



FOOD SAFETY AND STANDARDS
AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food
Ministry of Health and Family Welfare, Government of India

AUDITOR MANUAL

***[For Auditors of Third Party Food Safety Agencies
Recognised by FSSAI under Food Safety and Standards
(Food Safety Auditing) Regulations, 2018]***

TABLE OF CONTENTS

S. No	Contents	Page No.
1.	<i>Foreword</i>	4
2.	<i>Scope & Objectives</i>	5
3.	<i>Food Safety Audits : An introduction</i>	5
3.1	<i>Why the need of private auditing of FBOs arises?</i>	5
3.2	<i>What is a Food Safety Audit?</i>	5
4.	<i>Audit Framework</i>	6
4.1	<i>Role & Responsibilities</i>	6
	<i>(a) Role of Food Authority</i>	
	<i>(b) Role of Agencies/ Auditors</i>	
	<i>(c) Role of Food Business Operators</i>	
4.2	<i>Duties of Auditor</i>	7
4.3	<i>Food Safety Audit process</i>	7
4.4	<i>Mandatory vs Voluntary audits and its frequency</i>	8
4.5	<i>Audit frequency</i>	9
5.	<i>Code of Practices for Auditors / Audit Agency</i>	11
5.1	<i>Audit Principles (based on ISO 19011)</i>	11
5.2	<i>Behaviour skills of auditors (based on ISO 19011)</i>	12
5.3	<i>Confidentiality Requirements</i>	13
5.4	<i>Declarations for Conflict of Interest, Anti-bribery Norms and Subcontracting of audits</i>	13
6.	<i>Audit Planning</i>	14
6.1	<i>Audit Duration</i>	14
6.2	<i>Audit fees</i>	15
6.3	<i>Competence of auditors</i>	15
6.3.1	<i>Educational specifications</i>	15
6.3.2	<i>Initial Training</i>	15
6.3.3	<i>Work and Audit Experience</i>	15
6.3.4	<i>Auditor Training (by FSSAI)</i>	16
6.3.5	<i>Audit team requirements</i>	16
6.3.6	<i>Maximum Audits per year by an Auditor</i>	16
7.	<i>Audit Execution</i>	16
7.1	<i>Filling up of Audit Intake Form</i>	16
7.2	<i>Communication of audit plan to FBO</i>	17
7.3	<i>Conducting Audit</i>	17
7.3.1	<i>Opening Meeting</i>	17
7.3.2	<i>Conducting the audit activities</i>	17
7.3.3	<i>Audit Examination</i>	18
7.3.4	<i>Audit Conclusive report</i>	18
7.3.5	<i>Grading of Non-Conformities</i>	19
7.3.6	<i>Closing Meeting</i>	20
7.3.7	<i>Closure of audit findings</i>	20
	<i>(a) Closure of Major NC</i>	20

	<i>(b) Closure of Minor NC</i>	<i>20</i>
<i>8.</i>	<i>Suspension/Cancellation</i>	<i>21</i>
<i>9.</i>	<i>Renewal of recognition</i>	<i>21</i>
<i>10.</i>	<i>Audit Agency Integrity Monitoring Program</i>	<i>22</i>
<i>10.1</i>	<i>Verification Inspections</i>	<i>22</i>
<i>10.2</i>	<i>Review of submitted audit reports</i>	<i>22</i>
<i>11</i>	<i>Record Keeping</i>	<i>22</i>
<i>12</i>	<i>Handling Disputes</i>	<i>23</i>
<i>13</i>	<i>Complaints System</i>	<i>23</i>
<i>14</i>	<i>Terms and Definitions</i>	<i>23</i>
<i>15</i>	<i>Annexure</i>	<i>25</i>
	<i>Annex 1: Option form for selecting Kind of business and geographical location</i>	<i>26</i>
	<i>Annex 2: Intake form for Auditor</i>	<i>27</i>
	<i>Annex 3: Declaration of Conflict of Interest</i>	<i>28</i>
	<i>Annex 4: Confidentiality Agreement between FBO and Auditing Agency</i>	<i>29</i>
	<i>Annex 5: Audit Checklists and Grading System</i>	<i>30</i>
	<i>1. General Manufacturing</i>	<i>32</i>
	<i>2. Milk Processing</i>	<i>36</i>
	<i>3. Meat Processing</i>	<i>41</i>
	<i>4. Slaughter house</i>	<i>46</i>
	<i>5. Catering</i>	<i>50</i>
	<i>6. Retail</i>	<i>56</i>
	<i>7. Transport</i>	<i>60</i>
	<i>8. Storage & warehouse</i>	<i>63</i>
	<i>Annex 6: Food Safety and Standards (Food Safety Auditing) Regulation, 2018 including application form.</i>	<i>67</i>

1. Foreword

The Food Safety and Standards Authority of India (FSSAI) has been established under Food Safety and Standards Act, 2006 which consolidates various acts & orders that have hitherto handled food related issues in various Ministries and Departments. FSSAI has been created for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

Section 44 of the Food Safety and Standards Act, 2006 provides the power to Food Authority to recognize an organization or an agency for carrying out food safety audit and checking compliance with the Food Safety Management Systems.

Section 16(2)(c) of the Food Safety and Standards Act, 2006 specifies Food Authority may specify the mechanisms and guidelines for accreditation of certification bodies engaged in certification of Food Safety Management Systems (FSMS) for food businesses;

FSS Act, 2006 defines FSMS or “Food Safety Management System” as 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.” The establishment in which food is handled, processed & packed, by the FBO and the persons handling them should conform to the sanitary and hygienic requirement (as described in Schedule IV), Food Safety measures (based on HACCP Principles) and other standards (including FSSAI Product standards). **It shall also be deemed to be the responsibility of FBO to ensure adherence to necessary requirements.**

Food Safety (FSMS) audits will reduce the regulatory inspections conducted by Central or State Licensing Authorities. Food Businesses classified by Food Authority for mandatory Third Party Audits are liable to get their businesses timely audited by recognised Auditing Agencies. FSSAI may from time to time specify the kinds of businesses to be mandatorily audited. It shall be the responsibility of the FBO to get their businesses timely audited. Food businesses which are not subject to mandatory Third-party auditing can also conform to Auditing of their businesses.

The aim of this document is to provide recognised auditors with a consistent approach that can be used when conducting audits at licensed food businesses. This guidance document can also be used by food businesses to understand the audit process followed by FSSAI.

This Manual is an official document published by the FSSAI to inform recognised food safety auditors of the system implemented by the Food Authority to manage the audit process and reporting. The content of this manual should be read as being the minimum requirements and along with the Food Safety and Standards (Food Safety Auditing) Regulations, 2018. Failure to comply with the requirements of this manual is a breach of auditor / agency recognition.

2. Scope and Objectives

This Manual contains standardised operating procedures for the following:

- a. Industries (FBOs) recommended for mandatory and voluntary audit & its frequency based on FSSAI risk profile
- b. The processes for initiating the audit.
- c. FSSAI Code of Practices
- d. Audit planning covering audit duration, audit agenda and communication with the FBO & relevant authorities
- e. Conduct of audit based on FSSAI audit checklist and ISO19011, Audit Reporting, Audit conclusion & communication with relevant authorities
- f. Audit Agency Integrity Program

3. Food Safety Audits: An Introduction

3.1 Why the need of private auditing of FBOs arises?

With the advent of a large number of food businesses in India, inspecting and auditing food businesses is a humongous challenge for FSSAI, hence in order to cultivate and foster the growth of compliance culture, FSSAI is enabling compliance through private recognised Auditing Agencies. This will help in

- a) Strengthening the food safety surveillance system in the country.
- b) Reducing the regulatory Food Safety Inspections conducted by Central/State Licensing Authorities.
- c) Encouraging Self Compliance.
- d) Developing a self sustaining ecosystem for ensuring compliance of FBOs.
- e) Reducing the gap between regulator led enforcement & field level Non-Compliance.

3.2 What is a Food Safety Audit?

Before covering the specific character and nature of a food safety audit, let us first look at what an audit is in general. An audit is usually defined as a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. An audit is a process where an authorised auditor visits a facility to assess food safety compliance. During the audit the auditor carries out an inspection of the facility, observes the food handling practices, and reviews food safety documentation (including the food safety program and monitoring).

Food Safety Audit means a systematic and functionally independent examination of sanitary & Hygiene compliances as per schedule IV, Food safety measures (based on HACCP) and other standards (e.g. Product standards) adopted by FBO to meet the regulatory requirements.

According to the FSS Act, 2006, a *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 the objectives of food safety and the claims made in that behalf.

Audits on licensed food business will be carried out by the auditors of agencies recognised under the Food safety and Standards (Food Safety Auditing) Regulations, 2018.

4. Audit Framework

4.1 Roles and Responsibilities

	<i>Roles & Responsibilities</i>
<i>Food Authority</i>	<ul style="list-style-type: none"> a. Define the requirements for undertaking third party audits based on the risk categorization b. Describe the frequency of inspections by the state authorities based on the audit results as described in section 8 of Food Safety and Standards (Food Safety Auditing) Regulations 2018 c. Define the code of practices to be followed by audit agency / auditors d. Define the audit management protocol e. Define the communication channels between various stakeholders f. Assign the audits to the agencies , if required g. Monitor performance & integrity of audit agency
<i>Audit Agency</i>	<ul style="list-style-type: none"> a. Follow the complete criteria's as described in this manual, FSS (FSA) Regulations 2018 requirements and Accreditation Authority requirements. b. Auditors from audit agency will conduct the audit and submit the report. c. The responsibility of closure of the audit findings is to be followed as described in the section 7.3.7 of this manual. d. Submission of audit reports adhering to the timeline as prescribed in the FSS (FSA) Regulations, 2018. e. Requirements of conflict of interest to be ensured. f. Update the Authority about any changes in accreditation, scope of audit, details of auditors etc.
<i>Auditors</i>	<ul style="list-style-type: none"> a. Perform the duties as prescribed in section 10 of FSS (FSA) Regulation, 2018. b. Maintain confidentiality. c. Conduct audit in an unbiased, professional way and follow the Principles of Auditing.
<i>FBO</i>	<ul style="list-style-type: none"> a. It is deemed responsibility of the FBO to initiate the audit as per risk classification of the industry. b. Requirements of conflict of interest to be ensured while selecting the auditor / audit agency. c. Other FBOs, not listed in the risk categorization can also participate in the third-party audit program voluntarily.

4.2 Duties of auditors

The auditor shall perform the following duties as laid down in section 10 of the Food Safety and Standards (Food Safety Auditing) Regulations, 2018, namely,-

- (i) conduct food safety audit of Food Business Operator ;
- (ii) verify the compliance by the Food Business Operator of the provisions of the Act and the rules and regulations made thereunder;
- (iii) conduct pre-commissioning inspection of newly established food business unit, as and when directed by the Food Authority;
- (iv) maintain confidentiality in respect of commercial-in-confidence materials, which may include process and product formulation information, food safety programme information and audit outcomes;
- (v) forward the audit report to the Food Authority within fifteen days of the conduct of food safety audit;
- (vi) carry out necessary follow-up action, including further audits, to verify if any corrective action has taken to remove any deficiency of such food safety program identified during the audit;
- (vii) maintain confidentiality of food safety audit;
- (viii) such other duties as may be directed by the Food Authority.

4.3 Food Safety Audit Process

<i>The Food Safety Audit Process</i>	
FBO will select the audit agency	
	The shortlisted Audit agency will collect all the information on FBO, Scope, Number of production lines/ product group, consultancy/ training details , number of food handlers, area for storage (in case of storage & distribution)
	FBO will finalise the audit date with the agency and decide upon the Audit fee to be paid by the FBO.
The Audit agency fills in the audit intake form in FSSAI Audit management system web page	
	The Audit Agency will log in FSSAI audit portal using their credentials and fill in the details of scheduled audit in Audit Intake Form (Annex 2).
	Audit date, auditor details, audit man-days will be mentioned in the audit intake form. Once the form is filled, the information cannot be changed. Once filled, the details of the audit scheduled are visible to the Food Authority,

	concerned Agency and FBO.
	The agency will communicate the Audit Plan to FBO at least 8 days in advance.
FBO will get their businesses audited as per the audit plan on the scheduled date.	
	Auditor / audit agency will execute the audit as per inspection checklist and communicate the audit score and the draft audit report shall be submitted BEFORE leaving the FBO facility. All the findings shall be agreed by FBO. The FBO can represent to the Food Authority in case of disagreements, if any.
	In case of MAJOR Non-Conformity, the Food authority will be informed through the web portal within 24 hours (also email/phone). Information about the same should also reach Director (RCD), Central Licensing Authority and Commissioner of Food Safety of concerned State/UT through web portal/ mail/ other means.
	In case of Minor Non-Conformities, audit agency will close the findings within 15 days including its rectification and follow up. FBO has to close the findings and take corrective actions. In case of delay by FBO, concerned CLA or SLA shall be intimated by the agency through web portal/ mail/ other means for necessary action at their end.
	The FINAL audit report shall be uploaded on the FSSAI Audit management web page within 15 days from the date of audit.

4.4 Mandatory vs Voluntary audits and its frequency

4.4.1 Mandatory audits- Mandatory Third Party Audit by FSSAI recognized food safety auditing agency shall be conducted annually for all the *Central Licensed Manufacturers/Processors* under *High Risk Food Categories* as specified below-

- 01- Dairy products and analogues
- 08- Meat and Meat Products including poultry
- 09- Fish and Fish products including molluscs, crustaceans and echinoderms
- 10- Egg and Egg products
- 13- Foodstuffs intended for particular nutritional uses

16- Prepared Foods

18.1- Indian Sweets

99.5- Nutrients and their preparations (Fortified Rice Kernels only)

Also, Third Party Auditing of manufacturers/processors of high risk food categories having State license may be mandated by the concerned Commissioners of Food Safety in their respective States/UTs.

4.4.2 Voluntary Audits- Food business operators (FBOs) that are not subjected to mandatory food safety auditing as per specifications given above in Point 4.4.1, but are desirous of getting audited by a recognized auditing agency, may opt for the same.

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).

4.5 Audit Frequency

The Audit Frequency recommended by the Food Authority for FBOs to conduct the mandatory food safety audits is as per table below:

Note: The original Scope for recognised agencies is as per the declaration submitted by them as per Annex 1. The Kind of Business and product categories as per the existing FLRS are as indicated below:

Product ID	Product	Audit Score Range	Audit Frequency
1	Dairy products and analogues, excluding products of food category 2.0	Score: 81-100%	Once in 12 months
		Score: 51 – 80 %	Once in 09 months
		Score: < 50 %	Once in 06 months
2	Fats and oils, and fat emulsion	Score: 81-100%	Once in 18 months
		Score: 51 – 80 %	Once in 12 months
		Score: < 50 %	Once in 06 months
3	Edible ices, including sherbet and sorbe	Score: 81-100%	Once in 18 months
		Score: 51 – 80 %	Once in 12 months
		Score: < 50 %	Once in 06 months
4	Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and	Score: 81-100%	Once in 18 months
		Score: 51 – 80 %	Once in 12 months
		Score: < 50 %	Once in 06 months
5	Confectionery	Score: 81-100%	Once in 18 months
		Score: 51 – 80 %	Once in 12 months

		Score:< 50 %	Once in 06 months
6	Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes and pith or	Score: 81-100%	Once in 18 months
		Score:51 – 80 %	Once in 12 months
		Score:< 50 %	Once in 06 months
7	Bakery products	Score: 81-100%	Once in 18 months
		Score:51 – 80 %	Once in 12 months
		Score:< 50 %	Once in 06 months
8	Meat and meat products including poultry	Score: 81-100%	Once in 12 months
		Score:51 – 80 %	Once in 09 months
		Score:< 50 %	Once in 06 months
9	Fish and fish products, including molluscs, crustaceans, and echinoderms	Score: 81-100%	Once in 12 months
		Score:51 – 80 %	Once in 09 months
		Score:< 50 %	Once in 06 months
10	Eggs and egg products	Score: 81-100%	Once in 12 months
		Score:51 – 80 %	Once in 09 months
		Score:< 50 %	Once in 06 months
11	Sweeteners, including honey	Score: 81-100%	Once in 18 months
		Score:51 – 80 %	Once in 12 months
		Score:< 50 %	Once in 06 months
12	Salts, spices, soups, sauces, salads and protein products	Score: 81-100%	Once in 18 months
		Score:51 – 80 %	Once in 12 months
		Score:< 50 %	Once in 06 months
13	Foodstuffs intended for particular nutritional uses (eg. Food for infant nutrition etc)	Score: 81-100%	Once in 12 months
		Score:51 – 80 %	Once in 09 months
		Score:< 50 %	Once in 06 months
14	Beverages, excluding dairy products	Score: 81-100%	Once in 18 months
		Score:51 – 80 %	Once in 12 months
		Score:< 50 %	Once in 06 months
15	Ready-to-eat savouries	Score: 81-100%	Once in 18 months
		Score:51 – 80 %	Once in 12 months
		Score:< 50 %	Once in 06 months
16	Prepared Foods (catering etc)	Score: 81-100%	Once in 12 months
		Score:51 – 80 %	Once in 09 months
		Score:< 50 %	Once in 06 months
99	Substances added to food	Score: 81-100%	Once in 18 months
		Score:51 – 80 %	Once in 12 months
		Score:< 50 %	Once in 06 months

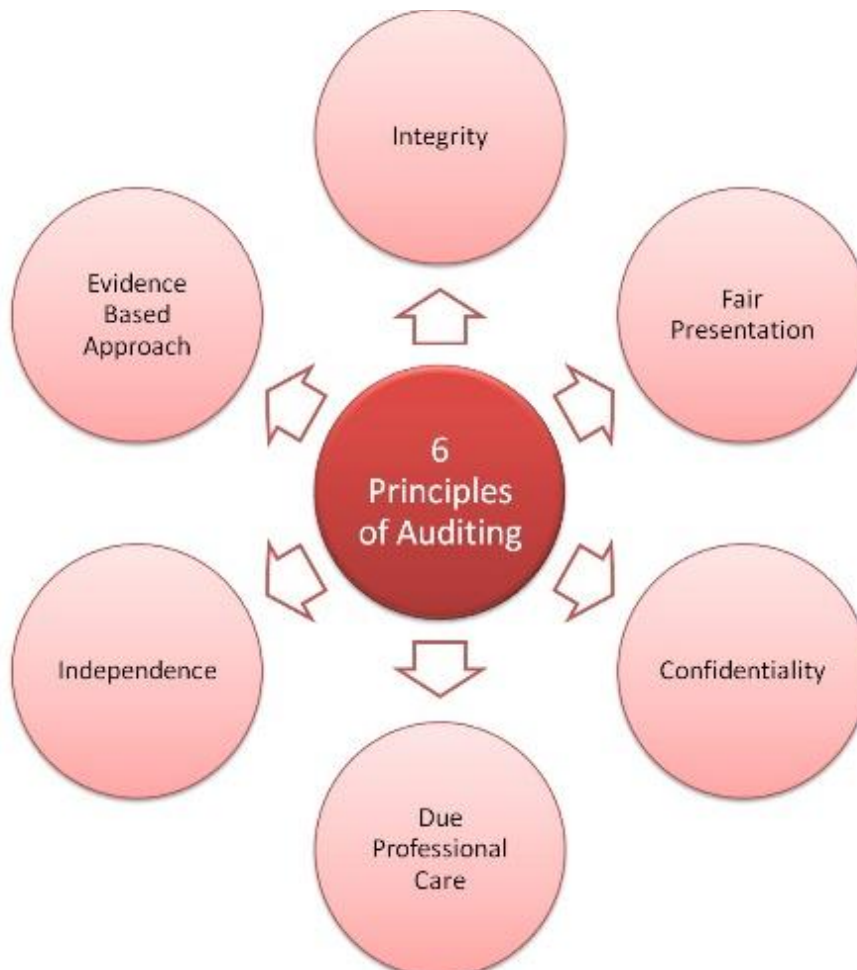
5. Code of Practice for Auditors / Agencies

5.1 Audit Principles

Following “**The Principles of Auditing**” (ISO 19011) is a prerequisite for enabling auditors, working independently from one another, to reach to the conclusions in the given scenarios. These principles are the effective tools in support of management policies and controls, to improve the performance.

Principle 1:	<p><i>Integrity - The foundation of professionalism</i></p> <p>In the course of an audit, auditors are expected to conduct themselves in an honest, diligent, and responsible manner. They ought to be aware of, and comply with, any legal requirements that apply to the auditee, its business type, or its location. Auditors need to be impartial and they also need to be aware of – and resist – any attempt to influence their judgment.</p>
Principle 2:	<p><i>Fair Presentation - The obligation to report truthfully and accurately.</i></p> <p>Auditors are obliged to report on the results of audits truthfully and accurately. All communications needs to be as timely, clear, complete, and objective as possible.</p>
Principle 3:	<p><i>Due professional care - The application of diligence and judgement in auditing</i></p>
Principle 4:	<p><i>Confidentiality - Security of information</i></p>
Principle 5:	<p><i>Independence - The basis for the impartiality of the audit and objectivity of the audit conclusions</i></p> <p>This principle goes hand-in-glove with the principle of fair presentation. In other words, the presentation (report) of my findings is more likely to be viewed as fair, impartial, and objective if the auditor is independent of the party/organization being audited.</p>
Principle 6:	<p><i>Evidence based approach - The rational method for reaching reliable and reproducible audit conclusions</i></p> <p>When an auditor comes up with nonconformity, he has to describe the</p>

	problem clearly and concisely so the auditee understands it and can identify it for themselves. It has to be indicated where and when the problem was identified, how you identified the problem (observed, interviewed, etc.), describe the requirement that is not being met, and describe the objective evidence that led you to your finding of a nonconformity or observation.
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5.2 Behaviour Skills of Auditor

Auditors should possess personal attributes to enable them to act in accordance with the principles of auditing. An auditor should be:

1. Ethical, i.e. fair, truthful, sincere, honest and discreet;
2. Open-minded, i.e. willing to consider alternative ideas or points of view;
3. Diplomatic, i.e. tactful in dealing with people;
4. Observant, i.e. actively aware of physical surroundings and activities;
5. Perceptive, i.e. instinctively aware of and able to understand situations;
6. Versatile, i.e. adjusts readily to different situations;

7. Tenacious, i.e. persistent, focused on achieving objectives;
8. Decisive, i.e. reaches timely conclusions based on logical reasoning and analysis; and
9. Self-reliant, i.e. acts and functions independently while interacting effectively with others.

5.3 Confidentiality Requirements

The purpose of the Confidentiality Policy is to ensure that all information relating to the FBO and/or audit process is handled in confidence. Besides, an agreement (as per Annex 4 of the document) shall be in place between the audit agency and FBO, which shall be uploaded on FSSAI audit portal.

Confidential Information shall mean any information in any form emanating, directly or indirectly, including, but not limited to, product lines, management systems, methods of business operation, technical information, economic information data, specifications, know-how, process information and methods of manufacture, distribution and sale relating to the development and marketing, Photos of Non-conformance etc.

Confidential Information does not include any information which:

- Is used in the appropriate performance of a service and/or discussed or disclosed with FBO's consent.
- At the time of disclosure is generally known by the public or thereafter becomes public knowledge.
- This policy shall not apply in any situation where disclosure is required in accordance with statute law to an official body having a legal right to require that information.

Specific business records and correspondence of a commercially sensitive nature (details of fees, letters relating to one company or person, etc.) shall be kept in confidence unless the Company has received written permission from the person(s) or entities involved, authorising release of the information.

5.4 Declarations for Conflict of Interest, Anti-bribery Norms and Subcontracting of audits

Declarations on below subjects shall be maintained by audit agencies and shall be submitted to FSSAI as and when required.

1. Conflict of Interest:

As prescribed in Section 12 of FSS(FSA) Regulations, 2018, Form C of FSS (Food Safety Auditing) Regulation 2018 shall be obtained by audit agency for every audit and uploaded on FSSAI audit portal. The auditing agency shall give a declaration in Form 'C' of the schedule before accepting food safety audit of a Food Business Operator. The form is also enclosed at Annex 3 of this document. The recognition of any auditing agency shall be suspended or cancelled immediately by the Food Authority on the event of providing false information on conflict of interest.

2. Anti-bribery:

No auditor / personnel of audit agency should have any financial interest in managing or otherwise controlling the FBO or any of its affiliate / parent / subsidiary. In case of breach, the recognition of the agency shall be suspended / cancelled.

3. Sub letting / Sub-contracting of audits:

The entire audit work must be carried out by the auditor of the recognised auditing agency himself/ herself. In other words, the auditor shall not assign the audit work to any agency/ auditor. Any violation in this regard shall lead to de-recognition of the auditor/ agency.

6. Audit Planning

6.1 Audit Duration

The Food Business Operators are broadly divided into 3 categories for calculation of audit time/duration viz.

- I. Manufacturing,
- II. Catering/ Quick Service Restaurants(QSR) / Restaurants,and
- III. Food Retail/Warehouse/Storage.

Audit time is calculated based on number of food handlers, product groups / HACCP study, etc.

The Audit Duration recommended by the Food Authority for conducting the food safety audits for the three categories are as below:

1. Manufacturing

Food handlers (Parameter 1)	No. of production lines/ Product group in FBO/ No. of HACCP study (Parameter 2)	On Site Man-days **
0- 50	1	0.5
51-100	1-2	1
101-300	4	1.5
301-600	6	2
601-1000	8	2.5
>1000	10+	3

Note: For calculating the number of man-days, the parameter with the higher number of man-days shall be taken into consideration.

For eg: If the number of food handlers is 80(i.e <100) and the number of production lines is 4 then the number of man-days will be 1.5 man-days (i.e. maximum of 1 and 1.5 man-days).

2. Catering/QSR/ Restaurants

Food handlers	On Site Man-days **
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0-25	0.5
26-50	1
51-100	1.5
101-100	2

3. Food Retail/ Warehouse/ Storage

Area (Sq. ft)	On Site Man-days **
<15,000	0.5
15001-50,000	1
>50,000	1.5

**** These are ON-SITE audit man-days prescribed and do not include reporting time.**

Any change in the duration of audits should be informed to FSSAI and permission for changing the same should be taken.

6.2 *Audit Fees*

The Audit fee will be as per mutual agreement between the Auditing Agency and the FBO. However, the Food Authority may issue guidelines regarding the fee structure as and when required.

6.3 *Competence of Auditor*

The requirements for Auditing Agencies with respect to the auditor competence and qualification process are as per Food Safety and Standards (Food Safety Auditing), Regulation, 2018. All auditors conducting Food Safety Audits should meet the following minimum requirements:

6.3.1 *Educational Specifications*

Educational qualification of Auditors prescribed in Section 3(c) of the FSS (FSA) Regulation, 2018 is as follows:

Bachelor’s degree in Food or Dairy or Fisheries or Oil Technology or Biotechnology or Agriculture or Veterinary Sciences or Bio-chemistry or Microbiology or Chemistry or Hotel management or Catering technology from a recognised university;

6.3.2 *Initial Training*

- Auditor should meet the requirements detailed in the section specific specifications;
- successful completion of Accredited Lead Auditor course in Food Safety Management System;
- knowledge of the FSS Act and the rules and regulations made thereunder;
- sector specific knowledge of hygienic and sanitary practices, processing techniques, hazards identification and analysis and control and knowledge of contaminants and allergens;

6.3.3 *Work & Audit Experience*

Auditor has a minimum of two years of full-time work experience in minimum of 10 audits (third party audits).

All audit agencies will submit the sector specific qualification (based on ISO 22000) as approved by NABCB or similar accreditation agencies. The FBO audits will be done by the auditor qualified for that specific sector.

6.3.4 Auditor Training (by FSSAI)

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 details of the training will be available in FSSAI Website. The expenditure for this training will not be borne by FSSAI.

The training must be attended by every Food Safety Auditor before commencing any food safety audits as recognised auditor.

6.3.5 Audit team requirements

The agency should also ensure that the audit team complies with the following requirements:

- a. Familiarity with the applicable legal regulations, certification procedures and certification requirements;
- b. Thorough knowledge of the relevant assessment method and assessment documents;
- c. Appropriate technical knowledge of the specific activities for which certification is sought and, where relevant, with associated procedures and their potential for failure (Technical experts who are not auditors may fulfil this function);
- d. Understanding sufficient to make a reliable assessment of the competence of the organization to provide products, processes or services in its certified scope;
- e. Ability to communicate effectively, both in writing and orally, in the required languages;
- f. Free from any interest that might cause team members to act in other than an impartial or non-discriminatory manner, for example: providing of consulting services, training etc. to the organization; As per agreement with the audit team members it is mandatory to inform its auditing agency, prior to the assessment, about any perceived conflict of interest.

7. Audit Execution

7.1 Filling up of Audit Intake Form

An Audit Intake Form on FSSAI web portal shall be filled in once all the relevant information is collected, verified and confirmed from the interested FBO by the audit agency. Once the form is filled on portal, it cannot be changed. The Intake form to be used should be as per Annex 2. The Audit Intake Form shall cover

- a) Information about the applicant FBO
- b) FSSAI license number of FBO
- c) Product groups / HACCP Study for the FBO
- d) Number of employees & production area of the FBO
- e) Auditor Details (as assigned by agency)
- f) Audit date and/or scheduled timings (as mutually decided)
- g) Current FSMS certifying agency, if any of FBO

7.2 Communication of audit plan to FBO

Audit agency will send a detailed audit plan / agenda to FBO at least 8 days in advance. The audits shall not be conducted as surprise audits, unless specified by the food authority.

The audit agenda shall cover audit Scope, objectives, criteria (i.e. Schedule IV, Food Safety Measures and Other Standards), auditor time per process / area / department, date, auditors etc.

7.3 Conducting Audit

The onsite audit should include:

- Opening meeting
- Visit of facilities
- Conducting audit as per audit plan
- Discussions of auditors on audit findings and coming to common understanding
- Feedback on findings to management team & acknowledging the nonconformities
- Audit reporting
- Closing meeting

7.3.1 Opening Meeting:

The audit activities at site shall start with an opening meeting to be held with the auditee's management and, where appropriate, those responsible for the functions or processes to be audited. If Guides are used their role must be explained. The purpose of the opening meeting is to:

- i. confirm the agreement of all parties (e.g. auditee, audit team) to the audit plan;
- ii. introduce the audit team;
- iii. ensure that all planned audit activities can be performed.

The meeting shall be chaired by the Auditor / Audit team leader, and the following items should be considered, as appropriate:

- i. introduction of the participants, including an outline of their roles;
- ii. confirmation of the scope of assessment;
- iii. confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the Licensee;
- iv. confirmation that the resources and facilities needed by the audit team are available;
- v. confirmation of matters relating to confidentiality;
- vi. the method of reporting, including any grading of audit findings, inspection checklists etc;
- vii. methods and procedures to be used to conduct the audit based on sampling;
- viii. confirmation that, during the audit, the Licensee will be kept informed of audit progress and any concerns;
- ix. opportunity for the FBO to ask questions

7.3.2 Conducting the audit activities:

7.3.2.1 The following document/photographs should be uploaded by auditors while submitting the audit report-

1. Picture of updated FSSAI license displayed at a prominent location of the premise.

2. Picture of the internal structure and fittings of the premise depicting that they are made of non-toxic and impermeable material.
3. Picture showing availability of personnel hygiene facilities. (Adequate number of hand washing facilities, toilets, change rooms, rest & refreshment room etc).
4. Document regarding potable water testing report from NABL accredited lab (meeting standards of IS: 10500), tested for quality semi-annually.
5. Document displaying availability of pest control program & pest control activities being carried out by trained and experienced personnel.
6. Document regarding annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine.
7. Picture of food handlers maintaining personal cleanliness (clean clothes, trimmed nails & water proof bandage etc).
8. Document of food handlers showing that they possess the necessary knowledge and skills and are trained to handle food safely.
9. Documents regarding retention of appropriate records and documents for a period of one year or the shelf- life of the product, whichever is more.
10. Documents/pictures displaying requisite time and temperature is being achieved, maintained, monitored & recorded while manufacturing/processing.
11. Picture showing packaging materials being used are of food grade and of sound condition. **(Specific to Milk and milk product processing, Meat processing and Fish and fish products)**
12. Pictures displaying premise is well equipped with chilling room, freezing room, freezer store or freezer as per the operations and fitted with temperature measuring or recording devices. **(Specific to Meat processing)**
13. Picture of room used for deboning, preparing, packing or other handling of meat is equipped with adequate facilities for cleaning & disinfecting implements such as knives, steel, cleavers, saws etc. **(Specific to Meat Processing and Fish and fish products)**
14. Picture displaying food establishment has an updated FSSAI License & NOC from local authority. **(Specific to Slaughter House- Meat)**
15. Documents showing all animals are being subjected to ante-mortem examination and post mortem inspection by the authorised veterinarian as per the specified proforma. **(Specific to Slaughter House- Meat)**
16. Picture showing facilities such as freezer, chillers, hot holding equipment are available for storing temperature sensitive products. **(Specific to Retail and Storage & Warehouse)**
17. Picture of design and construction of transport vehicle along with picture displaying internal structure of the vehicle to ensure intactness and no sign of rusting, flaking paint and corrosion. **(Specific to Transport)**

18. Records or temperature logs showing transport of chilled product and frozen products. **(Specific to Transport)**
19. Picture displaying that bulk foodstuffs in liquid, granulate or powder form are transported in containers/tankers reserved for the transport of foodstuffs and are marked as "for foodstuffs only". **(Specific to Transport)**
20. Picture showing an adequate and separate storage facility is in place for food products; chemical and other hazardous substances; personal items etc. **(Specific to Storage and Warehouse)**
21. Picture showing food materials are being stored on pallets/racks off the floor and away from the walls. **(Specific to Storage and Warehouse)**
22. Records showing frozen products are being stored in frozen rooms (maintained at -180°C or below) and chilled products are stored in cold rooms (maintained at 50°C or below). **(Specific to Storage and Warehouse)**
23. Picture showing cutlery, crockery used for serving and dinner accompaniments at dining service are clean, sanitized and free from unhygienic matter. **(Specific to Catering)**

7.3.2.2 The audit criteria

The audit team shall conduct an onsite audit as per the requirement and audit criteria. During the audit, information relevant to the audit objectives, scope and criteria, including information relating to interfaces between functions, activities and processes, shall be verified and recorded.

The audit criteria shall include the followings:

- Availability of valid FSSAI license
- Compliance of Schedule 4 of FSS Regulations
- Review any changes to activities conducted at the licensed food businesses that may affect the businesses food safety risk
- Review changes to approved activities or processes
- Review of previous audit report and pending actions if any including non conformities not addressed
- Review of enforcement action taken by the Food Authority
- Previously issued Non conformities reviewed and discussed (Non conformities not addressed will be escalated)
- Licensed food businesses must produce evidence of corrective actions taken for all non-conformities issued
- Review of food safety plan to ensure currency and accuracy including:
 - hazard analysis and control points (as determined by legislation),
 - finished product specifications,
 - monitoring records, flow charts,
 - product testing results, and verification records.
- Inspection of the licensed food business and observation of processing and manufacturing practices
- Establish Non conformities to be issued and severity
- Issue of corrective action requests
- Complete audit report and notes

The audit team shall use the inspection checklists prescribed by FSSAI for assessment of food businesses of relevant food category. ***The inspection checklists for various categories of food businesses are placed at Annex 5 of this manual.***

The auditing agencies should not issue any Food Safety Certificates to FBOs on behalf of FSSAI and should only submit audit reports as per inspection checklists at Annex 5 of this manual. Strict action shall be taken against agencies found issuing certificates without knowledge of FSSAI.

7.3.3 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.

7.3.4 Audit Conclusive 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 as the case may be clearly bringing out the findings or non-conformities or concerns and observations for improvement. The format for audit report to be used is enclosed at Annex 5 of this manual.

The auditor may recommend any change in audit frequency of the food business operator alongwith justification to the Central Licensing Authority or State Licensing Authority based on the audit.

7.3.5 Grading of Nonconformity:

The details on audit reporting and grading of Non-Conformities is as laid down in section 11 of FSS (Food Safety Auditing) Regulations, 2018. The non-conformities of the audit are broadly classified into two categories, namely,-

(i) ***Major Non-Conformity***- As per Section 11(2) of the regulations, 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.

Further, major non-conformity is the absence of, or the failure to implement and maintain, one or more requirements of the relevant standard under auditing, or a situation,

which would, on the basis of available objective evidence raise significant doubt as to the conformity of the product sent by the company, bearing high risk severity

A major non-conformity may be an individual non-conformity or a number of minor but related non-conformities, which when considered in total are judged to constitute a major non-conformity. In case of Major Non-conformity follow up audit can be planned depending upon the severity of the Non-conformity

(II) **Minor Non-Conformity**-As per Section 11(2) of the regulations, a Minor Non-Conformity is 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. In this case the auditor shall set up an appropriate timeframe of not more than 30 days 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.***

A minor non-conformity shall be allocated to a single isolated failure in the area concerned to comply with the requirement of relevant standard under auditing or with the specified requirements the organization is subscribed to as per the scope of the standard having moderate risk, without constituting an overall system failure.

For non-conformities as per requirement of certification and auditing, corrections (immediate disposition) and corrective actions (Appropriate actions against cause of detected nonconformities) are required to be taken.

7.3.6 Closing meeting (Conducted at completion of the audit):

It is important that the auditor reports the findings of the audit/ audit score 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. The number of people involved and the time taken for a closing meeting will depend on the size and complexity of the food business and the number and extent of the audit findings. The main objective is to ensure that all involved in the audit have a clear understanding of the findings.

The Agenda for closing meeting may include the followings:

- i. advising the FBO that the audit evidence collected was based on a sample of the information; thereby introducing an element of uncertainty;
- ii. the method and timeframe of reporting, including any grading of audit findings;
- iii. the procedure for closure of nonconformities including any consequences relating to the status of the FBO's license;
- iv. the timeframe for the FBO to present a plan for correction and corrective action for any nonconformities identified during the audit;
- v. Ensure all information recorded on report
- vi. Ensure FBO is fully aware of what information will be communicated back to the Food Authority
- vii. Ensure receiving of acknowledgement of the Nonconformities if any.
- viii. information about the complaint handling processes.

- ix. give opportunity for questions to the FBO.
- x. Discuss and resolve any diverging opinions regarding the audit findings or conclusions between the audit team and the FBO (if applicable and where possible).
Please record and refer any such diverging opinions that are not resolved, to the Food Authority through audit reports.

7.3.7 Closure of Audit Findings

(a) Closure of Major Non Conformities:

The auditor shall report any Major Non-Conformities (as defined in section 7.3.5(I) of this manual) to the Central or State Licensing Authority within twenty four hrs through mail/ phone/ web portal etc. The auditor should ascertain that the information reaches the concerned CLA/SLA and FSSAI (Director (RCD)/ Director (FSMS)). The Central or State Licensing Authority after ascertaining the seriousness of the situation shall take regulatory action against the concerned food business operator. Once the information and other details have been shared by the auditor with concerned CLA/SLA, the next steps will be taken by CLA/SLA and the role of auditor ceases.

(b) Closure of Minor Non Conformities:

In the case of Minor Non-Conformity (as defined in section 7.3.5(II) of this manual), the auditor shall set up an appropriate timeframe of not more than 30 days for its rectification and follow up, so that the non-conformance could be rectified. The complete audit report after rectification of non conformities will be uploaded by the agency on the FSSAI audit management portal. 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.

8 Suspension / Cancellation Policy

The suspension/ cancellation of the recognition of an auditing agency will be governed as per section 7 of the FSS (Food Safety Auditing) Regulation, 2018. The Food Authority may suspend or cancel the recognition granted to the auditing agency by an order on any of the following grounds, namely,-

- a. the auditing agency has been declared insolvent by a competent authority;
- b. the auditing agency has failed to performs its duties satisfactorily or in accordance with these regulations;
- c. the auditing agency has suppressed material information or committed fraud;
- d. the auditing agency has fails to perform satisfactorily or has become incompetent to continue to be accredited as auditing agency;
- e. the auditing agency has failed to provide access to their records and furnish necessary information to the Food Authority to conduct the assessment or investigation;
- f. the auditing agency has failed to take timely and necessary corrective measures, if any, as directed by the Food Authority;
- g. the recommendation of the Screening Committee on of the complaints received regarding conduct of the auditing agency;
- h. the auditing agency has provided false information with regard to conflict of interest;

- i. any other reason that the Food Authority may specify.

Failure to declare any conflicts of interest, as under Form C of the Schedule of the Regulation, may also result in the suspension or cancellation of an auditor's recognition by the Food Authority. The same is also enclosed at Annex 3 of this manual.

9 Renewal of recognition

The auditing agencies are granted recognition for three years. At the end of their three year recognition, they have to renew their recognition as per procedure laid down in Section 6 of the FSS (FSA) Regulations, 2018. If an agency does not renew its recognition prior to the expiry of validity of their date of recognition, their recognition will be cancelled and they will not be eligible to perform food safety audits on behalf of the Food Authority.

The Food Authority before renewing the Certificate of Recognition will consider the following:

- (a) the auditing agency continues to meet the criteria specified in regulation 3;
- (b) the performance of the auditing agency during the previous validity period;
- (c) the complaints, if any, received during the period of validity.
- (d) the recommendation of the Screening Committee for evaluation.

10 Audit Agency Integrity Monitoring Program

The **Monitoring Mechanism** shall include

- a. review of the audit reports and performance;
- b. on site assessment of the auditors to ensure their competency of auditing the food safety management systems and the regulatory requirements;
- c. assessment of auditing agency on the basis of report of the accreditation body and any other mechanism as specified by the Food Authority.

Verification systems are used to check for compliance to set standards, systems and legislative requirements. This system will also enable the Food Authority to assess and monitor the performance of recognised food safety auditors.

Verification audits may be triggered by complaints, system reviews, trends, audit reports and requests by licensees.

10.1 Verification Inspections

The Food Authority may conduct verification inspections on a random selection of facilities audited by auditors of recognised agencies to verify the accuracy of the audit findings. Auditors will be notified, in writing, of the results of the verification inspections. Should significant breaches be identified, a warning letter may be issued or disciplinary action be taken.

10.2 Review of submitted audit reports

Incoming audit reports will be reviewed to ensure compliance with the Food Authority's audit management procedure. Areas that may be included in the review are:

- Audit durations followed
- Relevance of Conformities/ Observations issued
- Severity of conformities/ Observations issued
- Notification of critical food safety issues
- Notification of audit failure
- Timeliness of report submission
- Layout of detailed Audit Summary

Auditors will be notified of any findings of the review of audit reports in writing. Should significant breaches be identified, a warning letter may be issued or disciplinary action be taken.

11. 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.

12. Handling disputes

The details on handling disputes in case of conflicts are given in Section 14 of part IV of FSS (FSA) Regulations, 2018 as below:

- (1) 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.
- (2) 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.

13. Complaints System

Complaints may be made via the website, email or by letter. The website of FSSAI has a link to address the complaints. This link will take all the complaints and queries and pass them on to the relevant divisions of FSSAI for investigations or response. The Food Authority's complaints system is accessible by licensees, auditors, other jurisdictions and the general public. The complainant may remain anonymous if they wish.

14. Terms and Definitions

1. **“Audit”** is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.
2. **“Auditing Agency”** means an auditing agency recognised by the Food Authority for undertaking food safety audit in accordance with FSS (Food Safety Auditing) Regulations.
3. **“Food business”** means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution of food, import and includes food services, catering services, sale of food or food ingredients;
4. **“Food Business Operator (FBO)”** 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 this Act, rules and regulations made thereunder;
5. **“Food Safety”** means assurance that food is acceptable for human consumption according to its intended use;
6. **“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;
7. **“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;
8. **“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;
9. **“Risk Analysis”**, in relation to any article of food, means a process consisting of three components, i.e. risk assessment, risk management and risk communication;
10. **“Risk Assessment”** means a scientifically based process consisting of the following steps : (i) hazard identification, (ii) hazard characterisation; (iii) exposure assessment, and (iv) risk characterisation;
11. **“Standard”**, in relation to any article of food, means the standards notified by the Food Authority;
12. **“Central Licensing Authority (CLA)”** means Designated Officer appointed by the Chief Executive Officer of the Food Safety and Standards Authority of India in his capacity of Food Safety Commissioner.
13. **“Licensing Authority”** means the Designated Officer appointed under section 36 (i) of the Act by the Commissioner of Food Safety of the state or by the Chief Executive Officer of the Food Safety and Standards Authority of India in his capacity of Food Safety Commissioner ;
14. **“Registering Authority”** means Designated Officer/ Food Safety Officer or any official in Panchayat, Municipal Corporation or any other local body or Panchayat in an area, notified as

such by the State Food Safety Commissioner for the purpose of registration as specified in these Regulations.

15. “**State Licensing Authority (SLA)**” means Designated Officers appointed under Section 36(1) of the Act by the Food Safety Commissioner of a State or UT.

16. “**Hazard Analysis and Critical Control Points or HACCP**” is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe, and designs measurements to reduce these risks to a safe level. In this manner, HACCP attempts to avoid hazards rather than attempting to inspect finished products for the effects of those hazards. The HACCP system can be used at all stages of a food chain, from food production and preparation processes including packaging, distribution, etc.

17. “**Screening Committee**” means the committee constituted as per section 4(4) of the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 for recommending Auditing Agencies to the food authority for grant of recognition.

15. ANNEXURE

Annex 1 : Option form for selecting Kind of business and geographical location

Annex 2 : Intake form for Auditor

Annex 3 : Declaration of Conflict of Interest

Annex 4 : Confidentiality Agreement between FBO and Auditing Agency

Annex 5 : Audit Checklists and Grading System

Annex 6 : Food Safety and Standards (Food Safety Auditing) Regulation, 2018.

Option form for selecting Kind of business and geographical location

(1) Please select the area of specialization for auditing (as per point (7) of the Form A of regulation(Annex1)):

S. No	Kinds of Businesses	Do you have qualified auditors available for this area? (If yes, attach relevant inspection/auditing record details for past two years as in point 11 of Form A)
1.	Food Processing	
	(i) Dairy	
	(ii) Slaughter Houses(Meat & Poultry)	
	(iii) Meat and Poultry Processing Units	
	(iv) Egg and Egg Products	
	(v) Fish and Fish Products	
	(vi) Other Sectors (e.g. Bakery, Edible Oil, Fruit & Vegetable Processing, ready to eat/cook etc) (Please Specify)	
2.	Food Storage/Warehouse/Cold Storage	
3.	Food Transportation	
4.	Food Retail and Distribution/Supplier	
5.	Food Catering (Catering, Hotels & Restaurants, Dhabas, Rail, Air & Port Catering, Canteens, or any other food vending establishment)	
6.	E-Commerce	

(2) **Can your Agency conduct Food Safety Audits for the entire country? Yes/No**
If No, Please specify the States/UTs where you can operate:

Signature of authorized signatory with stamp

Intake form for Auditor
(to be filled by Contact person of auditing agency)

I.	FBO Details	
1.	Name of FBO:	
2.	License Number:	
3.	Address:	
4.	Name of Contact person from FBO:	
5.	Scope (Kind of Business):	
6.	No of Production lines/Product Groups:	
7.	Number of Employees/Food Handlers:	
8.	Area of storage:	
9.	Agency empanelled for Consultancy(if any) :	
10.	Agency empanelled for training(if any) :	
II.	Agency Details	
1.	Name of Auditing Agency:	
2.	Recognition Number:	
3.	Name of Auditor detailed for audit:	
4.	Contact Details of Auditor:	
III.	Audit Details	
1.	Audit Date Scheduled:	
2.	No. of Man-Days Fixed:	
3.	Auditor Fee per Man- Day:	
4.	Date of sending Audit Plan:	

Declaration of Conflict of Interest
(as per Form C of regulation in Annex 6)

Declaration

(See sub-regulation (i) of regulation 12)

I _____ S/o, D/o _____ state that the food safety audit of M/s _____ having license number _____ has been audited by my auditing agency. In this context, I hereby declare that:

- a) my auditing agency or its personnel/auditor have 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 two years.
- b) my auditing agency or its personnel/auditor does not own or have financial interest in, manage or otherwise control to the above said food business operators or any of its affiliate, parent or subsidiary.
- c) my auditing agency or its personnel/auditor have not been employed by the above said food business operator for last two years.
- d) my auditing agency has not carried out the food safety audit of the above said food business operator for more than three consecutive audit.

Signature of authorised signatory /Auditor with stamp

CONFIDENTIALITY AGREEMENT

(to be signed by each auditor before commencing every audit)

1. Application/Licence No.
2. Name & Address of FBO:
to be audited
3. Date(s):
4. I accept to work as Auditor for conducting food safety audit of above mentioned FBO.
5. I declare that,
 - i) I have not acted as Consultant and/or undertaken internal audit or any other work for the above FBO or its subsidiary within the last two years;
 - ii) I have not provided specific and tailored training services to the client within the past two years,
 - iii) I do not have any commercial interest in the above FBO.
 - iv) I do not have any relationship with the above FBO.
6. I undertake that, I shall treat all the documentation and information provided by the FBO audited as strictly confidential.
 - i) I shall neither copy any documentation nor divulge any information to any third party without the written prior consent of the FBO assessed or FSSAI except as required by law or in demonstrating conformance with the requirements of national accreditation.
 - ii) I shall not act in any way prejudicial to the reputation or interest of FSSAI or the FBO assessed.
 - iii) I shall not accept payment, commission, discount or any other profit from the FBO assessed or from their representative or from any other interested person.
 - iv) In the event of any alleged breach of this undertaking, I know that FSSAI can blacklist me and also terminate the use of my services as auditing personnel.
 - v) Information about the client from sources other than the client (Eg complainant, regulators) shall be treated as confidential.
 - vi) In the event of any enquiry/investigation conducted due to unethical practice and breach of this undertaking, I shall fully cooperate with FSSAI.
 - vii) If during the course of an assignment I identify a situation in which I believe the impartiality of the audit has been compromised, I will notify my agency and FSSAI immediately.

By affixing my signature below I certify that I have read, understood and agree to abide with all parts of the above policies.

Signature :

Name :

Date :

Counter Sign by Concerned Agency

Audit Checklists and Grading System

Introduction:

FSSAI has developed inspection checklist for facilitating Food Safety Officers to efficiently inspect the Food Business Operators. These inspection checklists are based on revised Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011 and have been developed for following sectors -

1. *General Manufacturing*
2. *Milk Processing*
3. *Meat Processing*
4. *Slaughter house*
5. *Catering*
6. *Retail*
7. *Transport*
8. *Storage & warehouse*

The same can be also downloaded from FSSAI Website:
(<http://www.fssai.gov.in/home/compliance/FOOD-SAFETY-INSPECTION-CHECKLISTS-.html>)

Marking & grading system –

The **Inspection Checklist** has been divided into five major sections namely –

1. *Design & facilities*
2. *Control of Operation*
3. *Maintenance & sanitation*
4. *Personal Hygiene*
5. *Training & complaint handling*

The Auditor/FSO will inspect the facility of the Food Business Operator according to the requirements as laid down in the inspection checklist and accordingly will mark the finding as compliance (C), non-compliance (NC), partial compliance (PC) & Not applicable/Not observed (NA). All the requirements are allotted 2 marks and there are few requirements which are asterisk marked (*) which are allotted 4 marks. Non observance to any of the asterisk marked (*) finding will lead to Non-Compliance (NC), as they are critical to food safety. Each finding will be awarded marks as mentioned below –

S. No.	Finding	Marks to be awarded	Marks to be awarded in Asterisk Mark (*) question
1	Compliance (C)	2	4
2	Non-compliance (NC)	0	0
3	Partial compliance (PC)	1	0
4	Not applicable/ Not observed (NA)	2	4

Compliance – Yes, the requirement is fully documented and implemented. Adherence with the requirement with no major or minor conformance is observed.

Non-compliance - No, the requirement is not documented and implemented. Non adherence with the requirement with major non - conformance is observed.

Partial Compliance – Requirement is partially implemented but not documented or partially documented but not implemented. A non conformity that, based on the judgement and experience of the Auditor/FSO, is not likely to result in the failure of the food safety management system or reduce its ability to assure controlled processes or products. It may be either a failure in some part to a specified requirement or a single observed lapse. Partial Compliance is not applicable to asterisk marked (*) requirements as they are critical to food safety.

Not Applicable/Not observed (NA) – Requirements are not applicable to FBO & hence cannot be observed.

Sub-sequentially awarding the marks as per the finding against the requirements, total marks are calculated & based on the final marks, grading of the FBOs is done. The grading has been divided into 4 levels, i.e.

Grade	Status	Marks required
A+	Compliance – Exemplar	90% & above
A	Compliance – Satisfactory	80% - 89%
B	Needs Improvement	50 % - 79%
No grade	Non Compliance	Below 50%

GENERAL MANUFACTURING

Date		FBO Name	
Auditor Name		FBO's Representative Name	
Auditor Contact No.		Address	
		FBO License No.	

Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable(NA) and the corresponding score and relevant comments.

S. No.	Audit Question	Scoring		Comments
		Score	C/PC/NC/NA	
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2		
I	Design & facilities			
2	The design of food premises provides adequate working space; permit maintenance & cleaning to prevent the entry of dirt, dust & pests.	2		
3	The internal structure & fittings are made of non-toxic and impermeable material.	2		
4	Walls, ceilings & doors are free from flaking paint or plaster, condensation & shedding particles.	2		
5	Floors are non-slippery & sloped appropriately.	2		
6	Windows are kept closed & fitted with insect proof screen when opening to an external environment.	2		
7	Doors are close fitted to avoid entry of pests.	2		
8	Equipment and containers are made of non-toxic, impervious, non- corrosive material which is easy to clean & disinfect.	2		
9	Premise has sufficient lighting.	2		
10	Adequate ventilation is provided within the premises.	2		
11	Adequate storage facility for food, packaging materials, chemicals, personnel items etc available.	2		
12	Personnel hygiene facilities are available. (Adequate number of hand washing facilities, toilets, change rooms, rest & refreshment room etc).	2		

13*	<i>Potable water (meeting standards of IS:10500) is used as a product ingredient or in contact with food or food contact surface & tested for quality semi annually. Check for records.</i>	4			
14	Food material is tested either through internal laboratory or through an accredited lab. Check for records.	2			
II	Control of operation				
15	Incoming material procured as per internally laid down specification & from an approved vendors. Check for records (like specifications, name and address of the supplier, batch no., quantity procured etc).	2			
16	Raw materials is inspected at the time of receiving for food safety hazards.	2			
17	Incoming material, semi or final products are stored according to their temperature and humidity requirement, in a hygienic environment. FIFO & FEFO is practised.	2			
18*	<i>Requisite time and temperature is being achieved, maintained, monitored & recorded while manufacturing/processing. Check for records.</i>	4			
19	Food manufactured/processed is packed in a hygienic manner.	2			
20	Packaging materials is food grade & in sound condition.	2			
21	Cleaning chemicals & other hazardous substance are clearly identified & stored separately from food.	2			
22	Transporting vehicle for food use are kept clean and maintained in good repair.	2			
23	Transporting vehicle are capable of meeting requisite temperature (where applicable).	2			
24	Recalled products are held under supervision & destroyed or reprocessed/reworked in a manner to ensure their safety. Check for records.	2			
III	Maintenance & sanitation				
25	Cleaning of equipment, food premises is done as per cleaning schedule & cleaning programme.	2			
26	Preventive maintenance of equipment and machinery are carried out regularly as per the instructions of the manufacturer.	2			
27	Measuring & monitoring devices are calibrated periodically.	2			
28*	<i>Pest control program is available & pest control</i>	4			

	<i>activities are carried out by trained and experienced personnel. Check for records.</i>				
29	No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)	2			
30	Drains are designed to meet expected flow loads and equipped with traps to capture contaminants.				
31	Food waste and other refuse are removed periodically from food handling areas to avoid accumulation.	2			
32	Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986.	2			
IV	Personal Hygiene	2			
33	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2			
34	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2			
35*	<i>Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage etc) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc).</i>	4			
36	Food handlers equipped with suitable aprons, gloves, headgear, shoe cover etc; wherever necessary.	2			
V	Training & Complaint Handling				
37	Internal / External audit of the system is done periodically. Check for records.	2			
38	Food business has an effective consumer complaints redressal mechanism.	2			
39	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2			
40*	<i>Appropriate documentation & records are available and retained for a period of one year or the shelf-life of the product, whichever is more.</i>	4			

Overall findings of Auditor:

Improvements Suggested:



Total points/Score/90

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

Grading –

- A+
- A
- B
- No grade

Grade	Status	Marks Required
A+	Compliance-Exemplar	90% & above
A	Compliance- Satisfactory	80%-89%
B	Needs Improvement	50%-79%
No grade	Non Compliance	Below 50%

Signature of Auditor

Agency Stamp

MILK & MILK PRODUCT PROCESSING

Date		FBO Name	
Auditor Name		FBO's Representative Name	
Auditor Contact No.		Address	
		FBO License No.	

Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable(NA) and the corresponding score and relevant comments.

S. No.	Audit Question	Scoring		Comments
			Score	C/PC/NC/NA
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2		
I	Design & facilities			
2	Design of food premises provide adequate working space; permit maintenance, cleaning & prevent entry of dirt, dust & pests.	2		
3	The internal structure & fittings are made of non-toxic and impermeable material.	2		
4	Walls, ceilings & doors are free from flaking paint or plaster, condensation & shedding particles.	2		
5	Floors are non-slippery & sloped appropriately.	2		
6	Windows are kept closed & fitted with insect proof screen when opening to an external environment.	2		
7	Doors are close fitted at all ends to avoid entry of pests.	2		
8	Equipment and containers are made of non-toxic, impervious, non- corrosive material which is easy to clean & disinfect (preferably SS 316 for equipment& SS 304 for tanks/tankers).	2		
9	Premise has sufficient lighting.	2		

10	Adequate ventilation is provided within the premises.	2			
11	An adequate storage facility for food, packaging materials, chemicals, personnel items etc is available.	2			
12	Personnel hygiene facilities are available. (Adequate number of hand washing facilities, toilets, change rooms, rest & refreshment room etc).	2			
13*	<i>Potable water (meeting standards of IS:10500) is used as product ingredient or in contact with food or food contact surface. Tested for quality semi annually. Check for records.</i>	4			
14	Raw Milk Reception Dock (RMRD) facility is sufficiently raised with sides & top to prevent contamination while unloading of raw material.	2			
15	Separate processing facilities available for heat treated milk & milk products to avoid cross contamination.	2			
16	Food material is tested either through internal laboratory or through an accredited lab. Check for records.	2			
II	Control of operation				
17	Incoming material is procured as per internally laid down specification & from approved vendors. Check for records (like specifications, name and address of the supplier, batch no., quantity procured etc).	2			
18	Milk & other raw material are inspected at the time of receiving for food safety hazards.	2			
19	Raw milk received through bulk chilling centres, the temperature of milk is maintained at 5°C or lower.	2			
20	Raw milk when brought to dairy plant by farmers, should reach the plant within 4 hours from milking & is cooled to 5°C or lower as quickly as possible.	2			
21	Incoming material, semi or final products are stored according to their temperature and humidity requirement, in a hygienic environment. FIFO & FEFO is practised.	2			
22	Milk is brought to the collection centre within 4 hours and immediately chilled to a temperature of 4°C or lower.	2			
23	Pasteurization temperature & holding time (Ideally 72°C for 15 seconds for HTST) are properly maintained. (Batch pasteurization (63°C for 30 minutes, UHT (135°C for 1-2 sec))	2			
24	Post pasteurisation process, milk is cooled immediately to a temperature of 4°C or lower.	2			

25*	<i>Requisite time and temperature is being achieved, maintained, monitored & recorded while manufacturing/processing.</i>	2			
26	Packing or filling of heat treated milk and milk products are carried out hygienically.	2			
27	Packaging materials is food grade & in sound condition.	2			
28	Cleaning chemicals & other hazardous substance are clearly identified & stored separately from food.	2			
29	Transporting vehicle for food use are kept clean and maintained in good repair.	4			
30	Transporting vehicles for carrying milk are capable of meeting requisite temperature (where applicable).	2			
31	Recalled products are held under supervision & are destroyed or reprocessed/reworked in a manner to ensure their safety. Check for records.	2			
III	Maintenance & sanitation				
32	Cleaning of equipment (preferably CIP), food premises is done as per cleaning schedule & cleaning programme. Proper arrangements available for cleaning, sanitizing of road milk tankers, cans etc.	2			
33	Preventive maintenance of equipment and machinery is carried out regularly as per the instructions of the manufacturer.	2			
34	Measuring & monitoring devices are calibrated periodically.	2			
35*	<i>Pest control program is available & pest control activities are carried out by trained and experienced personnel. Check for records.</i>	4			
36	No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)	2			
37	Drains are designed to meet expected flow loads and equipped with traps to capture contaminants.	2			
38	Food waste and other refuse are removed periodically from food handling areas to avoid accumulation.	2			
39	Effluent Treatment Plant (ETP) is in place.	2			
40	Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986.	2			
IV	Personal Hygiene				
41	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check	2			

	for records.				
42	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2			
43*	<i>Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage etc) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc).</i>	4			
46	Food handlers are equipped with suitable aprons, gloves, headgear, shoe cover etc; wherever necessary.	2			
V	Training & records keeping				
47	Internal / External audit of the system is done periodically. Check for records.	2			
48	Food Business has an effective consumer complaints redressal mechanism.	2			
49	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2			
50*	<i>Appropriate documentation & records are available and retained for a period of one year or the shelf-life of the product, whichever is more.</i>	4			

Overall findings of Auditor:

Improvements Suggested:



Total points/110

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance.

Grading –

- A+
- A
- B
- No grade

Grade	Status	Marks Required
A+	Compliance-Exemplar	90% & above
A	Compliance- Satisfactory	80%-89%
B	Needs Improvement	50%-79%
No grade	Non Compliance	Below 50%

Signature of Auditor

Agency Stamp



MEAT PROCESSING

Date		FBO Name	
Auditor Name		FBO's Representative Name	
Auditor Contact No.		Address	
		FBO License No.	

Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable(NA) and the corresponding score and relevant comments.

S. No.	Audit Question	Scoring			Comments
		Score	C/PC/NC/NA		
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2			
I	Design & facilities				
2	Premise is located in area that is free from objectionable odour, smoke, dust & other contaminants.	2			
3	The design of food premises provides adequate working space; permit maintenance & cleaning.	2			
4	Internal structure & fittings are made of non-toxic, impermeable materials which prevent the entry of dirt, dust & pest.	2			
5	The premise is well equipped with chilling room, freezing room, freezer store or freezer as per the operations and fitted with temperature measuring or recording devices.	2			
6	Floors are non-slippery, non-toxic, impervious & sloped appropriately.	2			
7	Walls are non-absorbent, non-toxic, preferably light coloured, smooth & without crevices.	2			
8	Ceilings are free from accumulated dirt, mould development & flaking paint or plaster.	2			
9	Windows & other openings are free from accumulated dirt, those which open are fitted with	2			

	insect-proof screen.				
10	Doors are smooth, non-absorbent surface, close fitted & self closing (where appropriate).	2			
11	Premises have sufficient lighting i.e.540 lux (inspection points), 220 lux (work room) & 110 lux (other areas).	2			
12	Adequate ventilation is provided within the premises.				
13*	<i>Potable water (meeting standards of IS:10500 & tested semi annually with records maintained thereof) is used as product ingredient or in contact with food (ice & steam) or food contact surface.</i>	4			
14	Facilities for cleaning & disinfection of implements are made of non corrosive material & fitted with suitable means of supplying hot water in sufficient quantity.	2			
15	Equipment, utensils and containers is made of material that is non-toxic, impervious, non-corrosive, facilitate cleaning & do not provide harbourage to pests.	2			
16	Food material is tested either through internal laboratory or an accredited lab. Check for records.	2			
17	Personnel hygiene facilities are available including adequate number of toilets, hand washing facilities and change rooms. Hand washing facilities with warm or hot and cold water, adequate means to hygienically dry hands are provided adjacent to toilets and at entry to processing area.	2			
18	Premise has facility for storage of waste & inedible material such that contamination with food is avoided and is also free from any pest activity.	2			
II	Control of operation				
19	Incoming material procured as per internally laid down specification from approved vendors. Check for records (like specifications, name and address of the supplier, batch no., quantity procured etc).	2			
20	Raw materials inspected at the time of receiving for food safety hazards.	2			
21	Incoming material, semi or final products stored according to their temperature and humidity requirement, in a hygienic environment. FIFO & FEFO is practised.	2			
22*	<i>The temperature in room for boning out & trimming are controlled & held suitably low, unless cleaning of equipment & utensils are carried out at least every</i>	4			

	<i>four hours.</i>				
23*	<i>Room used for deboning, preparing, packing or other handling of meat is equipped with adequate facilities for cleaning & disinfecting implements such as knives, steel, cleavers, saws etc & these facilities are not used for any other purpose.</i>	4			
24	Meat shall be processed and packed using sound food grade materials in a hygienic manner.	2			
25	Containers used for storing inedible substances, cleaning chemicals & other hazardous substance are clearly identified; stored separately from food.	2			
26	Transporting vehicle for food use are kept clean and maintained in good repair.	2			
27	Transporting vehicle capable of meeting requisite temperature (where applicable).	2			
28	Recalled products are held under supervision & destroyed or reprocessed/reworked in a manner to ensure their safety. Check for records.	2			
III	Maintenance & sanitation				
29*	<i>All equipments, implements, tables, utensils including knives, cleaves, knife pouches, saws, mechanical instruments and containers are cleaned and disinfected at frequent intervals and immediately when they come in contact with infected material or otherwise become contaminated. They are also cleaned and disinfected at the end of each working day.</i>	4			
30	Preventive maintenance of equipment and machinery are carried out regularly as per the instructions of the manufacturer.	2			
31	Measuring & monitoring devices are calibrated periodically.	2			
32*	<i>Pest control program is available & pest control activities are carried out by trained and experienced personnel. Check for records.</i>	4			
33	No signs of pest activity or infestation in premises.	2			
34	Waste is removed from meat handling area at regular intervals (at least daily) & the receptacles are cleaned & disinfected.	2			
35	Drains are designed to meet expected flow loads and equipped with traps to capture contaminants.	2			
36	Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986 (BOD is less than	2			

	1500)				
IV	Personal Hygiene				
37	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2			
38	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2			
39*	<i>Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage) and personal behaviour (hand washing, no loose jewellery, , no smoking, spitting etc).</i>	4			
40	Food handlers equipped with suitable aprons, gloves, headgear, shoe cover etc;	2			
V	Training & records keeping				
41	Internal / External audit of the system is done periodically. Check for records.	2			
42	Food Business has an effective consumer complaints redressal mechanism.	2			
43	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2			
44*	<i>Appropriate documentation & records are available and retained for a period of one year or the shelf-life of the product, whichever is more.</i>	4			

Overall findings of Auditor:

Improvements Suggested:

Total points/100

Asterisk marked (*) requirements may significantly impact food safety & should be addressed as a priority. Failure in any of the asterisk mark (*) question, will lead to Non Compliance.

Grading –

- A+
- A
- B
- No grade

Grade	Status	Marks Required
A+	Compliance-Exemplar	90% & above
A	Compliance- Satisfactory	80%-89%
B	Needs Improvement	50%-79%
No grade	Non Compliance	Below 50%



Signature of Auditor

Agency Stamp

SLAUGHTER HOUSE - MEAT

Date		FBO Name	
Auditor Name		FBO's Representative Name	
Auditor Contact No.		Address	
		FBO License No.	

Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable(NA) and the corresponding score and relevant comments.

S. No.	Audit Question	Scoring		Comments
		Score	C/PC/NC/NA	
1	Food establishment has an updated FSSAI License & NOC from local authority.	2		
I	Design & facilities			
2	The premises have separate provision for the slaughter of different species of animals & for different methods of slaughter.	2		
3	There is an adequate resting area (lairage) with facility for watering and examination of animals or birds.	2		
4	The layout of the slaughter house is such that there is a forward movement from the introduction of the live animal to emergence of meat and offals without any possibility for overlap/intersection.	2		
5	Internal structure & fittings are made of non-toxic, impermeable materials which prevent the entry of dirt, dust & pest.	2		
6	Floors are impervious, epoxy coated and non-slippery.	2		
7	Walls are paved with imperious glazed tiles upto 1 meter height for poultry or small ruminant animals and upto 5 metre for large animals & are epoxy coated.	2		
8	Windows & other openings are free from accumulated dirt, those which open are fitted with insect-proof screen.	2		
9	Doors are smooth, non-absorbent surface, close fitted & self closing (where appropriate).	2		

10	Premises have sufficient lighting i.e.540 lux (inspection points), 220 lux (work room)& 110 lux (other areas).	2			
11	Adequate ventilation is provided within the premises.	2			
12	Personnel hygiene facilities are available including adequate number of toilets, hand washing facilities and change rooms. Hand washing facilities with warm or hot and cold water, adequate means to hygienically dry hands are provided adjacent to toilets and at entry to processing area.	2			
13*	<i>Clean potable cold water (meeting standards of IS 10500)with pressure hose pipes and supply of hot water is available in slaughter hall.</i>	4			
14	An equipped laboratory is available with qualified chemist/analyst & veterinary microbiologist.	2			
15	The equipment & containers (except for chopping blocks, cutting boards & brooms) are durable, made of corrosion resistant material which facilitates cleaning.	2			
II	Control of operation				
16	Animals suspected of infectious diseases are segregated and kept in separation.	2			
17	<i>Humane methods are used for slaughtering. Animals are rested before slaughter to reduce stress. Slaughtering of animals is not done in sight of other animals. Stunning of animals is done before slaughtering.</i>	4			
18	Equipment used for stunning is maintained in good working condition.	2			
19	The dressing of the carcasses is not done on floor. Suitable hoists are provided to hang the carcasses before evisceration	2			
20	Knives and sharpners (mushtala) are of stainless steel and sterilized/ sanitized before use.	2			
21*	<i>All animals are subjected to ante-mortem examination and post mortem inspection by the authorised veterinarian as per the specified proforma.</i>	4			
22	When dressed meat has to stored without further immediate processing, such storage is maintained at 0°C to 2°C.	2			
23	Carcasses, parts and the organs thereof found to be healthy and fit for human consumption are marked as “ <i>Inspected & passed</i> ”. Carcass or parts thereof which is unfit for human consumption is marked as “ <i>Inspected & condemned</i> ”.	2			
III	Sanitation, maintenance & waste disposal				
24	Cleaning of equipment, food premises is done as per cleaning schedule & cleaning programme. (Floorings are washed daily. Lime washing, colour washing or paint washing is done at least once in 12 months.)	2			
25	Preventive maintenance of stunning equipment is carried out regularly as per the manufacturer’s instructions.	2			
26	<i>Blood, manure, garbage, filth or other refuse from any animal slaughtered and the hide, viscera and offals are removed from the slaughter house within 8 hours after completion of slaughtering in a manner not to cause contamination. The container or receptacle used for these</i>	4			

	wastes is thoroughly cleaned and disinfected immediately after use.			
27*	Pest control programme is available and pest control activities are carried out by trained and experienced personnel.	4		
28	No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)	2		
29	There is an efficient drainage system and all drains and gutters are properly and permanently installed fitted with traps and screens . The drainage system for blood is either underground with facility for easy cleaning or a portable receptacle with lid).	2		
30	Sufficient space is there for separation and storage of condemned carcasses. Destruction of condemned carcasses, organs or parts thereof shall be carried out under the direct supervision of the authorised veterinarian.	2		
31	Slaughter house refuse and waste material is suitably processed to prepare animal by product or dumped in pits that are suitably covered.	2		
32	For large slaughter house, ETP is required. Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986.	4		
IV	Personal Hygiene			
33	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2		
34	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2		
35*	Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc).	4		
36	Food handlers are equipped with suitable aprons, gloves, headgear, shoe cover etc.	2		
V	Training & records keeping			
37	Internal / External audit of the system is done periodically. Check for records.	2		
38	Food Business has an effective consumer complaints redressal mechanism.	2		
39	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2		
40*	Appropriate documentation & records are available and retained for a period of one year or the shelf-life of the product, whichever is more.	4		

Overall findings of Auditor:

Improvements Suggested:

Total points/Score /90

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

Grading –

- A+
- A
- B
- No grade

Grade	Status	Marks Required
A+	Compliance-Exemplar	90% & above
A	Compliance- Satisfactory	80%-89%



B	Needs Improvement	50%-79%
No grade	Non Compliance	Below 50%

Signature of Auditor

Agency Stamp

CATERING

Date		FBO Name	
Auditor Name		FBO's Representative Name	
Auditor Contact No.		Address	
		FBO License No.	

Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable(NA) and the corresponding score and relevant comments.

S. No.	Audit Question	Scoring		Comments
			Score	C/PC/NC/NA
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2		
1.	Design & facilities			
2	The design of food premises provides adequate working space; permit maintenance & cleaning to prevent the entry of dirt, dust & pests.	2		
3	The internal structure & fittings are made of non-toxic and impermeable material.	2		
4	Walls, ceilings & doors are free from flaking paint or plaster, condensation & shedding particles.	2		
5	Floors are non-absorbent, non-slippery & sloped appropriately.	2		
6	Windows are kept closed & fitted with insect proof screen when opening to external environment.	2		
7	Doors are smooth and non-absorbent. Suitable	2		

	precautions have been taken prevent entry of pests.				
8*	<i>Potable water (meeting standards of IS:10500 & tested semi-annually with records maintained thereof) is used as product ingredient or in contact with food or food contact surface.</i>	4			
9	Equipment and containers are made of non-toxic, impervious, non- corrosive material which is easy to clean & disinfect.	2			
10	Adequate facilities for heating, cooling, refrigeration and freezing food & facilitate monitoring of temperature.	2			
11	Premise has sufficient lighting.Lighting fixtures are protected to prevent contamination on breakage .	2			
12	Adequate ventilation is provided within the premises.	2			
13	An adequate storage facility for food, packaging materials, chemicals, personnel items etc is available.	2			
14	Personnel hygiene facilities are available including adequate number of hand washing facilities, toilets, change rooms for employees.	2			
15	Food material is tested either through internal laboratory or through an accredited lab. Check for records.	2			
II.	Control of operation				
16	Incoming material is procured as per internally laid down specification from approved vendors. Check for records (like certificate of analysis, Form E, specifications, name and address of the supplier, batch no., mfg., use by/expiry date, quantity procured etc.)	2			
17	Raw materials are inspected at the time of receiving for food safety hazards.(Farm produce like vegetables, fruits, eggs etc. must be checked for spoilage and accepted only in good condition)	2			
18	Incoming material, semi or final products are stored according to their temperature requirement in a hygienic environment to avoid deterioration and protect from contamination. FIFO & FEFO is practised. (Foods of animal origin are stored at a	2			

	temperature less than or equal to 4°C)				
19	All raw materials is cleaned thoroughly before food preparation.	2			
20	Proper segregation of raw, cooked; vegetarian and non-vegetarian food is done.	2			
21	All the equipment is adequately sanitized before and after food preparation.	2			
22*	Frozen food is thawed hygienically. No thawed food is stored for later use. (Meat, Fish and poultry is thawed in refrigerator at 5 °C or below or in microwave. Shellfish/seafood is thawed in cold potable running water at 15 °C or below within 90 minutes.	4			
23*	<i>Vegetarian items are cooked to a minimum of 60°C for 10 minutes or 65°C for 2 minutes core food temperature. Non vegetarian items are cooked for a minimum of 65°C for 10 minutes or 70°C for 2 minutes or 75°C for 15 seconds core food temperature.</i>	4			
24*	Cooked food intended for refrigeration is cooled appropriately. (High risk food is cooled from 60° C to 21°C within 2 hours or less and further cooled to 5° C within two hours or less.)	4			
25	Food portioning is done in hygienic conditions. High risk food is portioned in a refrigerated area or portioned and refrigerated within 30 minutes. Large amount of food is portioned below 15 °C.	2			
26*	Hotfood intended for consumption is held at 65° Cand non-vegetarian food intended for consumption is held at 70°C. Cold foods are maintained at 5°C or below and frozen products are held at -18° C or below. (*Hot food is kept above 65°C and cold food is kept below 5°C but below 10 °C upto 42 hours for not more than two hours only once.)	4			
27*	Reheating is done appropriately and no indirect of reheating such as adding hot water or reheating under bainmaire or reheating under lamp are being used. (The core temperature of food reaches 75°C and is reheated for at least 2 minutes at this temperature.)	4			

28	Oil being used is suitable for cooking purposes is being used. Periodic verification of fat and oil by checking the color, the flavour and floated elements is being done.	2			
29*	Vehicle intended for food transportation are kept clean and maintained in good repair & are maintain required temperature. (Hot foods are held at 65°C, cold foods at 5°C and frozen item -18°C during transportation or transported within 2 hours of food preparation).	4			
30	Food and non-food products transported at same time in the same vehicle is separated adequately to avoid any risk to food.	2			
31	Cutlery, crockery used for serving and dinner accompaniments at dining service are clean and sanitized free from unhygienic matters.	2			
32	Packaging and wrapping material coming in contact with food is clean and of food grade quality.	2			
III.	Maintenance & sanitation				
33	Cleaning of equipment, food premises is done as per cleaning schedule & cleaning programme. There should be no stagnation of water in food zones.	2			
34	Preventive maintenance of equipment and machinery are carried out regularly as per the instructions of the manufacturer. Check for records.	2			
35	Measuring & monitoring devices are calibrated periodically.	2			
36	Pest control program is available & pest control activities are carried out by trained and experienced personnel. Check for records.	2			
37*	<i>No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)</i>	4			
38	Drains are designed to meet expected flow loads and equipped with grease and cockroach traps to capture contaminants and pests.	2			
39	Food waste and other refuse are removed periodically from food handling areas to avoid accumulation.	2			
IV.	Personal Hygiene				

40	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2			
41	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2			
42*	<i>Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage etc.) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc.)</i>	4			
43	Food handlers are equipped with suitable aprons, gloves, headgear, etc.; wherever necessary.	2			
V.	Training & records keeping				
44	Internal / External audit of the system is done periodically. Check for records.	2			
45	Food Business has an effective consumer complaints redressal mechanism.	2			
46	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2			
47*	<i>Appropriate documentation & records are available and retained for a period of one year, whichever is more.</i>	4			

Overall findings of Auditor:



Improvements Suggested:

Total points/114

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

Grading –

- A+
- A
- B
- No grade

Grade	Status	Marks Required
A+	Compliance-Exemplar	90% & above
A	Compliance- Satisfactory	80%-89%
B	Needs Improvement	50%-79%
No grade	Non Compliance	Below 50%

Signature of Auditor

Agency Stamp



RETAIL

Date		FBO Name	
Auditor Name		FBO's Representative Name	
Auditor Contact No.		Address	
		FBO License No.	

Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable(NA) and the corresponding score and relevant comments.

S. No.	Audit Question	Scoring		Comments
		Score	C/PC/NC/NA	
1	Retail store has an updated FSSAI license and is displayed at a prominent location.	2		
I	Design & facilities			
2	The design of retail store provides adequate working space; permit cleaning to prevent the entry of dirt, dust & pests.	2		
3	Premise has sufficient lighting. Lighting fixtures are covered to protect food from contamination.	2		
4	Adequate ventilation is provided within the premises.	2		
5	An adequate storage facility is in place for food products; chemicals & other hazardous substances; personal items etc.	2		
6*	<i>Facility is capable of achieving & maintaining temperature for storing temperature sensitive product such as freezer, chillers, hot holding equipment etc.</i>	4		
7	There is adequate facility for waste disposal.	2		

II	Control of operation				
8	Incoming material procured as per internally laid down specification & from an approved vendors. Check for records (like specifications, name and address of the supplier, batch no., quantity procured etc).	2			
9	Raw materials are inspected at the time of receiving for food safety hazards.	2			
10*	Incoming food material is stored according to their temperature and humidity requirement, In a hygienic environment. <i>Temperature sensitive products are stored and displayed at appropriate temperatures -</i> <i>i. at or below 5°C if cold or at or above 60°C if hot ;</i> <i>ii. frozen at -18°C if they are intended to be stored frozen.</i>	4			
11	Stock rotation is practiced through FIFO/FEFO and no expired product is available on shelf for sale.	2			
12	Vegetarian and non vegetarian products are stored separately to avoid cross contamination	2			
13	<i>Food items & non food items are stored separately to avoid cross contamination</i>	2			
14	Products are free from spillage/leakage. Packed food products are free from pin holes or damages.	2			
III	Maintenance & sanitation				
15	The store interior is kept clean and there are no seepage, cobwebs, dirt, dust, etc. that can compromise food safety.	2			
16	Cleaning of equipment, food premises is done as per cleaning schedule & cleaning programme.	2			
17	All equipment & premises is maintained in good repair & condition.	2			
18*	Pest control program is available & pest control activities are carried out by trained and experienced personnel. Check for records.	4			
19	No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)	2			
20	Food waste and other refuse are removed periodically from to avoid accumulation.	2			
21	Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986.	2			

IV	Personal Hygiene				
22	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2			
23	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2			
24*	<i>Food handlers maintain personal cleanliness and personal behaviour (hand washing, no smoking, no spitting etc).</i>	4			
25	Food handlers equipped with suitable aprons, gloves, headgear, shoe cover etc; wherever necessary.	2			
V	Training & records keeping				
26	Internal / External audit of the system is done periodically. Check for records.	2			
27	Food business has an effective consumer complaints redressal mechanism.	2			
28	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2			
29*	Appropriate documentation & records are available and retained for specific period.	4			

Overall findings of Auditor:



Improvements Suggested:

Total points/68

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

Grading –

- A+
- A
- B
- No grade

Grade	Status	Marks Required
A+	Compliance-Exemplar	90% & above
A	Compliance- Satisfactory	80%-89%
B	Needs Improvement	50%-79%
No grade	Non Compliance	Below 50%

Signature of Auditor

Agency Stamp



TRANSPORT

Date		FBO Name	
Auditor Name		FBO's Representative Name	
Auditor Contact No.		Address	
		FBO License No.	

Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable(NA) and the corresponding score and relevant comments.

S. No.	Audit Question	Scoring		Comments
		Score	C/PC/NC/NA	
1	Transporter has an updated FSSAI license.	2		
I	Design & facilities			
2	The design & construction of transport vehicle permit adequate maintenance, cleaning, storage of food and do not provide entry or harbourage to pests.	2		
3	The containers/crates used for transporting food are made of food grade material and designed to prevent contamination	2		
4*	<i>The vehicle is covered and inside structure is intact, well painted with no signs of rusting, flaking paint & corrosion</i>	4		
5	Transport vehicle is equipped to achieve & maintain the required temperature, wherever required and designed in a way that allows monitoring the temperature from outside	2		

6	The vehicle has proper locking/ sealing facility to ensure that the products are not exposed to external weather conditions and pilferage	2			
II	Control of operation				
7	Vehicle is inspected for debris, dust, previous loads, pest activity & other non-food or hazardous item before loading. Check for records	2			
8*	<i>Transport of chilled products is done at 5°C or below and of frozen products at -18°C or below. Check for records or temperature logs.</i>	4			
9	Hazardous material like chemicals, fuels, flammable materials are not transported with food material.	2			
10	If a vehicle is changed from transporting non-food products to transporting food products, proper cleaning is conducted to avoid contamination of food. Check for records	2			
11	Mix loads of food material are adequately compartmentalized to prevent cross contamination.	2			
12*	<i>Bulk foodstuffs in liquid, granulate or powder form are transported in containers/tankers reserved for the transport of foodstuffs & they are to be marked "for foodstuffs only".</i>	2			
13	In case of breakdown of vehicle or its cooling unit, an alternative vehicle conforming to standards is provided promptly to transport the foods to ensure their safety and hygiene	2			
III	Maintenance & sanitation				
14	The interior of vehicle is kept clean and there are no seepage, cobwebs, dirt, dust, etc. that can compromise food safety.	2			
15	Temperature monitoring devices are calibrated at a pre-determined interval.	2			
16*	<i>Pest control program is available & pest control activities are carried out by trained and experienced personnel. Check for records.</i>	4			
17	Foods which become unfit during transportation whether due to temperature abuse or otherwise are identified and disposed off in a manner that precludes the food from being used for human consumption.	2			
IV	Personal Hygiene				

18	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2			
19	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2			
20	Food handlers maintain personal cleanliness and personal behaviour.	4			
21	Food handlers equipped with suitable aprons, gloves, headgear, shoe cover etc; wherever necessary.	2			
V	Training Records keeping				
22	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2			
23*	<i>Appropriate documentation & records are available and retained for specific period.</i>	4			

Overall findings of Auditor:

Improvements Suggested:



Total points/56

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

Grading –

- A+
- A
- B
- No grade

Grade	Status	Marks Required
A+	Compliance-Exemplar	90% & above
A	Compliance- Satisfactory	80%-89%
B	Needs Improvement	50%-79%
No grade	Non Compliance	Below 50%

Signature of Auditor
Agency Stamp

STORAGE & WAREHOUSES

Date		FBO Name	
Auditor Name		FBO's Representative Name	
Auditor Contact No.		Address	
		FBO License No.	

Indicate the following – Compliance (C), Noncompliance (NC), Partial Compliance (PC) or Not Applicable(NA) and the corresponding score and relevant comments.

S. No.	Audit Question	Scoring		Comments
		Score	C/PC/NC/NA	
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2		
I	Design & facilities			
2	The design and layout of warehouse permit adequate maintenance and cleaning and do not provide harbourage to pests.	2		
3	There is adequate facility for potable & non-potable water supply.	2		
4	There is adequate facility for drainage & waste disposal.	2		
5	Premise has sufficient lighting. Lighting fixtures are covered to protect food from contamination (especially where unpacked food is stored).	2		
6	Adequate ventilation is provided within the premise.	2		
7	An adequate and separate storage facility is in place for food products; chemicals & other hazardous	2		

	substances; personal items etc.				
8*	<i>Facility capable of achieving & maintaining temperature is available (such as freezer, chillers etc.) for storing products requiring temperature control.</i>	4			
9	Ante room is available with frozen room maintaining temperature below 4°C for picking of frozen product.	2			
10	Personnel hygiene facilities are available. (Adequate number of hand washing facilities, toilets, change rooms, rest & refreshment room etc).	2			
II	Control of operation				
11	Food material is stored on pallets/racks off the floor and away from walls.	2			
12	Products handled with care at receiving picking and dispatch – material not lying on floor or in an unorganized manner or allowed to accumulate.	2			
13	Chilled products are received at 5°C or below. Frozen products are received at -18°C or below	2			
14*	<i>Frozen products are stored in frozen rooms maintained at -18°C or below. Chilled products are stored in cold rooms maintained at 5°C or below. Records of temperature monitoring are maintained.</i>	4			
15	Cold room and frozen room are maintained neat and clean, free from mold growth and any unwanted materials.	2			
16	Stock rotation is practiced through FIFO/FEFO and no expired product is available on shelf for sale.	2			
III	Maintenance & sanitation				
17	The premises is kept clean and there are no seepage, cobwebs, dirt, dust, etc. that can compromise food safety. Check for records.	2			
18	Cleaning of storage equipments (silos, pallets etc.), food premises is done as per cleaning schedule & cleaning programme.	2			
19	Food premises and equipment are maintained in an appropriate state of repair and condition. Check for records.	2			
20*	<i>Pest control program is available Only approved pest control chemicals or fumigants (in case of food grains) are used. Check for records.</i>	4			
21	Pest control activities are carried out by trained and experienced personnel. Check for records.	2			

22	Rodent traps are in sufficient numbers and are mapped. Insecticutors used are functional and cleaned regularly.	2			
23	No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)	2			
24	Food waste and other refuse are removed periodically from food storage areas to avoid accumulation.	2			
IV	Personal Hygiene				
25	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2			
26	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2			
27*	<i>Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage etc) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc).</i>	4			
28	Food handlers equipped with suitable aprons, gloves, headgear, shoe cover etc; wherever necessary.	2			
V	Training & records keeping				
29	Internal / External audit of the system is done periodically. Check for records.	2			
30	Food business has an effective customer complaints redressal mechanism.	2			
31	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2			
32*	<i>Appropriate documentation & records are available and retained for specific period.</i>	4			

Overall findings of Auditor:

Improvements Suggested:

Total points/74

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

Grading –

- A+
- A
- B
- No grade

Grade	Status	Marks Required
A+	Compliance-Exemplar	90% & above
A	Compliance- Satisfactory	80%-89%
B	Needs Improvement	50%-79%
No grade	Non Compliance	Below 50%



Signature of Auditor

Agency Stamp



Press note

Brief note on Food Safety and Standards (Food Safety Auditing) Regulations, 2018

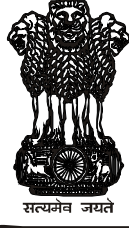
Inspecting and auditing food businesses is a humongous task, hence in order to cultivate and foster the growth of compliance culture FSSAI is enabling compliance through Auditing Agencies. While emphasising on self-compliance by the food businesses, to address the need to monitor such compliance, FSSAI is envisaging introducing Audit of the food companies by FSSAI Recognised Auditing Agencies.

This Food Safety and Standards (Food Safety Auditing) Regulations, 2018 includes the Procedure for recognition of Auditing Agencies, Procedure for Renewal/Cancellation/Suspension of recognition, Terms and conditions of recognition, auditing procedure, Duties of auditors, Audit reporting and audit monitoring system.

Selected Food Categories on the basis of their risk classification will be subject to mandatory food safety Auditing. Food Businesses falling under such category would be required to get their businesses timely audited by recognised Auditing Agencies on their own. Food businesses which are not subject to mandatory auditing can also voluntarily opt for Auditing of their businesses.

Food Businesses having satisfactory audits may be subjected to less frequent inspection by Central or State licensing authorities. Hence, Third party Audits will reduce the burden on the regulatory inspection conducted by Central or State Licensing Authorities and also encourage the efficient self-compliance by the food businesses

These regulations will come into force on the date of their publication in the gazette of India.



भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग III—खण्ड 4

PART III—Section 4

प्राधिकार से प्रकाशित

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स्वास्थ्य और परिवार कल्याण मंत्रालय

(भारतीय खाद्य सुरक्षा और मानक प्राधिकरण)

अधिसूचना

नई दिल्ली, 28 अगस्त, 2018

फा सं टी पी ए/01/रिग/एफ़ एस एस ए आई-2017.—जबकि, खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 के 34) की धारा 16 की उपधारा (2) के खंड (ग) के साथ पठित धारा 44 के द्वारा प्रदत्त शक्ति का प्रयोग करते हुए प्रारूप खाद्य सुरक्षा और मानक (खाद्य सुरक्षा संपरीक्षण) विनियम, 2017 उक्त अधिनियम की धारा 92 की उपधारा (1) के अधीन अपेक्षित भारतीय खाद्य सुरक्षा और मानक प्राधिकरण की अधिसूचना संख्यांक फा. सं. टीपीए / 01 / आरईजी / एफएसएसएआई-2017 तारीख 12 अक्टूबर, 2017 द्वारा भारत के राजपत्र, असाधारण, भाग III, धारा 4 में, उन व्यक्तियों से आपत्तियों और सुझावों को आमंत्रित करने के लिए, जिनकी इससे प्रभावित होने की संभावना है, उस तारीख से जिसको उक्त अधिसूचना के अंतर्विष्ट राजपत्र की प्रति जनता को उपलब्ध करा दी गई थी, तीस दिनों की अवधि समाप्त होने से पहले, प्रकाशित किया गया था;

और उक्त राजपत्र की प्रतियाँ जनता को 18 अक्टूबर, 2017 को उपलब्ध करा दी गई थीं;

और उक्त प्रारूप विनियम के सम्बन्ध में जनता से प्राप्त आक्षेपों और सुझावों पर भारतीय खाद्य सुरक्षा और मानक प्राधिकरण द्वारा विचार कर लिया गया है;

अतः, अब खाद्य सुरक्षा और मानक प्राधिकरण, उक्त अधिनियम की धारा 16 की उपधारा (2) के खंड (ग) के साथ पठित धारा 44 की शक्तियों का प्रयोग करते हुए, निम्नलिखित विनियम बनाता है, अर्थात् -:

विनियम

1. संक्षिप्त नाम और प्रारंभ.— (1) इन विनियमों का संक्षिप्त नाम खाद्य सुरक्षा और मानक (खाद्य सुरक्षा संपरीक्षण) विनियम, 2018 है।

(2) ये राजपत्र में उनके प्रकाशन की तारीख को प्रवृत्त होंगे।

भाग-I

साधारण

2. परिभाषाएं - (1) इन विनियमों में, जब तक कि संदर्भ से अन्यथा अपेक्षित न हो,-

क) "अधिनियम" से भारतीय खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 का 34) अभिप्रेत है;

ख) "प्रत्यायन" - का अर्थ है कि विशिष्ट अनुरूपता निर्धारण कार्य को निष्पादित करने के लिए इसकी क्षमता के औपचारिक प्रदर्शन को प्रवाहित करने वाले अनुरूपता निर्धारण निकाय से सम्बंधित तीसरे पक्ष के प्रमाणन से है;

ग) "प्रत्यायन निकाय" - का अर्थ है कि एक प्राधिकरण है जो प्रमाणन करता है;

घ) "संपरीक्षा रिपोर्ट" या "खाद्य सुरक्षा संपरीक्षा रिपोर्ट" से संपरीक्षा के अवलोकन, निष्कर्ष और निष्कर्ष के लिखित अभिलेख से अभिप्रेत है;

ङ) "संपरीक्षण अभिकरण" - से इन विनियमों के अनुसरण में खाद्य सुरक्षा संपरीक्षा उपक्रम के लिए खाद्य प्राधिकरण द्वारा मान्यता प्राप्त संपरीक्षण अभिकरण से अभिप्रेत है;

च) प्रारूप से इन विनियमों से संलग्न प्रारूप से अभिप्रेत है।

(2) जिन शब्दों और पदों के, जो इसमें प्रयुक्त हैं और इन विनियमों में परिभाषित नहीं हैं, परन्तु अधिनियम में परिभाषित हैं वही अर्थ होगा जो कि अधिनियम में है।

भाग-II

संपरीक्षण अभिकरण की मान्यता

3. संपरीक्षण अभिकरण की मान्यता के लिए मानदंड. - (1) खाद्य प्राधिकरण खाद्य सुरक्षा की संपरीक्षा परीक्षा करने के उद्देश्य से, संपरीक्षण अभिकरण को मान्यता प्रदान कर सकता है जो निम्नलिखित मानदंडों के अनुरूप हो, अर्थात्: -

(क) यह तत्समय प्रवृत्त विधि के अनुसार स्थापित या पंजीकृत हो;

(ख) संपरीक्षण अभिकरण के पास खाद्य प्राधिकरण द्वारा अपेक्षित विनिर्दिष्ट खाद्य प्रवर्गों के लिए नेशनल एक्रडीएसन बोर्ड ऑफ़ सर्टिफिकेशन बॉडीज से विधिमान्य प्रबंधन प्रणाली प्रमाणीकरण के लिए आईएसओ/आईसी 17020 या आईएसओ/आईसी 17021 या आईएसओ/टीएस 22003 वैध प्रत्यायन होनी चाहिए;

परन्तु, खाद्य प्राधिकरण किसी भी संपरीक्षण अभिकरण पर विचार कर सकेगा जो किसी अन्य प्रत्यायन निकाय द्वारा प्रत्यायित हो, जो अंतर्राष्ट्रीय प्रत्यायन फोरम का सदस्य हो और प्रबंधन प्रणाली के प्रमाण पत्र के लिए अंतर्राष्ट्रीय प्रत्यायन फोरम के बहुपक्षीय प्रत्यायन व्यवस्था का हस्ताक्षरकर्ता हो परन्तु इस शर्त के अधीन है कि वह नेशनल एक्रडीएसन बोर्ड ऑफ़ सर्टिफिकेशन बॉडीज के प्रत्यायन के लिए आवेदन करेंगे। इस तरह की एजेंसी को तब तक अस्थायी रूप से मान्यता दी जा सकती है जब तक कि यह मान्यता प्राप्त नहीं हो जाता है।

परन्तु यह और कि संपरीक्षण अभिकरण जो प्रमाणन निकायों के लिए नेशनल एक्रडीएसन बोर्ड ऑफ़ सर्टिफिकेशन बॉडीज से प्रत्यायन के लिए आवेदन कर चुकी है, भी मान्यता के लिए आवेदन कर सकती है, लेकिन इसे प्रत्यायन प्राप्त होने के बाद ही इसे मान्यता दी जाएगी।

(ग) इसके पास कम से कम तीन संपरीक्षक होने चाहिए जो कि निम्नलिखित अहर्ताओं को पूरा करते हों, अर्थात्:-

- (i) मान्यता प्राप्त विश्वविद्यालय से खाद्य या डेयरी या मत्स्य पालन या तेल प्रौद्योगिकी या जैव प्रौद्योगिकी या कृषि या पशु चिकित्सा विज्ञान या जैव-रसायन विज्ञान या सूक्ष्म जीव विज्ञान या रसायन विज्ञान या होटल प्रबंधन या आहार प्रबंधन प्रौद्योगिकी में स्नातक की डिग्री;
 - (ii) खाद्य सुरक्षा प्रबंधन प्रणाली में मान्यता प्राप्त लीड ऑडिटर पाठ्यक्रम सफलतापूर्वक पूरा किया हो;
 - (iii) अधिनियम और इसके अधीन विभिन्न नियमों और विनियमों का ज्ञान;
 - (iv) क्षेत्र विशेष की स्वच्छ और सफाई प्रथाओं, प्रसंस्करण तकनीकों, खतरों की पहचान, विश्लेषण और नियंत्रण के साथ-साथ दूषित पदार्थों, प्रत्यूर्जन क्षेत्र का विशिष्ट ज्ञान;
 - (v) कम से कम दस संपरीक्षण के साथ दो साल का कार्य अनुभव।
- (2) कारणों को लिखित में अभिलिखित करते हुए खाद्य प्राधिकरण द्वारा प्रत्यायन के लिए मानदंडों को शिथिल किया जा सकता है।
4. मान्यता देने की प्रक्रिया- (1) मान्यता प्राप्त करने के लिए कोई भी संपरीक्षण अभिकरण पांच हजार रुपये की फीस और अपेक्षित दस्तावेजों के साथ प्रारूप 'क' में आवेदन कर सकती है।
- (2) खाद्य प्राधिकरण आवेदन की जांच करेगा और किसी भी कमी के मामले में, इस तरह के आवेदन की प्राप्ति की तारीख से तीस दिनों के भीतर परिशुद्धि या पूरक जानकारी के लिए आह्वान करेगा।
 - (3) संबंधित संपरीक्षण अभिकरण सूचना की प्राप्ति के पंद्रह दिनों के भीतर पूरक जानकारी के परिशुद्धि या पूरक जानकारी प्रस्तुत करने के लिए आवश्यक कदम उठाएगी, जिसमें विफलता पर खाद्य प्राधिकरण द्वारा आवेदन अस्वीकार कर दिया जाएगा।
 - (4) खाद्य प्राधिकरण संपरीक्षण अभिकरण की प्रत्यायन के लिए समय समय पर एक जाँच समिति का गठन करेगी।
 - (5) संतुष्ट होने पर कि संपरीक्षण अभिकरण इन विनियमों में उल्लिखित सभी आवश्यकताओं को पूरा करती है, खाद्य प्राधिकरण आवेदन जाँच समिति के समक्ष खाद्य प्राधिकरण को इसकी मान्यता के सन्दर्भ में अनुशंसा के लिए रखा जाएगा।
5. मान्यता के निबंधन और शर्तें- (1) जाँच समिति की अनुशंसा पर और तीस हजार रुपये की मान्यता शुल्क जमा करने के बाद, खाद्य प्राधिकरण प्रारूप 'ख' में मान्यता प्रमाणपत्र जारी करके संपरीक्षण अभिकरण को मान्यता दे सकता है: परन्तु जाँच समिति, यदि आवश्यक समझे, तो मान्यता के लिए सिफारिश करने से पहले लेखा परीक्षा एजेंसी के संपरीक्षकों का मूल्यांकन कर सकती है।
- (2) उप-विनियम (1) के अधीन मान्यता प्रदान करने का प्रमाण पत्र तीन वर्ष के लिए विधिमान्य होगा।
 - (3) किसी भी मान्यता प्राप्त संपरीक्षण अभिकरण में विशेषज्ञता क्षेत्र बदलाव के लिए प्रारूप क में आवश्यक दस्तावेज और पांच हजार रुपये की फीस के साथ आवेदन कर सकती है।
 - (4) मान्यता का प्रमाणपत्र विनियम 7 में विनिर्दिष्ट किन्हीं आधारों पर खाद्य प्राधिकरण द्वारा निलंबन या निरस्तीकरण के लिए दायी होगा।
6. नवीकरण की प्रक्रिया (1) संपरीक्षण अभिकरण मान्यता प्रमाण पत्र के नवीकरण हेतु मान्यता प्रमाण पत्र में विनिर्दिष्ट तिथि की समाप्ति के कम से कम साठ दिन अपश्चात् पांच हजार रुपये की फीस के साथ आवेदन कर सकते हैं।
- (2) खाद्य प्राधिकरण मान्यता प्रमाण पत्र के नवीकरण करने से पूर्व निम्नलिखित को संदर्भित करेगा, अर्थात:-

(क) संपरीक्षण अभिकरण विनियमन 3 में निर्दिष्ट मानदंडों को पूरा करती रही है;

(ख) पिछली वैधता अवधि के दौरान संपरीक्षण अभिकरण का प्रदर्शन;

(ग) वैधता की अवधि के दौरान प्राप्त शिकायतों, यदि कोई हो।

(घ) मूल्यांकन के लिए स्क्रीनिंग कमेटी की सिफारिश।

(3) संतुष्ट होने पर और तीस हजार रुपये की मान्यता शुल्क जमा करने के बाद, खाद्य प्राधिकरण संपरीक्षण अभिकरण की मान्यता का और तीन वर्ष की अवधि के लिए नवीनीकरण करेगा।

7. मान्यता का निरस्तीकरण या निलंबन- (1) खाद्य प्राधिकरण संपरीक्षण अभिकरण को प्रदान की गई मान्यता को निम्नलिखित आधार पर निरस्त या निलंबन कर सकती है अर्थात्,-

- (i) संपरीक्षण अभिकरण को एक सक्षम प्राधिकारी द्वारा दिवालिया घोषित कर दिया गया हो;
- (ii) संपरीक्षण अभिकरण संतोषजनक रूप से या इन विनियमों के अनुसार अपने कर्तव्यों को निष्पादित करने में विफल रही हो;
- (iii) संपरीक्षण अभिकरण ने तात्विक सूचना को दबा दिया हो या कपट किया हो;
- (iv) संपरीक्षण अभिकरण, संपरीक्षण अभिकरण के रूप में प्रत्यायित रहने में असक्षम हो गई हो;
- (v) संपरीक्षण अभिकरण अपने मूल्यांकन या जाँच के लिए खाद्य प्राधिकरण को अपने अभिलेख उपलब्ध कराने और आवश्यक सूचना देने में असफल रही हो;
- (vi) संपरीक्षण अभिकरण खाद्य प्राधिकरण द्वारा यथा निदेशित सुधार के उपाय, यदि कोई हो, समय पर करने में असफल रही हो;
- (vii) संपरीक्षण अभिकरण के आचरण सम्बन्धी प्राप्त शिकायतों पर जाँच समिति की अनुशंसा पर;
- (viii) संपरीक्षण अभिकरण ने हित के संघर्ष के संबंध में मिथ्या सूचना दी हो;

(2) जहां खाद्य प्राधिकरण संतुष्ट है, कि एक संपरीक्षण अभिकरण को दी गई मान्यता निलंबित या निरस्त करने के लिए उत्तरदायी है, ऐसे संपरीक्षण अभिकरण की मान्यता को निलंबित या निरस्त करने के लिए एक कारण कारण नोटिस जारी कर सकता है

(3) संपरीक्षण अभिकरण खाद्य प्राधिकरण को अपना जवाब अपने निलंबन या निरस्तीकरण के प्रस्ताव के संबंध में प्राप्त कारण बताओ नोटिस की प्राप्ति की तिथि से पंद्रह 15 दिनों के भीतर प्रस्तुत करना होगा। ऐसा नहीं करने पर खाद्य प्राधिकरण के द्वारा प्रत्यायन के प्रमाण पत्र को निरस्त या निलंबित करने का निर्णय लिया जाएगा।

(4) खाद्य प्राधिकरण संपरीक्षण अभिकरण द्वारा फाइल किये गए जवाब पर विचार करने के बाद उसके जवाब की प्राप्ति की तिथि से तीस दिन के भीतर इन विनियमों के उपबंधों के अनुसार उचित आदेश जारी करेगी।

(5) जहां खाद्य प्राधिकरण ने मान्यता निलंबित कर दी हो, यदि संपरीक्षण अभिकरण द्वारा इन विनियमों के अनुसार सुधार कर लिए हो ये उसके निलंबन को रद्द कर सकती है।

(6) जहां खाद्य प्राधिकरण ने मान्यता निरस्त कर दी हो, संपरीक्षण अभिकरण खाद्य प्राधिकरण को निरस्तीकरण के 6 माह की अवधि के बाद प्रत्यायन के लिए नया आवेदन प्रस्तुत करेगा।

(7) खाद्य सुरक्षा संपरीक्षण अभिकरण की प्रत्यायन संस्था द्वारा उसका प्रत्यायन रद्द कर दिए जाने पर उसकी मान्यता निलंबित/निरस्त मानी जाएगी।

(8) संपरीक्षण अभिकरण, जो मान्यता को निरस्त या निलंबन के आदेश से असंतुष्ट है वह केंद्रीय सरकार को अपील कर सकती है।

भाग-III
संपरीक्षण प्रक्रिया

8. संपरीक्षण प्रक्रिया - (1) खाद्य प्राधिकरण जोखिम वर्गीकरण के आधार पर ऐसी खाद्य प्रवर्गों या प्रकार के खाद्य व्यापारों को विनिर्दिष्ट करेगी जिनकी खाद्य सुरक्षा संपरीक्षण कराना आज्ञापक होगा।
- (2) उप-विनियमन (1) के उद्देश्य के लिए यह खाद्य व्यापारों का वर्गीकरण प्रमुख जोखिम कारकों जैसे खाद्य का प्रकार, आशयित ग्राहक उपयोग, व्यापार की गतिविधि की प्रकृति, व्यापार की मात्रा, प्रसंस्करण की विधि और अन्य ऐसे कारक जिसे खाद्य प्राधिकरण आवश्यक समझे के आधार पर किया जाएगा।
- (3) एक खाद्य व्यापार जो उप-विनियमन (1) के अधीन अनिवार्य रूप से खाद्य सुरक्षा संपरीक्षण का विषय है, ऐसे खाद्य व्यापार को खाद्य सुरक्षा संपरीक्षण खाद्य प्राधिकरण के आदेश द्वारा निर्दिष्ट अन्तराल पर करना होगा।
- (4) एक खाद्य व्यापार जिसके लिए सुरक्षा संपरीक्षण करवाना अनिवार्य नहीं है किन्तु वह फिर भी मान्यता प्राप्त सम्परोक्षण अबिक्रम से संपरीक्षण करवाना चाहते हैं तो वे इस विकल्प को भी चुन सकते हैं।
- (5) ऐसे खाद्य व्यापार जिनकी खाद्य सुरक्षा संपरीक्षण रिपोर्ट संतोषजनक रही है उनमें केंद्रीय या राज्य अनुज्ञापन प्राधिकरण द्वारा विनियामक उद्देश्यों को छोड़कर निरीक्षण की बारम्बारता को घटाया जा सकता है :
- परन्तु खाद्य व्यापार के विरुद्ध कोई शिकायत की दशा में या खाद्य प्राधिकरण के संज्ञान में यह आने पर कि जनता का स्वास्थ्य और सुरक्षा खतरे में है तो खाद्य प्राधिकरण इस तरह के निरीक्षण बारम्बार में करवायेगा।
- (6) खाद्य व्यापारकर्ता की खाद्य सुरक्षा प्रबंधन प्रणाली संपरीक्षण प्रक्रिया आईएस/आईएसओ 19011:2011 (संपरीक्षण प्रबंधन प्रणाली के लिए जारी दिशानिर्देशों) पर आधारित होगी।
9. संपरीक्षण परीक्षा- (1) संपरीक्षण परीक्षा में वस्तुनिष्ठ साक्ष्य इकट्ठे करना और इकट्ठे किये या साक्षात्कार से प्राप्त संपरीक्षण अवलोकन दर्ज करना और कागजात की जाँच और गतिविधियों के अवलोकन शामिल हैं।
- (2) जहां कहीं भी कमियों या अपालन की स्थिति पाई जाए, उनका स्पष्ट और संक्षिप्त अभिलेख रखा जाना चाहिए और विनियमों की जिन अपेक्षाओं का उल्लंघन किया गया है उनका वर्णन किया जाना चाहिए।
- (3) संपरीक्षण प्रक्रिया के दौरान संपरीक्षण अभिकरण इस बात को सत्यापित करेगी कि खाद्य कारोबार न केवल खाद्य सुरक्षा संबंधी अपेक्षाओं का पालन कर रहा है, बल्कि यह भी कि उत्पाद के विशिष्ट प्रतिचयन और प्रयोगशाला विश्लेषण की अपेक्षा करने वाले विनियमों को छोड़कर लागू अधिनियम के अधीन बने नियम और विनियमों का अनुपालन भी कर रहा है और खाद्य कारोबार प्रचालक द्वारा बनाए गए प्रयोगशाला रिपोर्टों के सम्बंधित सुसंगत कागजात की जाँच करे।
10. संपरीक्षको के कर्तव्य : संपरीक्षक निम्नलिखित कर्तव्यों का पालन करेगा अर्थात्,-
- (i) खाद्य कारोबारी का खाद्य सुरक्षा संपरीक्षण करना।
- (ii) अधिनियम के प्रावधानों और उसके तहत बनाए गए नियमों और विनियमों के खाद्य व्यापार संचालक द्वारा अनुपालन की पुष्टि करना।
- (iii) खाद्य प्राधिकरण द्वारा निर्देशित किए जाने पर नए स्थापित खाद्य कारोबार इकाई के प्रारम्भ होने से पूर्व निरीक्षण करना।
- (iv) वाणिज्यिक-सह-गोपनीय सामग्री के संबंध में गोपनीयता बनाए रखें, जिसमें प्रक्रिया और उत्पाद निर्माण जानकारी, खाद्य सुरक्षा कार्यक्रम की जानकारी और संपरीक्षण परिणाम शामिल हो सकते हैं।
- (v) खाद्य प्राधिकरण को संपरीक्षण रिपोर्ट खाद्य सुरक्षा संपरीक्षण करने के पंद्रह दिन के भीतर प्रेषित करना।
- (vi) संपरीक्षण के दौरान पहचाने गए ऐसे खाद्य सुरक्षा कार्यक्रम की किसी भी कमी को दूर करने के लिए कोई सुधारात्मक कार्रवाई करने के लिए क्या किया गया है, यह सत्यापित करने के लिए आगे के संपरीक्षण सहित आवश्यक अनुवर्ती कार्रवाई करना शामिल है।

- (vii) खाद्य सुरक्षा संपरीक्षण के दौरान गोपनीयता बरतना।
 (viii) कोई अन्य कर्तव्य जिसे खाद्य प्राधिकरण विनिर्दिष्ट करे।

11. संपरीक्षण रिपोर्ट - (1) संपरीक्षक संपरीक्षण पूरा होने के बाद, संपरीक्षण के दौरान देखी गई कमियों या गैर-अनुरूपताओं के खाद्य कारोबारी को सूचित करेगा और संपरीक्षण रिपोर्ट को पूरा करने के लिए आवश्यक कोई और जानकारी या स्पष्टीकरण प्रदान करने का अवसर प्रदान करेगा और इसे संपरीक्षण रिपोर्ट में दर्शाएगा।
- (2) जब एक बड़ी गैर-अनुरूपता होती है जो खाद्य कारोबारी की खाद्य सुरक्षा प्रबंधन प्रणाली में गंभीर विफलता होती है और इसके परिणामस्वरूप स्वास्थ्य पर प्रतिकूल परिणाम होता है जो संभवतः घातक हो सकता है, तो संपरीक्षक केंद्रीय अनुज्ञप्ति प्राधिकरण या राज्य अनुज्ञप्ति प्राधिकरण को ऐसे निष्कर्षों की रिपोर्ट चौबीस घंटे के भीतर करेगा।
- (3) जब एक मामूली गैर-अनुरूपता है जो खाद्य सुरक्षा प्रबंधन प्रणाली में कमी या खाद्य कारोबारी के विनियामक उल्लंघन है और इससे कोई प्रतिकूल स्वास्थ्य परिणाम नहीं हो सकता है, तो संपरीक्षक इसके सुधार के लिए 30 दिनों से अनधिकतम समय का उपयुक्त समय सीमा निर्धारित करेगा और अनुवर्ती करेगा, ताकि गैर-अनुरूपता को सुधार दिया जा सके।
- (4) निर्दिष्ट समय सीमा के भीतर मामूली गैर अनुरूपता को सुधारने के लिए खाद्य व्यापार ऑपरेटर द्वारा की गई विफलता यथास्थिति केंद्रीय या राज्य अनुज्ञप्ति प्राधिकरणों को संदर्भित की जाएगी।
- (5) संपरीक्षण अभिकरण संपरीक्षण के पूरा होने के तुरंत बाद संपरीक्षण रिपोर्ट की प्रतिलिपि खाद्य कारोबारी को प्रस्तुत करेगी और संपरीक्षण रिपोर्ट को यथास्थिति केंद्रीय अनुज्ञप्ति प्राधिकरण या राज्य अनुज्ञप्ति प्राधिकरण को पंद्रह दिनों के भीतर अग्रेषित करेगी, जिसमें सुधार के लिए निष्कर्षों या गैर-अनुरूपताओं या चिंताओं और अवलोकनों को स्पष्ट रूप से सामने लाया जायेगा।
- (6) संपरीक्षक अपने संपरीक्षण के आधार पर केंद्रीय या राज्य अनुज्ञप्ति प्राधिकरण को लिखित में कारण बताते हुए खाद्य कारोबारी के संपरीक्षण की आवृत्ति में परिवर्तन की सिफारिश कर सकता है।
12. हितों का संघर्ष - (1) संपरीक्षण अभिकरण किसी भी खाद्य व्यापारी का खाद्य सुरक्षा संपरीक्षण करने से पूर्व अनुसूची के प्रारूप 'ग' में एक उद्घोषणा।
 (2) किसी भी संपरीक्षण अभिकरण की मान्यता को खाद्य प्राधिकरण द्वारा हितों के संघर्ष के संबंध में मिथ्या सूचना देने पर तुरंत रद्द या निलंबित कर दिया जाएगा।

भाग-IV

संपरीक्षण निगरानी प्रणाली

13. संपरीक्षण निगरानी- (1) खाद्य प्राधिकरण मान्यता प्राप्त संपरीक्षण अभिकरण के कार्यों पर निम्नलिखित रीति से निगरानी करेगी, अर्थात:-
- (i) निगरानी तंत्र में संपरीक्षण रिपोर्टों और कार्यों का पुनर्विलोकन, संपरीक्षकों की खाद्य सुरक्षा प्रबंध प्रणालियों के संपरीक्षण करने की और नियामक आवश्यकताओं को सुनिश्चित करने की योग्यता के मूल्यांकन लिए संपरीक्षकों के स्थल मूल्यांकन का आयोजन; निकाय की रिपोर्ट के आधार पर संपरीक्षण अभिकरण का मूल्यांकन और खाद्य प्राधिकरण द्वारा विनिर्दिष्ट कोई भी अन्य तंत्र शामिल है।
14. विवाद निस्तारण- (i) संपरीक्षकों के साथ किसी भी विवाद या असहमति के मामले में केंद्रीय या राज्य अनुज्ञप्ति प्राधिकरण खाद्य कारोबारी के लिए संपर्क बिंदु होंगे।

(ii) खाद्य कारोबारी द्वारा संपरीक्षण अभिकरण या लेखा परीक्षकों के कामकाज के लिए किसी भी असहयोग या प्रतिरोध के मामले में, इसे केंद्रीय या राज्य लाइसेंसिंग प्राधिकरणों को समाधान के लिए संदर्भित किया जाएगा।

15. अभिलेख का रख रखाव- (i) किए गए संपरीक्षण से संबंधित अंतिम अनुरूपता रिपोर्ट और अन्य सभी दस्तावेजों को, जिनमें प्रथम संपरीक्षण रिपोर्ट, सुधार के लिए की गई कार्रवाइयाँ और उत्तरवर्ती पत्राचार शामिल हैं, संपरीक्षण अभिकरण द्वारा कम से कम पाँच वर्ष तक संभाल कर रखे जाएँगे और उनको पूरी तरह गोपनीय रखा जाएगा।

(ii) खाद्य कारोबार प्रचालक संपरीक्षण परिणामों और किए गए सुधारों के सभी अभिलेख कम से कम पाँच वर्ष की अवधि के लिए सुरक्षित रखेगा।

**अनुसूची
प्रारूप क**

(उप-विनियम 4(1), 5(3) और 6(1) देखें)

संपरीक्षण अभिकरण की मान्यता /नवीनीकरण/ विशेषज्ञता क्षेत्र परिवर्तन के लिए आवेदन

**फोटो संपरीक्षण
आभिकरण की
स्थिति में प्राधिकृत
हस्ताक्षरी**

1) संपरीक्षण अभिकरण का नाम:	
2) संपर्क व्यक्ति का नाम:	
3) पता (पिन कोड सहित):	
4) संपर्क विवरण क) दूरभाष सं (एसटीडी कोड सहित) ख) संपर्क व्यक्ति के संगठन का ईमेल/संगठन का वेबसाइट का पता (यदि कोई हो)	
5) विधिक अस्तित्व की प्रस्थिति (दस्तावेजी साक्ष्य संलग्न करें):	
6) प्रत्यायन प्रमाण संबंधी विवरण (प्रति संलग्न करें):	प्रमाण पत्र सं. :
	विधि प्रत्यायन की तिथि :

7) कार्य की विशेषज्ञता का क्षेत्र					
8) नामंकित लेखा परीक्षकों का विवरण (प्रति संलग्न करे)					
9) संपरीक्षकों की शैक्षिक योग्यता					
10) संपरीक्षकों के प्रशिक्षण का विवरण (प्रमाण पत्र की प्रति)	क्र.सं	पाठ्यक्रम का नाम	संचालक /संगठन का नाम और पता	तारीख	
				से	तक
11) पिछले दो वर्ष में संचालित निरीक्षण/संपरीक्षण अभिलेख (खाद्य प्रवर्गों के अनुसार)					
12) खाद्य सुरक्षा संपरीक्षण की क्षमता के संबंध में कोई अन्य सूचना					
13) मान्यता संख्या (नवीकरण के मामले में)					

मैं(प्राधिकृत हस्ताक्षरकर्ता)..... सुपुत्र/ श्री सुपुत्री
निवासी.....निष्ठापूर्वक घोषणा करता हूँ/करती हूँ कि मेरे द्वारा यहाँ दिए गए सभी विवरण और सभी सूचनाएँ मेरे सर्वोत्तम ज्ञान के अनुसार सत्य और ठीक हैं। मैं यह भी घोषणा करता हूँ/करती हूँ कि मेरे अथवा मेरे संपरीक्षकके माध्यम से की जाने वाली खाद्य सुरक्षा संपरीक्षण खाद्य सुरक्षा और मानक (खाद्य सुरक्षा संपरीक्षण) विनियम, 2018 के अनुरूप होगी।

प्राधिकृत हस्ताक्षरकर्ता के मुहर सहित हस्ताक्षर

संलग्न किए जाने वाले दस्तावेजों की सूची:

- क) आवेदन फीस की रसीद / डिमांड ड्राफ्ट या पे आर्डर
- ख) प्रत्यायन प्रमाणपत्र
- ग) सभी लेखा परीक्षकों की अहर्ता संबंधी प्रमाण पत्र
- घ) अग्रता संपरीक्षकपाठ्यक्रम प्रमाण पत्र
- ङ) गोपनीयता संबंधी करार
- च) प्रत्यायन निकाय की पिछली निर्धारण रिपोर्ट की प्रति
- छ) सभी संपरीक्षकों के उद्योग में संपरीक्षण अनुभव के विवरण

प्रारूप ख



भारतीय खाद्य सुरक्षा और मानक प्राधिकरण
विश्वास के प्रेरक, सुरक्षित और पोषक आहार के आश्वासक

मान्यता सं.....

मान्यता प्रमाण पत्र-
(विनियम 5 देखें)

प्रमाणित किया जाता है कि(संपरीक्षण अभिकरण का नाम) को भारतीय खाद्य सुरक्षा और मानक प्राधिकरण द्वारा खाद्य सुरक्षा और मानक अधिनियम, 2006 के अधीन अनुज्ञप्ति प्राप्त खाद्य कारोबारियों की संपरीक्षण के लिए स्वीकृति दी गई है और यह खाद्य सुरक्षा और मानक (खाद्य सुरक्षा संपरीक्षण) विनियम, 2018 अधीन है।

संपरीक्षण अभिकरण का नाम और पता	को जारी किया गयाको / नवीनीकृत किया गया	तक विधिमान्य	विशेषज्ञता क्षेत्र

टिप्पण- इस प्रमाण पत्र में किसी प्रकार का कोई परिवर्तन न किया जाये। इस प्रमाणपत्र का जान बूझ कर दुरुपयोग करने पर इसे बिना कोई पूर्व सूचना के रद्द कर दिया जायेगा।

निदेशक के मुहर सहित हस्ताक्षर

प्रारूप ग**घोषणा**

[विनियम 12 का उप-विनियम (i) देखें]

मैं सुपुत्र/सुपुत्री श्री.....घोषणा करता हूँ/करती हूँ कि मेसर्स , जिसकि अनुज्ञप्ति संहै, का खाद्य सुरक्षा संपरीक्षण मेरे संपरीक्षण अभिकरण द्वारा किया गया है इस सन्दर्भ में मैं एतद्वारा घोषणा करता हूँ कि:

- क) मेरेपरीक्षक /संपरीक्षण अभिकरण या इसका कोई भी कार्मिक/संपरीक्षक ने उक्त खाद्य कारोबारी को तथा इसकी किसी मूल या सहायक संस्था का पिछले दो वर्षों में किसी भी प्रकार का कोई प्रशिक्षण, मार्गदर्शन, खाद्य सुरक्षा प्रमाणन और परामर्श कार्य नहीं किया है और उसका आंतरिक संपरीक्षण भी नहीं किया है।
- ख) मेरी संपरीक्षण अभिकरण या इसके कोई भी कार्मिक/संपरीक्षक मूल या सहायक संस्था के स्वामी नहीं हैं अथवा उनका इसमें कोई वित्तीय हित नहीं है और उनका इसके प्रबंधन या नियंत्रण से कोई भी संबंध नहीं है।
- ग) मेरी संपरीक्षण अभिकरण या इसके कोई भी कार्मिक/संपरीक्षक को उक्त खाद्य व्यापारी के द्वारा पिछले दो वर्षों के दौरान नियोजित नहीं किया गया है।
- घ) मेरी संपरीक्षण अभिकरण ने उक्त खाद्य कारोबारी का खाद्य सुरक्षा संपरीक्षण तीन सतत संपरीक्षण से अधिक संपरीक्षण नहीं किया गया है।

प्राधिकृत हस्ताक्षरकर्ता/संपरीक्षक के हस्ताक्षर मुहर सहित

पवन अग्रवाल, मुख्य कार्यकारी अधिकारी

[विज्ञापन/III/4/असा/205/18]

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 28th August , 2018

F.No. TPA/01/REG/FSSAI-2017.—Whereas, in exercise of the power conferred by clause (c) of sub-section (2) of section 16 read with section 44 of the Food Safety and Standards Act, 2006 (34 of 2006) the Draft Food Safety and Standards (Food Safety Auditing) Regulations, 2017, were published as required under sub-section (1) of section 92 of the said Act, vide notification of the Food Safety and Standards Authority of India number File No. TPA/01/REG/FSSAI-2017 dated the 12th October, 2017, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which the copies of the Gazette containing the said notification were made available to the public;

And whereas, copies of the said Gazette were made available to the public on the 18th October, 2017;

And whereas, objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (c) of sub-section (2) of section 16 read with section 44 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations, namely:-

Regulations

1. Short title and commencement- (1) These regulations may be called the Food Safety and Standards (Food Safety Auditing) Regulations, 2018.
- (2) They shall come into force on the date of their publication in the Official Gazette.

Part-I
GENERAL

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 related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment task;
 - (c) "accreditation body" means an authority that performs accreditation;
 - (d) "audit report" or "food safety audit report" means a written record of the observations, findings and conclusion of the audit;
 - (e) "auditing agency" means an auditing agency recognised by the Food Authority for undertaking food safety audit in accordance with these regulations;
 - (f) "form" means a form appended to these regulations.
- (2) Words and expressions used herein and not defined in these regulations but defined in the Act, shall have the same meaning as assigned to them in the Act.

Part-II
RECOGNITION OF AUDITING AGENCY

3. Criteria for granting recognition to auditing agencies.- (1) Food Authority may, for the purpose of carrying out food safety audit, grant recognition to auditing agencies which conform to the following criteria, namely:-

- (a) it is established or registered in accordance with the law for the time being in time;
- (b) it holds a valid accreditation on ISO/IEC 17020 or ISO/IEC 17021 or ISO/TS 22003 from National Accreditation Board for Certification Bodies for Management System Certification, for the required food categories specified by the Food Authority:

Provided that the Food Authority may consider auditing agency which are accredited by any other accreditation body which is a member of the International Accreditation Forum and signatory to the International Accreditation Forum Multilateral Recognition Arrangements for Management System Certification subject to the condition that they shall apply for National Accreditation Board for Certification Bodies accreditation. Such agency may be recognised provisionally till the time it has been so accredited.

Provided further that auditing agency which has applied for accreditation from National Accreditation Board for Certification Bodies may also apply for recognition, but it shall be granted recognition only after it has been so accredited.

- (c) it has atleast three auditors with the following qualifications and requirements, namely:-
 - (i) Bachelor's degree in Food or Dairy or Fisheries or Oil Technology or Biotechnology or Agriculture or Veterinary Sciences or Bio-chemistry or Microbiology or Chemistry or Hotel management or Catering technology from a recognised university;
 - (ii) successful completion of Accredited Lead Auditor course in Food Safety Management System;
 - (iii) knowledge of the Act and the rules and regulations made thereunder;
 - (iv) sector specific knowledge of hygienic and sanitary practices, processing techniques, hazards identification and analysis and control and knowledge of contaminants and allergens;
 - (v) work experience of two years with a minimum of ten audits carried out.

(2) The criteria for recognition may be relaxed by the Food Authority for the reasons to be recorded in writing.

4. Procedure for recognition.- (1) Any auditing agency seeking recognition may make an *application in Form A along with requisite documents and fees of rupees five thousands.*
- (2) The Food Authority shall scrutinise the application and in case of any deficiency, call for rectification or supplementary information within thirty days from the date of receipt of such application.

- (3) The auditing agency concerned shall take necessary steps for rectification or furnishing of supplementary information within fifteen days of receipt of the communication failing which the application shall be rejected by the Food Authority.
- (4) The Food Authority shall constitute a Screening Committee for granting recognition to the auditing agency.
- (5) On being satisfied that the auditing agency fulfills all requirements as specified in these regulations, the Food Authority shall place the application before the Screening Committee for recommending to it on grant of recognition.
5. Terms and conditions of recognition.- (1) On the recommendation of the Screening Committee and after the deposit of recognition fees of rupees thirty thousands, the Food Authority may grant recognition to the auditing agency by issuing a Certificate of Recognition in Form 'B' :
- Provided that the screening committee may, if it deems necessary, conduct an assessment of the auditors of the auditing agency before recommending for recognition.
- (2) The Certificate of Recognition granted under sub- regulation (1) shall be valid for a period of three years.
- (3) Any recognised auditing agency seeking change in the scope may apply for the same *in Form A along with requisite documents and fees of rupees five thousands.*
- (4) The Certificate of Recognition may be suspended or cancelled by the Food Authority on any of the grounds specified in regulation 7.
6. Procedure for renewal.- (1) The auditing agency may make an application for renewal of Certificate of Recognition not later than sixty days prior to the date of expiry specified in the Certificate of Recognition along with renewal fee of rupees *five thousands.*
- (2) The Food Authority shall before renewing the Certificate of Recognition, have regard to the following, namely:-
- (a) the auditing agency continues to meet the criteria specified in regulation 3;
- (b) the performance of the auditing agency during the previous validity period;
- (c) the complaints, if any, received during the period of validity.
- (d) the recommendation of the Screening Committee for evaluation.
- (3) On being satisfied and after depositing of recognition fees of rupees thirty thousands, the Food Authority shall renew the Certificate of Recognition for a further period of three years.
7. suspension or cancellation of recognition.- (1) The Food Authority may suspend or cancel the recognition granted to the auditing agency on any of the following grounds, namely,-
- (i) the auditing agency has been declared insolvent by a competent authority;
- (ii) the auditing agency has failed to perform its duties satisfactorily or in accordance with these regulations;
- (iii) the auditing agency has suppressed material information or committed fraud;
- (iv) the auditing agency has become incompetent to continue to be accredited as auditing agency;
- (v) the auditing agency has failed to provide access to their records and furnish necessary information to the Food Authority to conduct the assessment or investigation;
- (vi) the auditing agency has failed to take timely and necessary corrective measures, if any, as directed by the Food Authority;
- (vii) the recommendation of the Screening Committee on of the complaints received regarding conduct of the auditing agency;
- (viii) the auditing agency has provided false information with regard to conflict of interest.
- (2) Where the Food Authority is satisfied that the recognition granted to an auditing agency is liable to be suspended or cancelled may issue a show cause notice to such auditing agency for suspension or cancellation of recognition.
- (3) The auditing agency shall file its reply to the Food Authority within fifteen days from the date of receipt of the show cause notice, failing which the decision to cancel or suspend recognition shall be taken by the Food Authority.

- (4) The Food Authority shall consider the reply filed by the auditing agency and pass such order as it deems fit, within thirty days of the receipt of the reply of the auditing agency.
- (5) Where the Food Authority has suspended recognition, it may revoke the suspension if the auditing agency has taken necessary corrective measures in accordance with these regulations.
- (6) Where the Food Authority has cancelled the recognition, the auditing agency shall make a fresh application to the Food Authority for grant of recognition after a period of six months from the date of such cancellation.
- (7) The recognition of the auditing agency shall be deemed to be suspended or cancelled, if its accreditation is suspended or cancelled by its accrediting body.
- (8) The auditing agency may file an appeal to the Central Government, if it is aggrieved by the order of suspension or cancellation of recognition.

Part-III

AUDITING PROCEDURE

8. Audit process.- (1) The Food Authority shall specify the category or type of food businesses which shall be subject to mandatory food safety auditing, on the basis of their risk classification.
 - (2) For the purpose of sub-regulation (1) the classification of food businesses shall be made having regard to the major risk factors including food type, intended customer use, nature of activity of the business, volume of the business, method of processing and such other factors as the Food Authority may deem necessary.
 - (3) A Food business which is subject to mandatory food safety auditing under sub-regulation (1) shall get its business audited by a recognized auditing agency of such intervals as the Food Authority may by order specify.
 - (4) A Food business which is not subject to mandatory food safety auditing, but desirous of getting audited by a recognized auditing agency, may opt for the same.
 - (5) A Food business having satisfactory food safety audits report may be subject to less frequent inspections by the Central licensing authority or the State licensing authority:

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 undertake more frequent inspections.
 - (6) The audit process 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).
9. Audit examination.- (1) An audit examination shall include collection of objective evidence and recording of audit observations collected or made through interviews, examination of documents and activities.
 - (2) The deficiencies or non-conformities observed by the auditing agency shall be recorded clearly and concisely, pointing out the regulatory requirements that are being contravened.
 - (3) During the audit process, the auditing agency shall verify the compliance not only with the food safety measures, but also with the provisions of the Act and the rules and regulation made thereunder, except those which require specific sampling and laboratory analysis of the products and also verify relevant documents relating to laboratory reports maintained by the Food Business Operator.
10. Duties of auditors.-The auditor shall perform the following duties, namely,-
 - (i) conduct food safety audit of Food Business Operator ;
 - (ii) verify the compliance by the Food Business Operator of the provisions of the Act and the rules and regulations made thereunder;
 - (iii) conduct pre-commissioning inspection of newly established food business unit, as and when directed by the Food Authority;
 - (iv) maintain confidentiality in respect of commercial-in-confidence materials, which may include process and product formulation information, food safety programme information and audit outcomes;
 - (v) forward the audit report to the Food Authority within fifteen days of the conduct of food safety audit;
 - (vi) carry out necessary follow-up action, including further audits, to verify if any corrective action has taken to remove any deficiency of such food safety program identified during the audit;
 - (vii) maintain confidentiality of food safety audit;

- (viii) such other duties as may be directed by the Food Authority.
11. Audit report.- (1) The auditor shall after the completion of the audit, inform the Food Business Operator of the deficiencies or the non-conformities observed during the audit and give an opportunity to provide any further information or clarification required for completion of audit finding and reflect the same in the audit report.
- (2) When there is a major non-conformity which is a serious failure in the food safety management system of the Food Business Operator and may result in adverse health consequence possibly even fatal, the auditor shall report such findings to the Central Licensing Authority or State Licensing Authority within twenty four hours.
- (3) When there is a minor non-conformity which is shortcoming in the food safety management system or regulatory contravention of the Food Business Operator and may not cause any adverse health consequence, the auditor shall set up an appropriate timeframe of not more than 30 days for its rectification and follow up, so that the non-conformance could be rectified.
- (4) 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.
- (5) The auditing agency shall submit a copy of audit report to the Food Business Operator immediately after completion of the audit and forward audit report to the Central Licensing authority or State Licensing authority, as the case may be within fifteen days clearly bringing out the findings or non-conformities or concerns and observations for improvement.
- (6) The auditor may recommend in writing the reasons for the change in audit frequency of the food business operator to the Central Licensing Authority or State Licensing Authority based on the audit.
12. Conflict of interest. – (1) The auditing agency shall give a declaration in Form 'C' of the schedule before accepting food safety audit of a Food Business Operator.
- (2) The recognition of any auditing agency shall be suspended or cancelled immediately by the Food Authority on the event of providing false information on conflict of interest.

Part-IV

AUDIT MONITORING SYSTEM

13. Audit monitoring .- (1) The Food Authority shall monitor the performance of the recognized auditing agency in the following manner, namely:-

(i) 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.

14. Handling disputes.- (1)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.

(2) 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.

15. 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 the auditing agencies at least for a period of five years and full confidentiality of the documents shall be maintained.

(2) Food Business Operator shall maintain all records of audit findings and rectification for a period of five years.

SCHEDULE
Form A

(See sub-regulation 4(1), 5(3) and 6(1))

Application Form for Recognition/Renewal/Change in scope of Auditing Agency

<p>Photo</p> <p>(Authorised signatory in case of auditing agency)</p>

1) Name of auditing agency:				
2) Name of contact person:				
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 (attach documentary evidence):				
6) Detail of accreditation certificate (attach copy):	Certificate No:			
	Validity up to:			
7) Specialised areas of work:				
8) Detail of auditors enrolled (attach copy):				
9) Educational qualification of auditor				
10) Training details of auditor (copy of certificate)	S. No	Title of course	Conducted/Organized by(Name and Address)	Dates
				From
				To

11) Details of Inspection/audit conducted in last two years (food category wise)	
12) Any other information regarding food safety audit competency	
13) Recognition number : (in case of renewal)	

I (authorised signatory) _____ 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 the Food Safety and Standards (Food Safety Auditing) Regulations, 2017.

Signature of authorised signatory with stamp

List of documents to be enclosed:

- 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.

Form 'B'



Recognition Number.....

Certificate of Recognition

(See regulation 5)

this is to certify that(name of auditing agency) has been recognised by the Food Safety and Standards Authority of India for the purpose of auditing of food business operators licensed under Food Safety and Standards Act, 2006 and subject to the Food Safety and Standards (Food Safety Auditing) Regulations, 2018.

Name and address of auditing agency	Issued on/ renewed on	Valid up to	Scope

Note: This certificate must not be altered in any way. Intentional misuse of this certificate will result in cancellation without prior intimation.

Signature of Director with stamp

Form CDeclaration

[See sub-regulation (i) of regulation 12]

I _____ S/o, D/o _____ state that the food safety audit of M/s _____ having license number _____ has been audited by my auditing agency. In this context, I hereby declare that:

- a) my auditing agency or its personnel/auditor have 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 two years.
- b) my auditing agency or its personnel/auditor does not own or have financial interest in, manage or otherwise control to the above said food business operators or any of its affiliate, parent or subsidiary.
- c) my auditing agency or its personnel/auditor have not been employed by the above said food business operator for last two years.
- d) my auditing agency has not carried out the food safety audit of the above said food business operator for more than three consecutive times audit.

Signature of authorised signatory /Auditor with stamp

PAWAN AGARWAL, Chief Executive Officer

[ADV.T.-III/4/EXTY/205/18]

File No. 19(2)2018/FSA/RCD/FSSAI
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
Regulatory Compliance Division
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the **13 August, 2019**

ORDER

Subject: Mandating food safety audit of Food Businesses holding Central license and falling under high risk categories of food businesses under the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 -reg

In pursuance of Part III, Section 8(1) of the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 notified w.e.f 28.08.2018, the food authority herewith directs that the food business holding Central License and falling under the following 06 categories of businesses as per FLRS shall be subject to mandatory food safety auditing:

Product ID	Product
1	Dairy products & analogues, excluding products of food category 2.0
8	Meat and meat products including poultry
9	Fish and fish products, including molluscs, crustaceans, and echinoderms
10	Eggs and egg products
13	Foodstuffs intended for particular nutritional uses (Food for infant nutrition etc)
16	Prepared Foods (catering etc)

2. Further, as per Part III, Section 8(3) of the Food Safety and Standards (Food Safety Auditing) Regulations, 2018, the food businesses subject to mandatory food safety auditing (falling under above categories) shall get its business audited by a recognized auditing agency at intervals specified by the Food authority. The list of recognized audit agencies with their scope of audits is at Annex A. The audit frequency prescribed by the authority is at Annex B. An auditor manual with these details and list of agencies can also be downloaded from the link-<https://www.fssai.gov.in/cms/third-party-audit.php>

3. All Food Businesses are hereby directed to comply with the contents of this order. This issues with the approval of the Competent Authority.

Yours sincerely


(Dr. Shobhit Jain)

Executive Director (Compliance Strategy)

To,

- (i) All Food Business Operators
- (ii) All Central Licensing Authorities
- (iii) All Commissioners of Food Safety
- (iv) All Auditing agencies recognised under FSS (Food Safety Auditing) Regulations, 2018.

File No. 19(2)2018/FSA/RCD/FSSAI
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
Regulatory Compliance Division
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the **24 Sep, 2019**

Clarification

Subject: Clarification on order on the subject mandating food safety audit of Food Businesses holding Central license and falling under high risk categories under the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 dated 13.08.2019 -reg

In continuation to the order dated 13.08.2019, the following clarifications are being issued following lot of queries raised by auditing agencies and food businesses:

S. No	Query	Clarification
1.	When does the order come into effect?	The order comes into effect from the date of issue i.e. 13.08.2019. However, the food business directed for mandatory audits should get the first audit of their premises by 31st Dec 2019.
2.	Whether the complete chain (manufacturing, storage, transport, packaging etc) involved in these product categories should get mandatory auditing done?	It is important that the complete chain from manufacturing, transport, storage etc follow good hygienic practices, however, in the initial stage only the food businesses involved in manufacturing and processing sector under the product categories mentioned in the order dt 13.08.2019 should get their premises mandatorily audited. Further, the Head Offices wherein no food related activities are being done but are holding Central License are also not being mandated for audits .
3.	Can an audit agency, audit a food business that they have already Certified or provided training?	No, as per section 12(1) of Food Safety and Standards (Food Safety Auditing) Regulations, 2018 an agency or its auditor should not have provided any training, guidance, food safety certification or consultancy or not carried out internal audits to the food business or its parent or subsidiary for last two years.

2. All Food Businesses are hereby directed to comply with the contents of the order dated 13.08.2019 read with these above clarifications. This issues with the approval of the Competent Authority.

Yours sincerely


(Dr. Shobhit Jain)

Executive Director (Compliance Strategy)

To,

- (i) All Food Business Operators
- (ii) All Commissioners of Food Safety/ All Central Licensing Authorities
- (iii) All Auditing agencies recognised under FSS (Food Safety Auditing) Regulations, 2018.

Dated 2ND May 2022

Subject: Standard Operating Procedure (SOP) for Central Licensing Authority (CLAs) to review Third Party Audit (TPA) Reports-reg.

A. Background:

1. In order to cultivate and foster the growth of compliance culture, FSSAI has enabled compliance through Auditing Agencies. While emphasizing on self-compliance by the food businesses, to address the need to monitor such compliance, FSSAI has introduced audit of the food companies by FSSAI recognised auditing agencies.
2. For recognition of the audit agencies, FSSAI has notified Food Safety and Standards (Food Safety Auditing) Regulations, 2018 which includes the Procedure for recognition of Auditing Agencies, Procedure for Renewal/ Cancellation/Suspension of recognition, Terms and conditions of recognition, auditing procedure, Duties of auditors, Audit reporting and audit monitoring system. At present, FSSAI has recognised 33 Third Party Audit Agencies (TPAAs) for conducting Third Party Audits (TPA). These TPAAs are an extended arm of FSSAI and State Regulatory bodies in ensuring food safety compliance.
3. Further FSSAI vide Order no. 19(2)2018/FSA/ RCD/FSSAI dated 13th August 2019 has also mandated Third Party Audits of select high risk food categories of Centrally Licensed FBOs. Food Businesses falling under high risk categories such as Meat and Meat Processing, Fish and Fish Processing, Prepared Food, Bakery, etc. would be required to get their businesses timely audited by FSSAI recognised Third Party Auditing Agencies on their own. Food businesses which are not subject to mandatory auditing can also voluntarily opt for Auditing of their businesses.
4. TPAAs upload the audit reports on the Audit Management System (AMS) portal. The AMS portal has been linked with the Food Safety Compliance (FoSCoS) Portal of FSSAI. The same are accessible from the CLA dashboard.

B. Review of the TPA reports:

The TPA reports of the FBOs are reflected in the FoSCoS dashboard of the CLA/DO. It is the responsibility of the CLAs to ensure that FBO gets TPA done for the financial year and to take follow up action on the audit report, as required. The CLA should also check whether any FBO has opted voluntarily for getting TPA done. Following are the steps to be followed by the CLA to review the report:

1. In case the TPA is pending for the FBO mandated by FSSAI:
 - i. If audit is not done for previous year, then an improvement notice may be issued.

- ii. If the TPA is pending only for the current year then reminder may be sent to the FBO to complete the audit at the earliest (*Timeline: 1st reminder in October and 2nd Reminder in January*).
 - iii. In case the TPA is not completed by 31st March and no reason for delay is provided by the FBO then improvement notice may be issued to the FBO (Timeline for issuing improvement notice – April-May).
 - iv. The FBO shall intimate the reason for delay and the date of audit scheduled. In case the same is not intimated or the reasons provided for delay are not considered satisfactory, then necessary action should be taken in the matter.
2. In case TPA has been completed and the report is available in the FoSCoS dashboard:
- i. Following information should be reviewed in the audit reports submitted by Third Party Audit Agencies (TPAAs):
 - a) *Date of Audit*
 - b) *Whether correct inspection checklist has been used as per Kind of Businesses. If not, then the TPAA must be intimated to resubmit the report in correct format. Whether inspection checklist is duly filled and not incomplete. Evidences and observations should be enclosed for essential parameters*
 - c) *Major and Minor Non conformities (NCs) observed*
 - d) *Whether the major non-conformities have been reported by the auditor to FSSAI or CLA. If not, then TPAA to intimate the reason for the same.*
 - e) *Any action taken report by the FBO on NCs or improvement report by the auditor on completion of NCs. If not, then issue improvement notice to the FBOs for closing of NCs within stipulated time.*
 - f) *In case of no action from the FBO on closure of NCs, suitable regulatory action may be initiated.*
 - ii. In case the audit report submitted by the TPA is incomplete or any false or incorrect information has been reported, then the CLA/DO should inform Regulatory Compliance Division (RCD), FSSAI to take further necessary action.
 - iii. Regulatory Compliance Division (RCD), FSSAI to review the audit report and if necessary, review the competence of the auditor and TPAA. In case any malpractice is observed or TPAA is found to be incompetent then action may be taken against such agencies as decided by the Food Authority.
3. The CLAs must consider any other guideline/order/ notification issued by FSSAI in reference with Third Party Audits or similar schemes while reviewing the Third party audit report or status of Third Party Audit of the FBO.
4. In case, FBO with FSSAI State License or registration undergoes Third Party Audit (voluntarily or on directions of Commissioner of Food Safety/FSSAI) then the above provisions will be followed by the State Licensing Authority for reviewing Third Party Audit reports or status of Third Party Audit of the FBO.

This issues with the approval of the Competent Authority.

Indeefat Singh

(I.S. Hura)

Joint Director (RCD)

Copy to:

1. Regional Directors, FSSAI
2. All CLAs
3. Commissioner of Food Safety of State/UTs

F.No. RCD-02001/9/2021-Regulatory-FSSAI
Food Safety and Standards Authority of India
Regulatory Compliance Division
FDA Bhawan, Kotla Road, New Delhi- 110002

Dated nd02 May 2022

Order

FSSAI from time to time, has issued several orders/advisories/instructions with respect to conducting inspections of food businesses, as listed below:

- i. O.M. No. 03-01/2012/Enf-1/FSSAI dated 15.10.2012
- ii. O.M. No. 03-01/2012/Enf-1/FSSAI dated 4.12.2012
- iii. O.M. No. 03-01/Enf-1/FSSAI/2012 dated 22.10.2012
- iv. OM File No.1(5)/Enf-1/FSSAI/2012 dated 12.02.2015
- v. Letter No. 4(35) 2016/U.P./Enf/FSSAI dated 19.07.2017
- vi. Order no. 19(2) 2008/FSA/RCD/FSSAI dated 13.08.2019 & subsequent clarifications dated 24.09.2019 and 29.11.2019

2. It has been decided to review the above advisories/ instructions/ orders to consolidate and update the same and to issue the comprehensive order on inspection/auditing superseding all the above advisories/ instructions/ orders in the matter.
3. Accordingly, an inspection plan has been framed, based on risk associated with the Food Businesses, to enable the authorities to carry out the mandatory inspections of the premises of the Food Business Operators (FBOs) ensuring the safety of high risk food categories in a more systematic and intensive manner. There is also a provision for exemption from the inspection based on the score of Third Party Audit or Hygiene Rating Scheme as applicable.
4. Further, if Commissioner of Food Safety of any State/UT is of the view that more number of inspections needs to be added for a particular Financial Year, he/she may give directions to the Designated Officers in addition to already proposed list of scheduled inspections as per this inspection plan. Also, this plan shall not preclude the Registration or Licensing Authorities from carrying out the inspections of any other Food Business Operator in the situation of the health risk or food safety emergencies. The inspection plan is annexed at **Annexure-I**.
5. All Central Licensed Manufacturer/Processors under High Risk Food Categories as specified in the Annexure –I shall get its business audited by FSSAI recognised food safety auditing agency every year. Also, Third Party Auditing of manufacturers/processors of high risk food categories having State license may be mandated by the concerned Commissioners of Food Safety in their respective States/UTs.
6. The inspection plan shall be reviewed further from time to time by the Food Authority. The provisions of the annexed inspection plan shall be incorporated in the Food Safety Compliance System (FoSCoS) for systematic allotment of inspection to Designated Officers/Food Safety Officers.

7. Commissioners of Food Safety of all States/UTs shall ensure the strict implementation of the inspection plan and shall monitor the progress of inspections conducted. They shall also review the pendency, if any, regularly so that targeted inspections shall be conducted within the timelines as specified.

8. This issues with the approval of Food Authority.

Yours faithfully,


(Inoshi Sharma)

Executive Director (Compliance Strategy)

To,

1. Commissioners of Food Safety of All States/UTs
2. Directors of All Regional Offices, FSSAI
3. All Central Licensing Authorities
4. CITO- for making necessary changes in the FoSCoS portal and uploading on website

Copy for information to-

1. All Divisional Heads of FSSAI
2. PPS to Chairperson, FSSAI
3. PS to CEO, FSSAI

I. General principles for Inspections

1. As a general rule, inspection should be undertaken with the objective of bringing about systematic improvements rather than in the form of raids/searches and should be undertaken with prior notice to FBO unless the concerned officer has reason to believe/ definite information about serious food safety issues which could be in the contravention of FSS Act or the regulations made thereunder.
2. It is mandatory to use the inspection checklist developed and prescribed by FSSAI for different KOBs.
3. It is also mandatory that all inspections to be carried out only using Food safety compliance through regular inspection & sampling system (FoSCoRIS) developed by FSSAI. In case owing to any reason FoSCoRIS app is not used, the report of inspection must be uploaded on FoSCoS within 24hrs of inspection. Any additional aspect may be inspected/ checked and recorded in the report.
4. As a general rule, all inspections should be accompanied with sampling. In case sampling is not feasible to be carried out along with inspection, the reason for the same must be recorded in writing.
5. Local sensitivities/ festivals/ practices/media reports etc. need to be factored in while scheduling inspections.
6. E-Inspection- When regular inspection is not feasible (reason to be recorded in writing), e-inspection of FBO's premise/unit may be conducted. The authority may record the observations by the way of videos or images submitted by FBO. The mode of submission of videos or images related to the inspection may be through any possible media available including live streaming preferably, if possible. If the facility of downloading of videos or images is available through that media, the concerned authority shall download and keep a copy of these visuals in their electronic devices for future reference.
7. The frequency where ever prescribed for any year, the year should be taken as financial year.
8. FSSAI has identified the following food categories as high risk categories:
 - a) 01 - Dairy products and analogues
 - b) 08 - Meat and meat products including poultry
 - c) 09- Fish and fish products, including molluscs, crustaceans, and echinoderms
 - d) 10 - Eggs and egg products
 - e) 13- Foodstuffs intended for particular nutritional uses
 - f) 16- Prepared Foods
 - g) 18.1- Indian Sweets
 - h) 99.5 – Nutrients and their preparations (Fortified Rice Kernels only)
9. Mandatory Third Party Audit shall be conducted annually only for the Manufacturers/Processors holding Central License for high risk categories mentioned in point I (8) above.

10. The inspection of high risk food categories shall be carried out on priority and other inspections may be conducted only when mandatory inspections of all high risk food categories are exhausted.

II. Types of Inspections

1. **Pre-License Inspection:** No pre-licensing inspection is required except in case of **Manufacturer/ Processors of Milk & Milk products, Meat & Meat products, Fish & Fish products, Fortified Rice Kernels (FRKs) and Slaughter houses**, where inspection is mandatory before grant of license. In other cases, the license may be granted and inspection may be conducted in due course. The timelines given under 2.1.4 of FSS (Licensing and Registration of Food Businesses) Regulations, 2011 for conducting Pre-License Inspection shall be adhered to and any delay in processing of application should be avoided.
2. **Pre-Registration Inspection:** No pre-registration inspection is required except **Manufacturer/ Processors of Fortified Rice Kernels (FRKs)** where it is mandatory to carry out inspection before issuing Registration Certificate. The timelines given under 2.1.1 of FSS (Licensing and Registration of Food Businesses) Regulations, 2011 for conducting Pre-Registration Inspection shall be adhered to and any delay in processing of application should be avoided.
3. **Routine Inspection:** Regular inspections for Enforcement and Surveillance are undertaken as per the plans developed by each State on the basis of their respective risk profile and scale of operations of FBOs as reflected in Table 3.1. The Food Safety Officer should carry out inspections of FBOs as per the frequencies and exemptions prescribed below.

3.1 Frequency of mandatory inspections of Food Business Operators

The frequency of the inspections has been calculated on the basis of the risk categorisation of the KoBs. The following inspection frequency is valid for both licensed and registered FBOs.

S.No.	Kind of Business (KoB)	Food Product Category	Frequency of Inspection
i	Manufacturer / Processer	1, 8, 9, 10, 13, 16 & 18.1, 99.5(only FRK)	Once a year
		Other than 1, 8, 9, 10, 13, 16, 18.1 & 99.5 (only FRK)	Once in every two years
ii	Food Service Establishments*	All licensed FBOs	Once in every two years
iii	Storage (Frozen, Refrigerated & Controlled Atmosphere)*	All licensed FBOs of Milk and Milk products, Fish and Fish products, Meat and Meat products	Once in every two years
iv	Transporter (Frozen & Refrigerated)*	i.e FPC - 1, 8 and 9	Once in every two years
v.	Other KoBs	5 % of licensed FBOs and 2 % registered FBOs selected randomly or on the basis of the risk profile	Once a year

**For Registered FBOs, State may draw their own inspection plan in accordance with the number of the registered FBOs in these categories, number of FSOs/DOs available and scale of operation of FBos*

3.2 Exemption from Inspections^{###}

S. No.	Eligible KoB	Criteria	Exemption
i.	All KoBs* [#]	Obtaining 80% or above score in FSSAI's Third Party Audit.	2 years (two Financial Years i.e. First FY, in which Third Party Audit is conducted and succeeding FY)
ii.	Food Service Establishments, Meat Retail Shops, Sweet Shops, Bakery Retail Shops	Hygiene Rating 5 Smileys (Excellent)	2 years (two Financial Years i.e. First FY, in which Hygiene Rating Certificate has been awarded is conducted and succeeding FY)

**Third Party Audit report shall be used for awarding Hygiene Rating Certificate to FBOs eligible for the same under Hygiene Rating (HR) Scheme (Food Service Establishments, Meat Retail Shops, Sweet Shops and Bakery retail shop). No separate audit will be required to award HR certificate to such FBOs.*

Note: Hygiene Rating Scheme cannot replace Third Party Audit in case of KoBs such as High Risk Categories where Third Party Audit has been mandated by the Food Authority or Commissioners Food Safety of States/UTs.

FSSAI, by way of issuing orders from time to time, may also exempt any other Kind of Business from the inspections and/or frequency thereof, on the basis of any other scheme designed to ensure the safety and hygiene of such food business operators.

Illustration: If an FBO "X" has obtained Audit Score of 80% or above in FY 2021-2022 then the inspection by FSO during FY 2021-2022 & FY 2022-2023 will be exempted however, in the next FY i.e. 2023-2024, the inspection by FSO shall be carried out. If the FBO 'X' obtained audit score of 80% or above in the FY 2023-2024 as well then inspection by FSO during FY 2024-2025 will be exempted but shall be carried in the next FY i.e. 2025-2026.

Further, the above exemption from inspections may also be extended to other Kind of Businesses (KoBs) as identified and decided by the Food Authority from time to time.

4. Follow up inspections:

4.1 The FSO undertakes follow up inspection of the FBO's premise in cases where he believes, the reason for the same must be recorded in writing, that it is necessary to follow up to ensure and satisfy himself that FBO has fulfilled all the improvement suggestions provided by the FSO during previous inspection. Such an inspection may be a pre-informed or surprise inspection.

4.2 Similarly, the FSO on the directions of the DO, undertakes follow up inspection of the food establishment of a FBO to ensure and satisfy himself that the FBO has complied with all the suggestions mentioned in the improvement notice issued by the DO either at the time of Pre-License Inspection or Routine Inspection. Follow up inspections must be done within 3 months of previous inspection or issue improvement notice.

- 4.3 Further, **at least 2% of FBOs** who have undertaken Hygiene Rating in that financial year shall be inspected by FSOs.
5. **Inspection before renewal/modification of license:** Pre-renewal inspection is not mandatory. However, it may be done in select cases for the reasons to be recorded usually based on previous inspection/audit score. In case of modification of the license, inspection is not mandatory unless the modification is to include products type/ kind of business which were not manufactured/processed/ undertaken earlier and require inspection to be done.
 6. **Inspection for investigation of complaint:** The Food Safety Officer should investigate any complaint which is made to him in writing in respect of any contravention of the provisions of the Act or Rules & Regulations made there under. This may be pre-informed or surprise inspection. Food businesses shall be inspected as soon as possible on receipt of the complaint, irrespective of any food product category. It should be invariably done within **15 days** of receipt of the complaint.
 7. **Inspection in case of food safety emergency:** The FSO will initiate investigation and inspect premises of the FBO as per guidelines laid down by FSSAI for management of food borne illness outbreaks in India. This may be pre-informed or surprise inspection and needs to be done at the earliest.
 8. **Inspection in case of report of major non-conformity during Third Party Audit or Hygiene Rating Scheme:** In case of referral of a major non-conformity by an auditor or agency during food safety audit or hygiene rating, an inspection of the premises must be done within **30 days** of receipt of such information.
 9. **Inspection of expired licenses:** **At least 1% of FBOs**, whose licenses have expired in a given month, shall be inspected within next succeeding **two months**. For rest of Food businesses whose licenses have expired (remaining 99% or less as the case may be), the DO shall give notices within 15 days from the month. In cases, if there is no response received from the FBO within 15 days from the date of receipt of the notice or if response is found unsatisfactory then the DO shall direct inspection of such food businesses. Appropriate action against the FBO shall be taken as per the provisions of the FSS Act, 2006 and the Rules/Regulations made thereunder on the basis of findings of inspection reports.
 10. **Other Inspections:** Any other inspections prescribed by the Food Authority from time to time.

Note: The expression FSO also refers to Central Food Safety Officer (CFSO) and the expression DO also refer to Central Licensing Authority (CLA)

Disclaimer: This is a suggestive inspection plan to draw a minimum number of food safety inspections to be conducted by any State/UTs. The States/UTs may revise the inspections frequency/numbers on the basis of the number of FBOs per KoB and availability of FSO/DOs.

File No – 15(31)2020/FoSCoS/RCD/FSSAIpt1-Part(2)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
(Regulatory Compliance Division)
FDA Bhawan, Kotla Road, New Delhi -110002

Dated 02nd November, 2022

ORDER

Subject: Revision of Inspection checklists-reg.


FSSAI, vide order dated 9th March 2018 and further the corrigendum dated 14th May 2020, has implemented the revised Inspection checklist for facilitating Food Safety Officers to efficiently inspect Food Businesses as per Kind of Business [KoB]. These checklists have been developed based on the Schedule 4 requirements of FSS (Licensing and Registration of Food Businesses) Regulation, 2011, and subsequent Orders.

2. According to the above-mentioned order, Marks to be awarded for each point of the checklist as per the findings/observations i.e. Compliance, Non-Compliance, Partial Compliance, Not Applicable / Not Observed is mentioned. **In case of Not Applicable / Not Observed finding, full marks are to be awarded.**

3. To further improvise the checklist and the method of allotting the marks, Food Authority has decided that **marks shall be given only to those requirements which are applicable as per the respective KoB. The requirements that are 'Not Applicable' to a food business shall be omitted/ ignored while evaluating the Inspection Score / Grading.**

4. The above-mentioned change is also incorporated in online portals FoSCoS/ FoSCoRIS for conducting inspections, which shall come into effect from 28th October 2022.

5. This issue with the approval of the Competent Authority.


(Inoshi Sharma)

Executive Director (CS)

Email: ed-office@fssai.gov.in

To

1. All food business operators, associations, Food Safety Mitra, and other stakeholders.
2. Commissioners of Food safety of all states/UTs and directors of All regional offices
3. CTO, FSSAI, with a request for uploading on the FSSAI website

Copy for information to:

1. All Divisional heads of FSSAI
2. PPS to Chairperson, FSSAI
3. PS to CEO, FSSAI

RCD-02002/5/2023-Regulatory-FSSAI
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
(Regulatory Compliance Division)
FDA Bhawan, Kotla Road, New Delhi -110002

Dated, the 15th December, 2023

ADVISORY

Subject: Gaps observed in the Food Safety Audit Reports -reg.

Reference is drawn to Part IV of the Food Safety and Standards (Food Safety Auditing) Regulations, 2018, which stipulates the Food Authority's responsibility to oversee the performance of recognized auditing agencies.

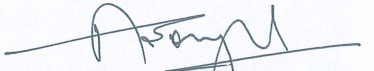
2. In the above context, a review of the Food Safety Audit Reports, prepared and submitted by the FSSAI-recognized Food Safety Auditing Agencies on AMS portal, was conducted, and the following have been observed:

- a. Use of incorrect checklist / checklist used was not as per the Kind of Business (KoB)
- b. Relevant photographs of plant premises, equipment, and utensils not provided
- c. Marks and Remarks do not commensurate
- d. Use of scanned 'Signature and Stamp'
- e. Submission of audit reports on AMS portal after stipulated time i.e. within the 15 days
- f. Relevant supporting documents are not being submitted/uploaded
- g. Checklist Section viz. "Overall Findings by Auditor" and "Improvements Suggested" are not being filled/left vacant
- h. Asterisk mark questions of the checklist are not being dealt with as per the rules
- i. Non-adherence to prescribed scoring rules

3. Such gaps in audit reports are not expected from recognized Food Safety Auditing Agencies and have been viewed very seriously by FSSAI.

4. In this regard, recognized Food Safety Auditing Agencies are hereby directed to conduct audit of FBOs very seriously and proper due diligence must be used while preparing and submitting the audit reports.

Yours Sincerely,



(Dr. Ajeet Singh)
Joint Director (RCD)

To:

1. All FSSAI-recognized Food Safety Auditing Agencies

Copy for information to:

1. All Regional Directors, FSSAI
2. All Central Licensing Authorities, FSSAI
3. Sr. PS to the CEO, FSSAI.