

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.

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(I.S. Hura)

Joint Director (RCD)

Copy to:

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