FSSC 22000

# FOOD SAFETY SYSTEM CERTIFICATION 22000

## ANNEX 3: CB AUDIT REPORT REQUIREMENTS FOR FSSC 22000-QUALITY V5

Version 5.1 | November 2020

# INTRODUCTION

This annex details the requirements for FSSC 22000 Quality Audit reports that are in addition or different to what is set out in Annex 2. Therefore, the requirements in Annex 2 applies as part of Annex 3 and is not referenced here to avoid duplication. This includes the level of detail required in the summary sections.

Audit checklists for ISO 22000:2018, the relevant PRP standard and the additional FSSC 22000 requirements are an inclusive part of the report and are to be issued with this report to the organization if they are separate documents.

The requirements for ISO 9001:2015 are incorporated into the ISO 22000:2018 checklist where there is synergy. Where a clause only applies to ISO 22000, this is indicated in brackets for the relevant clause requirement. Elements that relate only to ISO 9001:2015 are added as an additional checklist section.

All information in the report template shall be uploaded into the Portal along with attachments in PDF (original audit report, checklists, audit plan, audit program). Where nonconformity reports are separate to the audit report these shall be zipped with the audit report to facilitate uploading into the Portal.

This template is designed for food manufacturing audits and the ISO/TS 22002-1:2009 PRP is used here. For other PRPs the CB shall replace this PRP content with the relevant PRP based on the scope of the audit.

# STAGE 1 AUDIT REPORT

# 1 ORGANIZATION DETAILS

## 1.1 ORGANIZATION PROFILE

| | |
|---|---|
| **Registered legal name** | Name of organization to be certified |
| **Legal or official company registration number** | Applicable reference to legal registration (such a business registration number) |
| **Location/Address** | Full address (or other unique identification of site location (i.e., GPS, GLN etc. where a postal address is not available) |
| **Contact person** | Name & function |
| **General description of audited organization** | Brief history of company for example how long in business, purpose built/prior use, main markets (local/international)<br>Overview of products produced, main processes, number of processing lines, organizational structure including relationship with HO or off-site activities where relevant; Level of complexity and risk regarding food safety.<br>**No marketing jargon** |
| **Overview of seasonal activities** | Describe when various seasonal activities are conducted per scope. For example:<br>• Processing of stone fruit September - October<br>• Processing of vegetables March - October<br>Indicate "None" if not applicable |

## 1.2 HEAD OFFICE (WHERE APPLICABLE)

| | |
|---|---|
| **Registered legal name** | Name of Head office to be included in the certification |
| **Location/Address** | Full address (or other unique identification of site location (i.e., GPS, GLN etc. where a postal address is not available) |
| **Date and duration of head office audit** | |
| **Number of sites** | Number of sites included under the head office functions |
| **Description of Head office functions** | Describe which functions are conducted at Head Office that are common to the certified sites. For example: procurement, human resources, etc.<br>Indicate if head office is a separate audit or whether the head office representative is present at the site audit(s). |

### 1.3 OFF-SITE ACTIVITIES (WHERE APPLICABLE)

| | |
|---|---|
| **Site name** | Name of off-site facility |
| **Location/Address** | Full address (or other unique identification of site location (i.e., GPS, GLN etc. where a postal address is not available) |
| **Date and duration of off-site activity audit/s** | |
| **Activities at location** | Describe any activities that are conducted at off-site location, where they are under the same legal entity and same FSMS (refer Part 3, section 5.2.2). For example:<br>a) Off-site storage<br>b) Off-site manufacturing<br>c) Cross-docking |

### 1.4 MULTI-SITES (WHERE APPLICABLE)

| | |
|---|---|
| **Registered legal name of the Group** | Name of the group to be certified. |
| **Legal or official company registration number** | Applicable reference to legal registration (such a business registration number). |
| **Location/Address** | Full address (or other unique identification of site location (i.e., GPS, GLN etc. where a postal address is not available). |
| **Date and duration of Central Functions audit** | |
| **Overview of Central Functions** | Also refer to FSSC Additional Requirement 2.5.14 for report content requirements. |
| **Number of sites in the group** | Number of sites included in the group certification. |
| **List of sites included, with addresses, date/s of audit and activity (scope)** | Can be an addendum to the report. |

## 2 AUDIT DETAILS

| | |
|---|---|
| **CB Name and office location (if different from main CB)** | CB and office name if local office. |
| **Audit language** | Language audit conducted in – if translator is used provide detail. |
| **Audit objectives** | Reference ISO/TS 22003: 2013 – 9.2.3.1.2 |
| **Audit criteria** | Normative documents i.e., ISO 22000: 2018, ISO 9001: 2015, the specific PRP standard/s and the FSSC additional requirements (Version 5.1); |

| | |
|---|---|
| | Defined processes and documentation of the management system of the organization;<br>Legal and regulatory requirements and customer requirements. |
| **Audit Delivery** | *ICT Audit Approach / On-site<br>Note: include the extent of the remote audit i.e., full remote audit or partly remote audit. |
| **Audit dates and locations (where applicable)** | Start and end date DD/MM/YYYY<br>Add dates per off-site activity/separate locations audited where relevant. |
| **Audit Duration Stage 1** | In days for example 1.5 days |

## 2.1 AUDIT SCOPE

| | |
|---|---|
| **Food chain sub-category** | Food chain sub-categories supporting the scope statement (multiple food chain categories may be applicable, see ISO/TS 22003, Table A.1) and relevant ISO 9001: 2015 code. |
| **Scope statement** | Scope statement as per Annex I requirements. Where exclusions are applicable, the exclusion has to be included in the scope statement. |
| **Exclusions (when appropriate and detailed)** | Describe the exclusions from the scope (exclusions may not have an (negative) influence on the certified end products. |
| **Verification of the scope statement** | Confirm that the scope statement is an accurate reflection of the organization's activities. |

## 2.2 AUDIT PLAN

| | |
|---|---|
| **Deviation from audit plan:** | Describe deviations to the audit plan and their reasons where applicable |

## 2.3 AUDIT TEAM

| Name | Function | Audit delivery method | Date(s) | Time |
|---|---|---|---|---|
| Auditor name | Includes lead auditor, auditor, translators, Technical Expert, witnessor, trainees, observers | i.e., remote/onsite | DD/MM/YYYY | 08h00-17h00 |

Note: The table shall be completed per audit date and per audit team member in the case of an audit team and reflect the actual audit time. Where this differs from the audit plan, the justification shall be recorded under deviation from audit plan – 2.2.

# 3 AUDIT RESULTS

## 3.1 OVERVIEW OF CLIENTS' PREPAREDNESS FOR STAGE 2

| | |
|---|---|
| **Management system documentation including the ability to meet statutory, regulatory and customer requirements** | Overview of client's MS, level of documentation established and applicable legislative and customer requirements, including level of implementation |
| **Client's site-specific conditions (environment; equipment and processes)** | Summary description of site environment and any external risks<br>Short list of principle processes and key equipment used |
| **Organizational planning and control**<br>**Status with regard to:**<br>a) Key performance<br>b) Processes<br>c) Objectives<br>d) Operation of management system | ISO 22000 clauses 4, 5, 6, 7<br>Status with regard to key performance, processes, objectives, and operation of management system |
| **Operational planning and control including an overview of PRPs, HACCP system and level of controls established** | ISO 22000 clause 8<br>Provide an overview of the HACCP system, by including a summary of:<br>• Significant food safety hazards identified and their type<br>• Methodologies used to conduct the hazard assessment and the selection and categorization of control measures (OPRP and CCP)<br>• Overview of OPRP and CCP including their critical control limits, monitoring systems and corrective actions for breach of critical limits<br>• Validation process implementation and results<br>• Verification activities implementation status<br>• General description of level of implementation of hazard control plan |
| **Internal Audit** | ISO 22000 clause 9<br>Confirm if a full internal audit has been conducted with dates, general overview of procedure/system, outcomes, effectiveness etc. |
| **Management Review** | ISO 22000 clause 9<br>Confirm if a Management Review has been conducted, indicate date of review, and effectiveness including the input and output requirements |

| Review for Stage 2 Preparedness | |
|---|---|
| **Allocation of resources** | Confirm if audit duration is appropriate or whether additional time is required |
| **Planning needs** | Detail any particular planning required for Stage 2 (i.e., certain activities take place during afternoons/evening) |

## 3.2 AREAS OF CONCERN

| Number (#) | Requirement reference (standard) | Clause | Finding details |
|---|---|---|---|
| 1 | Example: ISO22000: 2018 | Example 7.1.6 | Detail issue with relation to requirement and provide objective evidence |

## 3.3 AUDIT CONCLUSION

| | |
|---|---|
| ☐ | **Stage 1 audit to be repeated** |
| ☐ | **Proceed to Stage 2 audit** |

# STAGE 2 AUDIT REPORT

# 1 ORGANIZATION DETAILS

## 1.1 ORGANIZATION PROFILE

| | |
|---|---|
| **Registered legal name** | Name of organization to be certified |
| **Legal or official company registration number** | Applicable reference to legal registration (such a business registration number) |
| **Location/Address** | Full address (or other unique identification of site location (i.e., GPS, GLN etc. where a postal address is not available) |
| **Contact person** | Name and function |
| **General description of audited organization** | Brief history of company for example how long in business, purpose built/prior use, main markets (local/international)<br>Overview of products produced, main processes, number of processing lines, organizational structure including relationship with HO or off-site activities where relevant; Level of complexity and risk regarding food safety.<br>**No marketing jargon** |
| **Significant changes since the previous audit** | Identify any key changes to the organization since the previous audit |
| **Seasonal activities** | Indicate whether the site has seasonal activities included in the scope, what they are and relevant production timings or example:<br>• Processing of stone fruit September - October<br>• Processing of vegetables March - October |

## 1.2 HEAD OFFICE (WHERE APPLICABLE)

| | |
|---|---|
| **Registered legal name** | Name of Head office to be included in the certification |
| **Location/Address** | Full address (or other unique identification of site location (i.e., GPS, GLN etc. where a postal address is not available) |
| **Date and duration of head office audit** | |
| **Number of sites** | Number of sites included under the head office functions |
| **Overview of Head office functions** | Describe which functions are conducted at Head Office that are common to the certified sites. For example: procurement, human resources, etc. |

## 1.3 OFF-SITE ACTIVITIES (WHERE APPLICABLE)

| | |
|---|---|
| **Site name** | Name of off-site facility |
| **Location(s)/Address** | Full address (or other unique identification of site location (i.e., GPS, GLN etc. where a postal address is not available) |

| | |
|---|---|
| **Date and duration of off-site audit/s** | |
| **Activities at location/s** | Describe activities that are conducted at an off-site location, where they are under the same legal entity and same FSMS (refer Part 3, section 5.2.2). For example:<br>a) Off-site storage<br>b) Off-site manufacturing<br>c) Cross-docking |

### 1.4 MULTI-SITES (WHERE APPLICABLE)

| | |
|---|---|
| **Registered legal name of the Group** | Name of the group to be certified |
| **Legal or official company registration number** | Applicable reference to legal registration (such a business registration number) |
| **Location/Address** | Full address (or other unique identification of site location (i.e., GPS, GLN etc. where a postal address is not available) |
| **Date and duration of Central Functions audit** | |
| **Overview of Central Functions** | Also refer to FSSC Additional Requirement 2.5.14 for report content requirements |
| **Number of sites in the group** | Number of sites included in the group certification |
| **List of sites included, with addresses, date/s of audit and activity (scope)** | Can be an addendum to the report |

## 2 AUDIT DETAILS

| | |
|---|---|
| **CB Name and office location (if different from main CB)** | CB and office name if local office |
| **Audit language** | Language audit conducted in – if translator is used provide detail |
| **Audit objectives** | Reference ISO17021-1 – 9.3.1.2 |
| **Audit criteria** | Normative documents i.e., ISO 22000: 2018, ISO 9001: 2015, the specific PRP standard/s and the FSSC additional requirements (Version 5.1);<br>Defined processes and documentation of the management system of the organization;<br>Legal and regulatory requirements and customer requirements |
| **Audit type** | Stage 2, surveillance, transition, recertification |
| **Announced/Unannounced** | |

| | |
|---|---|
| **Audit complexity** | Standalone FSSC 22000 audit<br>Combined/Integrated with another standard<br>Provide details: |
| **Audit delivery** | ICT Audit approach/Full On-site/Full remote audit<br>Detail the extent of ICT use as applicable |
| **Audit dates** | Audit start date; end date |
| **Audit Duration** | i.e., 1.5 days |
| **Deviation from audit duration** | Provide justification where audit duration differs from calculated duration |
| **Addendums included as part of the audit** | Indicate Addendum and audit duration if applicable |

## 2.1 AUDIT SCOPE

| | |
|---|---|
| **Food chain sub-category** | Food chain sub-categories supporting the scope statement (multiple food chain categories may be applicable, see ISO/TS 22003, Table A.1) and the relevant ISO 9001 code. |
| **Scope statement** | Scope statement as per Annex I requirements. Where exclusions are applicable, the exclusion shall be included in the scope statement |
| **Exclusions** (when appropriate) including justification) | Describe the exclusions from the scope (exclusions may not have an (negative) influence on the certified end products). |
| **Verification of the scope** | Confirm that the scope statement is an accurate reflection of the organization's activities and indicate any changes since the previous audit |

## 2.2 AUDIT PROGRAM AND PLAN

| | |
|---|---|
| **Deviation from audit program** | Describe issues impacting the audit program and their reasons. If none, state "None" |
| **Deviation from audit plan** | Describe deviations to the audit plan and their reasons where applicable |

## 2.3 AUDIT TEAM

| Name | Function | Audit delivery | Date(s) | Time |
|---|---|---|---|---|
| Auditor name | Includes lead auditor, auditor, translators, TE, witnessor, trainees, observers | i.e., remote/onsite | DD/MM/YYYY | 08h00-17h00 |

Note: The table shall be completed per audit date and per audit team member in the case of an audit team and reflect the actual audit time. Where this differs from the audit plan, the justification shall be recorded under deviation from audit plan section – 2.2.

## 2.4 PREVIOUS AUDIT

### 2.4.1 AUDIT DETAILS PREVIOUS AUDIT

| | |
|---|---|
| **Audit type** | Stage 1, Stage 2, Surveillance, Recertification |
| **Announced / Unannounced** | |
| **Audit date/s** | DD/MM/YYYY |
| **CB conducting previous audit if different to current CB** | In case of a transfer, indicate the name of the previous CB |
| **Actions taken on NCs raised at previous audit** | Provide comment on the organization's ability to determine the root causes of any previously identified nonconformities, as appropriate, and on the effectiveness of the actions it has taken to correct such situations and prevent their recurrence. It should also comment on the sufficiency of the organization's formal processes for corrective action. |

# 3 AUDIT RESULTS

## 3.1 EXECUTIVE SUMMARY

| | |
|---|---|
| **Audit summary** | High level summary – aimed at senior management of organization to understand how the FSMS is performing and what actions they need to take to address any shortfalls.<br>Provide a statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to:<br>• The capability of the management system to meet applicable requirements, food safety & quality objectives and expected outcomes;<br>• Progress the organization has made against its objectives since the last audit (however, for an initial certification, this section may need to acknowledge that the organization had not yet developed sufficient history of such achievement for auditing purposes);<br>• Significant issues that senior management need to be aware of (major/critical findings; trends in recalls etc.);<br>• The internal audit and management review process;<br>• Detail outcome of previous audit results;<br>• For recertification audit – indicate how the FSMS has evolved over the three-year cycle.<br>Structure of executive summary should follow the order of the main report. |

| | |
|---|---|
| **Confirmation that audit objectives have been fulfilled** | Positive statement, do not leave blank. If an objective was not met, indicate why. Also provide detail on progress made. |
| **Unresolved issues** | Record any unresolved issues (for example disagreement on findings, finding ratings etc.) resulting from the audit. |

## 3.2 SUMMARY OF AUDIT FINDINGS

| | |
|---|---|
| **# Critical nonconformities** | |
| **# Major nonconformities** | |
| **# Minor nonconformities** | |

# 3.3 NONCONFORMITIES

## CRITICAL NONCONFORMITIES

| # | **Requirement Reference** (std., clause) | **NC statement** (incl. objective evidence) | **Root Cause Analysis** (determine why it arose) | **Corrective Action Plan** (action to prevent repeat; person responsible, due date for completion) | **Correction** (to address the immediate issue) | **Acceptance of correction, CAP, and evidence** (auditor and date) |
|---|---|---|---|---|---|---|
| **1** | For example: ISO 22000:2018 §7.1 | Provide a clear statement of the deviation to the requirement.<br>Provide detailed objective evidence.<br>Indicate potential or actual impact on food safety | Completed by client | Completed by client | Completed by client | Auditor name and date of acceptance of Root cause analysis, CAP, and correction |
| **2** | | | | | | |

**Date of suspension: DD/MM/YYYY**

**Follow-up Audit**

**Date of follow-up audit: DD/MM/YYYY**

**Objective Evidence reviewed to close out the NC:**

Provide detail of evidence reviewed to address and close out the NC.

| **Result of Follow-up audit:** | Lift suspension and reinstate certificate/withdraw certificate |
|---|---|

## MAJOR NONCONFORMITIES

| # | Requirement Reference (std., clause) | NC statement (incl objective evidence) | Root Cause Analysis (determine why it arose) | Corrective Action Plan (action to prevent repeat; person responsible; due date for completion) | Correction (to address the immediate issue) | Objective Evidence Reviewed (to close out the NC) | Acceptance of correction, CAP, and evidence (auditor and date) |
|---|---|---|---|---|---|---|---|
| **1** | For example: ISO 22000:2018 §7.1 | Provide a clear statement of the deviation to the requirement. Provide detailed objective evidence. Indicate potential or actual impact on food safety | Completed by client | Completed by client | Completed by client | Indicate evidence reviewed to close the NC i.e., document name and number | Auditor name and date of acceptance of Root cause analysis, CAP , correction, and objective evidence |
| **2** | | | | | | | |
| **3** | | | | | | | |
| **4** | | | | | | | |
| **Onsite close out:** | | Yes/No | **Follow-up onsite audit date (where applicable)** | | DD/MM/YYYY | | |

## MINOR NONCONFORMITIES

| # | **Requirement Reference** (std., clause) | **NC statement** (incl objective evidence) | **Root Cause Analysis** (determine why it arose) | **Corrective Action Plan** (action to prevent repeat; person responsible; due date for completion) | **Correction** (to address the immediate issue) | **Objective Evidence Reviewed** (relating to the correction ) | **Acceptance of correction and CAP** (auditor and date) |
|---|---|---|---|---|---|---|---|
| **1** | For example: ISO 22000:2018 §7.1 | Provide a clear statement of the deviation to the requirement. Provide detailed objective evidence. | Completed by client | Completed by client | Completed by client | Indicate evidence reviewed for the correction i.e., document name and number | Auditor name and date of acceptance of Root cause analysis, CAP , correction, and objective evidence |
| **2** | | | | | | | |
| **3** | | | | | | | |
| **4** | | | | | | | |

Note: Corrective action reports for minor, major and/or critical nonconformities may be included in the audit report, or as a separate document.

## 3.4 AUDIT RECOMMENDATION

| | |
|---|---|
| **Initial certification granted** | Yes ☐ No ☐ Not applicable ☐ |
| **Continued certification** | Yes ☐ No ☐ Not applicable ☐ |
| **Re-certification** | Yes ☐ No ☐ Not applicable ☐ |

## 3.5 AUDIT DURATION

| *On-site audit time calculation – refer Table B.1 in ISO/TS22003: 2013 and V5 Part 4, clause 4.3* | | | | |
|---|---|---|---|---|
| D | H | MS | FTE | FSSC additional |
| 1.5 | 0.5 | 0.25 | 1.0 | 0.5 |
| **Audit duration calculation (man days)** | | Example:<br>Initial audit $T_s$ + $T_{fssc}$ = 3.75 man days<br>Surveillance audit = 1.5 man days<br>Recertification audit = 3 days | | |
| **Audit time reduction** | | Justify any reductions given to Ts | | |
| **Audit duration ISO 9001** | | | | |
| **Combined FSMS and QMS time (refer IAF MD11)** | | | | |
| **Existing Management system certification in place** | | Yes/No – if yes specify | | |
| **Number of HACCP studies** (linked to product groups) | | Indicate the number of HACCP studies – linked to the product group | | |
| **Number of employees (FTEs)** | | FTE = total number of employees including seasonal workers + office workers; where shifts with similar activities apply, then FTE = number of employees on main shift including seasonal workers and office workers | | |
| **Number of shifts** | | | | |
| **Description of activities per shift if different from main shift** | | Where activities are different across shifts, provide short overview of activities per shift | | |
| **Employees per main shift (FTE)** | | | | |

Note: The audit duration calculation may be uploaded in the FSSC portal as a separate document as long as all information required is captured

# 4 CHECKLISTS

Note: It is not required to reflect the sub-sub clauses (e.g., 7.5.3.1; 8.5.1.5.1) in the ISO 22000 checklist section of the audit report, but should a nonconformance be identified, this needs to be reflected to this level and included in the report. The portal checklist contains all the clauses to the lowest level.

## 4.1 ISO 22000:2018 & ISO 9001:2015

| ISO 22000:2018 & ISO 9001: 2015 | | Conform | | Grade | If No – detail NC | NC # |
|---|---|---|---|---|---|---|
| Clause | Requirement | Yes | No | Minor/Major/ Critical | | |
| **4** | **Context of the organization** | | | | | |
| **4.1** | Understanding the organization and its context | ☐ | ☐ | | | |
| **4.2** | Understanding the needs and expectations of interested parties | ☐ | ☐ | | | |
| **4.3** | Determining the scope of the food safety/ quality management system | ☐ | ☐ | | | |
| **4.4** | Food safety/quality management system and its processes | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| ISO 22000:2018 & ISO 9001: 2015 | | Conform | | Grade | If No – detail NC | NC # |
|---|---|---|---|---|---|---|
| Clause | Requirement | Yes | No | Minor/Major/ Critical | | |
| **5** | **Leadership** | | | | | |
| **5.1** | Leadership and commitment | ☐ | ☐ | | | |
| **5.2** | Policy | ☐ | ☐ | | | |
| **5.2.1** | Establishing the food safety & quality policy | ☐ | ☐ | | | |
| **5.2.2** | Communicating the food safety & quality policy | ☐ | ☐ | | | |
| **5.3** | Organizational roles, responsibilities, and authorities | ☐ | ☐ | | | |
| **5.3.1** | Top management shall ensure that responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization ((ISO22000: 2018) | ☐ | ☐ | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **5.3.2** | The food safety team leader shall be responsible for: a) - d) (ISO22000: 2018) | ☐ | ☐ | | | |
| **5.3.3** | All persons shall have responsibility to report problem(s) with regards to the FSMS to identified person(s) (ISO22000: 2018) | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| **ISO 22000:2018 & ISO 9001: 2015** | | **Conform** | | **Grade** | **If No – detail NC** | **NC #** |
|---|---|---|---|---|---|---|
| **Clause** | **Requirement** | **Yes** | **No** | Minor/Major/ Critical | | |
| **6** | **Planning** | | | | | |
| **6.1** | Actions to address risks and opportunities | ☐ | ☐ | | | |
| **6.1.1** | When planning for the QMS & FSMS, the organization shall consider the issues referred to in 4.1 and the requirements in 4.2 and 4.3 and determine the risks and opportunities that need to be addressed to: a) - d) | ☐ | ☐ | | | |
| **6.1.2** | The organization shall plan: a) - b) | ☐ | ☐ | | | |
| **6.1.3** | The actions taken by the organization to address risks and opportunities shall be proportionate to: a) - c) (ISO22000: 2018) | ☐ | ☐ | | | |
| **6.2** | Objectives of the food safety/quality management system and planning to achieve them | ☐ | ☐ | | | |
| **6.2.1** | The organization shall establish objectives for the QMS & FSMS at relevant functions and levels. The objectives of the FSMS shall: a) - f); the quality objectives shall: a) - g) | ☐ | ☐ | | | |
| **6.2.2** | When planning how to achieve its objectives for the FSMS/quality objectives, the | ☐ | ☐ | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | organization shall determine: a) - e) | | | | | |
| **6.3** | Planning of changes | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| **ISO 22000:2018 & ISO 9001: 2015** | | **Conform** | | **Grade** | **If No – detail NC** | **NC #** |
|---|---|---|---|---|---|---|
| **Clause** | **Requirement** | **Yes** | **No** | Minor/Major/ Critical | | |
| **7** | **Support** | | | | | |
| **7.1** | Resources | ☐ | ☐ | | | |
| **7.1.1** | General | ☐ | ☐ | | | |
| **7.1.2** | People | ☐ | ☐ | | | |
| **7.1.3** | Infrastructure | ☐ | ☐ | | | |
| **7.1.4** | Work environment | ☐ | ☐ | | | |
| **7.1.5** | Externally developed elements of the FSMS (ISO22000: 2018) | ☐ | ☐ | | | |
| **7.1.6** | Control of externally provided processes, products, or services (ISO22000: 2018) | ☐ | ☐ | | | |
| **7.2** | Competence | ☐ | ☐ | | | |
| **7.3** | Awareness | ☐ | ☐ | | | |
| **7.4** | Communication | ☐ | ☐ | | | |
| **7.4.1** | General | ☐ | ☐ | | | |
| **7.4.2** | External communication | ☐ | ☐ | | | |
| **7.4.3** | Internal communication | ☐ | ☐ | | | |
| **7.5** | Documented information | ☐ | ☐ | | | |
| **7.5.1** | General | ☐ | ☐ | | | |
| **7.5.2** | Creating and updating | ☐ | ☐ | | | |
| **7.5.3** | Control of documented information | ☐ | ☐ | | | |
| **7.5.3.1** | Documented information required by the FSMS/QMS and by this document shall be controlled to ensure: a) - b); | ☐ | ☐ | | | |
| **7.5.3.2** | For the control of documented information, the organization shall address the following activities as applicable: a) - d) | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| ISO 22000:2018 & ISO 9001: 2015 | | Conform | | Grade | If No – detail NC | NC # |
|---|---|---|---|---|---|---|
| Clause | Requirement | Yes | No | Minor/Major/ Critical | | |
| **8** | **Operation** | | | | | |
| **8.1** | Operational planning and control | ☐ | ☐ | | | |
| **8.2** | Prerequisite programs (PRPs) - (ISO22000: 2018) | ☐ | ☐ | | | |
| **8.2.1** | The organization shall establish, implement, maintain and update PRPs to facilitate the prevention and/or reduction of contaminants (incl food safety hazards) in the products, product processing and work environment | ☐ | ☐ | | | |
| **8.2.2** | The PRPs shall be: a) - d) | ☐ | ☐ | | | |
| **8.2.3** | When selecting and/or establishing PRPs, the organization shall ensure that applicable statutory, regulatory, and mutually agreed customer requirements are identified. The organization should consider: a) - b) | ☐ | ☐ | | | |
| **8.2.4** | When establishing PRPs the organization shall consider: a) - l) | ☐ | ☐ | | | |
| **8.3** | Traceability system (ISO22000: 2018) | ☐ | ☐ | | | |
| **8.4** | Emergency preparedness and response (ISO22000: 2018) | ☐ | ☐ | | | |
| **8.4.1** | General | ☐ | ☐ | | | |
| **8.4.2** | Handling of emergencies and incidents | ☐ | ☐ | | | |
| **8.5** | Hazard control (ISO22000: 2018) | ☐ | ☐ | | | |
| **8.5.1** | Preliminary steps to enable hazard analysis | ☐ | ☐ | | | |
| **8.5.1.1** | General | ☐ | ☐ | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **8.5.1.2** | Characteristics of raw materials, ingredients, and product contact materials | ☐ | ☐ | | | |
| **8.5.1.3** | Characteristics of end products | ☐ | ☐ | | | |
| **8.5.1.4** | Intended use | ☐ | ☐ | | | |
| **8.5.1.5** | Flow diagrams and description of processes | ☐ | ☐ | | | |
| **8.5.1.5.1** | Preparation of the flow diagrams | ☐ | ☐ | | | |
| **8.5.1.5.2** | On-site confirmation of the flow diagrams | ☐ | ☐ | | | |
| **8.5.1.5.3** | Description of processes and process environment | ☐ | ☐ | | | |
| **8.5.2** | Hazard analysis | ☐ | ☐ | | | |
| **8.5.2.1** | General | ☐ | ☐ | | | |
| **8.5.2.2** | Hazard identification and determination of acceptable levels | ☐ | ☐ | | | |
| **8.5.2.2.1** | The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment. The identification shall be based on: a) -e) | ☐ | ☐ | | | |
| **8.5.2.2.2** | The organization shall identify step(s) (e.g., receiving raw materials, processing, distribution, and delivery) at which each food safety hazard can be present, be introduced, increase of persist. When identifying hazards, the organization shall consider: a) - c) | ☐ | ☐ | | | |
| **8.5.2.2.3** | The organization shall determine the acceptable level in the end product of each food safety hazard identified, whenever possible. When determining acceptable levels, the organization shall: a) - c) | ☐ | ☐ | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **8.5.2.3** | Hazard assessment | ☐ | ☐ | | | |
| **8.5.2.4** | Selection and categorization of control measure(s) | ☐ | ☐ | | | |
| **8.5.2.4.1** | Based on the hazard assessment, the organization shall select an appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified significant food safety hazard to defined acceptable levels | ☐ | ☐ | | | |
| **8.5.2.4.2** | In addition, for each control measure, the systematic approach shall include an assessment of the feasibility of: a) - c) | ☐ | ☐ | | | |
| **8.5.3** | Validation of control measure(s) and combination of control measures | ☐ | ☐ | | | |
| **8.5.4** | Hazard control plan (HACCP/OPRP plan) | ☐ | ☐ | | | |
| **8.5.4.1** | General | ☐ | ☐ | | | |
| **8.5.4.2** | Determination of critical limits and action criteria | ☐ | ☐ | | | |
| **8.5.4.3** | Monitoring systems at CCPs and for OPRPs | ☐ | ☐ | | | |
| **8.5.4.4** | Actions when critical limits or action criteria are not met | ☐ | ☐ | | | |
| **8.5.4.5** | Implementation of the hazard control plan | ☐ | ☐ | | | |
| **8.6** | Updating the information specifying the PRPs and the hazard control plan (ISO22000: 2018) | ☐ | ☐ | | | |
| **8.7** | Control of monitoring and measuring (ISO22000: 2018) | ☐ | ☐ | | | |
| **8.8** | Verification related to PRPs and the hazard control plan (ISO22000: 2018) | ☐ | ☐ | | | |
| **8.8.1** | Verification | ☐ | ☐ | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **8.8.2** | Analysis of results of verification activities | ☐ | ☐ | | | |
| **8.9** | Control of product and process nonconformities (ISO22000: 2018) | ☐ | ☐ | | | |
| **8.9.1** | General | ☐ | ☐ | | | |
| **8.9.2** | Corrections | ☐ | ☐ | | | |
| **8.9.2.1** | The organization shall ensure that when critical limits at CCPs and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release | ☐ | ☐ | | | |
| **8.9.2.2** | When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products (see 8.9.4) | ☐ | ☐ | | | |
| **8.9.2.3** | Where action criteria for an OPRP are not met, the following shall be carried out: a) - c) | ☐ | ☐ | | | |
| **8.9.2.4** | Documented information shall be retained to describe corrections made on nonconforming products and processes, including a) - c) | ☐ | ☐ | | | |
| **8.9.3** | Corrective actions | ☐ | ☐ | | | |
| **8.9.4** | Handling of potentially unsafe products | ☐ | ☐ | | | |
| **8.9.4.1** | General | ☐ | ☐ | | | |
| **8.9.4.2** | Evaluation for release | ☐ | ☐ | | | |
| **8.9.4.3** | Disposition of nonconforming products | ☐ | ☐ | | | |
| **8.9.5** | Withdrawal/recall | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| ISO 22000:2018 & ISO 9001: 2015 | | Conform | | Grade | If No – detail NC | NC # |
|---|---|---|---|---|---|---|
| **Clause** | **Requirement** | **Yes** | **No** | Minor/Major/ Critical | | |
| **9** | **Performance evaluation** | | | | | |
| **9.1** | Monitoring, measuring, analysis and evaluation | ☐ | ☐ | | | |
| **9.1.1** | General | ☐ | ☐ | | | |
| **9.1.2** | Analysis and evaluation (ISO 22000: 2018) | ☐ | ☐ | | | |
| **9.2** | Internal audit | ☐ | ☐ | | | |
| **9.2.1** | The organization shall conduct internal audits at planned intervals to provide information on whether the FSMS/QMS conforms to: a) - b) | ☐ | ☐ | | | |
| **9.2.2** | The organization shall a) - g) for FSMS; a) - f) for QMS | ☐ | ☐ | | | |
| **9.3** | Management review | ☐ | ☐ | | | |
| **9.3.1** | General | ☐ | ☐ | | | |
| **9.3.2** | Management review input | ☐ | ☐ | | | |
| **9.3.3** | Management review output | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| ISO 22000:2018 & ISO 9001: 2015 | | Conform | | Grade | If No – detail NC | NC # |
|---|---|---|---|---|---|---|
| **Clause** | **Requirement** | **Yes** | **No** | Minor/Major/ Critical | | |
| **10** | **Improvement** | | | | | |
| **10.1** | Nonconformity and corrective action (ISO 22000: 2018) | ☐ | ☐ | | | |
| **10.1.1** | When a nonconformity occurs, the organization shall: a) - e) | ☐ | ☐ | | | |
| **10.1.2** | The organization shall retain documented information as evidence of: a) - b) | ☐ | ☐ | | | |
| **10.2** | Continual Improvement (ISO 22000: 2018) | ☐ | ☐ | | | |
| **10.3** | Update of the food management system (ISO 22000: 2018) | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

## 4.2 ISO 9001: 2015 SPECIFIC CLAUSES

| ISO 9001: 2015 | | Conform | | Grade | If No – detail NC | NC # |
|---|---|---|---|---|---|---|
| Clause | Requirement | Yes | No | Minor/Major/ Critical | | |
| **7** | **Support** | | | | | |
| **7.1.5** | Monitoring and measuring resources | ☐ | ☐ | | | |
| **7.1.5.1** | General | ☐ | ☐ | | | |
| **7.1.5.2** | Measurement traceability | ☐ | ☐ | | | |
| **7.1.6** | Organizational knowledge | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| ISO 9001: 2015 | | Conform | | Grade | If No – detail NC | NC # |
|---|---|---|---|---|---|---|
| Clause | Requirement | Yes | No | Minor/Major/ Critical | | |
| **8** | **Operation** | | | | | |
| **8.2** | Requirements for products and services | ☐ | ☐ | | | |
| **8.2.1** | Customer communication | ☐ | ☐ | | | |
| **8.2.2** | Determining the requirements for products and services | ☐ | ☐ | | | |
| **8.2.3** | Review the requirements for products and services | ☐ | ☐ | | | |
| **8.2.4** | Changes to the requirements for products and services | ☐ | ☐ | | | |
| **8.3** | Design and development of products and services | ☐ | ☐ | | | |
| **8.3.1** | General | ☐ | ☐ | | | |
| **8.3.2** | Design and development planning | ☐ | ☐ | | | |
| **8.3.3** | Design and development inputs | ☐ | ☐ | | | |
| **8.3.4** | Design and development controls | ☐ | ☐ | | | |
| **8.3.5** | Design and development outputs | ☐ | ☐ | | | |
| **8.3.6** | Design and development changes | ☐ | ☐ | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **8.4** | Control of externally provided processes, products, or services | ☐ | ☐ | | | |
| **8.4.1** | General | ☐ | ☐ | | | |
| **8.4.2** | Type and extent of control | ☐ | ☐ | | | |
| **8.4.3** | Information for external providers | ☐ | ☐ | | | |
| **8.5** | Production and service provision | ☐ | ☐ | | | |
| **8.5.1** | Control of production and service provision | ☐ | ☐ | | | |
| **8.5.2** | Identification and traceability | ☐ | ☐ | | | |
| **8.5.3** | Properties belonging to customers or external providers | ☐ | ☐ | | | |
| **8.5.4** | Preservation | ☐ | ☐ | | | |
| **8.5.5** | Post-delivery activities | ☐ | ☐ | | | |
| **8.5.6** | Control of changes | ☐ | ☐ | | | |
| **8.6** | Release of products and services | ☐ | ☐ | | | |
| **8.7** | Control of nonconforming outputs | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| **ISO 9001: 2015** | | **Conform** | | **Grade** | **If No – detail NC** | **NC #** |
|---|---|---|---|---|---|---|
| **Clause** | **Requirement** | **Yes** | **No** | Minor/Major/ Critical | | |
| **9** | **Performance evaluation** | | | | | |
| **9.1.2** | Customer satisfaction | ☐ | ☐ | | | |
| **9.1.3** | Analysis and evaluation | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

| **ISO 9001: 2015** | | **Conform** | | **Grade** | **If No – detail NC** | **NC #** |
|---|---|---|---|---|---|---|
| **Clause** | **Requirement** | **Yes** | **No** | Minor/Major/ Critical | | |
| | | | | | | |
| **10** | **Improvement** | | | | | |
| **10.1** | General | ☐ | ☐ | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **10.2** | Nonconformity and corrective actions | ☐ | ☐ | | | |
| **10.3** | Continual Improvement | ☐ | ☐ | | | |
| **Summary:** | | | | | | |

## 4.3 ISO/TS 22002-1:2009 (REFER ANNEX 2 FOR FULL DETAILS)

| ISO/TS 22002-1:2009 | | Conform | | | Grade | If No – detail NC<br>If N/A – provide justification | NC# |
|---|---|---|---|---|---|---|---|
| Clause | Requirement | Yes | No | N/A | Minor/major/ critical | | |
| **4** | **Construction and layout of buildings** | | | | | | |
| **4.1** | General requirements | ☐ | ☐ | ☐ | | | |
| **4.2** | Environment | ☐ | ☐ | ☐ | | | |
| **4.3** | Locations of establishments | ☐ | ☐ | ☐ | | | |
| **Summary:** | | | | | | | |

## 4.4 FSSC 22000 ADDITIONAL REQUIREMENTS (REFER ANNEX 2 FOR FULL DETAILS)

| FSSC 22000 Additional Requirement | | Conform | | | Grade | If No – detail NC<br>If N/A – provide justification | NC# |
|---|---|---|---|---|---|---|---|
| Clause | Requirement | Yes | No | N/A | Minor/major/ critical | | |
| **2.5.1** | Management of services and purchased materials | ☐ | ☐ | ☐ | | | |
| **Summary:** | | | | | | | |