Agencies: These are agencies applying to conduct assessment for only those FBOs whose turnover is less than 50 lakhs per annum.

1. The Applicant Agency should have a minimum of two years' experience in auditing Food industries. Documentary evidence and details to be provided to support the experience.
2. Should have access to technically qualified personnel equivalent to qualification mentioned in FSS Rules and well-experienced strong in-house or empanelled resource base.
3. The applicant should furnish an undertaking to the effect that the Agency has never been black listed in India or abroad.

Level 2 Agencies: These are agencies applying to conduct assessment for all FBOs, irrespective of turnover.

4. The Applicant Agency should have a minimum of two years' experience in auditing Food industries. Documentary evidence and details to be provided to support the experience.
5. The applicant Agency should be accredited, in FSMS, by a National or International Accreditation Body, which is an IAF member.
6. Should have access to technically qualified personnel equivalent to qualification mentioned in FSS Rules and well-experienced strong in-house or empanelled resource base.
7. The applicant should furnish an undertaking to the effect that the Agency has never been black listed in India or abroad.

4.0 REGISTRATION PROCESS

4.1 Documents to accompany Application:

The applications shall be complete with the following documents:

- Expression of Interest in **Form – I**.
- Details of experience in auditing food industry (at least for the last 1 year)
- Details of Financial status of the applicant in **Form-II**.
- Details of staff working in the organisation along with Name, Educational qualification, experience and trainings etc.
- Details of number of food establishments inspected/audited during the last 1 year.



- Self certified copy of documents establishing that organisation has been accredited for FSMS by an National or International Accreditation Body, which is an IAF member. (Copy of Registration or Accreditation Certificate).
 - A copy of the Agency's Quality manual.
 - A copy of the last assessment report by the accreditation body.
 - Any other information required in support to the scope of work.
 - Application fee as defined by FSSAI
- 4.2 On receipt of an application for assessment for accreditation from an Agency, FSSAI will appoint an Assessment Manager to be responsible for the accreditation process. The assessment manager will contact the Agency to:
- (i) confirm the geographic areas for which the Agency is seeking accreditation;
 - (ii) confirm the different locations from which the certification service is managed and/or delivered and whether key activities that are carried out at each of these;
Note: Key activities include: policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments.
 - (iii) The Agency's management system documentation will be examined for compliance with this procedure, the relevant sections of the FSS 2006 Act Standard and relevant guidance documents.

The purpose of the documentation review is for FSSAI to gain an understanding of the applicant Agency's legal constitution, governance, organisation structure, scope and location of activities, the management system and controls and the extent to which the accreditation requirements appear to have been addressed.

5.0 INITIAL EVALUATION

FSSAI will seek to establish by using various techniques, which may include on-site assessment, that:

- the management system is appropriate to the Agency's needs, organisational arrangements, processes, scope and scale of its operations including multiple locations, overseas activities and client base;
- all of the requirements have been satisfactorily addressed;
- that FSSAI can have confidence in the validity of the certification decisions made by the Agency

5.1 Procedure

The accreditation procedure will be in six steps.

Step 1. Preliminary investigation

In this initial phase the FSSAI determines whether the Agency is sufficiently prepared to commence an initial assessment within a certain period. This ensures that FSSAI does not commence an assessment schedule if essential elements are lacking. The preliminary investigation is completed with a report on any non-conformities identified. In consultation with the Agency FSSAI will then commence the initial investigation.

Step 2. Initial investigation



The initial assessment by FSSAI will be done on-site.

The duration of the assessment will be decided by FSSAI based on the size of the Agency, but shall be no less than 2 mandays at initial assessment.

During the initial assessment FSSAI verifies compliance. The results are documented in a report. If FSSAI discover any non-conformities, the Agency has two months thereafter in which to put them right. An Agency also has the opportunity to make a formal objection against any nonconformity.

If no nonconformities are found, then accreditation may be granted. FSSAI will then proceed to step 3 as quickly as possible: an accreditation decision.

Step 3. Accreditation decision

A follow-up assessment will be held within two months. FSSAI shall investigate whether the nonconformities have been corrected and are in accordance with the relevant standards and regulations. If that is the case, then the Agency may be accredited. This will be done on the basis of a report and the advice of the team leader.

The Accreditations Committee advises the Chief Executive of the FSSAI on granting accreditation. This accreditation shall be valid for three years. The accredited Agency will have the right to use the FSSAI logo, as per defined norms, in any of its communications. It will also be listed on the FSSAI website.

Step 4. Annual Surveillance assessment

Notice of the Surveillance assessment shall normally be given at least two months in advance, so that the conformity-certifying Agency can prepare for the assessment.

Surveillance assessments will be conducted at 12 months, and 24 months after initial accreditation.

Type of non-conformities:

During the assessment a Type A or Type B nonconformity may be identified:

- A Type A nonconformity must be corrected within 15 days.
- A Type B nonconformity must be corrected within two months.

The assessment team then has one month in which to assess the corrective step taken. After each assessment, the Chief executive will decide on whether to continue the accreditation.

Sometimes an accredited Agency is suspended because it fails to satisfy the requirements set by FSSAI. The suspended Agency then has a fixed period of time in which to correct everything. If it fails to do so in the time allowed, the FSSAI may take the decision to withdraw the accreditation.

6.0 ACCREDITATION DECISIONS

A report will be issued to the Agency on completion of the assessment. It will include a recommendation regarding accreditation. The report and recommendation is also subject to review by independent FSSAI staff for a decision following initial assessments, reassessments and any extension to scope. If the review identifies the need for any further information of action to be taken by the Agency, this will be requested by the Assessment Manager.

Following an initial assessment where the recommendation to accredit has been agreed by FSSAI, the decision will be confirmed in writing with the Proposed Accreditation Details. A copy



of the draft schedule and 3 year assessment effort estimate will also be provided to the Agency. The Agency shall agree these details before accreditation can be granted. The Agency will need to sign their acceptance of the Code-of – conduct for accredited agencies.

Once the assessment team is satisfied that all findings have been satisfactorily addressed, accreditation is granted. The grant letter is sent to the Agency with an Accreditation Certificate and a schedule detailing the agreed certification activities.

7.0 ONGOING MONITORING

Following accreditation, as part of routine monitoring, each accredited Agency will need to provide the following information to FSSAI on a monthly basis, normally by the 5th of each calendar month,

- a. the number and locations of audits performed
- b. the number and locations of consulting training provided
- c. the frequency and kind of violations and disciplinary measures
- d. the frequency and kind of exemptions
- e. the frequency and kind of complaints
- f. the frequency and kind of appeals
- g. the frequency and kind of infringements found

FSSAI would also check for continuing compliance, by carrying out surveillance visits to certification bodies, annually, with a reassessment in the third year.

Witnessed audits or visits by FSSAI staff of certificated FBOs may be carried out as part of surveillance.

Where corrective action by the Agency is required, this must be completed and evidence sent to FSSAI within one month for Type A non-conformities and 4 months for Type B non-conformities.

The verification of the effectiveness of the actions taken will normally be carried out at the next visit to the Agency, but FSSAI reserves the right to carry out this verification at any time after the agreed completion date.

8.0 REASSESSMENT

Reassessment will involve a comprehensive re-examination of the Agency's management system and certification activities and will be similar in approach and content to the initial assessment although the emphasis may be different dependent upon performance and changes over the past three year cycle.

The requirements for completion of close out of findings that require improvement action and submission of evidence to FSSAI are as for surveillance.

RECERTIFICATION EVERY THREE YEARS

In its scope, a re-certification is virtually identical to the initial assessment.

9.0 EXTENSION OF GEOGRAPHICAL AREAS

An accredited Agency may request an extension of the geographical areas it operates in. This may happen if, for example, the Agency expands its activities. On the basis of the application for extension, FSSAI will decide whether an investigation to extend scope can be carried out and, if



so, in what manner.

10.0 MULTI LOCATION CERTIFICATION AGENCIES

An applicant that operates from a central office and through a number of locations may seek a single accreditation.

On application, the Agency must indicate the number of locations where key activities take place. Information about any other locations and their range of activities shall also be provided.

FSSAI will seek to establish using various techniques that:

- all locations are operating under the same management system;
- all locations are included in the internal audit programme and central review process.

FSSAI must be advised of any changes to location addresses, activities and countries in which they have certificated organisations.

The establishment of any new locations from which the Agency proposes to undertake any part of the certification process must be notified to FSSAI before these can be included in the scope of accreditation; the need for assessment will be reviewed and, following the completion of any necessary assessment activities, the location will be added to the published details of the accreditation and included in the programme of surveillance and reassessment.

If FSSAI raises findings that require improvement action at the central office or at any one of the locations, the improvement action shall apply to all relevant locations.

Failure by one location to comply with FSSAI requirements may lead to removal of the location from the published details of the accreditation. If the cause of the nonconformity is lack of central control then the entire accreditation will be subject to review by FSSAI and may lead to sanctions across all locations.

11.0 RECORDS TO BE MAINTAINED BY ACCREDITED AGENCY

Records shall be kept by individual Inspection and Certification Agencies for: -

- Exceptions
- the number of inspections performed
- the frequency and kind of violations and disciplinary measures
- the frequency and kind of exemptions
- the frequency and kind of complaints
- the frequency and kind of appeals
- the frequency and kind of infringements found

12.0 SCHEDULE OF FEES

The following shall be the fee payable by applicant/ accredited Agency

Level 1 Agency:

Sr. No.	Purpose	Fee (Rs.)
1.	Application Fee: (Recognition / renewal of recognition for each scope) for each as specified under Clause No. 4.1.1	3,000/-
2.	Assessment Fee / Surveillance Fee / Special visit charges	5000/- per man-day plus expenses for travel and stay of assessors at actual
3.	Security Deposit	1,00,000/-
4.	Accreditation Fee (to be paid in advance on consideration for accreditation)	30,000/-
5.	Enhancement of Geographical Area (for each)	5,000/- per State + Assessment Fee as defined at Sr. No. 3 above

Level 2 Agency:

Sr. No.	Purpose	Fee (Rs.)
1.	Application Fee: (Recognition / renewal of recognition for each scope) for each as specified under Clause No. 4.1.1	5,000/-
2.	Assessment Fee / Surveillance Fee / Special visit charges	10,000/- per man-day plus expenses for travel and stay of assessors at actual
3.	Security Deposit	2,00,000/-
4.	Accreditation Fee (to be paid in advance on consideration for accreditation)	50,000/-
5.	Enhancement of Geographical Area (for each)	10,000/- per State + Assessment Fee as defined at Sr. No. 3 above

The Agency shall make these payments in the form of Demand Draft / Pay Order drawn in favor of Food Safety & Standards Authority of India, payable at Delhi

PROCEDURE FOR ASSESSOR COMPETENCY

Assessor Education Requirements

All FSMS assessors should possess the following minimum qualifications:



(i.) a degree in Food Technology or Dairy Technology or Biotechnology or Oil Technology or Agricultural Science or Veterinary Sciences or Bio-Chemistry or Microbiology or Masters Degree in Chemistry or degree in medicine from a recognized University, or

(ii.) Any other equivalent/recognized qualification notified by the Central Government, and

(iii.) Has successfully completed training as specified by the Food Authority in a recognized institute or Institution approved for the purpose.

(iv) Successfully completed a recognized FSMS auditor course.

Work Experience:

All FSMS assessors should have a minimum of three years work experience in the food industry.

Audit Experience:

12 days of Third Party/Second Party Food industry management system audits in the last 3 years

Competence Criteria for Food Safety Assessors

Parameters	Basic
Eligibility	Degree in Food Technology or dairy or biotechnology or oil technology or agricultural or veterinary or biochemistry or Microbiology of Master degree in Chemistry or Degree in Medicine from Recognized university. Experience: Minimum 2 year in food related jobs (manufacturing/food service quality/training/auditing/academic/consulting)
Competency	<ul style="list-style-type: none">• Ability to implement GMP/GHP• Ability to evaluate standard operating protocols for GMP/GHP/internal audit and legal requirements• Guidance /Auditing against national regulatory requirements
Knowledge	<ul style="list-style-type: none">• National food laws and regulations• Fundamental knowledge of food science and basics of food hygiene• General Principles of Food Hygiene (CAC/RCP-1) and Food Safety• Food Sector terminology• Basic knowledge on GMP & GHP• FSS Act & Regulation, Licensing/ Registration requirements for FBOs
Skills	<ul style="list-style-type: none">• Good Communication, Training and Auditing skills

Draft



Course Structure	<ul style="list-style-type: none">Regulatory knowledge - FSS Acts and Rules /Licensing and registration/ Packaging and Labelling requirement /Additives /Prohibition and restrictions on sale /Contaminants, Toxins and Residues /Food Analysis & sampling/Related provisions: Legal Metrology /Environmental Consent requirements /Factories ActGMP/GHP- Part 1 to 5 for Schedule 4 requirementsInternal Auditing-Principles and skills, Food safety Hazards and Risk analysis
Training	From FSSAI Approved/Registered training firm

An Inspectors/ Consultants/ Assessors/ Evaluators can be categorised into following 3 grades and must have following experience & skills:

(i) Grade I - minimum 3 years experience in food sector especially in food safety, & standards issues/ policies

(ii) Grade II - minimum 8 years experience, out of which atleast 2 years in supervisory capacity & 1 year of auditing etc.

(iii) Grade III- minimum 12 years experience, out of which atleast 6 years in supervisory capacity & 3 years of auditing etc.

Assessor Competence criteria

In general terms, FSMS assessors should:

- be familiar with the relevant FSMS procedures;
- be suitably trained in the profession;
- have a good knowledge and understanding of different assessment methods;
- be appropriately experienced and skilled for the job.

An FSMS assessor should be able to apply a process based approach to conducting assessments and should be capable of understanding the processes of an evaluated FBO and in relating them to the requirements of relevant requirements of the Act, international standards and guides. Additionally, an FSMS assessor should have the ability to trace back non conformities or deficiencies to the FBO's processes or management system

Accredited Certification / Inspection agencies shall have defined the criteria for the competencies needed to carry out assessments.

The competency criteria may be defined in terms of basic (generic) requirements and specific requirements (related to a particular scheme and sector and to other specific features).

In the following differing competency criteria are highlighted that an accredited certification / inspection should consider when selecting its assessors and consulting teams for a particular assessment:



Essential areas of knowledge and skill for the FSMS assessor are the following:

1) Thorough knowledge of food law(s) and pertinent regulations

It is essential that the food assessor has a thorough knowledge of the law(s) and regulations governing the operation of food processing facilities and the corresponding inspection procedures. In addition, the assessor must know other pertinent regulations such as those dealing with environmental issues and workplace safety. Also of importance to product quality and safety are regulations affecting agricultural practices, food transportation and food distribution.

2) Background information on the field of food safety and quality

Assessors must know and understand all elements of a quality and safety management system, the role these play in food safety and the way these elements interact with one another. Central to this understanding is knowledge of food processing operations, food microbiology and food chemistry.

3) Prerequisite sanitation, hygiene, and pest control practices

A thorough understanding of prerequisite programmes requires prior knowledge of the properties of various types of cleaning and sanitizing compounds, and their interactions with food matter, with each other and with other materials, particularly those materials that equipment is made of (e.g. chlorine and steel).

Moreover, it is important that the assessor is aware of the characteristics and effects of sanitizing compounds on target bacterial groups and the accepted limits for residues of such compounds in food.

The assessor must also be knowledgeable about hygiene practices, including personnel hygiene, and must be able to convey this knowledge to management and employees so that the objectives of relevant regulations are easily understood.

The field of pest control products and practices is another area in which assessors must be knowledgeable. Most pest control products can be deleterious if they find their way into food. The assessor should be able to communicate this knowledge to food processors.

4) Food Auditing / Inspection principles

Hazard Analysis and Critical Control Point (HACCP) approach is risk-based and its elements are helpful to use during an inspection / training. As such, it should be thoroughly understood by the assessor. Furthermore, the assessor should use inspections as an opportunity to promote HACCP to businesses. Ideally, food assessors will have taken courses and been certified in the application of HACCP.

5) Assessment techniques

Food assessment, as approached by this topic, is a review of the food safety and quality aspects of a primary processing operation or a food processing facility. It is expected that the topic will provide the assessor with sufficient insight into inspection techniques to properly fulfil his/her task.

6) Sampling techniques for product testing

Knowledge of sampling techniques, particularly aseptic techniques, and of sample handling for transportation to a laboratory are essential to guarantee the integrity of samples taken for verification. In addition, the assessor must have a good knowledge of testing techniques so that he/she can make informed decisions about sampling methods and properly interpret the results of testing.



7) Compliance verification skills

Beyond academic and practical knowledge of food regulations, food processing, food microbiology and chemistry, it is essential that assessors have sufficient professional experience and criteria to be able to focus the inspection on the truly important factors affecting food product safety: the risk factors associated with food-borne disease.

8) Communication and other skills

The food assessor must also possess good communication skills to enable him/her to adequately convey technical and regulatory information regarding safe food handling to others. In addition, the assessor must have professionalism and confidence and exhibit dignity and integrity.

9) Training certificate and required certificate updates

The food industry is in constant change. New food processing technologies, new controls, new equipment and new ingredients constantly come onto the market, as do new testing methods. The food assessor needs appropriate training and must have a diploma/certificate attesting to his/her professional standing and must attend certified continuing education courses to stay up to date with new developments. Mentoring of new assessors by experienced colleagues is highly desirable

Assessor Qualification process

The assessor/consultant qualification process should cover the initial selection, training, ongoing training and periodic evaluations that may be required to maintain and confirm continued competence. Assessors and Consultants need to be:

- selected (based on education, knowledge, experience and skills possessed);
- trained in the certification rules and methods and in the procedures, criteria and any relevant provision, by suitable training courses or equivalent means, as advised by FSSAI.
- continuously monitored and evaluated by appropriate techniques (Ref ISO 19011).

Management of Impartiality:

Confidentiality: security of information

Assessors should exercise discretion in the use and protection of information acquired in the course of their duties. Audit information should not be used inappropriately for personal gain by the assessor or the audit client, or in a manner detrimental to the legitimate interests of the auditee. This concept includes the proper handling of sensitive or confidential information.

Independence: the basis for the impartiality of the assessment and objectivity of the assessment conclusions. Assessors should be independent of the activity being audited wherever practicable, and should in all cases act in a manner that is free from bias and conflict of interest.



ASSESSOR COMPETENCE CHECKLIST

Documents Checklist For Assessor Qualification

Detailed Resume	
Educational Certificates	
Auditor Course Certificates	
Work Exp letters or other evidence of experience	
Confidentiality Agreement	
Training Record for Regulatory requirement wrt FSS	
Participation on 4 audits and at least 12 days audit experience. The audits should be completed within the last 3 consecutive years.	



PROCEDURE TO BE FOLLOWED BY ACCREDITED AGENCIES FOR FSMS CONFORMITY ASSESSMENT OF FBOs

1. SCOPE OF THIS PROCEDURE

This document provides the requirements for conformity assessment and consultancy, of FSMS, by accredited agencies

2. DEFINITIONS: As defined earlier

3 RESPONSIBILITY OF ACCREDITED CERTIFYING AGENCY

The accredited inspection/auditing Agency will be required to carry out the following jobs assigned by the Authority from time to time: -

- a) To inspect Food business in the light of sanitary and hygienic requirements mentioned in the conditions of license and schedule IV of Food Safety and Standards (Licensing and Registration) Regulations, 2011. These inspections will be as per the inspection report formats as defined by FSSAI.
- b) To conduct pre-commissioning inspection of newly established Food Business units.
- c) To conduct routine / unannounced inspections as directed by the Authority from time to time to verify the Food Business units so as to comply with FSS regulations made there under.
- d) To conduct periodical food safety inspections/ audit at least once a year of food businesses.
- e) To conduct re- inspections to verify rectification of deficiencies pointed out by the Licensing Authority.
- f) To guide and advise the licensees during inspections for rectification of non compliance and compliance with the FSS Regulations as well as to recommend measures for production of safe and wholesome of food;
- g) To impart training to Food Business Operators towards Food Safety and management systems.
- h) To inspect Food Business units for verification of complaints on the direction of the Authority from time to time;
- i) To devise and recommend to the Authority improvement measures in enforcement of rules/ regulations, problems faced by the FBO, creation of food safety awareness amongst the licensees as well as consumers; and
- j) Any other related assignment which the Authority may deem fit in the public interest.
- k) The format/ requirements of Inspection/ Audit will be as presented by FSSAI from time to time. Charges for Inspection/ Audit will also be notified by FSSAI.

4. CERTIFICATION PROCESS TO BE FOLLOWED BY ACCREDITED AGENCIES

4.1 Registration of Application

4.1.1 The certification Agency shall maintain and make publicly available accurate information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and geographical areas in which it operates The information shall include

- a) reference to the Certification Criteria,

- b) A detailed description of the initial and continuing certification activity, including the application, initial evaluation, periodic surveillance evaluations, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and recertification .
 - c) an Application form;
 - d) list of documents required to be submitted along with the application.
 - e) information about the fee for application, initial certification and continuing certification
 - f) documents describing the rights and duties of certified FBOs, and
 - g) information on procedures for handling complaints and appeals
- 4.1.2 The Agency shall respond to all enquiries received from prospective applicants for certification of food establishments with complete information for facilitating a registration of an applicant, within seven days of receipt of the query.
- 4.1.3 The prospective applicant food establishment shall apply to the Agency on the Application format prescribed by the Agency, and provide as a minimum information on
- i. the name and address of applicant with contact details,
 - ii. proof of legal entity,
 - iii. location of the food establishment,
 - iv. category of food establishment (as per Indian Food Code),
 - v. range of food products offered,
 - vi. description of production processes,
 - vii. own installed/existing food processing facilities,
 - viii. number of shifts of operation,
 - ix. number and competence of manpower,
 - x. logistics infrastructure if any.
- 4.1.4 The prospective applicant food establishment shall declare whether it has been an applicant or certified by any other certification Agency, and if yes then shall provide the previous evaluation reports to the new certification Agency. The certification Agency may verify the information provided by contacting the earlier certification Agency.
- 4.1.5 The prospective applicant food establishment shall along with the application declare any judicial proceedings relating to their operations/ product, any proceedings by any Regulatory Agency or suspension/cancellation/withdrawal of any certification/ approvals under any Regulations or otherwise.
- 4.1.6 Certification is granted only against the current relevant certification criteria. The certification Agency shall review all applications for the above and ensure the same.
- All applications for certification shall be reviewed by the certification Agency for adequacy and deficiencies observed, if any, shall be informed to applicant food establishment within fifteen days of receipt of application. Review of applications shall be done by a competent person. Records of review shall be maintained.
- 4.1.8 Only applications found to be completely filled and supported with all documents



sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration should be done within seven days of receipt of application or deficiencies communicated as per 4.1.6 above.

- 4.1.9 Antecedents of applicants shall be verified in relation to the Requirements, including information on prior FSMS audits.
- 4.1.10 Applications from food establishments found to be violating the terms and conditions of the Licensing while their application is being processed for grant of certificate, shall not be processed any further, and rejected after a due notice of 15 days.
- 4.1.11 Requests for grant of certificates from ex applicants shall be processed like a fresh applicant and the entire procedure for grant of certificate be adhered to subject to clause 4.1.8, 4.1.9 and 4.1.10 above.
- 4.1.12 Certification Bodies shall only reject or close all Application under the following conditions;
 - a) if Stage 2 of Initial Evaluation is not carried out within six months of registration of application
 - b) If hygienic facilities are observed to be deficient during the Initial Evaluation and/or during the follow up Evaluation carried out after food establishment has confirmed necessary corrective actions are not completed within one month of Initial Evaluation,
 - c) Non acceptance of internal quality assurance protocol within a month of Initial Evaluation;
 - d) Lack of competent personnel for food processing,
 - e) If food establishment shows no progress towards completion of corrective actions within one month of Initial Evaluation and six months of Registration of application.
 - f) Misuse of Certification Mark
 - g) Evidence of malpractice
 - h) Voluntary withdrawal of application.
- 4.1.13 In the event of a closure/rejection of an Application, the application fee submitted with the application may be refunded as decided by the certification Agency.

4.2 Initial Evaluation

- 4.2.1 Initial evaluation shall be carried out in two stages by a competent evaluation team.
- 4.2.2 Initial Stage 1 Evaluation of the food establishment shall be conducted within one month of registration of application and or satisfactory fulfillment of all application requirements.
- 4.2.3 During the Stage 1 evaluation the certification Agency shall review the Self Inspection Report submitted by the prospective applicant to ascertain the status of compliance to food safety regulation and applicant's state of preparedness with respect to the requirements of the certification criteria for the Stage 2 evaluation, and prepare a report. Certification Agency shall ensure that the Self Inspection

Report is structured around the certification criteria providing adequate information for reaching an informed judgement prior to proceeding to Stage 2 evaluation. This review shall be carried out off site.

- 4.2.4 Deficiencies observed with respect to the certification criteria during the Stage 1 evaluation shall be informed in writing to the applicant.
- 4.2.5 The Stage 2 evaluation by certification Agency shall take place only after necessary actions on the identified deficiencies have been taken and confirmed by applicant. The Certification Agency may seek documentary evidence to verify the implementation of corrective actions.
- 4.2.6 Timings and date of Initial Evaluation shall be fixed in consent with the food establishment ensuring that food production processes representative of normal business operations will be open for witnessing during the planned Evaluations.
- 4.2.7 The certification Agency shall communicate the composition of the teams and duration of Initial Evaluation to the applicant food establishment for identification of conflict of interest, if any. Any objections to the team by the applicant should be examined on merit.
- 4.2.8 Stage 2 Evaluation duration shall be based on the size of FBO; viz;

Turnover (per annum) of FBO	Duration (in man-days)
Upto 50 lakh	Need basis
50 lakh – 1 crore	2
1 crore – 5 crore	2
5 crore – 25 crore	3
25crore –100crore	3
100 crore& above	3

(One assessment day is equivalent to 8 hours)

- 4.2.9 During the Stage 2 evaluation of the applicant, the team shall
 - a) Witness the food production processes covering as many products applied for as possible;
 - b) Check for practices and process controls being exercised for ensuring food hygiene and safety and conformance to regulatory requirements and undertake verification of all records;
 - c) List the applicable regulations and check compliance on sampling basis, need to cover all in certification cycle,
 - d) Verify analysis reports of samples of food products being processed and provided to customers by the food establishment.
- 4.2.10 Any non-conformity to the certification criteria observed during Stage 2 evaluation with respect to the certification criteria shall be informed in writing to the applicant for taking necessary action. The non-conformities shall be classified as

Major: total or significant absence of compliance



Minor: significant compliance with requirements, some problems to be sorted to obtain full implementation

4.2.11 Based on the level of implementation and compliance observed during the evaluation, an on site evaluation report shall be prepared.

4.2.12 Certification Agency shall maintain records of all certification activities – application registration, documents provided by applicant, on site evaluation report.

4.2.13 Certification Agency shall send copies of the detailed reports to FSSAI and FBO within 15 days of assessment.

4.2.14 Certification Agency shall verify all Major non-conformances within 30 days of initial audit and all Minor non-conformances within 90 days of initial audit.

4.3 Grant of Certificate

4.3.1 The certification Agency shall ensure the following prior to processing the application for grant of certificate :

- a) The availability of all relevant processing equipment required for the production of food products.
- b) Availability of authorized and/or adequate power and water supplies, where such supplies are required for processing, production, storage and serving of food.
- c) Competent and qualified personnel for production of food product(s) and management of the facility.
- d) Compliance to the applicable food regulation.
- e) Conformity of the food establishment with requirements of the certification criteria as relevant to the specific category of food establishment;
- f) Conformity of the food product with microbiological requirements of the food regulations;
- g) Necessary documentation for proof of legal entity and authentication of premises of manufacture where certification is being sought.
- h) Acceptance from the applicant for other certification requirements like the fee, Brand name declaration, etc .
- i) Verification of implementation of corrective actions through a follow up valuation on site of major and minor Non conformities,

4.3.2 There shall be no conditional grant of certification

5. Certificates

5.2.1 The certification Agency shall provide certification documents to the certified client by any means it chooses.

5.2.2 The effective date on a certification document shall not be before the date of the certification decision.

5.2.3 The certification document(s) shall identify the following:



- i. the name and geographic location of each client whose management system is certified (or the geographic location of the headquarters and any sites within the scope of a multi-site certification);
- ii. the dates of granting, extending or renewing certification;
- iii. the expiry date or re-certification due date consistent with the re-certification cycle;
- iv. a unique identification code;
- v. the standard and/or other normative document, including issue number and/or revision, used for audit of the certified client;
- vi. the scope of certification with respect to product (including service), process, etc., as applicable at each site;
- vii. the name, address and certification mark of the certification Agency; other marks (e.g. accreditation symbol) may be used provided they are not misleading or ambiguous;
- viii. any other information required by the standard and/or other normative document used for certification;
- ix. in the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents.

6. Management of Impartiality:

All mandatory inspection/ auditing reports must be accompanied by “certification of No conflict of interest” statement. So any Agency that is doing any other work for FBO is not supposed to do the work of inspection/ auditing when ordered by FSSAI.

7. Schedule of Fees:

Fees, as established from time to time by the authority shall be paid by the FBO to FSSAI.

FSSAI shall pay the Agency as per the below schedule

Turnover (per annum) of FBO	Fee (Rs.)	Audit duration (Man- Days)
Upto 50 lakh	1,000	Need basis
50 lakh – 1 crore	2,500	2
1 crore – 5 crore	7,500	2
5 crore – 25 crore	15,000	3
25crore –100crore	25,000	3
100 crore& above	35,000	3

- There should be a minimum of 2 Experts/ Auditors/ Inspectors for S. No. 2 & 3 while at least 3 Experts for S. No. 4 to 6.
- In case of S. No. 4 to 6, TA/DA (if any) will be extra.
- Service tax will be paid extra for all categories.

NOTE:

The eligibility of Auditor/Inspector is as follows:

- GRADE I Individual/Auditors/Inspectors can conduct an inspection of FBO's whose turnover (per annum) is upto 1 crore.
- GRADE II Individual/Auditors/Inspectors can conduct an inspection of FBO's whose turnover (per annum) is upto 25 crore.
- GRADE III Individual/Auditors/Inspectors can conduct an inspection of all FBO's.



Annexure 1

FBO FSMS ASSESSMENT REPORT

Date: _____ Time: _____ Scheduled (S)/Unscheduled (U): _____

FBO Name: _____

FBO Address: _____

Person in Charge: _____ Food Safety
Assessor(s): _____

Production Capacity (SKU Wise):

Delivery Locations:

Document Review

1. Documents provided for review:

Type of Document	Reviewed (Y or N)	Comments/Strengths/Weaknesses Noted
Prerequisite Programs		
Food Preparation Process		
Flow Diagrams (Food Preparation)		
Equipment Layout		
Training Protocols		
Hazard Analysis		
Written Plan for Food Safety Management System		



Other		
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2. Schedule IV Requirements:

S. No.	Area/Function Audited	Y	Remarks
	1.General Requirements		
1	Location and construction of the factory and surrounding industries do not pose a food safety concern.		
2	All applicable valid legal licenses pertaining to state and country laws are available with the supplier.		
	2.Infrastructure		
5	The buildings shall be designed in such a way to prevent entry of pests, Toxic fumes, or effluents.		
6	Premises shall be free of weed growth, unused equipments, stagnant water etc.		
7	Demarcation of the process and restricted areas (eg. Yellow marking for process area, red boundary for restricted areas)		
8	The drains in premises are covered and kept clean.		
9	The building, floors and walls etc. must be in good state of repair		
10	Air curtains shall be installed at all entrances. The working and efficiency of the air curtain must be checked at defined intervals.		
11	Sufficient area allocated for processing, storage, refrigeration to allow for proper working.		
12	Placement of equipment/ vessels is in a manner that allows easy accessibility for cleaning and maintenance		
13	The floor shall be easy to clean and free of leakage and seepage, corners & the edges should be covered for easy cleaning.		
14	The wall and roof shall be smooth, coved for easy cleaning , free of leakage and seepage. No moldy smell in the rooms/ halls/ stores		
15	All windows, doors and other openings are adequately protected with wire mesh etc.		
16	Processing halls shall have an adequate lighting of desired intensity		
17	Eating areas are segregated from the critical areas such as processing/material storage.		
18	Adequate well-ventilated toilets, feet dips and hand wash facilities are available at suitable locations. Toilets should have continuous supply of water and soap solution available. The hand dryer/ exhausts should be working. GMP signages shall be displayed in the local language.		
19	Waste disposal area shall be away from processing area.		
20	Waste collection yard shall be cleared regularly. No pile up of		

	waste shall be visible at any time		
	3.Quality Control		
21	The Quality testing personnel shall have relevant experience to conduct required testing.		
22	The laboratory must be equipped with all necessary equipments/ glassware/ chemicals/ consumables to carry out the tests.		
23	Testing protocols shall be established; test methods and release criteria available.		
24	Records of quality inspection shall be maintained Product acceptance/ rejection criteria shall be defined and followed.		
	4.Product protection		
25	All incoming materials/In-process/Finished goods shall be handled in a way so as to avoid contaminations.		
26	All materials shall be stored properly (away from the wall and on pallet) in specified conditions (Humidity / sunlight / Temperature) so as to prevent quality deterioration		
27	Hazardous materials shall be stored in designated place away from processing sections.		
28	Air ventilation through the facility shall be adequate so that no odors or airborne contaminants could be carried over to product.		
29	Water used in processing is treated and potable Water treatment plant shall be designed to deliver potable water.		
30	Cleaning schedule of the Water Treatment and Water Storage Tanks is available		
	5.Incoming Material Control		
31	All raw and packing material shall be procured from approved vendor.		
32	All incoming material shall be identified with a unique no. Which can be traced to the vendor through the invoice.		
33	Quality inspection status shall be depicted on the material and records maintained.		
34	FIFO followed while usage of materials.		
35	Non-conforming materials shall be labeled, segregated and stored distinctly away from the conforming material.		
	6.Processing control		
36	Processing area shall be free of unwanted materials (Pipes, flanges, utensils, unused equipments, empty cans/ crates etc.)		
37	Process control parameters shall be established and monitored at regular intervals and recorded. Critical control points in processing are identified, monitored recorded and displayed		
38	Sampling and processing procedures are documented and complies with requirements.		
39	SOPs are authorized and displayed.		

	7. Final Product Control		
40	All products should be identified with a unique Batch Number, which can be traced both backward and forward. Product release criteria must be defined and followed.		
41	The test and FIFO status must be displayed for the product and followed. System in place to check stock rotation		
42	Product release criteria shall be followed strictly		
43	Product is stacked as per specified norms and in a manner to avoid damage and deterioration		
	8.Cleaning and sanitation practices		
44	A master cleaning and sanitation program shall be established. The frequency of cleaning, responsible position for task		
45	Individual accountability and sign-off for each task completed (a position or a name; typically the sanitation supervisor)		
46	Methods and procedures shall be defined (SOPs)		
47	Records shall demonstrate that cleaning and sanitations are done as per defined frequency.		
48	Cleaning and sanitizing agents shall be labeled, segregated from food and packaging material and stored in a designated place with controlled access.		
49	Effective cleaning practices shall be evident		
50	Training of the sanitation crew shall be carried out at defined intervals and records of the same maintained		
	9.Employee Hygiene		
51	Employees shall wash their hands before entering processing halls		
52	The uniforms/clothes worn by employees shall be clean		
53	The buttons on the uniform must be secured well		
54	No pockets above the waist level		
55	Use of proper head cover in place		
56	No loose jewellery, bangles, wrist watch is worn inside critical areas.		
57	No personal items shall be carried inside processing/packing areas		
58	Smoking/ tobacco shall not allowed inside the processing premises		
59	Hand wash / Personal hygiene signage in local language displayed at the key locations.		
60	All visitors /out sides shall adhere to good personal hygiene practices.		
61	Employees suffering with communicable diseases—Jaundice ,Diarrhea, Vomiting, Fever, Sore throat with fever, Visibly infected skin lesions, Discharges from the ear/ eye/ nose, having injury shall not be allowed to handle food/ food processing		

	utensil/equipments.		
62	Employees to practice hygienic behavior (No spitting, Sneezing or coughing over unprotected food)		
	10.Pest control		
63	Pest control Agency shall be licensed and accreditation certificate is available		
64	A documented pest control program shall be available with approved list of pesticides used in the plant.		
65	Updated schematic map of the baits, traps, glue boards etc. with the details of the chemicals used area wise. Baits should on the outside.		
66	Trained and experienced personnel shall carry out Pest control; personnel safety norms must be followed during the operation.		
67	The pest control operator's service record including usage logs shall be current and available for review		
	11.Training		
68	Induction Training shall be imparted to all employees on GMP, Safety and personal hygiene practices, apart from job specific training to all new recruits.		
69	Regular trainings are conducted at defined interval and records maintained for all personnel.		
70	The effectiveness of the training must be monitored. Trainee and trainer feedback shall be available with the facility.		
	12.Quality Assurance		
71	CCPs shall be monitored according to documented procedures with appropriate action taken and recorded.		
72	Employees should be aware of CCPs and the critical limits in their area.		
73	Internal audits of the food safety program and GMP shall be carried out at defined frequency; corrective actions shall be available for review.		
	13.Warehousing and Transportation practices.		
74	All the materials are stored on pallets and away from walls		
75	FIFO is followed		
76	The dispatch vehicles are inspected for pests/insects/Cleanliness prior loading.		
77	All the dispatch vehicles are adequately covered at the flooring & top to avoid rains, dust dirt to prevent damages and contaminations.		
78	All materials are properly identified during storage		
	14. Product Lot Identification		
79	Is product lot coding established and effective?		
80	Is the withdrawal programme effective with respect to <ul style="list-style-type: none"> - Planning - Practice / Mock withdrawals 		



	<ul style="list-style-type: none"> - Retrieval of non-conforming products - Actions to be taken for disposition - Actions required when withdrawal is not possible - Records 		
15. Corrective And Preventive Action Plan			
81	Has the FBO defined any procedure to carry out Corrective and Preventive action?		
82	Does the FBO carry out Appropriate Corrective and Preventive action determined during past audits?		

3. List Critical Control Points (CCPs) and Critical Limits identified by the establishment's FSMS plan.

Food Item or Process	Critical Control Point	Critical Limits	Comments/Problems Noted

4. What monitoring records are required by the plan?

Type of Record (Prerequisite Program Activities, Monitoring, Corrective Action, CCP Verification, etc.)	Monitoring Frequency and Procedure (How often?, Initialed and dated?, etc.)	Record Location (Where kept?)



5. Who is responsible for verification that the required records are being completed and being properly maintained?

Comments: _____

6. Describe the training that has been provided to support the system?

Comments: _____

7. Describe examples of any documentation that the above training was accomplished?

Comments _____

Record Review and On-site Inspection

(Choose at random one week from the previous four)

8. Are monitoring actions performed according to the plan?
(Full Compliance / Partial Compliance / Non-Compliance)



Comments: _____

9. When critical limits established by the plan are not met, are immediate corrective actions taken and recorded?

(Yes / No)

Comments: _____

10. Do the corrective actions taken reflect the same actions described in the establishment's plan?

(Yes / No)

Comments: _____

11. Are routine calibrations required and performed according to the plan?

(Yes / No)

Comments: _____

(Examine the current day's records, if possible)

12. Are the records for the present day accurate for the observed situation in the facility?

(Yes / No)

Comments: _____

13. Do managers and employees demonstrate knowledge of the system?

Managers: (Yes / No) Employees: (Yes / No)

Comments: _____



Continued Considerations

- 14. Have there been any changes to processes or in products manufactured since the last verification visit?
(Yes / No)
- 15. Was the system modified because of these changes?
(Yes / No)

Comments: _____

Sample Analysis Reports review:

Details of Samples Reports reviewed:

Unique Id	Description	Quantity Sampled	Lab Sent	Lab Report Attached(Y/N)	Comments



Certificate of registration



THIS IS TO CERTIFY THAT THE
FOOD SAFETY MANAGEMENT SYSTEM OF

FBO Name

SiteAddress, SiteSuburb
SiteCity, SiteState
SitePCode, SITECOUNTRY

HAS BEEN ASSESSED AND REGISTERED AS COMPLYING WITH FSSAI REQUIREMENTS
SHOWN ABOVE FOR THE PROVISION OF GOODS AND SERVICES AS DETAILED BELOW

The Registration covers:-

Product and Process Categories or Type of Operation

Registration Number:

Registration Date:

Certification Date

Expiry Date:

Serial Number

Accredited Agency Logo

Accredited Agency Address	FSSAI Address

This certificate is valid for 1 years from the date of certification. This Certificate remains the property of Accredited Agency and must be returned upon request. It must not be altered in any way. Intentional misuse of this certificate will result in cancellation without prior notification.



Code of Conduct for Accredited Agencies

Preamble..... 1
Principle 1, Fairness..... 1
Principle 2, Harmonization..... 2
Principle 3 Management of clients..... 2
3.1 Changes of Clients..... 2
3.2 Multiple certifications..... 2
Principle 4 Qualification..... 2
Principle 5 Information..... 3
Principle 6 Quality Assurance 3

Preamble

Certification is an important tool of consumer protection, but also of quality assurance in the market place at large. The accredited agencies (AGENCY) are therefore faced with highest expectations with regard to their performance and services. Many of them have obtained accreditation according to international norms for accredited agencies, however, the professional performance may often still be improved and the procedures optimized. In order to harmonize their procedures and to improve their professional client services, but also to strengthen the trustworthiness and reputation of FSMS certification as well as the quality assurance of FBOs at large, the undersigned accredited agencies herewith pledge to adhere to this Code of Conduct (CoC) and to implement its terms and provisions without condition.

Principle 1, Fairness

The signatories of this CoC pledge to adhere to a fair and professional business performance.

This includes the following specific exertions:

- The signatory will respect and support the independent responsibility and the right of self-determination of its clients and not bind them with improper contractual or other obligations;
The signatory will refrain from enticing away clients from other signatory AGENCYs by visits and special services. This does, however, not prevent submission of objective information and standard offers.

Principle 2, Harmonization

The signatories of this CoC pledge to work towards a harmonized interpretation of the FSS regulations and implementation of professional performance. This includes the following specific exertions:

- The signatory will support and actively engage in interaction with each other concerning interpretation of the FSS regulations.
In case such common opinion has been reached, the signatory pledges to consequently implement these minimum requirements in his own field of activities and to inform the partners if such implementation is not possible under certain conditions and the procedures should be changed;
The signatory will work with other certifiers and share best practice on methods to reduce fraud.

Principle 3 Management of clients



The signatories of this CoC pledge to adhere to a professional and harmonized procedure for taking over clients that have previously been certified by another Agency. This includes the following specific exertions:

- The signatory will request a Data Release authorization from the new applicant to get a summary of all previous reports, sanctions. certification decisions and other relevant information from the previous Agency;
- The signatory will inform the previous Agency on the client's desire to change and request a summary of all previous reports, sanctions. certification decisions and other relevant information from the previous Agency;
- In case the client is not submitting any data release authorisation, the signatory will not engage in a certification service for this client and inform FSSAI.
- Time frame of informing each other as an Agency, maximum 5 working days from the arrival of the request.

3.2 Multiple certifications

- Signatories will include contractual obligations to inform in case of multiple certifications and shall – if multiple certifications apply – establish relevant regular data exchange, including major infringements in respect to regulations/ FSMS, with other Agencies involved.

Principle 4, Qualification

The signatories of this CoC pledge to constantly improve the quality of their business performance. This includes the following specific exertions:

- The signatory will take maximum care to the qualification of their inspection and certification personnel.
- The signatory will take maximum care that the performance of their inspection personnel is continuously monitored and the outcome critically evaluated before certification of a client is granted;
- The signatory will take particular care during certification that control systems meet best suitable practice.

Principle 5, Information

The signatories of this CoC pledge to adhere to a timely and professional performance in information exchange practices. This includes the following specific exertions:

- The signatory will exchange information with other Agency duly justified with the protection of integrity. This includes, but is not limited to exchange of information in case of suspected fraud.
- The signatory will participate in information sharing – to inform FSSAI in a timely and professional manner on problems and potential problems with food products in the market place.

Principle 6, Quality Assurance

The signatories of this CoC pledge to support further developments and harmonization in the field of quality assurance of FSMS certification. This includes the following specific exertions:

- The signatory will send information to FSSAI on a monthly basis, on the clients certified including the scope of their certification.
- The signatory will develop and share with FSSAI risk assessment procedures.
- They will use the results of these risk assessments to improve identification



of potential fraud. Their risk assessment will also help to target spot inspections, and identify areas where cross checks should be made with other certifiers;