FOOD SAFETY SYSTEM CERTIFICATION 22000

ANNEX 2: CB AUDIT REPORT REQUIREMENTS

INTRODUCTION

This document has been developed to ensure a high caliber of audit reporting and sets out the minimum requirements and expectations in terms of the content and the level of detail required in audit reports. CBs shall ensure that their templates meet the requirements listed in this Annex with regard to content (the layout and order of the content are at the CB's discretion). It shall:

1. Clearly demonstrate that the Scheme requirements have been addressed by the organization and meet the ISO/IEC 17021-1:2015 as well as the GFSI requirements.
2. Be used by all Integrity Program Assessors to determine whether or not CBs are complying with FSSC 22000 audit reporting requirements;
3. Be used by all CBs to train their auditors and to ensure an informed certification decision is made in support of a robust certification process;
4. Be used by all Training Organizations in their training programs for internal auditor and lead auditor courses;

ISO/IEC 17021-1:2015, clauses 9.4.8.2 and 9.4.5.1, requires: "the audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made". In addition, it also requires "audit findings (audit findings summarizing conformity and detailing nonconformity…), reference to evidence and conclusions, consistent with the requirements of the type of audit" shall be included.

GFSI Version 2020.1 Part 2 – 5.17: The Certification Program Owner shall ensure that the audit report contains evidence that all the specified requirements of the Certification Program related to the GFSI scope(s) of recognition have been evaluated during the audit and clearly express the outcome of the evaluation.

This document details the minimum audit report content that is required in the audit reports for:

1. Stage 1 audit report
2. Stage 2 audit report (see note 1)

In the case of multi-site certification, one audit report may be produced for the multi-site organization, including the Central function information, specific information about each site audited ,and complying with the content of this Annex. The summary sections of the audit report shall clearly reflect what was audited at each site with supporting objective evidence to show that the Scheme requirements were audited at each site. The minimum content of the Central functions shall include a description of the centralized functions including detail on internal audits, how this is managed and controlled by the group, and the competency of the internal auditors. The requirements referenced in the FSSC Additional requirement 2.5.14. shall be included in the Central function section of the report. Alternatively, separate reports may be produced for the Central function (similar to a head office report) including a consolidated nonconformity report and reports for each of the sites respectively, in which case the site reports shall meet the content requirements as set out in this Annex.

Note 1:   A stage 2 audit report shall be used for all audits that are not stage 1 audits, head office audits or special audits. The audit criteria shall be adjusted relevant to the type of audit conducted (for example surveillance, recertification, transition etc.).

INSTRUCTIONS

1. This document sets out the minimum requirements in each section of the audit report. For the clauses of ISO 22000, the relevant PRP/s and the additional FSSC 22000 requirements it explains the minimum content required to be documented in each section.

2. The text in blue font represents an overview of what is expected to be detailed in the audit report, it is not intended to be an exhaustive list and the auditor(s) need to demonstrate that all requirements of the clause(s) have been assessed supported by objective evidence and suitable audit trails.

3. Checklists – summary section per clause shall contain:

   a) An overview of the section including evidence assessed to demonstrate compliance or non-compliance to the clauses in the section.

   b) Checklist summaries shall be sufficiently detailed to allow insight and an overview and not be oversimplified, or just indicate "conformance with the requirements was noted" or any other vague descriptions of similar effect.

4. Nonconformities are not to be reported against more than one clause within FSSC 22000 V5:

   a) The nonconformity shall always be written to the most specific clause and not be grouped unless a systemic issue is identified, in which case the expectation is that in most cases the NC is raised to a higher grade i.e. a major.

   b) Nonconformities shall reference the objective evidence to justify the nonconformity and clearly identify why the requirement is not being met.

5. Where Design and Development is permitted to be added in the scope of the certificate (and where it is not an FSSC 22000-Quality certificate) as per the requirements of Annex 1, section 3, then particular attention shall be paid to documenting what was audited, including the interface of the process with the FSMS. This includes detailing the design and development process in the audit plan, the audit program and the audit report.

6. Where ICT is used during an audit, the details of the type of ICT used and which clauses/departments were audited using ICT must be clearly indicated in the audit report and the audit plan and meet the requirements in Annex 9.

7. CBs are required to issue the full audit report to clients for all certification audits including surveillance audits. The full audit report consists of the audit checklists for ISO 22000:2018, the relevant PRP standard/s and the additional FSSC 22000 requirements, the content of which meets the requirements of this Annex.

8. Annexes provided to the client shall include the audit plan, the audit program and the attendance register.

9. All information in the audit report template shall be uploaded into the Portal along with attachments in PDF (final audit report, checklists, audit plan, audit program and attendance register). Where nonconformity reports are separate to the audit report these shall be zipped

with the audit report to facilitate uploading into the Portal. The audit report details and nonconformity details in the portal are required to be uploaded in English.

Notes:

1) This Annex is designed for Food manufacturing audits and the ISO/TS 22002-1:2009 PRP is used here. It applies to Food Chain Categories C, K and DII.
2) For Food Chain Categories A, DI, E, FI, G or I the CB shall substitute the relevant PRP checklist. The level of detail in the summary sections shall be aligned with what is reflected in this Annex, even though the content will vary.
3) In all cases, verify the latest BoS decision list available on the FSSC website to ensure all audit requirements are covered and reflected in the audit report.
4) Audit attachments: when uploading scans of documents, these must be legible and of good quality.

REVISION HISTORY

Date Published	Issue	Changes
November 2020	1	First publication of V5.1
October 2022	2	Updated the summary section for the FSSC 22000 Additional Requirement 2.5.7 on Environmental Monitoring to remove reference to allergens.

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 as a business registration number)
Location/Address	Full address (or other unique identification of site location (i.e. GP,S, GLN etc. where a postal address is not available)
Contact person	Name & function
General description of audited organization	Brief history of the company, for example how long in business, purpose built/prior use, main markets (local/international) 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 **No marketing jargon**
Overview of seasonal activities	Describe when various seasonal activities are conducted per scope. For example: • Processing of stone fruit September - October • Processing of vegetables March - October 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. 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: a) Off-site storage b) Off-site manufacturing 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, the specific PRP standard/s and the FSSC additional requirements (Version 5.1);

	Defined processes and documentation of the management system of the organization;
	Legal and regulatory requirements and customer requirements
Audit Delivery	*ICT Audit Approach / On-site
	*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
	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)
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

FSSC 22000

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 clients FSMS, 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. Short list of principle processes/activities and key equipment used.
Organizational planning and control **Status with regard to:** a) Key performance b) Processes c) Objectives d) Operation of management system	ISO 22000 clauses 4, 5, 6, 7 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 Provide an overview of the HACCP system, by including a summary of: • Significant food safety hazards identified and their type, • Methodologies used to conduct the hazard assessment and the selection and categorization of control measures (OPRP and CCP), • Overview of OPRP and CCP including their critical control limits, monitoring systems and corrective actions for breach of critical limits, • Validation process implementation and results, • Verification activities implementation status, • General description of level of implementation of hazard control plan.
Internal Audit	ISO 22000 clause 9 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 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). 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. **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: • Processing of stone fruit September - October • 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: a) Off-site storage b) Off-site manufacturing 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, the specific PRP standard/s and the FSSC additional requirements (Version 5.1);
	Defined processes and documentation of the management system of the organization;
	Legal and regulatory requirements and customer requirements
Audit type	Stage 2, surveillance, transition, recertification
Announced/Unannounced	
Audit complexity	Standalone FSSC 22000 audit
	Combined/Integrated with another standard
	Provide details:
Audit delivery	ICT Audit approach/Full On-site/Full remote audit
	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)
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.
	Provide a statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to:
	a) The capability of the management system to meet applicable requirements, food safety objectives and expected outcomes;
	b) 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) c) Significant food safety issues that senior management need to be aware of (major/critical findings; trends in recalls etc.) d) The internal audit and management review process; e) Detail outcome of previous audit results f) For recertification audit – indicate how the FSMS has evolved over the three-year cycle The 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
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 Provide detailed objective evidence 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: Initial audit T_s + T_{fssc} = 3.75 man days Surveillance audit = 1.5 man days Recertification audit = 3 days			
Audit time reduction	Justify any reductions given to Ts			
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 22000:2018		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 management system	☐	☐			
4.4	Food safety management system	☐	☐			

Summary:

Provide an overview of the context of the organization including internal and external, positive and negative factors (risks and opportunities) that impact the ability of the FSMS in achieving its intended results and how this aligns with continual improvement of the FSMS. This section can be cross-referenced with ISO 22000:2018 clause 6.1.2. What mechanisms are in place to stay up to date and meet relevant statutory, regulatory and customer requirements relating to food safety. Summarize the status of any governmental or regulatory inspection findings where relevant and include any significant changes to legislation which impacts the FSMS and whether the site has effectively adopted the changes.

ISO 22000:2018		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 policy	☐	☐			
5.2.2	Communicating the food safety 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	☐	☐			
5.3.2	The food safety team leader shall be responsible for: a) - d)	☐	☐			
5.3.3	All persons shall have responsibility to report problem(s) with regards to the FSMS to identified person(s)	☐	☐			

Summary:

Provide an overview including objective evidence assessed:

a) Demonstrate the leadership and commitment of top management with respect to the FSMS, including evidence that the food safety policy and objectives have been established by top management and are compatible with the strategic direction of the organization and have been integrated into the FSMS;

b) Overview of resources available to maintain the FSMS and are being supported by top management; responsibilities and authority for relevant roles have been established and communicated including responsibility for the FSMS, the food safety team and the FS team leader (incl. job description for food safety team leader meets requirements) and that the food safety team is multidisciplinary and has the right persons/expertise with brief overview of disciplines/areas covered;

c) Detail what mechanisms are in place to ensure communication within the organization and to interested parties is effective. Detail reporting mechanisms of team to top management and how all staff can report food safety issues. How does the organization make the policy relevant to each individual worker – linked to food safety culture;

d) Food safety culture: provide an overview of how food safety culture is addressed within the organization with specific reference to communication, training, employee feedback and engagement and performance measurement of defined activities covering all sections of the organization impacting on food safety

e) How continual improvement is promoted within the organization

The summary shall include an overview of what was covered during the interview with top management, including who was interviewed.

ISO 22000:2018		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 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)	☐	☐			
6.2	Objectives of the food safety management system and planning to achieve them	☐	☐			
6.2.1	The organization shall establish objectives for the FSMS at relevant functions and levels. The objectives of the FSMS shall: a) - f)	☐	☐			
6.2.2	When planning how to achieve its objectives for the FSMS, the organization shall determine: a) - e)	☐	☐			
6.3	Planning of changes	☐	☐			

Summary:

Provide an overview of how risks and opportunities are identified and addressed (including actions) relating to the performance and effectiveness of the FSMS and how the effectiveness of the actions will be evaluated

That objectives have been established and are SMART; describing the monitoring and review process and communication process (internal and external) with examples to illustrate

How changes within the FSMS are dealt with including PDCA principles. Describe findings related to changes (e.g. compared to previous audit, to FSMS, etc.) and the effect on the operational FSMS.

ISO 22000:2018		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	☐	☐			
7.1.6	Control of externally provided processes, products or services	☐	☐			
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 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:

Provide an overview including objective evidence assessed:

Resources; Competence & Awareness

Provide an overview including defined and documented competence requirements are available for all levels of the organization.   For external experts, details of requirements, competency, and scope of work (may be identified in contract). Training requirements for these individuals are identified and records of completion available including communication of the requirements in 7.3.

Control of externally provided processes, products or services

Detail which externally provided elements, processes, products or services are present. How is the impact on food safety assessed, criteria for control (selection, evaluation, monitoring and re-evaluation) determined, communication managed, and effectiveness verified?   Provide evidence that the organization has a procedure for procurement in emergency situations to ensure that products still conform to specified requirements and the supplier has been evaluated. Detail if any instance of emergency use of non-approved suppliers has occurred (date, supplier, material) and confirm if procedure was followed effectively.

Internal and External Communication

Detail the mechanisms for internal and external communication and how the effectiveness of communication is measured and reinforced.

Documented information

Provide an overview of the document control system, including creating, updating, storage and retention of documents (internal and external) and records; back-up systems for electronic systems.

ISO 22000:2018		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)	☐	☐			
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	☐	☐			
8.4	Emergency preparedness and response	☐	☐			
8.4.1	General	☐	☐			
8.4.2	Handling of emergencies and incidents	☐	☐			
8.5	Hazard control	☐	☐			
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	☐	☐			
8.7	Control of monitoring and measuring	☐	☐			
8.8	Verification related to PRPs and the hazard control plan	☐	☐			
8.8.1	Verification	☐	☐			
8.8.2	Analysis of results of verification activities	☐	☐			
8.9	Control of product and process nonconformities	☐	☐			
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:

Provide an overview of <u>*Operational planning and control*</u> *including how actions determined in 6.1 are addressed, including any subcontracted or outsourced processes. Do not list out individual PRP documents – make reference that details are reflected in the relevant PRP checklist (ISO/TS 22002-x as applicable). Comment on the effectiveness of the implementation of PRP's across the site in a general sense.*

<u>*Traceability System:*</u> *Define how the organization ensures traceability (one up- one down principle) and that it meets any relevant legislative and customer requirements. Reference the frequency of traceability testing (incl. mass balance) and when the last test was conducted and which product. Conduct a traceability exercise and report results (detail product tested, speed of completion by organization, outcome of test/mass balance). Where the organization undertakes rework, define how traceability is maintained.*

<u>*Emergency preparedness and response:*</u> *Detail the document that addresses potential emergency situations, including the requirement to report situations where there is an impact on food safety and/or the FSSC 22000 certificate. Detail if there have been any emergency situations since the last audit, how the organization handled these, and whether requirements were met. Where applicable, indicate if the CB was informed of the emergency situation. Document the date, nature and outcome of the periodic test (minimum once per annum test) and any changes to the procedures following the occurrence of any incident, emergency situations or tests. Is there a procedure for contingency planning in place including for example for disruption of water, electricity of refrigeration supply?*

<u>*Hazard control:*</u> *Brief overview of preliminary information collected, how it is maintained and updated, including intended use and vulnerable groups. Reference the flowcharts, indicate when the flowcharts were*

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last updated and if they have been revised following changes to the process. Reference flowchart/s verified during audit and whether the requirement has been met.

Describe the type of hazards (chemical, physical, microbiological, allergens), the methodology used to assess significant hazards, control measures and determining OPRPs and CCPs. Confirm that all CCPs and OPRPs have been validated and the effectiveness there-of. Document OPRPs & CCP's: what are they, control limits, monitoring and corrective actions in case of breach. Provide supporting information on records checked as part of the audit.

Where packaging is used to impart or provide a functional effect on food (e.g. shelf life extension) the organization has specified requirements in place.

HACCP review – detail process and when last update was made and how this ties back to the management review?

Control of product and process nonconformities: Where critical limits or action criteria have not been met, detail if the procedure followed and if effectiveness of corrective actions was verified. Document examples

Detail how the organization prevents potentially unsafe products from entering the food chain and positive release procedure. Indicate samples of nonconforming products and the actions taken based on records reviewed. Establish whether an effective recall system has been implemented and shall include the details of the last mock recall conducted and the effectiveness thereof. Document any actual withdrawals/recalls since last audit, the outcome and how this was reviewed, and any amendments made as a result of the recall/withdrawal. Further details on recalls in ISO/TS22002-1: clause 15.

ISO 22000:2018		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	☐	☐			
9.2	Internal audit	☐	☐			
9.2.1	The organization shall conduct internal audits at planned intervals to provide information on whether the FSMS conforms to: a) - b)	☐	☐			
9.2.2	The organization shall a) - g)	☐	☐			
9.3	Management review	☐	☐			
9.3.1	General	☐	☐			
9.3.2	Management review input	☐	☐			
9.3.3	Management review output	☐	☐			

Summary:

Monitoring, measuring, analysis and evaluation: Detail what is monitored/measured and whether the requirements of 9.1 are met in support of the evaluation and performance of the FSMS. Provide an overview of the analysis of information from the monitoring and measuring activities, including the results and trends of verification activities related to PRPs, the Hazard control plan and internal and external audits.

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Confirmation that analysis achieves 9.1.2 a-e and are used as an input for management review and updating the FSMS.

Internal audit: Provide an overview of the internal audit program, including frequency, competency and impartiality of internal auditors and how corrective actions are dealt with. The audit report shall confirm that the frequency of internal audits is based on risk (importance of the processes concerned, changes in the FSMS, and the results of monitoring, measurement) and the results of previous audit findings. Indicate whether the audit schedule includes all aspects of FSSC 22000 (ISO 22000, PRP's, FSSC 22000 part 2 and BoS decisions as applicable) and is sufficiently reflected in the audit program and the internal audit reports. Indicate status of audits (link to improvement) and escalation mechanisms should NCs not be addressed or audit program falls behind.

*Management review: Provide an overview of the management review process and its effectiveness including frequency of meetings and participation of senior management (goes to leadership). Reference any significant issues raised at the management review (internal/external risks/opportunities, and significant changes planned/occurred) and whether th*e organization is effectively handling these issues. *Provide an overview of the output of the management review and any changes to the FSMS, Food Safety Policy, and/or objectives, and any resource requirements. Indicate whether all aspects (inputs and outputs) of this clause are addressed in the agenda and minutes and suitable actions have been taken to ensure continual improvement and maintenance of the FSMS and the FSSC 22000 scheme. Detail the date of the last Management Review and if minutes are available that address the requirements of 9.3.2 and 9.3.3*

ISO 22000:2018		Conform		Grade	If No – detail NC	NC#
Clause	**Requirement**	**Yes**	**No**	Minor/Maj or/Critical		
10	**Improvement**					
10.1	Nonconformity and corrective action	☐	☐			
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	☐	☐			
10.3	Update of the food management system	☐	☐			

Summary:

Provide an overview of the nonconformity and corrective action system, including customer complaints. How corrective actions are reviewed for effective implementation including identification of trends, root cause analysis and elimination of the cause of the NC to prevent reoccurrence.

Describe mechanisms or actions taken by management to ensure continual improvement relating to the suitability, adequacy and effectiveness of the FSMS. Updating the FSMS – confirm that FSMS is continually updated and how this is monitored and achieved taking into consideration the requirements in 10.3.

4.2 ISO/TS 22002-1:2009

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

Summary:

General Requirements: Describe types of buildings (i.e. production, offices, storage, workshops, warehousing etc.) and their construction materials, state of repair and any updates or changes.

Environment: Describe what activities take place in adjacent areas to the site (i.e. industrial units, open paddocks etc.), and whether risks have been considered. Detail the last review date and outcome of the effectiveness of measures to protect against potential contamination.

Location of establishment: Describe site boundaries (fencing, adjacent buildings etc.) Access details can be referred to clause 18.2 of the Food PRP to avoid duplication. Comment on general maintenance of site.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	Minor/major/ critical	If N/A – provide justification	
5	**Layout of premises and workspace**						
5.1	General requirements	☐	☐	☐			
5.2	Internal design, layout and traffic patterns	☐	☐	☐			
5.3	Internal structures and fittings	☐	☐	☐			
5.4	Location of equipment	☐	☐	☐			
5.5	Laboratory facilities	☐	☐	☐			
5.6	Temporary or mobile premises and vending machines	☐	☐	☐			
5.7	Storage of food, packaging materials, ingredients and non-food chemicals	☐	☐	☐			

Summary:

Comment on adequacy of design, layout, equipment and traffic patterns with respect to impact on food safety, including facilitating cleaning and maintenance activities. Zoning, materials and human flow patterns mapped.

Overview of air filtration system, maintenance of floors, walls, ceilings etc. Indicate if there is standing water (i.e. drains not sufficient) and risk to product from potential broken windows (glass, dust, insects etc.) and roof vents/fans etc.

Where Laboratory facilities are present on the site, document location and if micro/chemical testing conducted and risks controlled. Detail how in-line/on-line testing facilities are controlled.

Where there are any temporary or mobile structures, vending machines used, detail how the hazards are assessed and controlled.

Provide an overview of the storage of food, packaging materials, ingredients on non-food chemicals and how the organization meets the requirements. If wooden pallets are used how are they treated to prevent insect infestation and/or chemical leaching.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
6	**Utilities – air, water, energy**						
6.1	General requirements	☐	☐	☐			
6.2	Water supply	☐	☐	☐			
6.3	Boiler chemicals	☐	☐	☐			
6.4	Air quality and ventilation	☐	☐	☐			
6.5	Compressed air and other gases	☐	☐	☐			
6.6	Lighting	☐	☐	☐			

Summary:

Detail how the organization monitors the quality of utilities to minimize product contamination risk.

Water supply: Detail the type (potable, non-potable) water types, their use and their source (i.e. municipal, bore water, in-house treated water plants). Indicate if specifications for water (various uses) are defined and if water meets specifications (type of testing, frequency, results) and any legislative requirements that might apply. Detail examples of records looked at.

Where Boiler chemicals are used, provide information on approval for use, storage, security measures and any areas of concern where steam comes in direct contact with product. Identify who is responsible for the addition of these chemicals.

Air quality and ventilation: Detail if air is used as an ingredient or is in direct product contact, how the organization ensures such air meets requirements (testing, specifications, quality monitoring program etc. document records reviewed). Detail records of maintenance of air systems including air filter replacement program. Provide overview of compressed air and other gasses if used (type, purpose etc.) If used, and is in contact with product, equipment etc. detail approved sources, use, and if filtered.

Comment if there are sufficient lighting in all areas (production, storage etc.) to facilitate hygienic operations; if light fixtures are suitably protected and where UV lights are in use.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
7	**Waste disposal**						
7.1	General requirements	☐	☐	☐			

7.2	Containers for waste and inedible or hazardous substances	☐	☐	☐			
7.3	Waste management and removal	☐	☐	☐			
7.4	Drains and drainage	☐	☐	☐			

Summary:

Provide an overview of the waste management system in place and if any hazardous substances have to be removed, how this is managed and controlled including destruction/removal.

Where trademarked materials are discarded or destroyed how the risk of re-use is being managed. Verify contract with waste removal company.

Drains – are suitable and appropriate for the size of the premises, including reference to cleaning and maintenance.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	Minor/major/ critical	If N/A – provide justification	
8	**Equipment suitability, cleaning and maintenance**						
8.1	General requirements	☐	☐	☐			
8.2	Hygienic design	☐	☐	☐			
8.3	Product contact surfaces	☐	☐	☐			
8.4	Temperature control and monitoring equipment	☐	☐	☐			
8.5	Cleaning plant, utensils and equipment	☐	☐	☐			
8.6	Preventive and corrective maintenance	☐	☐	☐			

Summary:

Provide a general overview on suitability of equipment, product contact surfaces and hygienic design requirements including the general condition of equipment.

Where temperature control and monitoring equipment are in use, comment on thermal process equipment regarding type, monitoring and temperature control measures, also in terms of meeting product specifications (temp gradient and holding conditions).

Detail the plant, utensil and equipment cleaning frequencies (refer to procedure/cleaning schedule, suitability of cleaning equipment etc.).

Provide an overview of the preventive and corrective maintenance program, including how corrective maintenance is carried out and temporary fixes are addressed. Indicate if lubricants are used and if they are food grade.

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ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	Minor/major/ critical	**If N/A – provide justification**	
9	**Management of purchased materials**						
9.1	General requirements	☐	☐	☐			
9.2	Selection and management of suppliers	☐	☐	☐			
9.3	Incoming material requirements (raw/ingredients/packaging)	☐	☐	☐			

Summary:

Provide an overview of the supplier approval program and how this is controlled, monitored and reviewed to ensure suppliers meet the specified requirements. Describe mechanisms for dealing with emergency use of non-approved suppliers, how this is evaluated and controlled including responsibilities. Detail if any instance of emergency use of non-approved suppliers has occurred (date, supplier, material) and confirm if procedure was followed effectively.

Food chain category CI only: verify procedure for suppliers of animals, fish and seafood which are subject to control of prohibited substances (e.g. pharmaceuticals, veterinary medicines, heavy metals and pesticides).

Has requirements for incoming materials been established including incoming inspection requirements and frequency and how to deal with non-compliances (including dealing with and identification of products on hold or rejected). Where bulk receiving lines are present, these shall be identified, capped and locked and approval/discharge systems in place.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	Minor/major/ critical	**If N/A – provide justification**	
10	**Measures for prevention of cross contamination**						
10.1	General requirements	☐	☐	☐			
10.2	Microbiological cross contamination	☐	☐	☐			
10.3	Allergen management	☐	☐	☐			
10.4	Physical contamination	☐	☐	☐			

Summary:

Provide an overview of the programs in place to prevent, control and detect contamination, including measures to prevent physical, allergen and microbiological contamination. Describe separation measures taken, zoning, access controls and traffic patterns as applicable and how rework is addressed, specifically as part of allergen management.

Food chain category CI only: detail if specified requirements are in place for an inspection process at lairage and/or at evisceration to ensure animals are fit for human consumption.

Allergens: Detail if there are allergens in the product(s) and which ones are present, if there are none indicate such. Reference specific training including allergen awareness training. Where allergen

declarations are made (on label or accompanying documentation), are these verified and validated and meeting any specific legislative/customer requirements?

**Reference may be made to the FSSC additional requirements for allergen management to avoid duplication.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
11	**Cleaning and sanitizing**						
11.1	General requirements	☐	☐	☐			
11.2	Cleaning and sanitizing agents and tools	☐	☐	☐			
11.3	Cleaning and sanitizing programs						
11.4	Cleaning in place (CIP) systems	☐	☐	☐			
11.5	Monitoring sanitation effectiveness	☐	☐	☐			

Summary:

Provide an overview of the cleaning and sanitation procedure/program, including whether it is suitable/appropriate to the relevant processes (incl. cleaning agents and tools), what validation of methods has been conducted and monitoring the effectiveness of cleaning.

Where CIP systems are used, provide detail on the CIP program including parameters and monitoring measures and requirements. Confirm lines are separated from active product lines.

Detail records reviewed to demonstrate parameters are met.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
12	**Pest Control**						
12.1	General requirements	☐	☐	☐			
12.2	Pest control programs	☐	☐	☐			
12.3	Preventing access	☐	☐	☐			
12.4	Harborage and infestations	☐	☐	☐			
12.5	Monitoring and detection	☐	☐	☐			
12.6	Eradication	☐	☐	☐			

Summary:

Describe pest control program and how it covers the requirements of this section. Reference the pest control contract when external companies are being used, licensing of operators, approved chemicals used, monitoring frequency and how follow up actions are monitored and implemented – also referencing where eradication has been required. Detail any trends identified in pest activity and how this was addressed.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
13	**Personnel hygiene and employee facilities**						
13.1	General requirements	☐	☐	☐			
13.2	Personnel hygiene facilities and toilets	☐	☐	☐			
13.3	Staff canteens and designated eating areas	☐	☐	☐			
13.4	Workwear and protective clothing	☐	☐	☐			
13.5	Health status	☐	☐	☐			
13.6	Illness and injuries	☐	☐	☐			
13.7	Personal cleanliness	☐	☐	☐			
13.8	Personal behavior	☐	☐	☐			

Summary:

Detail the procedure on personal hygiene for employees, visitors and contractors and how this is implemented and managed.

Comment on level of implementation and personal behavior of employees, also linked to internal communication of the procedures/policies.

Comment on the number and location of hygiene facilities and toilets, and whether they meet requirements. Where there is a staff canteen on site, detail how hygienic conditions are maintained, where cooking/holding temperatures/time limitations etc. are specified and storage facilities for food brought on site.

Workwear and protective clothing - detail type of work clothing used and how it is used/maintained, specific requirements for different zones i.e. high-risk areas where relevant and glove management as appropriate.

Health status – describe the company system used and how illness and injuries are managed.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
14	**Rework**						
14.1	General requirements	☐	☐	☐			
14.2	Storage, identification and traceability	☐	☐	☐			
14.3	Rework usage	☐	☐	☐			

Summary:

Where an organization has rework, detail how these requirements are met in terms of storage, identification, traceability and how rework is recorded when used, detail records reviewed and indicate if specifications for rework use are followed.

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ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC #
Clause	**Requirement**	**Yes**	**No**	**N/A**	Minor/major/ critical	**If N/A – provide justification**	
15	**Product Recall Procedures**						
15.1	General requirements	☐	☐	☐			
15.2	Product recall requirements	☐	☐	☐			

Summary:

Describe the process/procedure the organization has to manage a recall situation. Detail when the last mock recall was completed, the outcome and if any improvements were required. Where an actual recall occurred, provide details and actions taken.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	Minor/major/ critical	**If N/A – provide justification**	
16	**Warehousing**						
16.1	General requirements	☐	☐	☐			
16.2	Warehousing requirements	☐	☐	☐			
16.3	Vehicles, conveyances and containers	☐	☐	☐			

Summary:

Provide an overview of warehousing activities on the site and how requirements in the standard are met, including FIFO, FEFO, temperature & humidity requirements and any specific product or storage requirements. Where controlled atmosphere is used, how it is monitored (testing, frequency, records etc.)

Detail areas for waste materials, chemicals and nonconforming materials if not covered in cl 7.3, 5.7 and 14.2

Food chain category CI only: detail if specified requirements are in place that define post-slaughter time and temperature in relation with chilling or freezing of the products.

Vehicles, conveyances and containers: summary and extent to which these are used, how it is managed and maintained, including control over contracted vehicles, and specific temperature and/or humidity requirements.

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC#
Clause	**Requirement**	**Yes**	**No**	**N/A**	Minor/major/ critical	**If N/A – provide justification**	
17	**Product information/consumer awareness**						
17.1	Product information and consumer awareness	☐	☐	☐			

Summary:

Detail process of label approval that covers required information (customer and legislative requirements).

Document the sample(s) reviewed and report on conformance to requirements (labels, packaging etc. as well as website information).

ISO/TS 22002-1:2009		Conform			Grade	If No – detail NC	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
18	**Food defense, biovigilance and bioterrorism**						
18.1	General requirements	☐	☐	☐			
18.2	Access controls	☐	☐	☐			
Summary: *Food defense: can refer to Additional FSSC 22000 requirements to reduce duplication in report* *Access controls: Provide an overview of access control measures, site security and any reported breaches*							

4.3 FSSC 22000 ADDITIONAL REQUIREMENTS

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
2.5.1	Management of services and purchased materials	☐	☐	☐			
Summary: *Detail which testing is being conducted by external or internal laboratories, which laboratories are used for verification/validation of food safety elements, and how they are competent and have the capability to conduct the analysis (i.e. ISO17025). Where a laboratory does not have ISO 17025, document how they meet the competency/capability requirements e.g. proficiency testing programs, regulatory approved programs.* *Describe the process followed in the case of procurement under emergency situations to ensure that products still conform to specified requirements and the supplier has been evaluated, including reference to the documented procedure. Provide details where emergency suppliers were used since the previous audit.* *Where animals, fish and seafood are procured that are subject to control of prohibited substances (e.g. pharmaceuticals, veterinary medicines, heavy metals and pesticides), describe how the organization has included this in their supplier approval process and the controls established;* *Provide an overview of the review process for product specifications to ensure continued compliance with food safety, legal and customer requirements with examples.*							
FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical	If N/A – provide justification	
2.5.2	Product Labelling	☐	☐	☐			
Summary: *Detail site relevant legislation for final product labelling in the country of intended sale. Provide an overview of the system followed to ensure correct and accurate labelling, meeting both legislative and customer requirements and requirements around allergen labelling where applicable. Document which*							

product labels were reviewed and whether the samples meet requirements. In the case of bulk or unlabeled product – describe the labelling process or method of communication on product information to ensure the safe use of the food by the customer or consumer.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.3	Food Defense	☐	☐	☐			
2.5.3.1	Threat Assessment	☐	☐	☐			
2.5.3.2	Plan	☐	☐	☐			

Summary:

Reference procedure that addresses this requirement and detail:

   a) *Confirmation that threat assessment has been conducted and relevant threats addressed - both internal and external threats and control measures are suitable/sufficient.*
   b) *The significant threats identified, as well as the mitigation measures implemented.*
   c) *The potential Food Defense Acts (can refer to PRP clause 18 to avoid duplication), for the supply chain and if company complies with applicable legislation (to be kept up to date)*
   d) *Training and communication strategy for employees and site security measures*

Statement on effectiveness of implementation of Food Defense Plan, that it is supported by the organization's FSMS and how kept up to date.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.4	Food Fraud Mitigation	☐	☐	☐			
2.5.4.1	Vulnerability Assessment	☐	☐	☐			
2.5.4.2	Plan	☐	☐	☐			

Summary:

Reference procedure that addresses this requirement. Detail

   a) *Confirmation that food fraud threat assessment has been conducted, breadth of assessment (supply chain and not only at site level) and relevant threats addressed, and control measures are suitable/sufficient.*
   b) *The significant vulnerabilities, as well as the mitigation measures implemented.*
   c) *Any relevant legislation and the organization's conformance to it. If there are no legislative requirements, then note this fact*
   d) *Detail training and communication strategy for employees*

Statement on effectiveness of implementation of Food Fraud Plan and that it is included in the performance evaluation of the FSMS.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.5	Logo use	☐	☐	☐			

Summary:

Where the logo is used, document how/where it is used and confirm it is used correctly.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.6	Management of allergens (Food Chain Categories C, E, FI, G, I & K)	☐	☐	☐			

Summary:

Reference allergen management plan and detail which allergens are present. Confirm that the allergen risk assessment covers all potential sources, including cross contamination.

Detail measures used to prevent cross-contamination including storage, production and potential cross contamination and training of personnel. Where there are allergens on site that are out of scope, detail type and whether the HACCP study incorporates these potential risks and cross contamination are controlled.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.7	Environmental monitoring (Food Chain Categories C, I & K)	☐	☐	☐			

Summary:

Provide evidence that the organization has implemented a risk-based environmental monitoring program supported by a documented procedure for the evaluation of the effectiveness of all controls on preventing contamination from the manufacturing environment.

The environmental monitoring program shall include as a minimum, the evaluation of microbiological ~~and allergen~~ controls present and provide evidence that the organization collects and analyses data of the monitoring activities including regular trend analysis. Describe what monitoring activities are undertaken (microbiological ~~and allergen~~), frequency, general overview of results of testing (trend analysis etc.) and corrective actions or adjustments to the program as needed. Detail if the monitoring is conducted in-house or externally

This is not a section on cleaning - this is already covered in PRP clause 11

FSSC 22000

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.8	Formulation of products (Food Chain Category D)	☐	☐	☐			

Summary:

Reference the procedure that addresses this requirement. Provide an overview of the formulated products and the relevant customer and legislative requirements. Detail which ingredients are used that can have adverse animal health impacts, and how these are controlled.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.9	Transport and delivery (Food Chain Category FI)	☐	☐	☐			

Summary:

Provide an overview of the transport and delivery services involved. Detail conditions/systems that are aimed at minimizing potential contamination during transport and delivery.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.10	Storage and warehousing (all Food Chain Categories)	☐	☐	☐			

Summary:

a) Provide an overview of the specified stock rotation system that includes FEFO principles in conjunction with the FIFO requirements.

b) Where slaughtering is applicable and relevant, what controls are in place linked to post-slaughter time and temperature in relation with chilling or freezing of the products?

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.11	Hazard control and measures for preventing cross-contamination (Food Chain Category C & I)	☐	☐	☐			

FSSC 22000

Summary:

a) Where packaging is used to impart or provide a functional effect on food (e.g. shelf life extension), detail what packaging are being used and whether this has been assessed as part of the hazard analysis. Reference applicable measures taken where applicable.

b) Provide an overview of the inspection process at lairage and/or at evisceration to ensure animals are fit for human consumption where applicable.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.12	PRP Verification (Food Chain Categories C, D, G, I & K)	☐	☐	☐			

Summary:

Provide an overview of the site inspections/PRP checks conducted to verify that the site (internal and external), production environment and processing equipment are maintained in a suitable condition to ensure food safety, including the frequency and how findings are addressed.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.13	Product Development (Food Chain Categories C, D, E, F, I & K)	☐	☐	☐			

Summary:

Where product development is applicable, provide an overview of the process to incorporate new products and changes into the product or manufacturing processes.

This shall cover any potential hazards introduced (update to hazard analysis), impact on the process, equipment and maintenance and any shelf-life and production trials conducted. Reference any new product developments since the previous audit.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.14	Health Status (Food Chain Category D)	☐	☐	☐			

Summary:

Provide an overview of the procedure the organization has in place to monitor the health status of employees, the process for visitors and contractors and if any restrictions apply, including legislative requirements/restrictions.

FSSC 22000 Additional Requirement		Conform			Grade	If No – detail NC If N/A – provide justification	NC#
Clause	Requirement	Yes	No	N/A	Minor/major/ critical		
2.5.15	Requirements for Organizations with Multi-site Certification (Food Chain Category A, E, FI & G)	☐	☐	☐			
2.5.15.1	Central Functions	☐	☐	☐			
2.5.15.2	Internal Audit Requirements	☐	☐	☐			

Summary:

Centralized Function:

Provide an overview of the central function and how commitment to the food safety system is managed and ensured across all the sites. Describe how roles and responsibilities have been defined for key roles and that sufficient resources are available to manage the FSMS.

Internal Audits:

Provide an overview of the internal audit program, confirmation that all sites, the central function and FSMS have been included and audited prior to the audit. How are nonconformities addressed and are there any escalation mechanisms in place? Are sufficient number of internal auditors available to cover the number of sites and do they meet the internal auditor requirements? Provide examples of competency records checked. Describe the technical review process and whether the technical reviewers meet the competency requirements. How is performance monitoring and calibration of internal auditors and technical reviewers managed?