

Notice Calling for suggestions, views, comments etc from stakeholders within a period of 30 days on Food Safety and Standards (Third Party Food Safety Auditing) Regulations, 2017.

F. No TPA/01/REG/FSSAI-2017 - 1. Short title, - These regulations may be called the Food Safety and Standards (Third Party Food Safety Auditing) Regulations, 2017.

2. Definitions. - (1) In these regulations, unless the context otherwise requires,

- a) **“Act”**-means the Food Safety and Standards Act, 2006 (34 of 2006);
- b) **“accreditation”**-means a third party attestation of the competence of the Auditing Agencies to carry out specific food safety auditing tasks.
- c) **“accreditation body”**-means an authority that performs accreditation.
- d) **“applicant”**-means a person or an agency who has made an application, in the prescribed form, before the Food Authority, in accordance with these regulations;
- e) **“audit report”**,- means a written record of the observations or findings of the auditor against food safety audit criteria with a result/conclusion of the audit;
- f) **“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 the behalf;
- g) **“recognized auditor”**- means a person who has been recognized by the Food Authority as a Third Party Auditor for conducting food safety audits as per the processes outlined in these regulations;
- h) **“recognized auditing agency”**- means a third party organization recognized by the Food authority for undertaking food safety audit as per the processes outlined in these regulations;
- i) **“risk”**, in relation to any article of food, means the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard;
- j) **“third party”**-means an independent organization or person other than the Food Authority and Food Business Operators.

(2) All other words and expressions used herein and not defined in the Act, rules or regulations made thereunder shall have the meanings assigned to the same in the Act, rules or regulations respectively.

Chapter II

Scope

3. **Scope of the Third Party Audit.** -In accordance with these regulations, the food authority specifies the procedure for recognition of Auditing Agency and Independent Food Safety Auditor and process for conducting food safety audits, audit monitoring, audit reporting and management requirement.

Chapter III

Recognition of Third Party Auditing Agencies or Independent Food Safety Auditors

4. Criteria for Recognition of Auditing Agencies

- (1) The Auditing Agency shall be registered as a legal entity in India.
- (2) The Auditing Agency shall have a declaration of indemnity insurance.
- (3) Auditing Agency shall hold a valid accreditation against ISO/IEC 17020 and ISO/IEC 17021 for the required food categories as applicable and prescribed by the Food Authority. The accreditation body which has accredited the Auditing Agency shall be a member of International Accreditation Forum (IAF) and signatory to the International Accreditation Forum Multilateral Recognition Arrangements for Management System Certification.
- (4) Auditing Agency shall have a minimum of three qualified auditors with relevant knowledge and skills to effectively audit as given under regulation 5.
- (5) Criteria for recognition may be relaxed by the Food Authority for the reason to be recorded in writing.

5. **Competency of Food Safety Auditors,** -Individual Auditors whether part of any Third Party Auditing agency or willing to apply independently for selection as Independent Food Safety Auditor for conducting food safety audits of Food Businesses as prescribed under these regulations shall meet the following minimum requirements:

- (1) Bachelor's degree in Food/Dairy/ Fisheries /Oil Technology or Biotechnology or Agricultural/Veterinary Sciences or Bio-chemistry or Microbiology or Chemistry from a recognized University.
- (2) Any other equivalent /recognized qualification or criteria prescribed by Food Authority from time to time.
- (3) Auditors must have successfully completed Accredited Lead Auditor course in FSMS recognized by International Register of Certificated Auditors

(IRCA) and/or any other body prescribed by the Food Authority from time to time.

- (4) Knowledge of Act and the various rules and regulations there under.
 - (5) Sector specific knowledge of hygienic and sanitary practices, processing techniques, hazards identification, analysis and control as well as knowledge of contaminants, allergens etc.
 - (6) Any other additional requirement, process or mandatory training as maybe prescribed by the Food Authority.
6. Any Agency or person fulfilling the competency requirements given in regulation 4 and 5 above shall apply for recognition as Auditing Agency or Independent Food Safety Auditor.
 7. On the recommendation of the Evaluation Committee for Third Party Auditing as specified in the regulation 20 of these regulations, the Food Authority may recognize the Auditing Agency and their set of Auditors and/or Independent Food Safety Auditor and they shall be provided with a certificate of recognition as per the format prescribed in Form B of schedule III with a unique identification number. The certificate of recognition granted under these regulations shall be valid and subsisting, unless otherwise specified, for period of three years.
 8. The recognition that has been granted to the Auditing Agency or Independent Food Safety Auditor shall be liable to be suspended or cancelled by the Food Authority based on the recommendation of the Evaluation Committee after giving a reasonable opportunity of hearing and for reasons to be recorded in writing.
 9. The procedure for recognition, renewal of recognition and suspension or cancellation of recognition shall be as prescribed in Schedule I of these regulations.
 10. The auditing agency or auditor aggrieved by the order of suspension or cancellation of recognition may place an appeal to the Chairperson of the Food Authority.

Chapter IV

Audit Process

11. The Authority shall from time to time, declare the category/type of food businesses which will be subject to mandatory third party auditing, primarily based on their risk classification. The classification of Food Business as shall be done after consideration of the major risk factors like food type, intended customer use, nature of activity of the business, volume of the business, method of processing and/or any other factors that the Authority may prescribe. Such Food Businesses shall get their business audited by the recognized Auditing

Agency or Independent Food Safety Auditors as per the frequency prescribed by the Food Authority.

12. Food businesses which are not mandatorily subject to Third party auditing but are desirous of using this provision of getting audited by the recognized audit agency or auditors, can opt for the same.
13. Food Authority also may assign food safety audit of food business units to specified auditing agencies or independent food safety auditor.
14. Food businesses in which Food safety audits have been satisfactory completed may be subjected to less frequent inspections by Central or State licensing authorities except for regulatory purpose.

Provided that in case of any specific complaints against the food businesses or when it comes to the knowledge of the Authority that the public health and safety is at risk, the Authority will have the discretion to undertake more frequent inspections.

15. The procedure for conduct of audit, duties of auditors and audit reporting including the classification of non conformance shall be as prescribed in schedule-II of these regulations.
16. **Conflict of Interest.** - (1) An Auditing Agency/ Independent Food Safety Auditor shall demonstrate to protect against conflicts of interest through a declaration as prescribed in Form C of Schedule III of these regulations before accepting food safety audit of an Food Business Operator.

(2) The recognition of any Auditing Agency/ Independent Food Safety Auditor shall be suspended or cancelled immediately by the food authority on the event of providing false information on conflict of interest.

Chapter V

Audit Monitoring System

17. Audit Monitoring

The Food Authority shall monitor the performance of the recognized Auditing Agency and Independent Food Safety Auditors. The monitoring mechanism may include review of the audit reports and performance; on site assessment of the Food Safety Auditors to ensure their competency of auditing the food safety management systems and the regulatory requirements; assessment of Auditing Agency on the basis of report of the Accreditation Body and any other mechanism as prescribed by the Food Authority.

18. Handling disputes

- (1) The Central or the State licensing authorities shall be the contact point for FBO to engage in case of any dispute or disagreement with auditors.
- (2) In case of any non-cooperation or resistance to the working of the Auditing agencies or auditors by FBO, the same shall be referred to the Central or the State licensing authorities for resolution.

19. Record Keeping

- (1) The final conformance report and all other documents related to the audit conducted including the first audit report, actions taken and successive communications on rectification measures shall be preserved by Auditing agencies or food safety auditors at least for a period of five years and full confidentiality of the documents shall be maintained.
- (2) FBO shall also maintain all records of audit findings and rectification for a period of at least five years.

Chapter VI

Evaluation Committee for Third Party Auditing

- 20.** The Food Authority shall constitute an Evaluation Committee for Third Party Auditing consisting of two members from Food Authority, one representative each from Quality Council of India, Agricultural and Processed Food Products Export Development Authority, Export Inspection Council and may include other relevant stakeholders.
- 22.** The said committee shall make recommendation on the Recognition and renewal of recognition of Auditing Agency/ Independent Food Safety Auditors after evaluation of their application and if necessary, assessment of the Auditor/ Agency, application Fees for recognition/renewal of recognition and Suspension or cancellation of recognition.
- 23.** Committee may also make recommendation on issues arising from implementation of these regulations; Fees for Food Safety Auditing; formats for reports; audit frequency and advice on matters related to risk classification of food businesses.

Schedule-I

(see regulation 9)

1. Procedure for recognition of Auditing Agencies/ auditors

- a) Application for recognition of Auditing Agency or Independent Food Safety Auditor shall be made in the *Application form along with the documents as prescribed in Form A and Annexure I of schedule III respectively along with requisite fees as prescribed by the Food Authority from time to time.*
- b) In case the Independent food safety auditor is employed, he/she will need to submit a No Objection Certificate from his/her employer for carrying out the Audit or work assigned by the Food Authority in the event of being recognised as a Food Safety Auditor.
- c) The Food Authority shall scrutinize all applications for recognition for completeness and deficiencies. On scrutiny, deficiencies, if any, shall be informed to applicant within 30 days from the date of receipt of application. The applicant shall provide the information required by the Food Authority within 15 days of the receipt of the communication, failing which the application shall be rejected without any further reference. The fees paid by the applicant for recognition shall not be refunded under any circumstances.
- c) If the Food Authority finds that the applicant fulfills the requirements as specified in these regulations the application shall be placed before the Evaluation committee for third party audit for making recommendations to the Food Authority for recognition of the Auditing Agency and/or Independent Food Safety Auditors.

2. Procedure for Renewal of recognition

- a) The Auditing Agency/ Independent food safety auditor, may if so desire make an application for renewal as per Annexure I, not later than 60 days prior to the expiry date indicated in the certificate of recognition.
- b) The Food Authority will consider the application for renewal on the basis that it continues to meet the criteria for recognition as specified in the regulations and also based on the performance of the Auditing Agency over the period of three years and place the same before the committee for evaluation.
- c) On the recommendation of the committee the food authority may renew the certificate of recognition.

3. Procedure for cancellation/suspension of registration

- a) The food authority, may suspend or cancel the recognition of auditing agency/ Independent food safety auditor by an order for following conditions:
- (i) The auditing agency/ auditor has made an application to be declared an insolvent;
 - (ii) The auditing agency/ auditor has failed to carry out any orders issued by the Food Authority;
 - (iii) The auditing agency/ auditor has committed a fraudulent act;
 - (iv) The auditing agency/ auditor has in any other manner become incompetent to continue to be accredited as food safety auditor as required under these regulations;
 - (v) The auditing agency/ auditor has failed to provide access to their records and furnish necessary information to the food authority to conduct an assessment or investigation on them;
 - (vi) The auditing agency/ auditor has failed to take timely and necessary corrective measures, if any, as may be directed by the Food Authority;
 - (vii) After proposal of the Evaluation Committee on investigation of complaints and conduct of agency/food safety auditors;
 - (viii) The auditing agency/auditors have provided false information on conflict of interest.
 - (ix) Any other reason that the Food Authority deems fit and necessary.
- b) The auditing agency/ auditor shall provide a reply to the Food Authority within 15 days from the date of receiving the show cause notice regarding the proposal for suspension or cancellation. Failing which the decision shall be taken by the committee on the basis of available evidences.
- c) The Food Authority shall, upon considering the reply made by the auditing agency/ auditor, pass such orders as it may deem fit under the provision of these regulations within 30 days of the receipt of the reply from the Auditing Agency/ Independent food safety auditor.
- d) The food authority may revoke the suspension issued to auditing agency/ Independent food safety auditor upon consideration of the corrective measures made as per these regulations.

- e) In case of cancellation, the applicant may make a fresh application for recognition to the food authority after a period of 6 months from the date of cancellation.
- f) Further, the recognition of a Food Safety Auditing Agency shall be deemed to be suspended/ cancelled if its accreditation is suspended/ cancelled by its accreditation body.

Schedule-II
(see regulation 15)

1. Preparing and Planning for Audit

The audit process followed for assessing food safety management system of a FBO shall be based on IS/ISO 19011:2011 Guidelines for auditing management systems.

2. Audit Examination

- a) Audit examination shall cover collection of objective evidence and documenting audit observations. Evidence can be collected through interviews, examination of documentation and observation of activities.
- b) Where there are deficiencies or non-conformances detected they shall be documented clearly and concisely and shall point out the regulatory requirements that are being contravened.
- c) During the audit the auditor will be verifying that the food business is complying not only with the food safety measures but also with the Food Safety Standards Regulations as applicable other than those which may require specific sampling and laboratory analysis of the products.
- d) The auditor however, can check relevant documents related to laboratory reports maintained by the FBO as part of compliance with various applicable regulations.

3. Duties of Auditors:

- a) To conduct food safety audit of FBO.
- b) To check compliances with respect to the requirements specified in various applicable regulations made under the Act.
- c) To conduct pre-commissioning inspection of newly established Food Business units if directed by the Food Authority.

- d) To keep all commercial-in-confidence material confidential. This includes process and product formulation information, food safety program information and audit outcomes.
- e) To report the results of audits to Food Authority within the time frame specified by Food Authority.
- f) To carry out any necessary follow-up action, including further audits, if necessary, to check if any action has been taken to remove any deficiencies of such food safety program identified in an audit.
- g) Maintenance of the confidentiality during food safety audit.
- h) Any other related assignment which the Food Authority may specify time to time.

4. Audit Reporting & Actions thereof:

- a) The auditor shall report the findings of the audit to the food business at the completion of the audit so that the food business has an opportunity to discuss the findings and provide further information to the auditor, if appropriate.
- b) The Auditing Agency/Auditor must submit an audit report in the format as prescribed by Food Authority to the FBO immediately after completion of the audit and to the concerned authority within 15 days. The audit report should clearly bring out the finding/Non conformities.
- c) Any non-conformances observed during audit may be classified into one of the following two categories:
 - 1) Major Non-Conformance-** When the audit finding is a serious failure in the food safety management system of the FBO, which may result in serious adverse health consequence possibly even fatal, the auditor shall report such finding to the concerned authority within 24 hrs. The concerned Authority after ascertaining the seriousness of the situation shall take steps as per procedures laid down in the Act.

2) Minor Non-Conformance- When the audit finding is a shortcoming in the food safety management system or regulatory contravention of the FBO, which may not cause any adverse health consequence, the auditor shall setup an appropriate timeframe for rectification and follow up as to how the non-conformance has been rectified. These minor non-conformances along with the timeframe for rectification by the Food Business shall be reported as part of the Audit Report.

- d) Failure by food business to rectify any minor non conformity within the suggested timeframe has to be referred to the Central or State Licensing Authorities, as the case may be.
- e) The auditor may recommend in writing with reason for the change in audit frequency of the FBO to the concerned authority based on the audit.

Schedule-III

(see regulation 4 and 5)

Form A

Application Form for Recognition/Renewal of Auditing Agency/ auditor for Third Party Auditing

Photo
(Authorized
signatory in
case of auditing
agency)

Application for: **1. Auditing Agency**
2. Independent food safety Auditors

| | |
|--|--|
| 1) Name of Auditing Agency/ Independent food safety Auditor: | |
| 2) Name of Contact person(in case of Auditing Agency): | |
| 3) Address(with Pin Code): | |
| 4) Contact Details: a) Tel No.(with STD code) b) E-mail of the contact person/Website address of the Organization (if any) | |
| 5) Legal Entity Status in case of auditing agency (attach documentary evidence): | |
| 6) Detail of accreditation certificate (attach copy): | Certificate No: |
| | Validity Up to: |
| 7) Specialized areas of work: | |
| 8) Detail of Auditors enroll under the Auditing Agency (attach copy): | |
| 9) Employment Details(for Independent food safety auditors): | Self-employment <input type="checkbox"/> Sub-contracting <input type="checkbox"/> employee (provide details) <input type="checkbox"/> |

| | | | | | |
|--|-------|-----------------|--|-------|----|
| 10) Educational Qualification of Auditor | | | | | |
| 11) Training details of Auditor (copy of certificate) | S. No | Title of course | Conducted/Or ganized by (Name & Address) | Dates | |
| | | | | From | To |
| | | | | | |
| 12) Inspection/Auditing record details from past 2 year food category wise | | | | | |
| 13) Any other information regarding food safety audit competency | | | | | |
| 14) Recognition number : (in case of renewal) | | | | | |

I (authorized signatory in case of auditing agency) _____ S/o,
D/o _____ R/o _____ do
hereby solemnly affirm and declare that all information and particulars furnished here
by me are true and correct to the best of my knowledge. I further declare that the food
safety auditing to be conducted by me or through my Auditor shall conform to the
requirements of Food safety and Standard (Third Party Food Safety Auditing)
Regulations, 2017.

Signature of authorized signatory /Auditor with stamp

Annexure I

List of document to be enclosed with the application:

- a) Application fee receipt/DD or pay order
- b) Certificate of accreditation
- c) Educational qualification certificate of all auditors.
- d) Lead Auditor course certificate.
- e) Confidentiality agreement
- f) A copy of the last assessment report by the accreditation body
- g) Details of Industry Auditing Experience of all auditors.
- h) Declaration of indemnity insurance.
- i) NOC from employer if employed in case of Independent Food Safety Auditors



Recognition Number

Certificate of Recognition

(see regulation 7)

THIS IS TO CERTIFY THAT
(Auditing Agency/Individual Auditor Name)

Has been recognized by FSSAI for the purpose of third party auditing of food business operators licensed under food safety and standards act, 2006. This certificate is issued subject to the provision of food safety and standards (third party food safety auditing) regulations, 2017 all of which shall be complied with by the auditing agency/ auditor

| Auditing Agency Address/ Independent food safety Auditor Name and address | Issued on/ renewed on | Valid upto | Scope |
|--|--------------------------|------------|-------|
| | | | |
| | | | |

It must not be altered in any way. Intentional misuse of this certificate will result in cancellation without prior notification.

Signature of Director with stamp

Declaration of conflict of interest

(see regulation 16)

I _____ S/o, D/o _____ state that the food safety audit of M/s _____ having license number _____ has been audited by me/ my auditing agency. In this context I hereby demonstrate the no conflict of interest that:

- a) I/my auditing agency or its personnel/auditor have/has not provided any training, guidance, Food Safety Certification or consultancy to and not carried out internal audits of the above said food business operator or any of its parent or subsidiary for last 2 years.
- b) I/my auditing agency or its personnel/Auditor does not own or have a financial interest in, manage or otherwise control to the above said food business operators or any of its affiliate, parent or subsidiary.
- c) I/my auditing agency or its personnel/Auditor have/ has not been employed by the above said Food Business Operator for last 2 years.
- d) I /my auditing have/has not carried out the food safety audit of the above said food business operator for more than three consecutive audit.

Signature of authorized signatory /Auditor with stamp