

The background is a vibrant, abstract composition of geometric shapes in shades of orange, yellow, green, and brown. A large, light green oval is positioned in the lower right quadrant, serving as a backdrop for the chapter title. The overall style is modern and graphic.

CHAPTER 14

Third Party Food Safety Audits

To strengthen the food safety surveillance system, FSSAI has envisaged audits of Food Business Operators through Private Auditing Agencies. A Draft Food Safety and Standards (Food Safety Auditing) Regulations, 2017, FSSAI has been prepared for the same. In accordance with the draft regulation, FSSAI has now started the procedure to Provisionally recognise Auditing Agencies to create a pool of recognised Auditing Agencies. Presently, the Provisionally recognised Auditing Agencies will only be engaged by FSSAI to audit some food businesses as decided by the FSSAI from time to time. Once the Draft Food Safety and Standards (Food Safety Auditing) Regulations, 2017 after considering the comments from relevant stakeholders, is finally vetted and notified, the food authority shall from time to time specify the category of food businesses which shall be liable for mandatory audits.

A. Need for private auditing of FBOs

Inspecting and auditing food businesses is a humongous task for FSSAI, hence in order to cultivate and foster the growth of compliance culture, FSSAI is enabling compliance through private recognised Auditing Agencies.

Food Safety Audits will reduce the regulatory Food Safety Inspections conducted by Central or State Licensing Authorities. Satisfactory Audits will lead to less frequent regulatory inspections by Central or State Licensing Authority except the regulatory sampling.

Food Businesses classified by Food Authority for mandatory Food Safety Audits are liable to get their businesses timely audited by recognised Auditing Agencies. Food Authority will declare the category/type of food businesses subject to mandatory audit based on risk classification and the frequency of audits. This classification will be based on factors like Food type, Intended Customer use, nature of activity of the business, Volume of the business & Method of processing/any other factors prescribed by Authority.

Food businesses which are not subject to mandatory Food Safety auditing can also conform to auditing of their businesses on voluntary basis. This will encourage self compliance among them.

Objectives of Food Safety Audits

- a) Strengthen food safety surveillance system.
- b) Reduces the regulatory Food Safety Inspections conducted by Central/State Licensing Authorities.
- c) Encourage Self Compliance.
- d) Develop a self sustaining ecosystem for ensuring compliance of FBOs.
- e) Reduce the gap between regulator led enforcement & field level Non-Compliance.

Criteria for Recognition of Auditing Organisations/Agencies:

- a. They should be a legal entity in India.
- b. They should have valid accreditation against ISO/IEC 17020 and ISO/IEC 17021.
- c. Accreditation body is member of IAF (International Accreditation Forum) and signatory to IAF Multilateral Recognition Arrangements.
- d. Should have a minimum of 3 qualified auditors.
- e. It is desirable to have indemnity insurance.

Qualifications prescribed for the Food Safety Auditors of the Auditing Agency:

- 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
- Accredited Lead Auditor course in FSMS recognized by IRCA/or any body specified by Food Authority
- Knowledge of FSS Act, Rules & Regulations
- Sector specific knowledge
- Any other additional requirement/mandatory training

Criteria for approval and recognition of Auditing Agency:



B. Auditor Training

Each potential recognised food safety auditor as part of an agency must attend a training session with the FSSAI on policies, procedures, reporting and other requirements. The training must be attended by every Food Safety Auditor before commencing any food safety audits as recognised auditor. An Auditor Manual/Guide will be provided during the training.

Duties of Auditors:

- They should conduct food safety audit of Food Business Operator ;
- They should check compliance with the provisions of the various regulations made under the Act;
- They should conduct pre-commissioning inspection of newly established food business units, as directed by the Food Authority;
- They should keep all commercial-in-confidence material confidential, which includes process and product formulation information, food safety program information and audit outcomes;

5. They should forward the audit report to the Food Authority within fifteen days of the conduct of food safety audit;
6. They should carry out necessary follow-up action, including further audits, to check whether any corrective action was taken to remove any deficiency of such food safety program identified in an audit;
7. They should maintain the confidentiality during food safety audit;
8. Any other related assignment which the Food Authority may specify from time to time.

C. Audit Process

The Food Authority shall, from time to time specify the category or type of food businesses which shall be subject to mandatory food safety auditing, primarily based on their risk classification. The classification of food business 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 Food Authority may specify in this behalf. Such food businesses shall get their business audited by the recognized auditing agency as per the frequency specified by the Food Authority. Food businesses which are not mandatorily subject to food safety auditing but are desirous of getting audited by the recognized auditing agency, can opt for the same.

Food businesses in which food safety audits have been satisfactorily conducted may be subject to less frequent inspections by the Central or the State licensing authorities except for regulatory purpose. Provided that in case of any complaints against the food businesses or when it comes to the knowledge of the Food Authority that the public health and safety is at risk, the Food Authority shall have the discretion to undertake more frequent inspections.

The audit process involved for assessing the food safety management system of a Food Business Operator shall be based on IS/ISO 19011:2011 (Guidelines for auditing management systems).

D. Audit Examination:

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. Where the deficiencies or non-conformances detected, they shall be documented clearly and concisely and shall point out the regulatory requirements that are being contravened. During the audit process, the auditing agency shall verify the compliance 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. The auditing agency shall check relevant documents related to laboratory reports maintained by the Food Business Operator as part of compliance with various regulations made under the Act.

E. Audit Report:

The auditor shall report the findings of the audit to the food business after the completion of the audit, wherein the food business shall be given an opportunity to discuss the findings and provide further information or clarification to the auditor, if necessary. The auditing agency shall submit the audit report in the format specified by Food Authority to the Food Business Operator immediately after completion of the audit and also to the Central or State Licensing authority within fifteen days. The audit report shall clearly bring out the finding or non conformities. The non-conformities of the audit may be classified into two categories, namely,-

- (I) Major Non-Conformity- When there is a serious failure in the food safety management system of the Food Business Operator, which may result in adverse health consequence possibly even fatal, the auditor shall report such findings to the Central or State Licensing Authority within twenty four hrs. The Central or State Licensing Authority after ascertaining the seriousness of the situation shall take regulatory action against the concerned food business operator.
- (II) Minor Non-Conformity- When there is a shortcoming in the food safety management system or regulatory contravention of the Food Business Operator, which may not cause any adverse health consequence, the auditor shall set up an appropriate timeframe for its rectification and follow up, so that the non-conformance could be rectified.

Failure by food business operator to rectify the minor non conformity within the specified timeframe shall be referred to the Central or State Licensing Authorities, as the case may be. The auditor may recommend in writing the reasons for the change in audit frequency of the food business operator to the Central or State Licensing Authority based on the audit.

F. Audit monitoring:

The Food Authority shall monitor the performance of the recognized auditing agency in the following manner, namely:-

- (1) The monitoring mechanism shall include review of the audit reports and performance; on site assessment of the 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 specified by the Food Authority.
- (2) Handling disputes.-**
 - (i) The Central or the State Licensing Authorities shall be the contact point for Food Business Operator to engage in case of any dispute or disagreement with auditors.
 - (ii) In case of any non-cooperation or resistance to the working of the auditing agencies or auditors by food business operator, the same shall be referred to the Central or the State Licensing authorities for resolution.
- (3) Record keeping.-**
 - (i) 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 the auditing agencies at least for a period of five years and full confidentiality of the documents shall be maintained.
 - (ii) Food Business Operator shall maintain all records of audit findings and rectification for a period of five years.