FSSC Development Program

FSSC DEVELOPMENT PROGRAM

GUIDANCE DOCUMENT

PACKAGING MANUFACTURING (I)

www.fssc.com

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REVISION HISTORY

Date Published	Issue	Changes
April 2026	1	First publication

1. PURPOSE

This document provides guidance for FSSC Development Program (conforming) organizations on how to implement the Program requirements for their specific sector. This is a voluntary document that aims to provide practical information, clarifications and support to organizations and are therefore not mandatory for use.

2. INTRODUCTION

The FSSC Development Program is a food safety system assessment program designed for organizations to demonstrate the conformance of their food safety system.

The Program is owned by the not-for-profit organization, Foundation FSSC, that has an independent governance structure.

The Program was developed taking into account requirements and elements from the Codex HACCP standard and ISO 22000, including the relevant technical specifications for the applicable sector. The structure of the Program document aligns with that of the FSSC 22000 Scheme.

What is the purpose of the FSSC Development Program and why is it needed?

- With a growing world population, there is an increasing need for affordable and safe food products. To fulfil this need, Foundation FSSC offers the FSSC Development Program, which fits the needs of small and medium-sized enterprises (SMEs) in the food supply chain and their customers to achieve a conforming food safety system.
- Organizations that conform to the FSSC Development Program requirements have the added benefit of being listed on the FSSC website which increases transparency and safety throughout the food supply chain.
- Integrating the FSSC Development Program in vendor or supplier assurance programs also further supports larger food organizations in contributing to the food safety of their SME suppliers.

The sectors covered within the scope of the FSSC Development Program include:

- Food and feed manufacturing
- Catering and food service
- Production of Food/Feed Packaging and packaging materials
- Retail, wholesale and E-commerce, and
- Transport and storage

It can benefit both ingredient manufacturers that supply to other food/feed manufacturers and those that supply to retailers and food service organizations.

The Program is ideal for organizations that are not yet familiar or ready for full food safety management system certification. The Program requirements are therefore more specifically detailed to aid in the implementation process. Organizations can start by implementing an effective food safety system according to the requirements of this Program and then build on it until the system meets the full requirements of the FSSC 22000 Scheme for food safety management system certification.

The assessment requirement documents established per sector lays out an easy-to-use solution for organizations when developing their food safety system. Sector specific self-assessment templates are also available in order for organizations to assess themselves against the requirements of the Program.

3. SCOPE

This FSSC Development Program Guidance Document is meant as a guideline for the Packaging Manufacturing (Category I) sector, to provide practical information and guidance on implementing the FSSC Development Program Sector Assessment Requirements.

4. SECTOR ASSESSMENT REQUIREMENTS: PACKAGING MANUFACTURING (FCC I)

Sector requirements are normative and defined in the assessment requirements of the Program as set out in Part 1, Table 1. Based on the scope of the organization, the relevant sector requirements are determined against which an organization will be assessed. Refer to Part 2 of the Program document and the related Sector Assessment Requirements document(s) on our website for further details.

5. GUIDANCE FOR IMPLEMENTATION

This section provides guidance for the majority of the sector assessment requirements. Guidance has not been provided where the requirement was thought to be sufficiently self-explanatory.

A reminder that the information included within the guidance column in the below table(s) is voluntary and not designed to be exhaustive and cover every situation, but rather provide guidance and examples for implementation of the requirements. The sector assessment requirements included within the first column is however mandatory, as this is a replica of the sector assessment requirements for which an organization will be assessed against.

In this document, the following verbal forms are used:

- “shall” indicates a requirement that has to be met as it directly corresponds with the corresponding assessment requirement;
- “should” indicates a recommendation;
- “need/s to” indicates an action is necessary to demonstrate compliance.

Clause no.	Requirement	Guidance
1. Food Safety System Requirements		
1.1	**Leadership and commitment**	
1.1.1	Evidence shall be available to demonstrate that management is committed to providing sufficient and necessary resources to develop, implement and maintain their food safety program to comply with customer and legal requirements.	**Guidance:** Top management shall ensure that sufficient resources are available. Resources include human and financial resources, infrastructure e.g., tools, equipment, etc. The organization should monitor the current and projected workload and schedules to ensure that adequate food safety system resources are provided, when and where needed. **Examples of evidence:** • Capex planning. • Onsite observations.
1.1.2	Senior management shall ensure that employees are aware of their responsibilities related to food safety including the importance of the food safety program.	**Guidance:** Top management to assign the relevant roles in relation to the food safety system, in order to ensure employees are aware of their responsibilities relating to food safety and the importance of the food safety system. In some organizations, there could be a limited number of persons with the required competence available to carry out the tasks required; it could be useful to plan for sharing of roles and responsibilities. Such plans are valuable during holidays, when managers are away from the facility or in cases of accident or illness. **Examples of evidence:** • Job descriptions, work instructions, duty statements, organization charts, manuals, procedures. • Top management needs to determine how to communicate the relevant responsibilities to employees.

Clause no.	Requirement	Guidance
1.1.3	The organization shall maintain the appropriate legal registration for a food packaging establishment, when required by legislation.	**Guidance:** The organization needs to identify its statutory and regulatory requirements related to its food packaging operation and maintain compliance. **Examples of evidence**: • Business license registration, local authority approval of a food packaging establishment (where applicable), inspection reports, compliance certificate, legal register, actions taken to address legal noncompliance, etc.
1.2	**Organizational roles, responsibilities and authorities**	
1.2.1	The organization shall establish a clear organizational chart outlining the organizations' structure.	**Guidance:** The organization needs to document its structure to define how the organization's activities are organized, directed, and coordinated; encompassing roles and reporting relationships. **Examples of evidence:** • Organogram/organizational chart.
1.2.2	Documented roles, responsibilities and authorities related to food safety and legality shall be defined, implemented, communicated and understood in a manner to ensure product safety.	**Guidance:** The key issue is to make sure responsibilities and authorities at all levels are clearly defined, communicated and understood by all personnel, at all levels within the organization and to make sure that individuals are assigned to manage each of the food safety and legality related activities and roles. **Examples of evidence:** • Documents reflecting roles, responsibilities and authorities of the processes of the food safety system e.g., job descriptions, procedures, responsibility and authority matrix; competency matrix; manuals; work instructions, etc. **Examples of responsibilities that can be assigned:** • Conducting a hazard analysis - Food safety team, • Development of food safety objectives - Relevant managers, • Development of the food safety policy - Top management,

Clause no.	Requirement	Guidance
		• External customer communication - Customer services, • Conform to food safety requirements - All personnel, relevant to their area of work.
1.3	**Externally developed elements of the food safety system**	
1.3.1	Externally developed elements of the food safety system shall be verified to ensure they cover and are suitable for the activities of the organization. The responsibility for the operation of the food safety system still belongs to the organization. Note: externally developed elements may include PRPs, the hazard analysis and the hazard control plan.	**Guidance:** Identify elements within the food safety system which are established using externally developed elements. Determine if the externally developed elements are applicable to your site, its activities, processes and products, and adapt them where necessary. Ensure to also implement, maintain and update the elements in line with the requirements of this Program relevant to these elements. **Examples of elements that can be developed externally:** • PRPs, hazard analysis, hazard control plan, recall procedure, traceability system, etc. **For example**, where an organization utilizes an externally developed hazard analysis, the organization is still responsible to review the hazard analysis and ensure it fully covers all the processes and activities of the site, that it is suitable for the operation and that it fully meets the requirements of Section 3 - HACCP control, of the Assessment Requirements for the FSSC Development Program. This includes that all relevant hazards have been identified and are effectively addressed within the hazard analysis.
1.4	**Competence**	
1.4.1	The organization shall ensure that all people are adequately trained in food safety and practices according to their job responsibilities. Training records shall be maintained.	**Guidance:** Develop and implement a training program/plan to train personnel in food safety and practices in accordance with their area of work and job responsibilities. Check that the employees with activities related to food safety are well aware of their responsibilities and are competent to fulfill them. Where employees are found to lack the required competence, implement a corrective action process and evaluate its effectiveness. Maintain records to demonstrate employee competency.

Clause no.	Requirement	Guidance
		Examples of evidence: • Training program/plan; competency matrix; proof of training e.g., training attendance register and/or certificate; evidence of competency evaluation; competency evaluation interview record; CV; etc.
1.4.2	All new personnel (including maintenance personnel) shall be effectively trained on hygiene requirements, allergen awareness, cleaning, and pest control awareness.	**Guidance:** Implement a training program to ensures that all new personnel including personnel involved in maintenance activities receive training on hygiene requirements, allergen awareness, cleaning, and pest control awareness before starting work. The training program needs to include all personnel including full time, part time and temporary employees. Training should be easy to understand and provided in local language. **Examples of evidence:** • Training records for new personnel (including maintenance personnel), training material/content, trainer competency records, etc.
1.4.3	A HACCP training program shall be in place, for the HACCP/food safety team and those responsible for the operation of the hazard control plan.	**Guidance:** Implement a training program that includes HACCP training for relevant personnel including for the food safety team (incl. team leader) and those responsible for the operation of the hazard control plan e.g., for the hazard control plan operators and those personnel monitoring CCP(s) and OPRP(s), etc. The food safety team leader should have externally provided HACCP training, and once trained then the food safety team leader can provide training to the food safety team members. For training for the personnel responsible for the operation of the hazard control plan, specify the frequency of training and develop site specific training content that addresses site-specific CCP(s) and OPRP(s). The training content can be adjusted to suit the training audience, for example the food safety team may require a longer and more in-depth training session, than an operator who is only responsible for one of the CCP(s) or OPRP(s).

Clause no.	Requirement	Guidance
		Training should be easy to understand and provided in local language. **Examples of evidence:** • HACCP training records, training material/content, trainer competency records, etc.
1.4.4	A refresher training program shall be documented and implemented. All relevant personnel shall receive refresher training, to ensure personnel remain aware of all procedures necessary to maintain the food safety of the products produced.	**Guidance:** Make sure that the training program also includes refresher training for all personnel. The program should be routinely reviewed and updated where necessary, including when there are updates to standards and regulations. Systems need to be in place to ensure that all personnel remain aware of all procedures necessary to maintain food safety. Training should be easy to understand and provided in local language. **Examples of evidence:** • Refresher training plan/schedule, refresher training records, training material/ content, trainer competency records, etc.
1.4.5	A documented training program shall be in place and effectively implemented for all personnel whose work can impact food safety.	**Guidance:** Implement a training program for all personnel whose work can affect food safety. Personnel can include, for example, but not limited to, those responsible for purchasing, receiving, storage, production, dispatch, transport, quality, technical, maintenance, etc. The program should include all levels within the organization such as shopfloor personnel, supervisors, managers and top management. **Examples of evidence:** • Training program/plan, training needs analysis, proof of training e.g., training attendance register and/or certificate.
1.4.6	Food defense awareness training shall be in place.	**Guidance:** Implement a training program that includes food defense. This training can be included as part of other food safety related training. For those responsible for developing the food defense program, they should receive training covering food defense threat assessment methodology and possible mitigation measures. All personnel shall receive general food defense awareness training.

Clause no.	Requirement	Guidance
		Examples of evidence: • Food defense training plan, food defense training records, training material/content, evidence of competency evaluation, etc.
1.5	**Communication**	
1.5.1	**External communication**	
1.5.1.1	Food safety requirements or technical guidance, from statutory and regulatory authorities, customers and industry organizations, shall be available and kept up to date.	**Guidance:** Ensure that there is mechanism for the proper transfer of information between external stakeholders (customers, suppliers, contractors, industry organizations, statutory and regulatory authorities) and the organization. Understand, implement and maintain external interested party requirements. Implement a system to ensure that the organization is kept up to date with changes in external interested party requirements. Compile a register of all related requirements. Subscribe to automatic updates on changes (where possible). **Examples of evidence:** • Customer specifications, supplier specifications, regulatory and statutory register, copies of relevant regulations and standards (hard or soft copy), emails, contracts, subscription to journals, membership to associations, meeting minutes, attendance at trade shows or conferences, automatic updates on changes, etc.
1.5.1.2	Effective arrangements for communicating with external stakeholders (suppliers and contractors, customers, statutory and regulatory authorities, and industry organizations) shall be established, implemented and maintained. A designated and responsible person shall be identified to manage these communications.	**Guidance:** Establish a communication plan or similar documented arrangement to define the channels of external communication. This may include information on what to communicate, who is responsible for the communication, when to communicate, with whom to communicate, how to communicate and why the communication is needed. Ensure that designated persons have defined responsibility and authority to communicate externally including persons responsible for customer and consumer communication including complaints.

Clause no.	Requirement	Guidance
		Examples of evidence: • Documented communication arrangements such as a communication procedure or communication plan/matrix; emails; customer and consumer complaint records, etc.
1.5.1.3	Organizations shall inform their Conformity Assessment Body within three (3) working days of the commencement of the events or situations listed below: • Serious events that impact the food safety system, legality and/or the integrity of the conformity statement, as a result of a Force majeure, natural or man-made disasters (e.g., war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.); • Serious situations where the integrity of the conformity statement is at risk and/or where the Foundation can be brought into disrepute. These include, but are not limited to (1) recalls, (2) actions imposed by regulatory authorities as a result of a food safety issue(s), where additional monitoring or forced shutdown of the site/facility is required, (3) legal proceedings, prosecutions, malpractice, and negligence; and (4) fraudulent activities and corruption.	**Guidance:** Establish and implement a process for managing the communication of serious events and serious situations. Ensure that the procedure includes the notification of the Conformity Assessment Body within 3 working days of the commencement of the serious event and/or serious situation. Make sure that the correct contact details are available i.e. contact name, email address and telephone number. Ensure that there is a system in place to regularly verify and update contact details. **Refer to Appendix 1 of the Program document for a definition of a serious event.** **Examples of evidence:** • Email records, incident report, corrective action details, communication procedure/register, etc.

Clause no.	Requirement	Guidance
1.5.1.4	Records of communication with suppliers, contractors, customers, statutory and regulatory authorities, and industry organization, shall be maintained.	**Guidance:** Ensure that evidence of external communication is retained as documented information. **Examples of evidence:** • Emails, meeting minutes, contracts or service level agreements, etc.
1.5.2	**Internal communication**	
1.5.2.1	Senior management shall ensure effective internal communication within its organization on all relevant information related to food safety and legality, including when changes relevant to the food safety system occur.	**Guidance:** In relation to internal communication, ensure that sufficient relevant information and data relating to food safety and legality is available to all relevant personnel involved with the various operations and procedures of the organization, including when changes occur that are relevant to the food safety system. The organization should establish a process to ensure that the food safety team is informed in a timely manner of intended changes in raw materials, additives, packaging, production/packaging systems, processes, technologies, supplier and customer requirements, statutory and regulatory requirements, new or emerging food safety hazards, etc. The food safety team needs to manage the change once identified, and determine the impact on the organization's food safety system and take the necessary actions to manage the change. **Examples of evidence:** • Emails, meeting minutes incl. food safety team meetings, noticeboards, documents that describe how communication is conducted internally, etc.
1.6	**Specifications including product release**	
1.6.1	Specifications shall be accurate and available for all product inputs (raw materials, additives, packaging materials, rework), intermediate and finished products.	**Guidance:** Ensure that specifications are available for all product inputs, intermediate and finished products. Specifications for packaging material inputs can be obtained from the suppliers. Customer specifications also need to be available, where relevant.

Clause no.	Requirement	Guidance
		Evaluate the specifications to ensure that they are accurate and appropriate for their intended use. Specifications should include information such as raw material description; grade inclusion of any recycled materials; composition of formulated ingredients, additives and processing aids; country of origin; allergen declarations and other mandatory advisory or warning statements/declarations; applicable regulatory or statutory requirements relevant to the packaging materials; packaging information; usage information; recommended storage and transportation information; traceability information; physical specifications, chemical specifications, and microbiological specifications, etc. Specifications also need to be taken into consideration when undertaking the hazard analysis, as the specifications (especially the raw material specifications) will include detail regarding physical, chemical and microbiological hazards that need to be considered. **Examples of evidence:** • Specifications register, supplier specifications (for raw materials, inks, additives, processing aids, packaging materials), customer specifications, intermediate and finished packaging/packaging materials specifications, rework specification, etc.
1.6.2	Specifications shall be compliant with relevant safety, legislative and customer requirements.	**Guidance:** The organization shall be aware of the relevant safety, legislative and customer requirements linked to the packaging material inputs, intermediate and finished packaging/packaging materials, and ensure that these requirements are being met within the specification. Provide evidence to demonstrate that specifications conform to legal and customer requirements. Demonstrate that the processes established are capable of meeting legal and customer specifications. For example, where an organization produces a product that is regulated and the legislation specifies certain characteristics that shall be met e.g., chemical (retained solvent levels, set-off migration, mineral oil hydrocarbons, bisphenol A, isocyanates, phthalates, heavy metals, perfluorooctanoic acid, etc.), physical (e.g., density,

Clause no.	Requirement	Guidance
		compression, color, gel count, moisture vapor transmission rate, oxygen transmission rate, dimensions, etc.) or microbiological (specific legislated microbiological limits), then the product characteristics/limits included within the specification needs to meet these legislated requirements. **Examples of evidence:** • Customer specifications/agreements/requirements, supplier specifications/ agreements, intermediate and finished packaging/packaging materials specifications, regulatory and statutory register, copies of relevant regulations and standards (hard or soft copy), statement of legal or customer compliance, etc.
1.6.3	Specifications shall be kept up to date, unambiguous and available to relevant personnel.	**Guidance:** Establish and implement a process to periodically review specifications (e.g., once every three years) as well as when any changes occur to the product formulation and suppliers. Ensure to communicate any changes internally within the organization to all relevant personnel and externally with relevant external stakeholders. Specifications need to be available at their points of use or available to those personnel who need to use the specifications. Specifications need to be clear, unambiguous, and not misleading. Assign personnel responsible for controlling, updating, maintaining the documented specifications and communicating the specification requirements internally and externally. **Examples of evidence:** • Specification review procedure, established frequency for specification review, evidence that specifications have been reviewed according to this procedure/review frequency, records of communication e.g., emails, etc.
1.6.4	Changes to specifications shall be clearly communicated both internally and externally as applicable. Evidence of this shall be available.	
1.6.5	A documented product release procedure shall be in place and implemented to ensure that the final product meets the specification.	**Guidance:** Implement a product release procedure that includes steps to ensure that the final product meets specifications. The product release parameters can be checked during the

Clause no.	Requirement	Guidance
		production process OR at the end of the product's production before the product is released. Note: This may be of a sampling nature; it does not require that all individual products are checked prior to release. This requirement also does not require that all products be put on hold or blocked prior to release. The procedure should include steps to be taken in the case the products do not meet the product specifications including the need to isolate the nonconforming product and prevent the release of these products. Assign responsibility for personnel responsible for product release activities including for the management of nonconforming product. Ensure that there is proper segregation of nonconforming products from other products suitable for release. **Examples of evidence:** • Product release procedure, product specifications, product release records (this could be included within production records or as a separate record), quarantine or nonconforming product area, job description of responsible person(s), appointment letters for assigned roles on decision making, nonconforming product/isolation records, disposal records (if nonconforming product needed to be disposed of).
1.6.6	A designated person with responsibility for controlling specifications shall be appointed.	**Guidance:** Assign responsibility to manage, evaluate and approve specifications to designated personnel. Assign personnel responsible for controlling, updating, maintaining the documented specifications and communicating the specification requirements internally and externally. **Examples of evidence:** • Job descriptions, responsibility matrix, appointment letters, etc.

Clause no.	Requirement	Guidance
1.7	**Documented information**	
1.7.1	Records shall be available to demonstrate that the organization complies with the food safety system, including all applicable regulatory and customer food safety requirements.	**Guidance:** Develop and establish documented information to ensure effective operation of the food safety system and operations. Ensure that the documented information is understood by personnel and relevant interested parties, and that information is accessible, legible and useful. Documented information in the form of records needs to be retained as evidence of the results achieved or activities performed, in order to demonstrate effective implementation of the food safety system requirements and compliance with applicable regulatory and customer requirements. **Examples of evidence:** • Written procedures and records (paper and electronic). **Examples of records include, however are not limited to, the following:** • Receiving or incoming goods records • Production records • Dispatch and vehicle check records • Temperature check records (if applicable) • Product release records • Quality check records • Equipment inspection records e.g., knife checks, glass and hard plastic checks • Cleaning records • Pest control records • Waste disposal records • Test results (e.g., microbial test results, allergen swab results) • Site inspection reports • COAs or COCs • Internal audit records

Clause no.	Requirement	Guidance
1.7.2	Records shall be: • genuine and maintained in good condition, to preserve legibility. • securely stored and accessible. • protected from unintended alterations, and alterations or corrections to completed records shall be approved and justification for this maintained. Electronic records shall be secured and backed up to prevent loss.	**Guidance:** Records need to be completed to capture a true reflection of the activities and protected from being damaged, for example by water damage or spillages, intentional adulteration or misuse etc. Records shall be legible (clear and easy to read). Records shall be securely stored and access restricted to those who need to use the records. Records should be stored in clearly identified files if using a hard copy system. Where records are saved electronically they shall be backed up to prevent loss and evidence to demonstrate this needs to be available. Implement a system to control making changes to completed records, such as rules against the use of correction fluid/tape; where a justified correction needs to be made, make a clear cross-out/line through the incorrect text, the person making the correction should initial next to the correction, and require an additional signature to approve or support the change, including clear justification for the change. **Examples of evidence:** • Completed records. Demonstrate who can access the records. • File location with labelled files, or named folders when using an electronic system. • For electronic systems, implement a file back-up system that runs at planned intervals or scheduled times such as daily or weekly or bi-weekly and have evidence available to demonstrate that back-ups have been completed as planned.
1.7.3	The organization shall set timescales for record retention which comply with regulatory or customer requirements. Where there are no regulatory or customer requirements, records shall be kept covering the shelf life of the product as a minimum.	Self-explanatory.

Clause no.	Requirement	Guidance
1.8	**Procedures**	
1.8.1	Procedures shall be documented, implemented and maintained for all processes and operations that affect food safety.	**Guidance:** A procedure is defined as a specified way to carry out an activity or a process. Procedures relevant to a food safety system include, however are not limited to, the following: • Receiving/Incoming goods procedure • Cleaning and disinfection procedure • Pest control procedure • Personal hygiene procedure • Allergen management procedure • Waste management procedure • Supplier management procedure • Dispatch procedure • Storage procedure • Transportation / Distribution procedure • Verification procedure • Traceability procedure • Recall and withdrawal procedure • Complaint handling procedure • Communication procedure • Product release procedure • Nonconforming product procedure • Nonconformity and corrective action procedure • Procedures relating to processes/services • Procedures relating to CCPs and OPRPs Ensure that procedures are controlled and protected from unauthorized changes. The document control should allow for documents to be easily identified with a document name/title, document reference number, document issue or revision date, and the name of the author and approver of the document. In some instances, it may be required to

Clause no.	Requirement	Guidance
		translate the documents into various languages, depending on the native languages of the personnel and it is advisable to make sure that the information is not complex and that it is easy to understand. There should be a process to review and approve new and existing documented information. Make sure that documented information is protected from unauthorized changes, loss of confidentiality and damages. Obsolete documented information should be prevented from circulation. A master document list is a useful tool for controlling documented information. **Examples of evidence:** • Hard copy or soft copy (electronic) procedures. • Procedures being available at points of use. • Interviewing of personnel relating to procedures relevant to their area of work.
1.8.2	Procedures shall be clearly communicated to relevant personnel.	**Guidance:** Implement a system to communicate what procedures exist within the food safety system. Make procedures available for personnel use with various levels of access, such as reading only, reading and editing and or the ability to download. Communicate through training when new people join the organization or department, or when there are new or updated procedures. Procedures should also be available at points of use. **Examples of evidence:** • Training attendance registers. • Evidence can include emails with links to the relevant procedures. • Demonstrate that relevant procedures are available at the point of use.

Clause no.	Requirement	Guidance
1.9	**Traceability System**	
1.9.1	The traceability system shall be implemented and maintained to uniquely identify incoming material from suppliers, through all stages of production and the first stage of the distribution route of the end product.	**Guidance:** Ensure traceability of all incoming materials and additives received and used in the organization through different stages of production until delivery to the customer or the distribution center. Implement a system to identify which products come from which suppliers, this can be adapted from the approved suppliers' list; and which products are distributed to which customers. Allocate a numbering system that uses either lot codes, batch numbers, receiving dates, expiry dates (where applicable) to trace. **Examples of evidence:** Receiving/incoming goods records that capture the following details: • material/additive received, • supplier name, • date received, • expiry date (where applicable), • batch number/lot code, • quantity received, • indicate if COA/COC has been received and whether it meets the specification, include a section for comments in case additional information is required, such as follow up on COC/COA not being received, • whether the product is approved for release to production, • details/signature of the authorized person, i.e. the person receiving the material. Production/packing records that capture the following details: • production/packing date, • product name, • quantity produced/packed, • batch number/lot code, • expiry date (where applicable),

Clause no.	Requirement	Guidance
		• production/packing related checks, • details/signature of the authorized person, i.e. those who produced or packed the product, and those who approved the product for release. Dispatch records that capture the following details: • product dispatched, • vehicle identification, • customer name, • date dispatched, • expiry date/shelf-life information where applicable, • batch number/lot code, • quantity dispatched, • indicate if COA/COC has been supplied with the product, • vehicle checks, • details/signature of the authorized person, i.e. the person dispatching the material.
1.9.2	The traceability system shall be fully operational and effective, and shall consider as a minimum the: a) relation of lots of received materials, and intermediate products to the end products; b) reworking of materials/products; c) distribution of the end product. The organization shall ensure that applicable statutory, regulatory and customer requirements are met.	**Guidance:** Effective traceability shall track the specific lot codes/batch numbers of received materials, and intermediate packaging materials through to the specific lot code/batch number of finished packaging/packaging materials. And, specific lot codes/batch numbers of finished packaging/packaging materials shall be able to be tracked to their first stage of the distribution route. Allow identification of materials and packaging/packaging materials through all the stages of production, processing, packing and storage/distribution. This applies to and includes rework identification - the organization shall be able to trace packaging materials reworked back into another batch of product. Implement practical measures to ensure traceability of bulk raw materials in silos and ink press returns. Legislation and customer requirements need to be identified and incorporated in the traceability system.

Clause no.	Requirement	Guidance
		Examples of evidence: • Production/process records completed to show ingoing materials at the different stages of the process, in relation to the end products produced, including quantities and lot codes/batch numbers of materials used to produce a specific batch of end product, and the quantity of the end products produced also needs to be recorded.
1.9.3	The traceability process shall incorporate all relevant records of: • receipt • processing at all steps • use of rework • work in progress • distribution. Traceability shall be ensured and recorded until delivery to the customer.	Self-explanatory.
1.9.4	There shall be clear labelling procedures that ensure continuous identification of the product through all stages of production and delivery.	Self-explanatory.
1.9.5	The effectiveness of the traceability system shall be verified and tested (backwards and forwards) at least annually. The verification of the system shall include the reconciliation of quantities of end products produced and distributed.	**Guidance:** Implement a schedule to conduct an annual traceability exercise to follow a end product through to the first point of sale or next in line customer, as well as a backwards to trace all incoming materials used in the production of the end product sampled. The organization should also trace all the relevant related records e.g., for PRPs, OPRPs, and CCPs. A mass balance exercise shall be done to trace the quantities of end products produced and compare it to the quantities of end products distributed.

Clause no.	Requirement	Guidance
		The organization should specify a specific duration that the traceability exercise should be completed within such as 4 hours, and include how long the exercise took to complete in the traceability exercise record. **Examples of evidence:** • Traceability procedure. • Traceability exercise schedule. • Records of traceability exercises and their outcomes and related actions.
1.9.6	The system shall be documented, updated as necessary and records shall be maintained.	Self-explanatory.
1.10	**Food safety incident management**	
1.10.1	**Withdrawal/recall**	
1.10.1.1	The organization shall have an effective incident management procedure for all products including incident reporting, communicating with interested parties, and management of product withdrawal and recall.	**Guidance:** Implement a procedure defining what will be done when incidents occur that result in product withdrawal and/or product recall needing to be initiated. The procedure needs to define the incident reporting process, how to manage the product withdrawal and product recall process (incl. step-by-step instructions), as well as identify designated responsible persons for: • being part of the incident team • undertaking decisions relating to product recall/withdrawal • communicating internally with the relevant departments • communicating externally with customers, consumers, regulatory authorities, the media and other external stakeholders. Up to date contact information shall be maintained. The procedure needs to clearly define how to identify, locate and remove affected products from all the necessary points in the supply chain including a step-by-step process. This may include whether products are to be returned to the facility, or whether they are to immediately be sent for disposal, and evidence of disposal maintained. It may
1.10.1.2	This shall include having systems in place to ensure that products failing to meet requirements are identified, located and removed from all necessary points of the supply chain.	
1.10.1.3	A designated responsible person shall be identified to provide information to customers, consumers and regulatory authorities.	

Clause no.	Requirement	Guidance
		also refer to the procedure for handling of potentially unsafe products. Refer to guidance on handling of potentially unsafe products further down in this guidance document, next to the relevant clause. **Examples of evidence:** • A documented procedure for Incident management/Product recall and withdrawal. • Records of actual incidents that have occurred including for product recall and withdrawal. • Signed appointment letters or job descriptions for designated responsible person(s).
1.10.1.4	The incident management system shall be reviewed, tested and verified at least once a year and records thereof shall be maintained.	**Guidance:** Schedule to conduct mock recall and withdrawal exercises at least once a year. Define what records should form part of the exercise, this can be included in a mock recall/withdrawal checklist. Implement a mass balance to reconcile the amount of affected product produced vs the amount of affected product recalled/withdrawn. The organization should specify a specific duration that the mock recall/withdrawal exercise should be completed within such as 4 hours, and include how long the exercise took to complete in the mock recall/withdrawal exercise record. Legislation and customer requirements need to be addressed. **Examples of evidence:** • Records of exercises and their outcomes and related actions.
1.10.1.5	All incidents shall be recorded and assessed to establish their severity and the risk to the consumer. Relevant actions shall be taken to address the risks identified.	Self-explanatory.

Clause no.	Requirement	Guidance
1.10.2	**Emergency preparedness and response**	
1.10.2.1	Top Management shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety which are relevant to the role of the organization in the food chain. Note: Emergency situations include natural disasters, environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents, e.g. interruption of essential services such as water, electricity or refrigeration supply.	**Guidance:** Implement a procedure to manage the impact on food safety when an emergency situation/incident arises and include an emergency preparedness and response plan. For each identified emergency situation that could possibly occur, define how to respond to the emergency situation and what measures would be implemented to manage the impact on food safety during/after the emergency situation. For each potential emergency situation, define who will be responsible to respond to and manage the situation, what measures need to be implemented, how the situation will be monitored, etc. **Examples of evidence:** • Documented procedures for emergency preparedness and response. • In the case an actual emergency situation occurred, provide documented evidence of how the situation was effectively responded to and managed. • Emergency contact list with the latest contact information. • Internal and external communication procedures. • Evidence that relevant personnel have been trained on how to respond to and manage these situations.
1.10.2.2	Documented information shall be established and maintained to manage these situations and incidents.	
1.11	**Nonconformity and Corrective Action**	
1.11.1	When a nonconformity occurs, the organization shall: • react to the nonconformity and take appropriate correction to deal with the immediate issue; • undertake a root cause analysis to determine the cause of the nonconformity;	Ensure that there is defined process to appropriately respond to a deviation against the food safety system. Implement procedures that describe how to manage nonconformities when they are identified. Examples of nonconformities can include: out of specification testing results (for end product, product inputs, environment, etc.), food safety incidents, justified customer/consumer complaints, CCP and OPRP failures/deviations, process control loss, internal audit findings, PRP verification deviations, etc.

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	• implement suitable and effective corrective action in a timely manner to prevent recurrence, and • maintain records there-of.	The procedure needs to define the process that needs to be followed when a nonconformity arises: • Undertake immediate corrections to deal with the nonconformity identified. This includes handling of potentially unsafe product as a result of the nonconformity that was identified (refer to handling of potentially unsafe product clause for further guidance). For example, where a nonconformity was raised due to an employee not adhering to the personal hygiene requirements as jewelry was observed to have been worn, examples of correction may include instructing the employee to remove the jewelry and confirming that the jewelry has been removed before the employee continues with their tasks. • Conduct a root cause analysis to determine the root cause of the nonconformity in order for action to be taken to prevent the nonconformance from recurring. Root cause analysis includes asking investigative questions until the causes of the non-conformities or deviations are identified. Various methods to determine the root cause are available such as the Five Whys method, the Six M's method (Machines, Materials, Methods, Manpower, Measurement and Mother Nature), the Fishbone diagram method, etc. For example, in relation to the nonconformity regarding the employee not adhering to the personal hygiene requirements, the root cause analysis may look as follows: ○ Why 1: Why was the employee wearing jewelry? The employee was not aware that they could not wear jewelry. ○ Why 2: Why was the employee not aware that they could not wear jewelry? This was a new employee to the site who had not been trained on the hygiene requirements. ○ Why 3: Why had the new employee not yet undergone hygiene training? The food safety team leader (FSTL), who was responsible for induction training, was not aware a new employee had commenced working for the organization. ○ Why 4: Why was the FSTL not aware? Relevant department manager was not aware that they needed to inform the FSTL when a new employee was due to commence work.
1.11.2	The organization shall have a documented procedure for nonconformity management and corrective actions.	

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		○ Why 5: Inadequate training of the relevant department managers on the related procedure which identified that they needed to inform the FSTL when a new employee was to commence work. • Implement suitable and effective corrective action in a timely manner to prevent recurrence of the nonconformity. The severity of the non-conformity should determine the extent of the action to be taken, although all deviations should be addressed. For example, in relation to the nonconformity regarding the employee not adhering to the personal hygiene requirements, the corrective action taken may have included immediate training of the new employee on the hygiene requirements as well as all other trainings that are required to be undertaken at the time of induction. And, the relevant department managers being trained on the procedure that defines that the FSTL shall be informed prior to a new employee commencing work, so that all relevant trainings can be provided. **Examples of evidence:** • Nonconformity management and corrective action procedure. • Nonconformity log and trending. • Completed nonconformity and corrective action reports.
1.12	**Complaint Handling**	
1.12.1	A documented complaint management program shall be in place and effectively implemented for the management of customer and consumer complaints relating to food safety (not quality), including analysis of trends.	**Guidance:** Establish and implement a documented program for the management of customer and consumer complaints relating to food safety, including what actions will be taken when food safety complaints are received. This should include responsibility to receive, capture, investigate, communicate internally and respond to the complaint. Maintain a log of all food safety related complaints for trending purposes, and undertake trending. Determine if actions need to be taken as a result of any trends identified.

Clause no.	Requirement	Guidance
		Examples of evidence: • Complaint handling procedure, customer/consumer complaint log, completed records reflecting investigation details, including root cause analysis and corrective actions taken for justified complaints. Results of trending and related actions taken.
1.12.2	Records of all customer and consumer complaints, including investigations and corrective actions for food safety issues, shall be maintained.	Self-explanatory and as above.

Clause no.	Requirement	Guidance
2. Pre-Requisite Programs		
2.1	**Construction and layout of buildings**	
2.1.1	The facility shall be of suitable size and located, designed, constructed and maintained so as to reduce the risk of contamination and enable the production of safe and legal products.	**Guidance:** Follow the applicable local legislation for packaging manufacturing premises. Consider local activities and the site environment, which may have an adverse impact on finished product integrity, with measures to prevent contamination. Where measures have been put in place to protect the site from potential contaminants, flooding, etc. it needs to be reviewed in response to any changes. **Examples of evidence:** • Certificate of approval by the local authority or business registration as packaging manufacturer.
2.1.2	The facility shall be effectively maintained, cleaned and disinfected (where appropriate) to prevent physical, chemical and microbiological product contamination.	Self-explanatory.
2.1.3	The grounds and surrounding areas of the facility shall be maintained and kept free of waste and accumulated debris. Vegetation surrounding the facility shall be tended or removed and not attract and harbor pests. Any potential harborage, such as decommissioned equipment, should be removed.	Self-explanatory.

Clause no.	Requirement	Guidance
2.1.4	Buildings shall be provided with adequate ventilation.	**Guidance:** A sufficient flow of natural and artificial airflow, either through ventilation systems, windows, doors and openings that are screened and made of material that is suitable for the production environment of the product handled, needs to be provided to prevent condensation or excessive dust.
2.1.5	Buildings shall be protected from pest entry.	**Guidance:** All external openings should be screened for pests. **Examples of evidence:** • Include screens or wire mesh on windows, strip curtains on external doors, ceiling and extractor fans should also be screened with wire mesh or suitable coverings that do not hinder or block ventilation.
2.1.6	Where outside space is used for storage, stored items shall be protected from weather or pest damage.	**Guidance:** Provide suitable protection of the material stored outside. **Examples of evidence:** • Installation of overhead canopies, coverings, double layers of outer packaging material to cover the materials stored outside.
2.2	**Layout of premises and workspace**	
2.2.1	The organization's premises and workspace shall be designed and maintained to reduce the risk of contamination and enable the production of safe and legal products.	Self-explanatory.
2.2.2	Structures, surfaces and materials that come in contact with food packaging or packaging material shall be easy to maintain, cleanable and where appropriate allow for disinfection.	**Guidance:** Surfaces should be made from stainless steel or other durable material. Cleaning regimes should be suited to the type of environment that will not create an opportunity for cross contamination of the product type handled/ manufactured by the organization. Cleaning methods for example, water with detergent should not be absorbed by wooden

Clause no.	Requirement	Guidance
	Materials of construction shall be resistant to the cleaning system applied.	structures or surfaces, or metal surfaces should not experience any corrosion because of applied methods of cleaning or the cleaning agents used.
2.2.3	Adequate drainage and waste disposal systems and facilities shall be provided and well maintained. They shall be designed and constructed so that the likelihood of contaminating food packaging or the water supply is avoided.	**Guidance:** The design of waste accumulation and collection should be from clean to dirty areas and not find its way back to where open product packaging is being handled. Waste-water should flow away from clean areas, and machinery and piping arranged so that, wherever feasible, process waste water goes directly into a drain. **Examples of evidence:** • Organizations should use their floor plan to map out the flow of clean vs dirty water and be able to show that there is no risk of contamination.
2.2.4	Internal structures and fittings The organization shall design and maintain:	
	• floors, walls, doors, openings, ceilings and overhead fixtures to a degree of hygiene appropriate to the operation;	**Guidance:** Floors - suitably hard-wearing to meet the demands of the process, impervious, and withstand cleaning materials and methods. Walls - made of durable material and finished and maintained to prevent the accumulation of dirt, minimize condensation and mold growth, and facilitate cleaning.
	• drains shall be trapped and covered.	Self-explanatory.
	• ceilings and overhead fixtures that are constructed and finished to minimize the build-up of products, foreign matter, dirt and condensation, and the shedding of particles;	Self-explanatory.

Clause no.	Requirement	Guidance
	• external openings (e.g. doors, windows) to prevent entry of foreign matter, including pests, appropriate to the operation;	**Guidance:** External doors have to be close fitting or adequately proofed, also to prevent pest ingress. These should include additional screening depending on the nature of operational activities. Where plastic strip curtains are present, it needs to be maintained in good condition, clean, fitted correctly, and not pose a food safety risk. **Examples of evidence:** • External doors are suitable and external openings are appropriate for the type of the operation. • Openings include strip curtains, wire mesh screens, double door systems or air curtains as appropriate.
	• floors and joints to avoid stagnant water;	Self-explanatory.
	• drains to prevent entry of foreign matter and pests and to be appropriate to the operation, to be cleanable and repairable;	**Guidance:** Floor drains should be durable and be able to withstand abrasive cleaning and disinfection chemicals, they must be easy to clean to prevent bacteria, and there should not be cracks that will allow ingress of pests. **Examples of evidence:** • Install screens and catch traps that allow the flow of water but not have gaps so large that rats and mice or crawling insects can gain access into the production areas.
2.2.5	The lighting shall be of the appropriate intensity and design to ensure that food safety practice is effective. Light fixtures shall be protected to ensure that materials, product or equipment are not contaminated in the case of breakages.	**Guidance:** Natural and artificial light need to be provided to allow for the correct operation of processes, inspection of product and effective cleaning. **Examples of evidence:** • If hard plastics and other types of breakable material are used to cover light fixtures, these have to be protected against breakage, e.g. have a layer of film that will catch the hard plastic in case it breaks to prevent contaminating the products handled.

Clause no.	Requirement	Guidance
		• Lighting Design - adequate lux levels for visibility, inspections, and hygiene appropriate to the operational activities and in line with local legislation. • Use shatterproof covers or protective shields to avoid contamination from broken bulbs.
2.2.6	The movement patterns of materials, products and people, and the layout of equipment, shall be designed to protect against potential contamination sources.	**Guidance:** Plan for a flow from clean to dirty areas and not back, including consideration of: • production risk zones linked to the different levels of pathogen contamination • access points for personnel and routes of movement for personnel • access points for raw materials, semi-finished and open products • routes of movement for raw materials including packaging • routes for waste removal • routes for the movement of rework • location of staff facilities, including changing rooms, toilets, canteens and smoking areas • production process flows • any area where time segregation is used to complete different activities **Examples of evidence:** • Site map defining the movement patterns of materials, products and people, including the layout of equipment.
2.3	**Utilities**	
2.3.1	The organization's utilities shall be designed and maintained to reduce the risk of contamination and enable the production of safe and legal products.	**Guidance:** Utilities systems such as water, air, steam, refrigeration, drainage shall not be a source of possible cross contamination, not introduce hazards into the production environment, and be designed, installed, and maintained to safeguard product safety and legality. All water (including ice and steam) used as a raw material in the manufacturing process, food packaging, the preparation of product, hand-washing or for equipment or plant cleaning needs to be supplied in sufficient quantity, be potable at the point of use or pose no risk of contamination according to applicable legislation. Where water is stored and handled

Clause no.	Requirement	Guidance
		on site (e.g. in storage or holding tanks) these need to be managed to minimize food safety risks. Utilities must be monitored and verified at planned intervals. **Examples of evidence:** Utility Design that considers: • Hygienic Design Principles - use of food-grade, corrosion-resistant materials. • Segregation of Clean and Dirty Area - drainage, air ducts should not allow backflow from dirty to clean zones. Use backflow preventers on water lines. • Clearly separate potable vs. non-potable water lines with clear signage or identification. Utility monitoring schedules and records.
2.3.2	Processes shall be in place to ensure that the quality of water, steam and ice does not compromise the food safety of the finished product. The facility shall be equipped with clean or potable water inlets appropriate to the intended use.	**Guidance:** Implement a water quality testing and steam testing procedure as relevant to your products and cleaning activities. The sampling points, scope of the test and frequency of analysis defined based on risk, taking into account the source of the water, on-site storage, distribution routes and usage. **Examples of evidence:** • Water quality test results including the microbiological and chemical quality of water used. • If the organization uses municipal water, the local municipality water report can also be used.
2.3.3	Potable and non-potable water pipes shall be identified, and a system shall be in place to prevent the cross-contamination of potable water by non-potable water.	**Guidance:** Implement a system to identify potable and non-potable water pipes by physically marking the actual pipes, or another form of unique identification or utilize a mapping system such as the building floor plans for example to be able to identify the location of pipes. Identify on the map the flow of potable and non-potable water.

Clause no.	Requirement	Guidance
		Examples of evidence: • Building plan layout or utility drawings: Color-coded or uniquely labelled to differentiate potable and non-potable lines, their routes and end uses. • Pipe identification tags or color-coding specifications: Referencing a documented scheme (e.g., blue for potable, yellow/grey for non-potable). • Testing and Verification Records - to verify microbiological testing, Chemical analysis and Cross-connection test records.
2.3.4	Suitable and sufficient ventilation shall be provided to remove excess or unwanted steam, dust and odors, and air shall not flow from contaminated areas to clean areas.	**Guidance:** In case the building structure does not contain external windows and openings that can be screened, the organization should install appropriate extraction fans that will assist with removing excess steam, dust and odors, especially in areas where excess steam, dust or odors are produced. Check that the flow of air is designed to move away from clean areas and that reflux is avoided. The Engineering team can be used to set this up or it can be achieved by outsourcing the service from example the ventilation/fan manufacturers. **Examples of evidence:** • Sufficient air vents and ducts • No evidence of condensation or excess dust
2.3.5	Controls shall be in place for compressed air and other gas systems, where there is a direct or indirect food safety risk.	**Guidance:** The organization needs to implement controls based on the risk assessment to ensure that the compressed air and other gases that are used do not introduce a risk of contamination to the final products manufactured by the organization. These can include choosing to use oil free compressors, food grade compressed air and the application of monitored filters and filter changes at planned intervals. **Examples of evidence:** • Engineering drawings showing pipelines, filtration stages, and point-of-use installations. • Commissioning reports verifying correct installation and initial testing.

Clause no.	Requirement	Guidance
		• Supplier specifications for compressors, filters, dryers, and gas regulators. • Material certifications for parts that contact food packaging or the food packaging environment. • Preventive maintenance logs, Calibration certificates, Service reports, Filter change records • Monitoring and Testing Records (e.g. microbiological test results and Particulate and oil mist test results).
2.4	**Waste disposal**	
2.4.1	The organization shall have a program in place for the collection and disposal of waste material.	Self-explanatory.
2.4.2	Suitable provisions shall be in place for the storage and removal of waste, which prevents product contamination.	**Guidance:** Provide dedicated space for suitable waste storage facilities/containers. The waste container and waste storage will be determined by the type of waste being stored/collected, e.g. dry or wet waste, and placement e.g. waste containers in production areas shall be limited, but if used then it must be properly closed, and regularly emptied and cleaned to prevent product contamination. A frequency of daily or twice daily removals from production to the external waste storage areas should be implemented. Waste storage should prevent the attraction of pests and pest harborage. **Examples of evidence:** • Visual inspection: confirm suitable waste containers and waste storage areas provided, regularly emptied, clean and not overflowing.
2.4.3	Waste shall be kept away from production and storage areas. Bins and containers for waste shall be appropriately identified, emptied regularly and if necessary, provided with lids.	Containers shall be: • clearly identified, • designated for ease of use and effective cleaning, • well maintained to allow cleaning, and where required disinfection, • emptied at defined and appropriate frequency.

Clause no.	Requirement	Guidance
2.4.4	The organization shall have in place a documented waste management program including the identification of waste; waste collection; and containment, removal and disposal of waste.	**Guidance:** Write up a procedure that defines the controls in place regarding waste, addressing who will be responsible for waste removal, i.e. will it be managed internally or outsourced, the method and frequency of removal and disposal. Controls around the sign-off of waste that leaves the premises to ensure that no unnecessary losses are experienced, issuance of records of waste disposal, including waste sent to recycling, and hazardous waste such as certificates of safe disposal. **Examples of evidence:** • Documented waste management program. • List of approved waste control service providers • Records of waste disposal, particularly products waste and the specific instructions to be followed to ensure safe disposal.
2.4.5	Food packaging identified and designated as waste shall be disfigured or destroyed so that trademarks or product information cannot be reused and cannot enter the supply chain again.	**Guidance:** Prior to disposing of food packaging or rejected food packaging materials, organizations need to have implemented a process to disfigure or destroy it. Methods could include tearing up the labels, destroying them by writing over the product labels using material that cannot be removed or wiped off, such as permanent markers etc. If it is printed flexible packaging, ensure to physically rip it apart so that it cannot be used by somebody else outside the organization to fraudulently pack products in or resell discarded, rejected food packaging. **Examples of evidence:** • Documented Food Packaging Material Destruction Procedure • Obsolete Label and Packaging Disposal Procedure • These procedures could be included as part of the Waste Management Procedure

Clause no.	Requirement	Guidance
2.5	**Equipment suitability, cleaning and maintenance**	
2.5.1	Equipment, containers and surfaces used in production and packaging areas shall not be a source of contamination.	**Guidance:** Refer to the FSSC Guidance document on Equipment management for hygienic design of equipment, available on the FSSC website
2.5.2	Equipment, containers and surfaces in direct contact with food packaging and packaging materials shall: • be designed and constructed to ensure that they can be cleaned, disinfected, drained, inspected and maintained. • be smooth, accessible and have cleanable surfaces. • be made from material compatible with the intended products and cleaning chemicals/methods. • not be penetrated by holes, nuts and/or bolts on its framework. • have piping and ductwork (where relevant) which is cleanable, drainable, with no dead ends and not cause condensation or leakage that could contaminate food packaging. • have product contact surfaces which are impermeable and rust or corrosion free.	**Guidance:** Refer to the FSSC Guidance document on Equipment management for hygienic design of equipment, available on the FSSC website
2.5.3	Forklifts and other driven transport trolleys shall be clean, well maintained and of suitable type to avoid contamination through emissions.	Self-explanatory.

Clause no.	Requirement	Guidance
2.5.4	Manufacturer's instructions shall be followed to install, use and maintain equipment which may affect food safety.	Self-explanatory.
2.5.5	**Maintenance**	
2.5.5.1	The organization shall establish and implement a documented program/ system of planned, preventive and corrective maintenance to ensure an adequate level of food safety in the facility.	**Guidance:** Identify all equipment in the packaging facility, including spares that are not used as frequently, with the type of service/maintenance required for each of the equipment. The service/maintenance frequency needs to be based on the manufacturer's specifications and the risk to food safety. Lastly determine if the service will be carried out internally or if it will be outsourced. If it is to be outsourced, the details of the service provider should be included in the schedule, and maintenance records maintained. **Examples of evidence:** • A documented procedure detailing what preventive and corrective maintenance activities will be carried out, the schedule showing the frequency, responsible person as well as dates. If service providers are used, remember to include them under the controls in place for management of outsourced activities.
2.5.5.2	A documented hygiene and clearance procedure shall be in place and effectively implemented for all maintenance activities.	**Guidance:** The hygiene and clearance procedure needs to define the requirements for cleaning and hygiene after all maintenance activities in the production environment to avoid potential cross contamination. This includes a sign off or approval from designated personnel e.g. a food safety team member or production manager, that cleaning has been conducted, all tools have been accounted for and removed, and no potential cross contamination is visible. **Examples of evidence:** • The documented maintenance procedure. • Evidence of hygiene clearance following maintenance, e.g. release maintenance slips that can also be incorporated in the maintenance worksheets/ job cards etc.

Clause no.	Requirement	Guidance
2.5.5.3	Equipment failure, and defects to premises, which are essential to food safety shall be identified, assessed and documented to enable prompt actions and improvement of the maintenance program.	**Guidance:** Include in the procedure what actions must be taken when equipment fails, including: • the responsibility for communication • record keeping of the failures, and • what actions were taken. **Examples of evidence:** • Maintenance procedure and records of breakdowns and actions taken to resolve them.
2.6	**Management of purchased materials**	
2.6.1	The organization shall control purchasing processes to ensure that all externally sourced materials (raw materials, additives, packaging materials, processing aids, etc.) and services conform to specifications and contractual agreements to ensure product safety.	**Guidance:** The purchasing process shall be controlled to ensure food safety and be based on specifications and contractual agreements. This includes all externally sourced materials (raw materials, additives, packaging materials, processing aids, etc.) and services. Design and implement a procedure that describes how purchasing or sourcing of materials and service providers will be controlled, including what criteria will be used to determine whether a supplier/service provider is acceptable or can be approved. Product specifications should be established and maintained for reference and made available to the Procurement team to use at the stage of purchasing. All suppliers and service providers need to be identified and listed within a verifiable document e.g. an approved suppliers and services list. The following information should be captured as a minimum: • name of the material/ additive/packaging/ service sourced, • name and address of the service provider, supplier and secondary supplier (if available, secondary suppliers are recommended in case of shortages), contact person with contact details, how the criteria are being met e.g. type of third-party certification that they hold, evaluation method and frequency, etc.

Clause no.	Requirement	Guidance
		Examples of evidence: • Purchasing procedure or supplier and services approval procedure; • Approved supplier list, supplier audit schedule, certifications that the supplier or service provider holds or is affiliated with. These should always be the latest, i.e., for example the most valid FSSC 22000 certificate or Development Program conformity statement.
2.6.2	Purchased materials that have an impact on food safety shall be sourced from approved suppliers that are identified, evaluated, and monitored.	**Guidance:** Identify the purchased materials that are required for the operational activities of the organization that will have an impact on food safety. Set criteria for each supplier and conduct an analysis of whether they meet the criteria or not, depending on risk of identified gaps against the set criteria, establish risk-based monitoring program, such as supplier audits, submission of latest valid third-party certification, supplier questionnaire etc. Stricter requirements should be established the higher the risk to food safety. **Examples of evidence:** • Documented supplier list, written criteria of what qualifies a supplier as approved. • Example: a completed supplier questionnaire confirming the status of the organization and their commitment to food safety, evidence of supplier third-party certification either in electronic or hard copy format. • Evidence of reviews conducted on information received from the suppliers and how they were approved.
2.6.3	Purchased products shall be inspected upon delivery.	**Guidance:** Incoming products shall be inspected upon delivery. Part of the incoming inspection should include confirmation that what is being received is what was ordered, that it is clean, intact, protected by outer case packaging (where applicable), that there is no visible physical contamination such as glass, hard plastics, broken pieces of wood or torn paper, moisture damage etc.

Clause no.	Requirement	Guidance
		There should be a designated authorized person who is assigned the role of conducting receiving inspections. The same applies for bigger consignments that are delivered e.g. tankers and such means of transport **Examples of evidence:** • Completed receiving records confirming that inspections are done for all materials received, this should have a section that shows that there was a decision made to either accept or reject the inspected material with reasons.
2.6.4	Records shall be kept of purchased products with the identification of the supplier and documented information relevant to food safety.	Self-explanatory.
2.6.5	Testing results or a COA or COC shall be available to verify conformity with specified requirements prior to acceptance or use.	Self-explanatory.
2.6.6	Delivery vehicles shall be checked prior to, and during unloading to verify the quality and safety of the material has been maintained during transit (e.g. integrity of seals, free from infestation, temperature records where applicable). Delivery vehicles and deliveries that do not conform with specifications shall be refused or their access limited to a controlled area until the product has been disposed of or returned to the supplier.	Self-explanatory.

Clause no.	Requirement	Guidance
2.6.7	Results of evaluation, inspection and monitoring of suppliers and purchased products, investigations, analyses and follow up actions shall be recorded.	**Guidance:** Maintain records of the evaluations that are conducted, based on the outcomes of the monitoring program, i.e. if the program requires that the supplier must be audited, then records of audits need to be available and show that the frequency has been met. If, for example, the program requires that the supplier needs to have evidence of third-party certification, then copies of the latest valid certificates have to be available on file. An overall analysis of results should be made available to identify any follow up actions and confirmation that issues identified have been resolved by the supplier. **Examples of evidence:** • Filed records of completed evaluations.
2.6.8	Outsourced activities which have an impact on food safety shall be sourced from approved contractors that are identified, evaluated, and monitored.	**Guidance:** Identify what services are required for the operational activities of the organization that need to be outsourced. Set criteria of what needs to be in place with each service provider and conduct an analysis of whether they meet the criteria or not, depending on risk of identified gaps against the set criteria. Establish a risk-based monitoring program, such as service provider audits, submission of service level agreements or contracts, questionnaires etc. Stricter requirements should be established the higher the risk to food safety. **Examples of evidence:** • Documented service provider list for outsourced activities • Written criteria of what qualifies a provider as approved. • Evidence of reviews conducted on information received from the service providers and how they got approved. • Evaluation and monitoring records
2.6.9	Outsourced activities which have an impact on food safety shall be recorded with the identification of contractors.	Self-explanatory.

Clause no.	Requirement	Guidance
2.6.10	Procedures shall be available and implemented for the approval and monitoring of all suppliers whose products or services affect product safety. The results of the evaluations and follow-up actions shall be recorded.	**Guidance:** Define in the procedure how suppliers are selected, what criteria the different suppliers must meet before they are approved, the frequency of monitoring, assigned responsibilities for communicating with suppliers and what documented information is required for each supplier. **Examples of evidence:** • Documented supplier approval and monitoring procedure. • Records of supplier evaluations and re-evaluation showing the criteria and evidence that has been met. • Evidence that the set timelines for frequencies have been achieved or adhered to.
2.7	**Measures for prevention of cross-contamination**	
2.7.1	The organization shall ensure that appropriate facilities (e.g., physical barriers) and effective measures and procedures are in place to minimize the risk of any potential physical, chemical or microbiological contamination of the product.	Self-explanatory.
2.7.2	**Physical contamination control**	
2.7.2.1	Where brittle materials are used, periodic inspection requirements and defined procedures in the case of breakage shall be put in place. Brittle materials, such as glass and hard plastic components in equipment, should be avoided where possible. Records for monitoring of brittle materials (glass and hard plastic) shall be in place, including in the case of breakage.	Self-explanatory.

Clause no.	Requirement	Guidance
2.7.2.2	Measures shall be in place to prevent, control or detect potential physical contamination, with consideration for the following: • restriction on use of snap-off blades, staples, paperclips and drawing pins; • adequate covers over equipment or containers for exposed packaging materials or products; • use of screens, magnets, sieves or filters; • use of detection or rejection devices such as optical sorters. Note: Potential physical contamination sources include wooden pallets and tools, rubber seals, and personal protective clothing and equipment, etc.	**Guidance:** Implement procedures that define rules around control of potential physical contamination. Specify what is allowed and what is not allowed to be brought near open products or in areas where the risk of contamination is high. The use of posters or photographic images used during training can be helpful. Where relevant use devices such as optical sorters. **Examples of evidence:** • Personnel hygiene procedures. • Foreign object control. • Foreign object policy that prohibits the use of snap-off blades, staples, paperclips and drawing pins and so on.
2.7.3	**Chemical contamination control**	
2.7.3.1	Measures shall be in place to prevent contamination of food packaging or packaging materials by chemicals (e.g. cleaning agents, disinfectants, lubricants, pesticides, etc.)	**Guidance** Implement measures and specify rules related to the control of all chemicals as listed in the requirements. Specify purchasing of chemicals from approved suppliers who can provide confirmation of the food safety status and registration of chemicals. Define controlled storage practices such as locked storage, authorization of issuing and usage of chemicals and maintaining records. **Examples of evidence:** • Approved chemical supplier list.

Clause no.	Requirement	Guidance
		• Food safety and usage information of chemicals, e.g. MSDS
2.7.3.2	The organization shall ensure the chemicals used:	
	• have been approved by competent authorities for its intended use, where applicable;	**Guidance:** Ensure to source all chemicals from an organization that can provide information of its registration, approval and information such as safety data sheets and certificates of conformances. **Examples of evidence:** • Material safety data sheets, COC's and approved suppliers list.
	• are applied according to the manufacturers/product instructions (concentrations, temperature, mechanical action/method of application, waiting time before rinsing, if any, etc.);	**Guidance:** Implement the application procedures in line with the usage instructions contained in the data sheets and supplier's product specifications. **Examples of evidence:** • Procedures, completed records of chemical dilution and usage logs etc.
	• are applied by competent personnel;	Self-explanatory.
	• are labelled;	**Guidance:** All chemicals on-site should have clear, legible, and durable labels, showing the following information: • Product name, • Hazard classification or pictograms (as per System of Classification and Labelling of Chemicals/ Occupational Safety Health Act / or local regulations), • Instructions for safe handling, • Expiry/Use by dates if applicable, • Lot numbers or supplier traceability, Original labels shall not be removed

Clause no.	Requirement	Guidance
		Labels should be maintained even on secondary containers (i.e., when decanted from bulk to smaller containers or bottles). The labelling should support: • Prevention of misuse • Emergency response in case of spills, accidental consumption or exposure, • Training and awareness for food handlers and maintenance staff. **Examples of evidence:** Confirmation during site inspection that all chemicals, including lubricants are clearly labelled.
	• are stored separately from food packaging and packaging materials, in a locked or secured area; and	Self-explanatory.
	• lubricants coming into contact with food packaging or packaging materials and water shall be approved for food contact purpose.	**Guidance:** Organizations shall only use approved lubricants. Clearly label and store lubricants separately from food packaging materials. Ensure to clean up spills and dispose of lubricants appropriately to avoid the contamination of water and food packaging and packaging materials. **Examples of evidence:** • Food grade lubricant information. • List of approved food-contact Lubricants, certificates of food-grade compliance for lubricants used.
2.7.3.3	Where there is a potential food safety hazard due to migration or other transfer mechanism, controls shall be implemented to prevent or control the hazard.	**Guidance:** Implement procedures for the control of possible chemical migration when the hazard analysis indicates this as a significant risk. Implement controlled manufacturing conditions such as: • Curing/Drying Controls: Monitor curing time and temperature for coatings, inks, and adhesives to prevent residual solvents or monomers.

Clause no.	Requirement	Guidance
		• Cross-contamination Controls: Prevent use of non-food-grade materials on shared lines through color-coded tools or dedicated equipment. • Environmental Monitoring: Control ambient temperature, humidity, and air quality during production and storage. **Examples of evidence:** • Control measures for chemical migration, included in the hazard analysis. • Supplier Qualification: Use only approved suppliers who provide food-grade certified materials (e.g., inks, plastics, coatings). • Certificate of Compliance (CoC) or Migration Test Reports must be obtained for all packaging materials and input materials. • Verify that raw materials meet specifications (e.g., no non-compliant additives) and reject material that do not.
2.7.4	**Microbiological cross-contamination control**	
2.7.4.1	Areas with the potential for microbiological cross-contamination shall be identified and suitable controls implemented.	**Guidance:** Identify areas or zones in the facility where harmful microorganisms for example yeast, mold, Escherichia coli, Listeria monocytogenes can: • Transfer from raw materials to finished packaging materials, • Spread via airflow, surfaces, personnel, or equipment • Thrive due to moisture, temperature, or poor cleaning practices. Examples include raw material receiving and storage areas, packing tables, sorting and quarantine areas, transfer points between raw materials and processed material zones, equipment used for both raw and finished packaging materials, drains, rooms with different temperatures, etc. In considering the areas of potential contamination, define rules around separating raw materials and finished packaging materials, people, tools, and equipment, and consider: • The use of physical barriers such as walls, closing doors, dust extractor, product covers/wrappers

Clause no.	Requirement	Guidance
		• Change rooms where movement between low risk and high-risk areas to facilitate PPE changes. • The airflow in the facility and between zones. **Examples of evidence:** • A risk-based zoning plan or layout • Evidence that zones are clearly identified or physically separated, • Training logs showing personnel are aware of zoning requirements, • Monitoring of cross-contamination indicators (e.g., environmental swabbing results).
2.8	**Allergen management**	
2.8.1	A documented program shall be in place to control allergens and prevent cross-contamination of product through all stages of production.	**Guidance:** Develop, implement, and maintain a documented allergen control program that is: • Integrated into the food safety system, • Based on a hazard analysis and risk assessment, • Specific to the allergens relevant to your products, raw materials, and production process environment, • Reviewed periodically and updated as necessary. **Examples of evidence:** • Documented allergen control, procedure or program, • Documented allergen hazard analysis, • Evidence of control measures, validation and verification activities.
2.8.2	Regulations and appropriate customer requirements shall be addressed in the development of the allergen control program.	**Guidance:** Identify relevant food safety laws and regulations related to allergens in all markets where your product is sold. **Examples of evidence:** • Local laws, labelling legislation and Food Allergen Labelling and Consumer Protection Act (FALCPA), Codex Alimentarius, Customer specifications and contractual agreements etc.

Clause no.	Requirement	Guidance
2.8.3	Potential causes of cross-contamination shall be identified and procedures established for the handling of raw materials, intermediate and finished products to avoid cross contamination.	**Guidance:** Implement a systematic identification, control, and prevention of food safety hazards — particularly allergen cross-contamination — during all stages of production and handling. Consider the raw materials, intermediate and finished products when identifying the risk of allergen cross-contamination. Risks of cross-contamination (e.g., from improper storage, handling, or equipment use) can be considered during the hazard analysis. **Examples of evidence:** • Allergen risk assessment and control plan (can be included in the hazard analysis and HACCP plans). • Allergen procedures that details hygiene and handling practices for raw materials, intermediate and finished products where a cross-contamination risk has been identified, and documented actions to address cross-contamination by allergens.
2.8.4	Allergens present in the product by design shall be declared. The need for allergen labelling due to potential manufacturing cross-contact shall be assessed. The declaration shall be on the outer label or the accompanying documentation for products intended for further processing. Applying warning labels does not exempt the organization from implementing the necessary allergen control measures.	**Guidance:** Accurate and transparent labelling of allergenic substances in food packaging shall be done for the purpose of informing the next in line customer and consumers. Labelling needs to be clear, and can be on the outer label or on the accompanying documentation of packaging being sent to manufacturers using the packaging for their production. Take into account any local legislation and regulatory requirements of the country of sale. Alibi labelling does not exempt the organization from implementing the necessary allergen control measures or undertaking verification testing, it can be used where risk cannot be prevented through reasonable controls. **Examples of evidence:** • Labels, allergen list/matrix, product specifications, records of staff training

Clause no.	Requirement	Guidance
2.9	**Cleaning**	
2.9.1	Documented cleaning procedures shall be in place and effective, including monitoring and verification activities, to ensure the cleanliness of the facility and equipment. Records of monitoring and verification shall be maintained.	**Guidance:** Establish written Standard Operating Procedures (SOPs) or Sanitation Operating Procedures for cleaning tasks. These should include: • Objective - Purpose of the cleaning (e.g., remove allergens, prevent microbial growth, remove debris) • Scope - Equipment, areas to be cleaned, or items covered • Frequency - Daily, per shift, weekly, monthly, or based on usage • Responsibility - Designated staff or department • Cleaning materials - Approved chemicals, sanitizers, and cleaning tools. • Dilution and contact time - Specific concentrations and exposure durations • Method - Step-by-step instructions (e.g., pre-rinse → detergent wash → rinse → sanitize) • Safety precautions - PPE, ventilation, chemical handling. The procedure needs to include monitoring activities, verification activities, records to be kept and how to handle nonconformities. **Examples of evidence:** • Cleaning procedures • Cleaning schedules • Planned cleaning verification activities • Corrective actions for deviations.
2.9.2	Operating procedures shall specify:	
	• The premises and equipment subjected to cleaning,	**Guidance:** The cleaning program or operating procedure shall specify the name of the areas and / or equipment to be cleaned.

Clause no.	Requirement	Guidance
	• A description of the process or method of cleaning,	**Guidance:** The process or method of cleaning refers to how the cleaning should be done (e.g. dismantling and removal of parts or manual cleaning and tools to be used), Which chemicals to use (e.g. concentration, minimum contact time), and Verification methods (e.g., ATP testing, swabbing).
	• Frequency of cleaning,	**Guidance:** Frequency refers to how often each of the areas/ equipment will be cleaned. This can be after use, daily, weekly, every two weeks, monthly, quarterly or annually depending on the use and risk to food safety. Example - high level structures such as mezzanine floors might need quarterly to half yearly cleaning, whereas the glass lehr exit (cold end) or line covers might need cleaning as frequently as after use or job change.
	• Responsibility for cleaning,	**Guidance:** Reference the responsible person to clean each area or piece of equipment, and if an additional person should be assigned with the task to verify and sign off on the cleaning activity.
	• Cleaning agents and tools,	**Guidance:** Include what chemicals shall be used and the use of cleaning tools such as mops, buckets, brushes, squeegees, microfiber cloths or disposable wipes, Spray bottles or automated sprayers, Floor scrubbers or vacuums. Designated tools should be used for different areas based, sharing of tools should be avoided where possible to reduce the risk of contamination
	• Source of water, and	**Guidance:** Include the source of the water to be used for cleaning e.g. rainwater, municipal water or treated water, recycled/reclaimed water, etc. The decision should be based on the risk to food safety, for example, recycled water can be used to clean toilets and external grounds, but might not be suitable for cleaning production line surfaces, utensils and containers etc.

Clause no.	Requirement	Guidance
	• Monitoring and verification arrangements for the effectiveness of cleaning, including frequency of these activities.	**Guidance:** Develop a monitoring and verification schedule that includes: • routine checks to verify that cleaning activities have been carried out as planned, • that the intended hygiene or contamination-control objectives have been achieved, and • that cleaning activities are documented and traceable for internal assurance and regulatory compliance. Arrangements can include the following: • Visual inspections by persons other than the ones who performed the cleaning, • Microbiological Testing, ATP (Adenosine Triphosphate) Testing, Allergen Testing, Residue Analysis and trend analysis review of results to identify recurrent issues or system failures, • Frequency - which can range from after cleaning, daily, weekly or monthly. **Examples of evidence:** • The monitoring and verification schedule, verification records, verification results, trend reports etc.
2.9.3	Cleaning equipment and chemicals shall be clearly marked, stored in a segregated area away from product, equipment, packaging and suitable for intended use.	**Guidance:** Use a standardized color-coding system to designate cleaning tools by area (e.g. blue for raw material areas, white for finished product areas, etc.). Clearly label specific items to say for example, “Allergen Area Use Only” Assign cleaning tools to specific zones and track via cleaning logs or audits. **Cleaning chemicals:** Keep chemicals in manufacturer-labelled containers when possible If decanting is needed, use durable, food-safe containers and ensure proper labelling with product name, concentration, hazards, and expiry date has been transferred from the original container. Labels should be resistant to water and chemicals.

Clause no.	Requirement	Guidance
		Storage: Storage Areas should be Physically Separate, and enclosed or locked when not in use, Ensure the area is well-ventilated to avoid chemical buildup which might be hazardous to the personnel handling the chemicals.
2.9.4	Cleaning equipment shall be fit for purpose and utilized in accordance with the manufacturer's instructions and in such a way that cleaning is effective.	**Guidance:** The equipment used for cleaning should be appropriate for the type of soil or contamination to be cleaned (e.g., paper, dust, fluff, ink residue, adhesive buildup, coating, shavings etc.) It should be compatible with the surfaces and equipment being cleaned, meaning it should not cause abrasion or damage) to the cleaned surface. It should support hygienic design principles—easy to clean, disinfect, and maintain. It can be used effectively and safely in the facility's specific operational and environmental conditions without causing undesirable results. **Examples of evidence:** • Brushes, Mops - should be color-coded, material-specific, periodically replaced before they cause physical contamination risks. • High-Pressure Washers - Prevent aerosolization near food packaging contact surfaces.
2.9.5	The cleaning program shall be validated.	**Guidance:** To confirm that the cleaning program is effective, reproducible and fit for purpose, validation is required. **This should be done when:** A new cleaning process or cleaning product is introduced. Process changes occur (e.g., facility design, new equipment, updated products, when a new allergen is added to the existing list). A deviation or non-conformance suggests current cleaning is inadequate.

Clause no.	Requirement	Guidance
		Periodic revalidation is due (based on risk or schedule, e.g., every 1–3 years), based on risk and pre-determined frequencies. **Example of a validation:** • Develop a Validation procedure • Conduct a Risk Assessment to evaluate surface types (e.g., food packaging materials contact vs non-contact), pathogen/allergen risk levels, environmental conditions (e.g., humidity, temperature), type of contamination and the difficulty of removal • Conduct the validation trials -it is recommended to base this on the worst-case scenario • Sampling and Testing - use appropriate methods • Set and Justify Acceptance Criteria • Define documentation requirements.
2.10	**Pest Control**	
2.10.1	An effective pest control program shall be in place to reduce or eliminate the risk of pest infestation, which shall:	**Guidance:** Establish and implement pest control procedures that identify the types of pests to be controlled, the frequency of servicing should be based on the risk related to the industry/ sector, surrounding, product type etc. Appoint a registered pest control service provider that will be able to conduct treatment of the facility without the risk of contaminating products and processing areas. Nominate an internal person to liaise with the service provider and report back to the food safety team on pest control issues. Train employees on pest control procedures and what they need to be looking out for. **Examples of evidence:** • Service level agreement with the pest control service provider, pest control procedures, facility map with traps and detectors indicated, Inspection logs, Treatment records, training records.

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	• be appropriate to the raw material, product, process and facility;	**Guidance:** Design the pest control strategy program based on the: • Type of raw material. • Product sensitivity • Process • Facility layout and environmental exposure.
	• have identified and designated a competent person(s) to manage the program and related activities;	Self-explanatory.
	• identify target pests (e.g., rodents, insects and birds), relevant to the organization and operation;	**Guidance:** The type of operation of the organization will determine what kind of pests will need to be monitored, treated and controlled. **Examples:** • Packaging and storage facilities - risks might include moths, birds, and rodents. Therefore, identify the target pests based on your type of environment, type of materials handled, types of products produced, surrounding areas (paved/wild vegetation, densely populated, industrial areas etc., coastal or marine). **Examples of evidence:** • The list of target pests based on the risk analysis. • Service level agreement with the service provider including the target pests where the service is outsourced.
	• have documented plans, methods, schedules and control procedures; and	**Guidance:** Document a Pest Control Plan that outlines the structure and intent of the program. Contents of the plan can include the following: • Objectives (e.g., prevent pest ingress, eliminate active infestations) • Scope (entire facility, with zonal risk classification) • Target pests (e.g., rodents, insects, birds, other wildlife)

Clause no.	Requirement	Guidance
		• Roles and responsibilities (internal team vs. external pest control contractor) • Pest contractor details: license, contact info, and scope of service etc. **Examples of evidence:** • The documented plan, including inspection schedules and records to confirm effectiveness.
	• include documentation of the chemicals used.	**Guidance:** As part of the records maintained on file, include a pesticide usage log to monitor chemical usage. The use of pesticides should be restricted to the service provider technicians, the designated site pest control officer and competent personnel who have been adequately trained on the use of pesticides. **Examples of evidence:** • Pesticide usage log • MSDS for chemicals used
2.10.2	Pest-monitoring programs shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. Detectors and traps shall be sufficient in number, designed for purpose, placed in appropriate positions and located to prevent potential contamination of materials, products or facilities.	**Guidance:** Use appropriate traps and monitoring devices such as: • Rodent bait stations e.g. external and internal (mechanical traps that usually do not contain poison). Toxic baits shall not be used in production and storage areas where open product is present, except when treating an active infestation. Where toxic baits are used, these needs to be secured. • Insect light traps. • Pheromone traps for flying and crawling insects. • Glue boards in high-risk or difficult-to-inspect areas. Map all monitoring devices on a site plan, ideally each of these should be numbered. The number of detectors should be based on the size of the facility, the number of external openings which may pose a risk pest ingress. Where possible include digital tracking systems for trend analysis if available.

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		Placement of traps and detectors to be determined based on the pest, and not be a potential contamination source for materials, products or facilities. Traps and detectors need to be properly maintained, be in a fixed location, and tamperproof. **Examples of evidence:** • Map of traps and detectors • Visual inspection to verify placement and if maintained
2.10.3	The inspection program shall be undertaken by a competent person at an appropriate frequency and findings shall be addressed.	**Guidance:** **Monitoring and Detection** Implement a routine inspection schedule with defined frequency (e.g. weekly, monthly, quarterly based on risk). **The pest control operator needs to:** • have technical knowledge of pest behavior, life cycles, and risks; • be trained in pest identification, control methods, and food safety implications; • be familiar with regulatory requirements and internal hygiene standards; • have the ability to evaluate the effectiveness of pest control measures and suggest improvements to be implemented, and • be licensed as applicable based on local legislation **Examples of evidence:** • Inspection schedule • Pest control operator licenses, training records, registration certificates with the local authorities etc.
2.10.4	Pest control inspections and resulting actions shall be documented/recorded, including the monitoring and implementation of actions.	Self-explanatory.

Clause no.	Requirement	Guidance
2.10.5	Any infestation shall be documented and appropriate control measures taken in a timely manner.	**Guidance:** All pest sightings, droppings, damage, or suspected infestation signs should be reported to designated personnel (e.g., Quality Manager, Appointed Pest Control Officer) in a timely manner. The report should include: • Date/time of observation • Location (specific zone or room) • Type of pest (if known) • Name of person reporting • Evidence (photos, samples if applicable) **Examples of evidence:** Documented pest incident register that records: • Pest activity events. • Corrective actions taken. • Root cause analysis (when required). • Follow-up inspections and outcomes. Documentation should be retained and available for internal review, third-party audits, and regulatory inspections.
2.10.6	The cause of infestation shall be identified, and corrective action taken to prevent reoccurrence. Records shall be kept of infestation, monitoring and eradication.	**Guidance:** Identify the underlying cause of the infestation to prevent recurrence and to ensure lasting control. Common Causes of pest infestation could include but are not limited to: • Structural issues - cracks, gaps in doors/windows, damaged air vents. • Sanitation failures - accumulated food debris, stagnant water, poor waste handling. • Process/environmental factors - Nighttime operations without adequate controls, poorly sealed raw material intake. • Logistics and suppliers - infested packaging, vehicles, or pallets.

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		• Climate or seasonal patterns: Higher activity in certain months or areas with high humidity. **Examples of Root Cause Analysis Techniques that can be used:** • Use 5 Whys or Ishikawa (Fishbone) Diagrams. • Conduct a thorough site inspection with pest control professionals. • Interview staff in affected zones to identify procedural lapses.
2.11	**Personal hygiene and employee facilities**	
2.11.1	The organization shall ensure the implementation and adherence to appropriate hygiene practices for all personnel, visitors and contractors, including requirements on: • handwashing; • protective clothing / workwear; • restrictions on smoking, eating, drinking, spitting, personal items, nail polish / false nails, jewelry, etc.; and • illness and injury. These requirements shall be compliant with legislation (if applicable) and be available in a form that is easily understood.	**Guidance:** The conforming organization has to implement a system to ensure adherence to hygiene practices and any applicable legislation, that addresses the following: **Personal Cleanliness** Regular handwashing with soap and warm water before entering production areas, after breaks, restroom use, or handling waste. No jewelry, watches, or unsecured accessories in production areas or near open product and materials. Short, clean fingernails, no artificial nails or nail polish. Maintaining daily personal hygiene (clean clothes, hair hygiene, etc.) **Protective Clothing / PPE includes:** Hairnets / beard snoods / facial hair covers Clean coats / overalls Gloves, where required (these need to be controlled as their breakage can cause a potential for cross contamination), Shoe covers or designated factory footwear, as appropriate, PPE should be clean, undamaged, and changed as necessary (e.g., when moving between zones or after contamination).

Clause no.	Requirement	Guidance
		Illness Reporting and Exclusion Anyone experiencing symptoms like vomiting, diarrhea, fever, or open wounds should: Be excluded from food packaging material handling areas. Report immediately to their supervisor. A return-to-work protocol must be in place (e.g., 48-hour symptom-free rule can be implemented depending on the situation). **Access Control & Zoning** Restrict access to sensitive areas (e.g., high-care or high-risk zones). Visitor/contractor sign-in and approval before entry. Visitors should be briefed and supervised and wear appropriate protective clothing. **Behavior in Production Areas** No smoking, eating, chewing, or drinking in production/storage zones. In hot working environments, the provision of water could be considered as appropriate for staff health. No personal items (phones, bags) allowed. **Training and Monitoring** Hygiene training needs to be provided as part of onboarding, with refresher training at defined intervals (e.g., annually for existing employees) and updated when changes are made to the FSS. Routine audits/spot checks to enforce compliance should be done. Clear visual signage and hygiene station instructions needs to be available.
2.11.2	Where appropriate, personnel, visitors and contractors shall wear suitable protective clothing that is cleaned and changed regularly. Adequate protection shall provide coverage so that hair, perspiration and loose items cannot contaminate raw materials, intermediate products, food	**Guidance:** Where appropriate, implement procedures that require the cleaning and or laundering of PPE and footwear so that it remains clean prior to each use. Procedures should describe the requirements to PPE to be laundered either by the company on site or managed by an external service provider. The use of approved cleaning chemicals should be adhered to and

Clause no.	Requirement	Guidance
	packaging or equipment based on a food safety hazard analysis.	All hair should be appropriately covered using hairnets, beard snoods, etc., so that perspiration and loose items cannot contaminate products, food packaging or equipment based on a food safety hazard analysis. **Examples of evidence:** • Laundry and cleaning procedures where applicable, that includes laundry and cleaning requirements, frequency of cleaning, detergents used, and any temperature requirements as applicable. • Suitable PPE provided and visual confirmation of implementation. • Risk assessment for the use of PPE.
2.11.3	Personnel, visitors and contractors shall wash hands frequently, sanitize where necessary, and cover injuries on hands or forearms with suitable waterproof dressings. Where gloves are used for food packaging contact, they shall be fit for purpose and in good condition.	**Guidance:** All staff, including visitors and contractors who enter or work in packaging and production areas, adhere to high standards of hand hygiene and wound protection, to prevent contamination of food, packaging, equipment, and food contact surfaces. Hands should be washed using warm water and fragrance-free soap that has been approved for use in the food industry. The frequency of washing hands should be: **Before** entering production, packaging, or storage areas. **After:** • Using the restroom • Eating, drinking, or smoking • Handling waste or cleaning chemicals • Touching face, hair, or any potentially contaminated surfaces • Sneezing, coughing, or blowing nose • Removing gloves Injuries on hands and forearms shall be covered with suitable waterproof dressing. Controls have to be implemented to ensure dressings/plasters does not fall off or end up in the product. The use of gloves should have a process that describes the issuing and return of gloves.

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		This can be included in the personnel hygiene checks to ensure that used gloves do not go missing or end up in the product. Gloves should not be torn and should ideally be a different color that is easily noticeable in comparison to the manufactured food packaging materials. **Examples of evidence:** • Personnel hygiene procedure • Visitor's policy/procedure • Plaster control procedure and register • Glove procedure • Glove register
2.11.4	Personnel, visitors and contractors shall leave personal belongings in a dedicated place.	Self-explanatory.
2.11.5	Personnel, visitors and contractors, known to be infected with, or carrying a disease or illness transmissible through food or people, shall be prevented from handling food packaging and packaging material.	**Guidance:** Establish and implement a health declaration form for all personnel, contractors, and visitors. Include questions on symptoms such as fever, vomiting, diarrhea, recent contact with infected persons, recent travel, and open wounds. Require that it be completed before entry into any food packaging and packaging material production area. An authorized person from the conforming organization should review the answers given on each of the questionnaires before the decision is made to allow the visitor access into the production area. This can be demonstrated by means of a signature from the responsible person at the organization. **Include a self-reporting policy:** All staff should notify a supervisor/manager if they develop relevant symptoms at work or offsite.

Clause no.	Requirement	Guidance
		Examples of evidence: • Records of self-declaration • Visitors' health questionnaires.
2.11.6	**Personnel hygiene facilities and toilets**	
2.11.6.1	The organization shall ensure that staff facilities are designed, located and operated to prevent contamination.	**Guidance:** Suitable staff facilities need to be provided by the organization such as: • Changing rooms • Toilets • Handwashing basins • Canteens or break areas • Designated smoking shelters/areas • Showers (if applicable) The facilities need to be properly designed and located away from food packaging production or storage areas, and operated and maintained in a way that eliminates the risk of contamination of raw materials, additives, packing materials, finished products, and work surfaces. These should form part of the cleaning and disinfection programs as well as PRP verification activities. **Any local legislation shall be adhered to in terms of requirements around staff facilities e.g. the number of toilets, handwashing basins in relation to the number of workers.** **Examples of evidence:** • Provided staff facilities. • The master cleaning schedule • Reports of locker inspections and change room audits.

Clause no.	Requirement	Guidance
2.11.6.2	Suitable changing rooms shall be provided for personnel.	**Guidance:** Changing rooms/locker rooms shall be provided and should be located at the transition point between external environments and production zones. They should include: • Separate areas for clean and dirty clothes • Individual lockers for personal belongings • Benches, coat hooks, and PPE storage • Layout should promote a clean workflow: arrive → change → wash hands → enter production. **Examples of evidence:** • Designated change rooms, provided with personal lockers, storage for PPE, and separate food lockers.
2.11.6.3	Toilets shall be provided, operational, accessible and adequately segregated from processing and food handling areas.	**Guidance:** Conforming organizations need to provide a sufficient number of toilets, based on: • Staff count • Shift patterns • Facility size Consider separate toilets for: • Men and women • Visitors and staff • High-risk and low-risk area workers (where zoning is implemented) **All units should -** Flush properly. Be stocked with toilet paper, soap, and hand-drying materials. Be cleaned frequently and maintained in working order. Be located reasonably close to workstations, without requiring long walks or leaving the building, and be clearly signposted.

Clause no.	Requirement	Guidance
		Examples of evidence: • Suitable and well-maintained toilet facilities provided • Toilet facility inspection checklists • Internal audit reports • Cleaning records
2.11.6.4	Suitable and sufficient hand-washing and drying facilities shall be provided and accessible, including the supply of water at a suitable temperature, soap and, where relevant, sanitizer. Taps and waste bins should be handsfree.	**Guidance:** Facilities have to be fit-for-purpose, and designed for food packaging materials handling environments, Made from non-corrosive, easy-to-clean materials such as stainless steel, Properly drained and sealed to avoid pooling or leaking. Enough handwash stations must be available so that: All staff can access them without delay and The water supply must be of potable water that is warm enough to effectively remove oils, soils, and microbes (typically between 35°C–45°C) The use of liquid soap is preferred followed by sanitizer. Taps should be operated without the use of hands to minimize the risk of re-contaminating washed hands. Where paper towel is used, hands-free/ pedal operated or sensor-based waste bins should be installed or used. **Examples of evidence:** • Handwash Stations - Located near all entrances, toilets, and before entry into production areas, • Water Supply - Warm, potable, consistent pressure • Soap Dispensers - In good working order, fragrance-free liquid antibacterial soap used, regularly refilled • Sanitizer - where required (e.g. open product handling areas). • Taps - Hands-free (pedal, sensor, elbow, knee), • Drying Method - Disposable paper towels or air dryers.

Clause no.	Requirement	Guidance
		• Waste Bins - Covered, hands-free, emptied regularly.
2.11.6.5	Separate eating facilities shall be provided away from production, packaging and storage areas.	**Guidance:** Eating areas must be located away from production, packaging and storage areas. Make provision for separate canteen areas and personal meal storage areas such as refrigerators and microwave ovens or food warmers. Canteens should be fitted with hand washing and drying facilities to ensure that cross contamination from staff lunches is minimized. **Examples of evidence:** • Separate canteen areas located away from production, packaging and storage areas. • Handwashing and drying facilities for all staff
2.12	**Rework**	
2.12.1	Rework shall be managed effectively to prevent contamination and maintain food safety.	**Guidance:** The organization needs to have a system in place to deal with rework. Rework needs to be clearly identified and labelled and traceability has to be maintained. Details can include for example: • Date and batch numbers, lot numbers for traceability • Product type/ name and • Reason for rework • Quantity. Assess suitability to determine that the product can still be re-used or regraded and not wasted. The assessment should consider that the rework material is free from contaminants e.g. foreign bodies, does not show signs of damage, whether chemical migration need to be managed, and if the product is still within the expiry or shelf-life parameters. Sign off for quality and safety by an authorized person should be done.

Clause no.	Requirement	Guidance
		Examples of evidence: • Rework handling procedures • Rework tags/ Color coded labels/other visual method • Production records reflecting when rework was used if applicable.
2.12.2	Rework shall be stored, handled and used in such a way that product safety, traceability and regulatory compliance are maintained.	**Guidance:** Storage - rework needs to be stored in clean, designated areas while maintaining suitable temperature and humidity requirements linked to the product. Handling - where possible use dedicated equipment and tools managed by trained personnel. Usage - approved proportions that have been calculated in line with the final product specification should be used, i.e. the quantity of rework material should not affect the final product quality. Traceability - records of the current batch in which rework has been used has to include the batch details of rework material used. Regulatory requirements - ensure to not exceed the regulatory limits such as using expired products, omitting allergen information and recycled material content for example. **Examples of evidence:** • Designated storage areas • Rework handling procedures • Training records.
2.13	**Warehousing**	
2.13.1	The organization shall ensure that all raw materials (including packaging), intermediate and finished product are stored and transported under conditions that protect product integrity.	**Guidance:** Organizations need to understand what could compromise product integrity during storage and transport activities and implement appropriate controls, as applicable, for example: • appropriate storage conditions

Clause no.	Requirement	Guidance
		• use of vehicles that provide adequate protection from damage and contamination • avoiding potential contamination by enforcing hygiene and cleaning protocols **Examples of evidence:** • Visual inspection to confirm proper storage and transport conditions • Monitoring records such as logs, sensors, and hygiene and cleaning verification records to ensure proper conditions are maintained.
2.13.2	All vehicles, including contracted vehicles used for the transportation shall be suitable for the purpose, maintained in good repair and be clean.	**Guidance:** The organization should specify vehicle requirements based on the product (e.g., temperature control, ventilation, loading capacity). Written transportation procedures or supplier agreements should be in place, that also addresses vehicle maintenance and cleaning. Implement inspection routines where drivers or receiving personnel inspect vehicles before loading, and ensure records are kept. Check for cleanliness, temperature calibration, and integrity. Train staff/employees and contractors to understand vehicle hygiene and the relevant standards. **Examples of evidence:** • Documented maintenance and cleaning records/logs/service records. • Vehicle inspection records • Cleaning schedules and records should be easily retrievable. • Training records.
2.13.3	There shall be adequate facilities for the storage of raw materials, packaging materials, intermediate and finished products, including: • Storage off the floor and with sufficient space between the material and the	Self-explanatory.

Clause no.	Requirement	Guidance
	walls to allow inspection and pest control activities to be carried out. • Storage in clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odors or other sources of contamination.	
2.13.4	The storage facilities shall be properly constructed/organized to protect materials (raw materials, packaging materials, intermediate, and finished products, etc.) and avoid cross-contamination.	**Guidance:** Consider Building Design & Structure - walls, ceilings, and floors should be smooth, impervious, and easy to clean. Free from cracks or peeling paint that could harbor pests or debris, or potential for physical cross contamination. Drains and water systems prevent contamination (e.g., sloped floors to avoid stagnant water). Lighting must be adequate for visibility, with shatterproof covers. Ventilation prevents mold, condensation, and dust buildup etc. Doors and windows should be sealed or screened to prevent pest entry. Loading docks should have air curtains or strip curtains. Organizations should consider the following: • Staff movement in and around the storage areas, i.e. limit access to trained staff and implement good hygiene practices for staff who are required to work in these areas. • Allergen cross contamination • FIFO and FEFO principles • Chemical and non-food item storage. **Examples of evidence:** • Suitable storage facilities • Procedures that define specifications for building structures.

Clause no.	Requirement	Guidance
2.13.5	Storage and transport shall be appropriate to minimize the deterioration of the raw materials, intermediate and finished products (e.g., by temperature and humidity control).	**Guidance:** Storage and transport should not increase the chances for microbiological spoilage, chemical degradation such as discoloration and physical damage of materials, intermediate and finished packaging materials. **Examples of evidence:** • Humidity control • Temperature control • Ventilation • Air quality and contamination control • Transport specific controls • Storage facility practices etc.
2.13.6	Maintenance and hygiene processes shall be effectively implemented for vehicles and equipment used for loading and unloading.	**Guidance:** Implement preventive maintenance that include procedures such as scheduled checks and servicing (e.g., monthly inspection of hydraulic lifts or refrigeration units on trucks, regular maintenance/services of vehicles and equipment, etc.). Corrective Maintenance - immediate repair of faults or damage that could affect safety or hygiene (e.g., fixing worn tires, repairing cracked loading bays). **Examples of evidence:** • Maintenance plans or schedule and supporting maintenance and service records; • Recordkeeping logs of inspections, including any corrective actions taken.
2.13.7	A product transport procedure shall be in place and effectively implemented.	**Guidance:** Establish and implement a procedure that outlines how products are transported. Ensure that this procedure is followed consistently in practice to maintain product safety, quality, and integrity during transit. This can include all products—raw materials, intermediate goods, and finished products—and includes internal movements (e.g., between facilities) and external transportation (e.g., deliveries to customers or from suppliers).

Clause no.	Requirement	Guidance
		Examples of evidence: Procedure that describes the following but not limited to: • Transport Conditions • Vehicle Suitability • Loading and Unloading Protocols • Traceability and Documentation • Emergency plan/ Crisis response plan etc. • Breakdown procedure • Security Measures such as the application of seals or use of surveillance • Personnel training.
2.14	**Management of analysis/testing services**	
2.14.1	The organization shall implement a program to ensure that analysis of products and input materials is systematically undertaken for issues that are identified as being critical to food safety and legal requirements, as well as customer specifications.	**Guidance:** Create a program for the analysis of products and input materials in line with food safety, legal and customer requirements. The program should include a plan of what types of verification activities will be undertaken for products and input materials that are critical to food safety. Make a list of the materials and note the verification type, including the frequency. COA's and product specifications can be used as a basic guideline of what needs to be tested.
2.14.2	Where out of specification results are obtained, the organization shall handle the affected lot(s) of product as nonconforming products and apply appropriate correction and corrective actions.	Self-explanatory.
2.14.3	Appropriate methods, relevant for food safety, shall be used to provide valid results (e.g. by procedures set forth in ISO 17025 and/or industry recognized methods).	**Guidance:** Refer to the Interpretation article on Laboratory analysis for critical food safety parameters, available on our website: www.fssc.com for more information

Clause no.	Requirement	Guidance
2.14.4	Analysis procedures shall be in place to ensure that all specified product requirements are met, including legal requirements and customer specifications.	**Guidance:** To re-affirm and reinforce product safety, regulatory compliance, and customer satisfaction, create and document a procedure that has structured analytical controls which: • Verify compliance with legal limits (e.g., contaminants, additives, labelling). • Ensures that the product meets customer-defined requirements and • Confirm conformity to internal specifications **Examples of evidence:** • Procedure describing the requirements (regulatory or customer specific requirements), methods of analysis, what the required results and limits should be, sampling and how often it must be done, what actions are to be taken for out of specification results and records to be kept.
2.15	**Food packaging information and customer communication**	
2.15.1	Packaging products shall be accompanied by, or bear adequate information, to enable the next organization in the food chain to handle, prepare, display, store, and/or use the products safely and correctly. This shall include allergen declarations and meet legislative and customer requirements.	**Guidance:** The product packaging shall carry or be accompanied by complete and correct information that enables the customer (e.g. retailer, caterer, food service), or the end consumer to safely handle, display, store and/or use the product. The information needs to include the following but not limited to: • Legally required content (labelling laws, allergens, storage conditions, usage instructions), where printed information is applicable. • Customer-specific requirements (e.g. private label instructions for branding purposes, certifications, languages) **Examples of evidence:** • Labelling procedures defining the steps to be followed for label creation, approval and review, including customer communication and agreement. • Labelling verification procedures, including version-controlled label template removal and customer and regulatory requirements.

Clause no.	Requirement	Guidance
2.15.2	Information shall be presented to consumers in such a way that enables them to understand its importance and make informed choices.	**Guidance:** Ensure transparency and clarity in the way food safety information is communicated to consumers as applicable for printed information and label production. Ensure that the information is not just available, but is also accessible, delivered in a format or language that the consumer can understand. The label should enable the consumer to make choices aligned with their dietary needs or restrictions. **Examples of evidence:** • Clear labels that communicate allergenic information or information for immune compromised individuals.
2.16	**Labelling**	
2.16.1	The organization shall ensure that where finished products are labelled, the organization shall have labelling procedures in place and ensure that applicable statutory and regulatory requirements in the country of intended sale, including allergen and customer specific requirements, are complied with.	**Guidance:** Establish and maintain a list of the latest legislation that addresses labelling as well as customer requirements, linked to the country of sale. Ensure that labelling of all finished products reflects accurate product identification and ensures traceability. Where applicable, ensure that product labelling contains the relevant allergen information in accordance with regulatory and customer requirements, to prevent consumer harm. Label versions need to be controlled to prevent errors during changeovers or reprints, when changes and customer design updates take place. This can be managed through change procedures. **Examples of evidence:** • Labelling procedures for regulatory and customer label compliance, documented label approval systems, Allergen labelling must follow recognized regulatory lists (e.g. FDA, EU, Codex Alimentarius), Customer-specific needs (e.g., color schemes, font size, layout, barcodes) etc.

Clause no.	Requirement	Guidance
2.16.2	Line start-up and change-over procedures shall be established and implemented to ensure products meet applicable customer and legal requirements. This shall include having controls in place to ensure product from the previous run have been removed from the line.	**Guidance:** Create and use procedures to be followed whenever food packaging production line is started up (e.g., at the beginning of a production shift or after a stoppage), or change over (e.g., when switching from one product packaging to another or from one batch to another). The procedures should ensure that the relevant aspects of product integrity including the correct product packaging and identification are verified and controlled before the line starts up or resumes production. This needs to consider specific customer requirements and legislation requirements. **Examples of evidence:** • Documented procedures for line start up and changeover procedures, pictorial instructions for the packing department to follow, verification and sign off records by relevant personnel, e.g. line supervisors or production managers.
2.17	**Logo Use**	
2.17.1	Conforming organizations shall use the FSSC 22000 Development Program logo only for marketing activities such as the organization's printed matter, website, and other promotional material.	**Guidance:** To protect the credibility and the integrity of the FSSC Development Program logo it is important to prevent misleading use of the logo, and to ensure its authorized usage in non-product contexts. Conforming organizations are only allowed to use the logo as instructed by FSSC. **Examples of evidence:** Permitted areas for use are as follows: • Company website (e.g., in a section about food safety systems or food safety journey) • Brochures and flyers about the organization or its quality assurance systems • Corporate PowerPoint presentations • Exhibition materials and trade show displays • Business cards and letterheads (only if used for promotional rather than regulatory purposes).

Clause no.	Requirement	Guidance
2.17.2	The confirming organization is not allowed to use the FSSC 22000 Development Program logo, any statement or refer to its conforming status on: • a product; its labelling; its packaging (primary, secondary or any other form); • certificates of analysis or certificates of conformance (CoA's or CoC's); • in any other manner that implies FSSC approves a product, process, or service and • where exclusions to the scope apply.	Self-explanatory.
2.17.3	Where the FSSC 22000 Development logo is being used, it shall comply with the design specifications included within the Program document.	**Guidance:** Conforming organizations have to obtain the logo and design specifications from their CABs and follow these to comply.
2.18	**Food Defense**	
2.18.1	The threats to the product as a result of intentional product tampering or intentional contamination shall be assessed.	**Guidance:** Food defense focuses on malicious acts intended to cause public health harm, panic, or brand damage. Therefore, assess the potential for intentional harm to products (such as sabotage, extortion, disgruntled employee activity, ideological attacks). Recognize that these threats may occur internally (staff) or externally (intruders, supply chain actors) and consider them in your assessment. **Refer to the FSSC 22000 Food Defense Guidance document for more information, available on www.fssc.com**

Clause no.	Requirement	Guidance
		Examples of evidence: Implemented threat assessment and mitigation strategy (e.g. TACCP – Threat Assessment and Critical Control Points) that covers: • The Scope • Identification of Potential Threat Scenarios, • Common Threat Scenarios such as open product, access points for stored materials, or public facing or low security areas. • Assessment of Threat Likelihood and Impact.
2.18.2	The points in the process which are vulnerable to intentional product tampering/intentional contamination shall be identified and subjected to additional control.	**Guidance:** Identify specific points in the food packaging materials production, packing, and distribution processes where intentional contamination or tampering could occur. Evaluate these potential vulnerable points using structured threat assessments (e.g., TACCP) as described above. Apply additional protective controls (physical, procedural, or technological) at those points to prevent, detect, or respond to intentional attacks. The focus should be on deliberate harm (malicious contamination or sabotage), not accidental failures. Incorporate the food defense plan as part of internal audit schedules. Review and update assessments annually or when major changes (e.g., new product lines, equipment layout, geopolitical risks, etc.) **Examples of evidence:** • Documented threat assessments, food defense plan, control records, surveillance logs, and incident reports.
2.18.3	Measures shall be in place to address what to do with the product, if prohibited access took place and the product may have been tampered with or intentionally contaminated.	**Guidance:** Implement a Food Defense Incident Response Protocol to initiate corrective actions to address affected products. Appoint an incident management team, this can be the same as the food safety team.

Clause no.	Requirement	Guidance
		Steps to be taken could include: • Isolating the affected product • Activating the Food Defense Incident Response Team • Conducting an initial risk assessment to determine the nature of the tampering, location and methods of tampering, extent of exposure and potential risk to health, etc. • Keeping samples of evidence until the investigation outcomes and conclusions are reached, • Formulating an incident report • Inform stakeholders and customers. Note: Responsibility to communicate should be assigned to a senior member from leadership **Examples of evidence:** • Documented incident management procedures, Food defense plan (revised), minutes of meetings, traceability of communication etc.
2.19	**Food Fraud Mitigation**	
2.19.1	The organization shall conduct a food fraud vulnerability assessment identifying potential vulnerabilities in raw materials, packaging materials and outsourced processes.	**Guidance:** Conduct and document a Food Fraud Vulnerability Assessment (FFVA), focusing on the intentional adulteration or deception of raw materials, additives, packaging materials and outsourced processes linked to the finished product(s) for economic gain. Make a list of all materials and additives, packaging materials and outsourced processes (e.g. contract manufacturing, outsourced cleaning or logistics), and assess the vulnerabilities based on for example: • Historical fraud incidents, • Economic value, • Supply chain complexity, Geographical origin, • Ease of detection and • Supplier reliability.

Clause no.	Requirement	Guidance
		Use a risk matrix to determine the likelihood and impact of the risk. Categorize the risks and plan an annual review of the assessment or when triggers occur. **Refer to the FSSC 22000 Food Fraud Guidance document for more information, available on www.fssc.com** **Examples of evidence:** • Documented Food Fraud Vulnerability Assessment (FFVA), Updated list of all materials, packaging materials and outsourced processes, review records.
2.19.2	For each vulnerability identified, the organization shall establish and implement appropriate mitigation measures.	**Guidance:** Once specific vulnerabilities (e.g. risk of adulteration, substitution, counterfeit packaging) have been identified, your organization should take active, documented steps to reduce or eliminate those that have been determined to be significant. It is important to note that every vulnerability identified will NOT automatically be determined to be significant and will NOT automatically be required to be addressed by a mitigation measure. Identifying as many vulnerabilities as possible is important so they can be assessed. Also, bear in mind that vulnerabilities and their related severity can change over time, including when significant changes occur in the organization and the industry. It is therefore, essential to conduct a regular review of the assessment to ensure that it is still relevant and that the mitigation measures are appropriate. Plan an annual review of the control measures or when triggers occurs. **Examples of evidence:** • Supplier control measures that include the approval of suppliers, supplier audits and contractual agreements. • Analytical Testing to conduct authenticity tests. • Procurement Strategy that considers the use of more than one supplier per commodity or material. • Training & Awareness programs for the food safety team, the procurement department and relevant selected members of staff.

Clause no.	Requirement	Guidance
2.19.3	Document the above mentioned within a food fraud mitigation plan, which shall be kept up to date and reviewed annually.	**Guidance:** Establish and document a mitigation plan that includes risk score rating, responsible people for action and verification methods. **Examples of evidence:** • Documented food fraud mitigation plan and evidence of at least annual review. Check to see if the plan was reviewed where changes or triggers occurred.
2.20	**PRP Verification**	
2.20.1	The organization shall establish, implement, and maintain routine (e.g., monthly) site inspections/PRP checks to verify that the site (internal and external), production environment and processing equipment are maintained in a suitable condition to ensure food safety. The frequency and content of the site inspections/PRP checks shall be based on risk with defined sampling criteria.	**Guidance:** Organizations need to routinely inspect the packaging manufacturing and storage environment to verify ongoing compliance with food safety requirements. These inspections support the effectiveness of PRPs, which forms the basis of a food safety system. Assign dedicated personnel to lead the inspections, and involve personnel from different areas e.g. maintenance, hygiene, and quality control personnel in joint inspections. The frequency and content of the inspections needs to be based on risk and cover the PRPs in the Development Program. For example: • Monthly inspections for general site and infrastructure • Daily or weekly for high-risk processing areas or allergens • Quarterly for building fabric or equipment. **Examples of evidence:** Risk based inspection program schedule (e.g. monthly, weekly, or daily depending on risk), checklists aligned with PRPs such as • Floors, walls, ceilings (cleanliness, damage, contamination risks) • Equipment condition (rust, cracks, cleanliness, calibration) • Air handling units and filters • Water sources and drainage

Clause no.	Requirement	Guidance
		• Personnel hygiene stations • Pest control points and evidence of infestation • Waste disposal areas • Site perimeters and access points etc. • Corrective actions and actions reports from negative findings.

Clause no.	Requirement	Guidance
3. HACCP Control		
CODEX Alimentarius General Principles of Food Hygiene (CXC 1-1969 - Latest Edition) provides a wealth of knowledge relating to HACCP and its implementation. However, please keep in mind that the FSSC Development Program also includes OPRPs (Operational Pre-requisite Programs) which is not covered by this CODEX standard. Therefore, please ensure that you always meet the minimum requirements as detailed in the FSSC Development Program Sector Assessment Requirements Section 3 for HACCP Control, and only use the CODEX standard as guidance. References to clause numbers in the below sections relates to the clauses in CODEX Alimentarius General Principles of Food Hygiene (CXC 1-1969 - Latest Edition). Refer to relevant links below: • CODEX Alimentarius website • Current latest edition of the above mentioned standard For further understanding on HACCP and the identification and control of significant hazards with CCPs and OPRPs, refer to the ISO 22000:2018 standard, and specifically clause 8.5 on hazard control. Additionally, ISO has also published "A practical guide to ISO 22000:2018" which is a handbook that provides a practical approach and a wide range of information to develop, document, implement and maintain a robust FSMS according to ISO 22000:2018. This standard, as well as the handbook, can be purchased from the ISO webstore: • ISO 22000:2018 Standard • A Practical Guide A reminder that the use of these ISO standards are not mandatory for the FSSC Development Program.		
3.1	**Preliminary steps to enable hazard analysis**	
3.1.1	The organization shall identify and comply with relevant regulatory and customer requirements related to the product and product categories.	Self-explanatory.
3.1.2	Task 1: Establish a multi-disciplinary food safety team. A multi-disciplinary team with different responsibilities for food safety shall have	For guidance, refer to clause 19.1: Assemble a HACCP team and identify scope (Step 1).

Clause no.	Requirement	Guidance
	undertaken the tasks described in this section of the checklist (Tasks 2 -5). Note: The team should comprise of personnel with the knowledge and experience in the organization's products, processes, equipment and food safety hazards.	
3.1.3	Task 2: A complete product description shall be available of the product/product category including all raw materials, packaging, intermediate and finished product, and the conditions for storage and distribution. The product description shall include product characteristics (biological, chemical and physical), composition, source, place of origin, method of production, packaging, storage and delivery conditions and shelf life, and preparation and/or handling before use or processing.	For guidance, refer to clause 19.2: Describe product (Step 2).
3.1.4	Task 3: The intended use of the product shall be described and the target consumer identified, including vulnerable consumer groups.	For guidance, refer to clause 19.3: Identify intended use and users (Step 3).
3.1.5	Task 4: All the process steps taken to produce the product shall be documented in a process flow diagram. Flow diagrams shall be clear, accurate and sufficiently detailed to the extent needed to conduct	For guidance, refer to clause 19.4: Construct flow diagram (Step 4).

Clause no.	Requirement	Guidance
	the hazard analysis. It shall include the following as appropriate: • sequence and interaction of the steps; • any outsourced processes; • where raw materials, processing aids, packaging materials, utilities and intermediate products enter the flow; • where reworking and recycling take place; • where end products, intermediate products, by-products and waste are released or removed.	
3.1.6	Task 5: Onsite verification of the process flow diagram(s) shall take place at least annually, or more often when changes occur, to ensure it accurately reflects the production process.	For guidance, refer to clause 19.5: On-site confirmation of flow diagram (Step 5). **Additional guidance:** In addition to the initial onsite confirmation of the flow diagram, and when changes occur, the organization should also schedule an annual process verification walk to be done by the appointed food safety team. This can be done by the entire team all at the same time or at different times of the day to gain a different perspective, followed by a comparison of each team members' findings at the end of the exercise. **Examples of evidence:** • Flow diagrams for each product/ product group/ category verified and signed off by the food safety team. • This can be in the form of signed flow diagram records, with notes if any changes/updates were observed during the verification walk. • Meeting minutes.

Clause no.	Requirement	Guidance
3.2	**Hazard analysis** *The approach for analysis and control of hazards shall be in line with the seven (7) HACCP principles and 12 steps of the CODEX Alimentarius.*	
3.2.1	The organization shall conduct a hazard analysis of their food packaging manufacturing process, based on the preliminary information, to determine if there are any food safety hazards associated with the production of their food packaging products that might cause a food safety risk.	Self-explanatory.
3.2.2	**Principle 1:** A hazard analysis shall be conducted for each process step in the manufacturing of the food packaging item: • identify and document all food safety hazards that are reasonably expected to occur; • determine the acceptable level in the end product for each food safety hazard identified; and • conduct a hazard assessment for each food safety hazard identified (likelihood of occurrence versus severity of its adverse health effects)	For guidance, refer to clause 19.6: List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/Principle 1).
3.2.3	The hazard analysis shall be conducted by a competent multi-disciplinary team.	The appointed food safety team needs to conduct the hazard analysis. Where expertise is not in available within the organization, then this can be sourced externally. Where the help of external experts is used, this should be clearly documented and agreed in writing by the expert as well as a representative of the organization.

Clause no.	Requirement	Guidance
		The organization is still responsible to review the hazard analysis and ensure it fully covers all the processes and activities of the site, that it is suitable for the operation and that it fully meets the requirements of Section 3 - HACCP control, of the Assessment Requirements for the FSSC Development Program. This includes that all relevant hazards have been identified and are effectively addressed within the hazard analysis.
3.2.4	**Principle 2:** Determining Critical Control Points (CCPs) and Operational Prerequisite Programs (OPRPs) Where the hazard analysis indicates any significant hazards not minimized or eliminated by PRPs, and based on the outcome of the decision tree, then OPRPs and/or CCPs shall be identified for their control and properly categorized.	Refer to Annex 3 - HACCP (CCP/OPRP) Decision Tree of the FSSC Development Program for a decision tree that can be used to determine the Critical Control Points (CCPs) and Operational Prerequisite Programmes (OPRPs). Use the above-mentioned decision tree or an equivalent tool to determine the control measure(s) (CCPs / OPRPs). **Additional guidance:** Refer to clause 19.7: Determine the critical control points (CCPs) (Step 7/Principle 2) of CODEX Alimentarius General Principles of Food Hygiene. A reminder that this standard does not define requirements for OPRPs and the FSSC Development Program includes OPRPs. The requirements of the FSSC Development Program shall be met. For further guidance, including for OPRPs, refer to clause 8.5 of ISO 22000:2018 and the related handbook, A Practical Guide to ISO 22000:2018. **Examples of evidence:** • Completed decision tree to show how CCP and OPRP determination was done.
3.2.5	If these hazards are identified within the process/operation, the organization shall have effective control measures that ensure the elimination of the hazards or to reduce them to acceptable levels. The organization shall implement specific controls for all relevant steps not identified as CCPs or OPRPs e.g., effective implementation and management of PRPs.	Self-explanatory.

Clause no.	Requirement	Guidance
3.2.6	**Principle 3:** Critical Limits shall be established for each CCP and action criteria for OPRPs. Critical limits at CCPs shall be measurable. Action criteria for OPRPs shall be measurable or observable.	For guidance, refer to clause 19.8: Establish validated critical limits for each CCP (Step 8/Principle 3) and 19.11.1: Validation of the HACCP plan, of CODEX Alimentarius General Principles of Food Hygiene. A reminder that this standard does not define requirements for OPRPs and the FSSC Development Program includes OPRPs. The requirements of the FSSC Development Program shall be met. For further guidance, including for OPRPs, refer to clause 8.5 of ISO 22000:2018 and the related handbook, A Practical Guide to ISO 22000:2018.
3.2.7	Critical limits and action criteria shall be validated, and the validation shall be documented.	
3.2.8	**Principle 4:** Monitoring procedures shall be established for each CCP and OPRP and undertaken by competent personnel to ensure that CCPs and OPRP's are effectively implemented. It shall consist of: • monitoring methods or devices used; • monitoring frequency; • monitoring results; • responsibility and authority related to monitoring; and • responsibility and authority related to evaluation of monitoring results. Deputies shall be identified, trained and available in case of the absence of the person responsible for monitoring.	For guidance, refer to clause 19.9: Establish a monitoring system for each CCP (Step 9/Principle 4) of CODEX Alimentarius General Principles of Food Hygiene. A reminder that this standard does not define requirements for OPRPs and the FSSC Development Program includes OPRPs. The requirements of the FSSC Development Program shall be met. For further guidance, including for OPRPs, refer to clause 8.5 of ISO 22000:2018 and the related handbook, A Practical Guide to ISO 22000:2018.
3.2.9	**Principle 5:** Corrections and/or corrective actions shall be established for each CCP and OPRP in the event that critical limits or	For guidance, refer to clause 19.10: Establish corrective actions (Step 10/Principle 5) of CODEX Alimentarius General Principles of Food Hygiene.

Clause no.	Requirement	Guidance
	action criteria are not met. It shall ensure that: the potentially unsafe products are not released; the cause of nonconformity is identified; the parameter(s) controlled at the CCP or by the OPRP is (are) returned within the critical limits or action criteria; and recurrence is prevented.	A reminder that this standard does not define requirements for OPRPs and the FSSC Development Program includes OPRPs. The requirements of the FSSC Development Program shall be met. For further guidance, including for OPRPs, refer to clauses 8.5 and 8.9 of ISO 22000:2018 and the related handbook, A Practical Guide to ISO 22000:2018. **Additional guidance:** In relation to the organization ensuring that the parameter(s) controlled at the CCP or by the OPRP is (are) returned within the critical limits or action criteria, this means that the organization needs to ensure that parameters are back within the required critical limits or action criteria, prior to recommencing with the process.
3.2.10	**Principle 6:** Verification procedures shall be established and effectively implemented for PRPs, OPRPs and CCPs.	For guidance, refer to clause 19.11: Validation of the HACCP plan and verification procedures (Step 11/Principle 6) and specifically clause 19.11.2: Verification procedures, of CODEX Alimentarius General Principles of Food Hygiene. A reminder that this standard does not define requirements for OPRPs and the FSSC Development Program includes OPRPs. The requirements of the FSSC Development Program shall be met. For further guidance refer to clauses 8.6 and 8.8 of ISO 22000:2018 and the related handbook, A Practical Guide to ISO 22000:2018.
3.2.11	**Principle 7:** Record keeping and documentation for HACCP procedures shall be established and effectively implemented.	For guidance, refer to clause 19.11.3: Establish documentation and record keeping (Step 12/Principle 7) of CODEX Alimentarius General Principles of Food Hygiene. A reminder that this standard does not define requirements for OPRPs and the FSSC Development Program includes OPRPs. The requirements of the FSSC Development Program shall be met. For further guidance refer to clause 7.5 of ISO 22000:2018 and the related handbook, A Practical Guide to ISO 22000:2018. This defines the requirements for documented information, however, what documented information needs to be kept relating to HACCP and what needs to be included within a specific piece of documented information is detailed under the respective clauses of the standard e.g., 8.5, 8.8, 8.9, etc.

Clause no.	Requirement	Guidance
3.2.12	The organization shall establish, implement and maintain a documented hazard control plan which shall include the following for each CCP or OPRP: • food safety hazard(s) to be controlled at the CCP or by the OPRP; • critical limit(s) at CCP or action criteria for OPRP; • monitoring procedure(s); • correction(s) to be made if critical limits or action criteria are not met; • responsibilities and authorities; and • records of monitoring.	Self-explanatory.
3.2.13	In the event of changes to raw materials, packaging materials, processes, infrastructure, equipment, etc., the hazard control plan (HACCP / OPRP Plan) shall be reviewed and updated if needed.	Self-explanatory.
3.3	**Control of monitoring and measuring**	
3.3.1	Measuring and monitoring devices critical to food safety and regulatory requirements shall be appropriate to the intended use, reliable, accurate, and function properly. They shall be well maintained and, where appropriate, calibrated.	Self-explanatory.

Clause no.	Requirement	Guidance
3.3.2	Measuring and monitoring devices critical to food safety shall be identified, calibrated on a regular basis, traceable to recognized national or international standards, and be effectively controlled.	**Guidance:** Create a list of all the measuring and monitoring devices critical to food safety and regulatory requirements. This may include, for example, scales and mass pieces (where weighing is critical to food safety), spectrophotometer, gas chromatograph and camera systems, etc. Create identification by means of labels, stickers and or other forms of coding for traceability of measuring and monitoring devices. Define what each one's method and frequency of calibration and/or verification is. This may include internal verification more frequently e.g., daily or weekly, depending on the use, and externally calibration, for example, annually. Consider the manufacturer's instructions for use. Ensure the service provider used for external calibration offers calibrations/verifications that are traceable to recognized national or international standards, this can be in the form of accreditation. Maintain records. **Examples of evidence:** • Calibration/verification schedule. • Calibration/verification records. • Evidence to demonstrate the calibrations where traceable to recognized national or international standards.
3.3.3	Actions shall be taken and recorded when measuring and monitoring devices are found to be outside of specified limits.	**Guidance:** When measuring and monitoring devices are found to be outside of specified limits, the organization shall take the necessary actions. The organization should define planned corrections and corrective actions to be taken in advance, so that the responsible persons are aware of what actions to take. Examples of actions may include: • Remove the out of specification device from use. If no replacement device is available onsite, arrange a loan device from the service provider, until such time the repaired or new device is available.

Clause no.	Requirement	Guidance
		• Depending on the device, action may need to be taken with product(s) that was produced between the time the device was last operating within specification and when it was found to be outside the specified limits. Define what action must be taken. **Examples of evidence:** • Calibration/verification records. • Corrective action reports.
3.4	**Handling of potentially unsafe products**	
3.4.1	The organization shall ensure that potentially unsafe product is clearly identified and controlled to prevent unintended use or delivery. It shall be reprocessed or further processed within or outside the organization to ensure that food safety hazards are eliminated or reduced to acceptable levels or destroyed and/or disposed of as waste.	**Guidance:** Organizations need to establish, implement, and maintain a documented procedure that addresses: • What to do when a nonconforming product/material/ equipment is identified e.g., all personnel must be made aware that they need to report any nonconforming items to the relevant manager/supervisor. • Who is responsible for handling, evaluating and decision making – this person(s) needs to be competent and sufficiently trained to manage the control of nonconforming product. • How affected product/material/equipment is identified (e.g., labelled as on hold/quarantined/nonconforming before evaluation, and labelled as rejected after evaluation if not safe for release) and isolated (e.g., segregated from conforming items, or placed in a dedicated area). • How affected product/material/equipment is assessed (e.g., designated person must evaluate or arrange the evaluation of the nonconforming item) – the evaluation can be via visual inspection, analytical testing, physical evaluation (e.g., seal strength), microbiological testing, etc. – the type of evaluation depends on the type of nonconformity that resulted in the nonconforming product/material/equipment and the related risk.
3.4.2	Products affected by a nonconforming situation shall be held under control until they have been evaluated.	
3.4.3	The organization shall be able to take measures for the reporting, containment, reprocessing, withdrawal or recall when products are potentially unsafe.	
3.4.4	The control of non-conforming product shall be managed by competent and sufficiently trained personnel.	

Clause no.	Requirement	Guidance
3.4.5	A documented procedure shall be in place to identify and manage all non-conforming raw materials, product inputs, semi-finished and finished products, processing equipment and packaging materials.	• What action must be taken (e.g., rework, reprocessing, disposal, return to supplier, recall/withdrawal, etc.) – the action taken will be dependent on the outcome of the evaluation/assessment and the related risk. • What records need to be maintained. Products that do not conform to food safety requirements can result from the following, for example: • Not meeting critical limits for CCPs • Not meeting action criteria for OPRPs • Contamination (microbiological, chemical, allergenic, physical) • Incomplete or inaccurate labelling (e.g., allergens not specified) • Packaging defects that compromise food safety **Examples of evidence:** • Documented nonconforming product/material/equipment procedure. • Training records showing relevant staff are competent in applying the procedure. • Nonconforming product records and/or Corrective action reports. • Quarantine records, Reprocessing records, Final release records, etc.