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4	**CONTEXT OF THE ORGANIZATION**				
4.1	**UNDERSTAND THE ORGANIZATION AND ITS CONTEXT**				
	The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended safety management system.				
	The organization shall identity, review and update information related to these external and internal issues.				
With reference to the note in 4.1					
	Issues can include positive and negative factors or conditions for consideration.				
	Understanding the context can be facilitated by considering external and external issues not limited to legal, technological, competitive, market, cultural, social, economic environment, cybersecurity and food fraud, food defense, and intentional contamination, knowledge and performance of the organization whether international, national regional or local.				
4.2	**UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES**				
	To ensure that organization has the ability to consistently provide products and service that meet applicable statutory/regulatory and customer requirements with regard of food safety the organization shall determine:				
	• The interested parties that are relevant to the food safety management system.				
	• The requirements of the requested parties that are relevant to the food safety management system.				
	• The organization shall identify review and update information related to the interest parties and their requirements.				

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4.3	**DETERMINING THE SCOPE OF THE FOOD SAFETY MANAGEMENT SYSTEM**				
	The organization shall determine the boundaries and applicability of the food safety management system to establish its scope the scope shall specify the products and services. processes and production sites that are addressed by the food management systems and shall include the activities, processes product or service that can have an influence on the food safety of the end products.				
	When determining this scope, the organization shall consider:				
	The external and internal issues referred to in 4.1				
	The requirements referred to in 4.2				
	The scope shall be available and maintained as documented information.				
4.4	**FOOD SAFETY MANAGEMENT SYSTEM PERFORMANCE OF LABORATORY ACTIVITIES**				
	The organization shall establish implement, maintain, update and continually improve a food safety management system including the processes needed and their interactions, in accordance with the requirements of document.				
5	**LEADERSHIP**				
5.1 **LEADERSHIP AND COMMITMENT TOP MANAGEMENT**					
	Top management shall demonstrate leadership and commitment with respect the food safety management system by:				

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	Ensuring the integration of food safety management system requirements into the organization's business process:				
	Ensuring that the resource needed for the food safety management system are available;				
	Communicating the importance of effective food safety management and of confirming to the food safety management system requirements, statutory/regulatory requirements and mutually agreed customer requirements related to food safety;				
	Ensuring that the food safety management system is evaluated and maintained to achieve it intend outcome(s) results (see4.4)				
	Directing and supporting persons to contribute to the effectiveness of the food safety management systems;				
	Promoting continual improvement;				
	Supporting other relevant management roles to demonstrate their food safety leadership as it applied to their areas of responsibility.				
With reference to the note in 5.1					
	Refers to" business" in this document can be interpreted broadly to mean those activities that are core to the purpose of the organization existence.				
5.2	**FOOD SAFETY POLICY**				
5.2.1	**ESTABLISHING THE FOOD SAFETY POLICY**				
	Top management shall establish, implement, and maintain a food safety policy that:				
	Is appropriate to the purpose and context of organization;				
	Provides a framework for setting n reviewing the objectives of food safety management system;				
	Includes a commitment to satisfy applicable food safety requirements including statutory/regulatory requirements and mutually agreed customer requirements related to food safety;				

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	Address internal and external communication;				
	Includes a commitment to continual improvement of the food safety management system;				
	Address the need to ensure competencies related to food safety.				
5.2.2	**COMMUNICATING THE FOOD SAFETY POLICY**				
	The food safety policy shall:				
	Be available and maintained as documented information;				
	Be communicated, understood, and applied at all levels within the organization;				
	be available to all relevant interested parties, as appropriate.				
5.3	**ORGANIZATIONAL ROLES, RESPONSIBILITIES, AND AUTHORITIES**				
	Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization.				
	Top management shall the responsibility and authority for:				
	Ensuring that the food safety management system conforms to the requirements of this document;				
	Reporting on the performance of the food safety management system to top management;				
	Appointing the food safety team and the food safety team leader;				
	Designation person with defined responsibility and authority to initiate and document action(s).				

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5.3.2 THE FOOD SAFETY TEAM LEADER SHALL BE RESPONSIBLE FOR:					
	Ensuring the food safety management system is established, implemented, maintained and updated;				
	Managing and organizing the work of the food safety team; and				
	Ensuring relevant training of food and competencies for the food safety team (see 7.2)				
	Reporting to top management on the effectiveness and suitability of the food safety management system.				
	All person shall have responsibility to report problem(s) with food safety management system to identified person(s).				
6	**PLANNING**				
6.1	**ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES**				
6.1.1	• When planning for the food safety management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:				
	• Give assurance that food safety management system can achieve its intended outcome(s) results;				
	• Prevent or reduce, undesired effects;				
	• Achieve continual improvement.				
With reference to the note in 6.1.1:					
	In the context of this document, the concept of risk and opportunities is limited to events and their consequences relating to the performance and effectiveness of food safety management system. Organization are not required to directly address public health risks which are under the responsibility of the appropriate authorities. However, they are required to manage food safety				

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	hazards (see 3.22) and the requirements related to this process are laid down in Clause 8.				
6.1.2	**The organization shall plan:**				
	• Actions to address these risks and opportunities;				
	• How to:				
	• Integrate and implement the actions into its food safety management system processes;				
	• Evaluate the effectiveness of these actions.				
6.1.3	The actions taken by the organization to address risks and opportunities shall be proportionate to:				
	• The potential impact on food safety requirements, and;				
	• The conformity of food products and services to customers, and;				
	• Requirements of interested parties in the food chain.				
With reference to the note 1 in 6.1.3					
	• Options to address risks and opportunities can include: avoiding risks, taking risks in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risks, or accepting the presence of risk by informed decision.				
With reference to the note 2 in 6.1.3					
	• Opportunities can be lead to the adoption of new practice (modification of products or processes), using new technology and other desirable and viable possibilities to address the organization ‘s or its customer’s food safety needs.				
6.2	**Objectives of the food safety management system and planning to achieve them**				
6.2.1	The organization shall establish objectives of the food safety management system at relevant functions and levels.				
	The objectives of the food safety management shall:				
	• Be consistent with food safety policy; authorization of results				
	• Be measurable (if practicable);				
	• Take into account applicable food safety requirements including statutory/regulatory and customer requirements				

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	• Be monitored and verified;				
	Be communicated;				
	Be maintained and updated as appropriate.				
	The organization shall retain documented information on the objectives of the food safety management system.				
6.2.2	When planning how to achieve its objective of the food safety management system, the organization shall determine:				
	What will be done;				
	• What resources will be required;				
	• Who will be responsible;				
	• When it will be completed;				
	• How the results will be evaluated.				
6.3	**Planning of changes**				
	When the organization determine the need for change to the food safety management system, including personnel changes, the changes shall be carried out and communicated in planned manner.				
	The organization shall consider:				
	• The purpose of the changes and their potential consequence for supply and maintenance of safe food production;				
	• The integrity of the food safety management system;				
	• The availability resources to effectively implement the changes;				
	• The allocation or re-allocation of responsibilities and authorities,				
7	**Support**				
7.1	**Resources**				
7.1.1	**General**				
	The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, updating and continual improvement of the food safety management system.				
	The organization shall consider:				
	• The capability of and any constraints on existing internal resources; and				
	• Resources required from external source.				

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7.1.2	**People**				
	The organization shall determine and provide the competent persons (7.2) that are necessary to operate and maintain and effective food safety management system.				
	Where the assistance of external experts is used for development, implementation, operation or assessment of the food safety management system, evidence of agreement or contracts defining the competency, responsibility and authority of external experts shall be retained as documented information.				
7.1.3	**Infrastructure**				
	The organization shall provide the resources for the determination establishment and maintenance of the infrastructure necessary to achieve conformity with requirements of the food safety management system.				
With reference to the in 7.1.3					
	Infrastructure can include:				
	Land vessels, buildings and associated utilities;				
	Equipment, including hardware and software;				
	Transportation resources;				
	Information and communication technology.				
7.1.4	**Work environment**				
	Then organization shall determine, provide and maintain the resources for the establishment and maintain the resources for the establishment management and maintenance the resources for the establishment, management and maintenance of the environment necessary to achieve conformity with requirements of the food safety management system.				
With reference to the in 7.1.4					
	A suitable environment can be a combination of human and physical factors.				
7.1.5	**External developed elements of the food safety management system**				
	When an organization establishes, maintains, and continually improves its food safety management system by externally developed elements of a food safety management system including PRPs and the hazard control plan, the organization shall ensure that the provided elements are:				

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	• Developed in conformance with requirements of this document;				
	• Applicable to the sites, processes, and products of the organization;				
	• Specifically adapted, by the food safety team to the processes and products of the organization;				
	• Implemented, maintained, and updated as required by this document;				
	• Retained as document information.				
7.1.6	**Control of externally provided processes, products, or services**				
	The organization shall:				
	• Establish and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers of processes, products, or services;				
	• Ensure that externally provided processes, products or services do not adversely affect the organization's ability to consistently meet the requirements of its food safety management system;				
	• Ensure adequate communication of requirements to external provider(s);				
	• Ensure that external providers conform to the established criteria (see 7.1.2);				
	• Retain documented information of these activities and any necessary actions as a results of the evaluation and re-evaluations.				
7.2	**Competence**				
	The organization shall:				
	• Determine the necessary competence (see3.4) of person(s) including external providers doing work under its control that affects its food safety performance and effectiveness of food safety management system;				
	• Ensure that these persons, including the food safety and those responsible for operation of the hazards control plan, are competent on the basis of appropriate education, training, or experience;				

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	• Ensure that the food system team has a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system. This includes but are not limited to the organizations products, processes, equipment, and food safety hazards within the scope of the food safety management system;				
	• Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the action taken;				
	• Retain appropriate documented information as evidence of competence**.**				
	What reference to the note 1 in 7.2:				
	▪ Application actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.				
7.3	**Awareness**				
	The organization shall ensure that all relevant persons doing work under the organization control shall be aware of :				
	• The food safety policy;				
	• The objective of the food safety management system relevant to their task(s)				
	• Their individual contribution to the effectiveness of the food safety management system, including the benefits of improved food safety performance;				
	• The implications of not conforming with the food safety management system requirements.				
7.4	**Communication**				
7.4.1	**General**				
	The organization shall determine the internal and external communication relevant to the food safety management system including:				
7.4.2	**External communication**				
	The organization shall ensure that sufficient information is communicated externally and is available for interested parties of the food chain.				

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	The organization shall establish implement and maintain effective communications with:				
	• External providers and contractors				
	• Customers and/or consumers in relation to:				
	• Product information to enable the safe handling display, storage, preparations, distribution and use of product within the food chain or by the consumer;				
	▪ Identified foods safety hazards that need to be controlled by the other organizations in the food chain, and/or consumers;				
	▪ Contractual arrangements, enquiries and orders including their amendments; and				
	▪ Customer and/or consumer feedback including complaints;				
	• Statutory/regulatory authorities; and				
	• Other organization that have an impact on, or will be affected by, the effectiveness or updating of the food safety management system.				
	Designed person shall have defined responsibility and authority for the external communication of any information concerning food safety. Where relevant, information obtained through external communication shall be included as input for management review (see9.3) and updating the food safety management system (see4.4).				
	Evidence of external communication shall be retained as documented information.				
7.4.3	**Internal communication**				
	The organization shall establish, implement, and maintain effective arrangements for communicating between persons on issues having an impacting on food safety.				
	To maintain effectiveness of the food safety management system, the organization shall ensure that the food safety team informed in a timely manner of changes, including but not limited to the following:				
	Products or new products;				

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	Products or new products;				
	Raw materials, ingredients, and services;				
	Production systems and equipment;				
	Cleaning and sanitation programmes				
	Packaging, storage and distribution systems;				
	Competencies and/or allocation of responsibilities and authorizations;				
	statutory/regulatory				
	Knowledge regarding food safety hazards and control measure;				
	Customer, sector, and other requirements that the organization observes;				
	Relevant enquiries and communications from external interested parties;				
	Complaints, risks, and alerts indicating food safety hazards associated with end product;				
	Other conditions that have impact on food safety.				
	The food safety team shall ensure that this information is included when updating the food safety management systems (see 4.4)				
	Top management shall ensure that relevant information is included as input to the management review (see 9.3)				
7.5	**Document information**				
7.5.1	**General**				
	The organization food safety management shall include:				
	• Documented information required by this document;				
	• Document information determined by the organization as being necessary for the effectiveness of the food safety management system;				

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	• Documented information and food safety requirements required by statutory/regulatory authorities and customer.				
With reference to the note in 7.5.1					
	The extent of documented information for a food safety management system can differ from one organization to another due to:				
	• The size of organization and its type of activities, processes, products, and services. • The complexity of processes and their interaction. • The competence of persons.				
7.5.2	**Creating and updating**				
	When creating and updating documented information, the organization shall ensure appropriate:				
	• Identification and description (e.g., a title, date, author, or reference number);				
	• Format (e.g. language, software version, graphics) and media (e.g. paper, electronic);				
	• Review and approval for suitability and adequacy				
7.5.3	**Control of documented information**				
7.5.3.1	Documented information required by the food safety management system and by this document shall be controlled to ensure;				
	• It is available and suitable for use, where and when it is needed;				
	• It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).				
7.5.3.2	For the control of documented information the organization shall address the following activities, as applicable:				
	• Distribution, access, retrieval, and use;				
	• Storage and preservation, including preservation of legibility;				
	• Control of changes (e.g. version control);				
	• Retention time and deposition.				
	Documented information of external origin determined by the organization to be necessary for the planning and operation of the food safety management system shall be identified as appropriate and controlled.				

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With reference to the note in 7.5.3.2:					
	Access can imply a decision regarding The permission to view the documented Information only, or the permission And authority to view and change the documented information.				
With reference to the note in 8.3:					
	Where appropriate, the verification of the system is expected to include the reconciliation of quantities of end product with quantity of ingredients as evidence of effectiveness.				
8.4	**Emergency preparedness and response**				
8.4.1	**General**				
	Top management shall prepare and plan to identify preventive actions that deal with potential emergency situation and incidents that may impact on food safety and which are relevant to the role of the organization in the food chain.				
	Document information shall be established and maintained to manage these situations and incidents.				
8.4.2	**Handling of emergencies and incidents**				
	The organization shall:				
	• Respond to actual emergency situation and incidents by:				
	• Complying with statutory/regulatory requirements				
	○ Communicating internally;				
	○ Communicating externally (e.g., suppliers, customers, appropriate authorities, media);				
	• Take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or incident and the potential food safety impact;				
	• Periodically test procedures where practical;				
	• Review and where necessary, update the documented information, in particular, after the occurrence of any incident, emergency situation or test.				
With reference to the note in 8.4.2:					

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	Examples of emergency situations that affect food safety and/or production are natural disaster ,environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents like interruption of essential services such as water, electricity, or refrigeration supply.				
8.5	**Hazard control**				
8.5.1	**Preliminary steps to enable hazard analysis**				
	In order to carry out the hazard analysis preliminary information shall be collected, updated, and maintained by the food safety team. This shall include but not be limited to:				
	▪ The organization products, processes, customers' requirements, equipment; and				
	▪ Food safety hazards relevant to the food safety management system.				
8.5.1.1	**Characteristics of raw materials, ingredients and product contact**				
	materials				
	The organization shall ensure that all applicable statutory/regulatory food safety requirements are identified for all raw materials, ingredients and product contact materials.				
	The organization shall maintain documented information concerning all raw materials, ingredients and product contact materials to the extent needed to conduct the hazard analysis (see8.5.2), including the following, as appropriate:				
	• Biological, chemical and physical characteristics;				
	• Composition of formulated ingredients including additives and processing aids**;**				
	• Source, origin or provenance, as applicable (see the note);				
	• Method of production;				
	• Packaging and delivery methods;				
	• Storage conditions and shelf life;				
	• Preparation and/or handling before use or processing;				
	• Food safety related acceptance criteria or specification of purchased materials appropriate to their intended use.				
With reference to the note in 8.5.1.1:					

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	When the organization determines origin it includes the place of provenance and source (e.g. animal origin, plant origin).				
8.5.1.2	**Characteristics of end products**				
	The organization shall ensure that all applicable statutory/regulatory food safety requirements are identified for all the end products intended to be produced.				
	The organization shall maintain documented information concerning the characteristics of end product to the extent to conduct the hazard analysis (see 8.5.2), including information on the following, as appropriate:				
	• Product name or similar identifications;				
	• Composition;				
	• Biological, chemical and physical characteristics relevant for food safety;				
	• Intended shelf life and storage conditions;				
	• Packaging;				
	• Labelling relating to food safety and/or instruction for handling, preparation and its intended use;				
	• Method(s) of distribution.				
8.5.1.3	**Intended use**				
	The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be maintained as document information to the extent needed to conduct the hazard analysis (see 8.5.2)				
	Where appropriate, groups of consumer/users shall be identified for each product.				
	Groups of consumer/users known to be specifically vulnerable to specific food safety hazard shall be identified.				
8.5.1.4	**Flow diagrams and description of processes**				
8.5.1.4	**Preparation of flow diagrams**				
	The food safety team shall establish, maintain, and update flow diagrams as a documented information for the products or product categories and the processes covered by the food safety management system.				
	The flow diagrams shall be used when conducting the hazards analysis as a basis for evaluating the possible occurrence increase, decrease or introduction of food safety hazards.				

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	Flow diagrams shall be clear, accurate and sufficiently detailed to extent needed to conduct the hazard analysis. Flow diagrams shall, as appropriate, include the following:				
	• The sequence and interaction of the steps in operation;				
	• Any outsource processes and subcontracted work;				
	• Where raw materials, ingredients, processing aids, packaging materials and intermediate products enter the flow;				
	• Where reworking and recycling take place and				
	• Where end products intermediate products, by products and waste are released or removed.				
8.5.1.4.2	**On-site confirmation of flow diagrams**				
	The food safety team shall confirm on site the accuracy of the flow diagrams, update where appropriate and retain as documented information.				
8.5.1.4.3	**Description of processes and environment**				
	the food safety team shall describe, to the extent needed to conduct the hazard analysis:				
	• Layout of premises including food and non-food handling areas, processing equipment and contact materials, processing aids and flow of materials;				
	• Existing PRPs, process parameters, control measures if any and/or the strictness with which they are applied, or procedures that many influence food safety:				
	• External requirements (e.g. from statutory/regulatory authorities or customers) that may impact the choice and the strictness of the control measures.				
	The variation resulting from expected seasonal changes or shift patterns shall be included as appropriate.				
	The description shall be updated as appropriate and maintained as documented information.				
8.5.2	**Hazard analysis**				
8.5.2.1	**General**				
	The food safety team shall conduct a hazard analysis, based on the preliminary information (see 8.5.1.1-8.5.1.4) to determine the hazard that need to be controlled. The degree of control shall ensure combination of control measure shall be used.				
8.5.2.2	Hazard identification and determination of acceptable levels				

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8.5.2.2.1	The organization shall identify and document all food safety hazard that are reasonably expected to occur on relation to the type of product, type of process environment.				
	The identification shall be based on:				
	• The preliminary information and data collected according to 8.5.1.1 to 8.5.1.4				
	• experience				
	• internal and external information including to extent possible epidemiological, scientific and other historical data;				
	• information from the food chain on food hazards that may be relevance for the safety of the end products and the food at consumption; and				
	• statutory/regulatory and customer requirements.				
With reference to the notes 1 & 2 in 8.5.2.2.1:					
	• experience can include staff and external experts who are familiar with the product and/or processes in other facilities. • Statutory/regulatory requirements can include food safety objectives(FSOs). The Codex Alimentarius Commission defines FSOs as the maximum frequency and/or concentration of hazard in food at time of consumption that provides or contributes to the appropriate level of protection (ALOP)"				
8.5.2.2.2	the organization shall identify step(s) (e.g. receiving raw materials, processing and distribution) at which each food safety hazard can be present, introduced, increased or persist.				
	When identifying hazards, the organization shall consider:				
	• The steps preceding and following in the process;				
	• The process equipment utilities/services, process environment and personnel;				
	• The stages preceding and following in the food chain.				
8.5.2.2.3	The organization shall determine the acceptable level in the end product of each food safety hazard identified, wherever possible.				
	When determining acceptable levels, the organization shall consider:				
	• Statutory/regulatory and customer requirements;				
	• Intended use of end products;				

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	• Any other relevant information.				
	The organization shall maintain documented information concerning the determination of acceptable levels and justification for the acceptable levels.				
8.5.2.3	Hazard assessment				
	The organization shall conduct for each identified food safety hazard, assessment to determine, whether its prevention or reduction				
8.5.2.4.1	Based on the hazard assessment, the organization shall select an appropriate control measure or combination control measures that will be capable of preventing or reducing the identified significant food safety hazards to define acceptable levels.				
	The organization shall categorize the selected identified control measure(s) to be managed as OPRPs (3.31) or at CCPs (3.11)				
	The categorization shall be carried out using a systematic approach that for each of the control measures includes assessment of the following:				
	• The likelihood of failure of its functioning or significant processing variability;				
	The severity of the consequence in the case of failure of its functioning. This assessment shall include:				
	○ The effect on identified significant food safety hazard;				
	○ The location in relation to other control measure(s)				
	○ Whether it is specifically established and applied to eliminate or significantly reduce the level of hazards;				
	○ Whether it is single measure or is part of combination of control measure(s), i.e. if there is interaction in this combination that creates synergistic effects being higher than the sum of their individual effects.				
8.5.2.4.2	In an addition for each control measure, the systematic approach shall include an assessment of the feasibility of:				
	• Establishing measurable critical limits and/or measurable/observable action criteria;				
	• Monitoring to detect any failure to meet critical limit and/or measurable/observable action criteria;				
	• Applying timely corrections in case such failure.				
	The decision making process and result of selection and categorization shall be maintained as documented information.				

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	External requirements (e.g. statutory/regulatory and customer requirements) that may impact the choice and the strictness of the control measures shall also be maintained as documented information				
8.5.3	**Validation of control measure(s) and combination(s) of control measure**				
	Prior implementation of control measure(s) to be included in the hazard control plan (see 8.5.4) and after change therein (see 7.4.2, 7.4.3, 10.2, 10.3), the food safety team shall validate that:				
	• The selected control measure are capable of achieving the intended control of the food safety hazard(s) for which they are designated; and				
	• The control measure are effective and capable of in combination, ensuring controlled of the identified food safety hazard(s) to obtain end product that meet the defined acceptable levels.				
	When the result of the validation study show that control is not effective, the food safety team shall modify and re-assess the control measures and/or combination(s) of control measure(s).				
	The food safety team shall maintain the validation methodology and evidence of capability of the control measure(s) to achieve the intended results as documented information.				
With reference to the note in 8.5.3					
	Modification may include changes in control measure(s) (i.e. process parameters, rigorousness and/or their combination) and/or change(s)in the raw material manufacturing technologies, end product characteristics, method of distribution and/or intended use of the end products.				
8.5.4	**Hazard control plan (HACCP/OPRP plan)**				
8.5.4.1	**General**				
	The organization shall establish implement and maintain a hazard control measure(s) is (are) categorized at CCPs or as OPRPs (see 8.5.2.4).				
	The hazard control plan shall be maintained as documented information and shall include the following information for each control measure at each CCP or OPRP:				

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	• Food safety hazard(s) to be controlled at the CCP or by the OPRP;				
	• Critical limits at CCP or action criteria for OPRP;				
	• Monitoring procedure(s);				
	• Correction and corrective action(s) to be taken if critical limits or action criteria are not met;				
	• Responsibilities and authorities;				
	• Records of monitoring.				
8.5.4.2	**Determination of critical limits and action criteria**				
	Critical limits at CCPs and action criteria for OPRPs shall be specified. The rationale for their determination shall be maintained as documented information.				
	Critical limits at CCPs shall be measurable. Conformance with critical limits shall assure that the acceptable level is not exceeded.				
	Action criteria at CCPs shall measurable or observable. Conformance with action criteria shall contribute to the assurance that the acceptable level is not exceeded.				
8.5.4.3	Monitoring system shall be established for each control measure or combination of control measure(s) to detect any failure to meet critical limits. The system shall include all scheduled measurements relative to critical limit(s).				
	For each OPRP, a monitoring system shall be established for each control measure or combination of control measure(s) to demonstrate that action criteria are met.				
	The monitoring system at each CCP and for each OPRP, shall consist of documented information including procedures, instruction and records and shall include but is not limited to:				
	• Measurements or observation that provides results within an adequate time frame;				
	• Monitoring methods or device used;				
	• Applicable calibration methods or, for OPRPs equivalent methods for verification of reliable measurements or observations (see 8.7);				
	• Monitoring frequency;				
	• Responsibility and authority related to monitoring and evaluation of monitoring results.				

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	At each CCP, the monitoring method and frequency shall be capable of timely detection of any failure to meet critical limits, to allow timely isolation and evaluation of product (see 8.9.4).				
	For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of failure and the severity of consequences.				
	When monitoring an OPRP is based on subjective data from observations (e.g. visual inspection), it shall be supported by instruction or specifications.				
8.5.4.4	**Actions when critical limits or action criteria are not met**				
	The organization shall specify in the hazard control plan the corrective actions (see 8.9.2) and corrections (8.9.3) to be taken when critical limits or action criteria are not met. The actions shall ensure that:				
	• The cause of nonconformity is identified;				
	• The parameters controlled at the CCP or by the OPRP is returned within the critical limits or action criteria; and,				
	• Recurrence is prevented.				
	The organization shall take corrective action in accordance with 8.9.4 and corrections according with 8.9.3.				
8.5.4.5	**Implementation of the hazard control plan**				
	The hazard control plan shall be implemented and maintained, and relevant evidence retained as document information.				
8.6	Updating the information specifying the PRPs and the hazard control plan				
	Following the establishment of the hazard control plan, the organization shall update the following information, if necessary;				
	• Characteristics of raw materials, ingredients and product – contact materials;				
	• Characteristics of end product;				
	• Intended use;				

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	• Flow diagrams and description of processes and process environment.				
	When required, the hazard control plan and/or the PRP(s) shall be updated				
8.7	**Control of monitoring and measuring**				
	The organization shall provide evidence that the specified monitoring and measuring methods and equipment is in use is adequate for the monitoring and measuring activities related to the PRP(s) and the hazard control plan.				
	The monitoring and measuring the equipment used shall be:				
	• Calibrate or verified at specified intervals prior to use;				
	• Adjusted or re-adjusted as necessary;				
	• Identify to enable the calibration status to be determined;				
	Safeguard from adjustments that would invalidate the measurement result; and				
	• Protect from damage and deterioration.				
	The results of calibration and verification shall be retained as documented information. The calibration of equipment shall be traceable to international measurements standards where no ISO?DIS 22000:2017 (E) ISO 2017- all rights reserved retained as documented information.				
	The organization shall assess the validity of the previous measurement results when equipment by the food safety management.the organization. The organization shall take appropriate action on the equipment or process environment and any product.				
	The assessment and action shall be maintained as document information.				
	Software used in monitoring and measuring within the food safety management system shall be validated by the organization, software supplier, or third party prior to use. Documented information on validation activities shall be maintained by the organization and software shall be updated in timely manner.				
	Whenever there are changes including software configuration/modification to commercial off-the-shelf software				

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	they shall to be authorized, documented and validated before implementation.				
With reference to the note 8:7					
	Commercial off-the-shelf software in general use within designed application range can be considered to sufficient validated.				
8.8	Verification related to PRPs and the hazard control plan				
	The organization shall establish, implement and maintain verification activities that define the method of method. Frequencies and responsibilities for activities				
	• The PRP(s)are implemented and effective;				
	• Input to the hazard analysis is updated periodically;				
	• The hazard control plan is implemented and effective;				
	• Other actions are determined by the are implanted and effective.				
	The organization shall insure verification activities are not caried by person responsibly by monitoring the activity or control measure.				
	Verification results shall be maintained as document information document and shall communicated the food safety team.				
	Where verification is based on testing of the end product sample direct process samples and where such test samples show nonconformity with acceptable level of the food safety hazard (8.5.2.2) the affected lots of product shall be handled as potential unsafe (see8.9.4)				
	The organization shall apply corrective actions according to 8.9.2				
8.8	**Analysis of results of verification 8.9.2**				
8.8.2	**Analysis of results of verification activities**				
	The food safety team shall systematical evaluate the individual results of the verification plan including internal and external audits. Where verification does not demonstrate conformance with the plan arrangements, the organization shall take appropriate actions.				
	The analysis of the results of the verification of food safety management system (see Clause9).				
8.9	**Control of and process nonconformities**				
8.9.1	**General**				

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	The organization shall ensure that data derived from monitoring of OPRPs and CCPs are evaluated by designated persons with sufficient competence and authority to initiate corrective actions and corrections.				
8.9.2	**Corrective action**				
	The need for corrective action shall be evaluated when critical limits at CCPs and/or action criteria for OPRPs are not met.				
	The organization shall establish and maintain document information that specify appropriate action to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to return the process to control after a nonconformity is identified.				
	These action shall include: reviewing nonconformities identified by customer and/or consumer complaints/regulatory inspection reports;				
	• Reviewing trends in monitoring results that ma indicate loss of control;				
	• Determining the cause (s) of nonconformities ;				
	• Documenting the results of corrective action taken; and				
	• Reviewing corrective action taken to ensure that they are effective.				
	Document information on all corrective actions shall be retained.				
8.9.3	**Corrections**				
8.9.3.1	The organization shall ensure that when critical limits at CCPs and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release.				
	The organization shall establish maintain and update documented information that includes:				
	• Methods of identification assessment, correction for affected products to ensure their proper handling: and				
	• Arrangements for review of corrections carried out.				

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8.9.3.2	When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products (see 8.9.4)				
8.9.3.3	Where action criteria for an OPRP is not met, the following shall be carried out:				
	Identification of affected products and handling (see 8.9.4)				
	• Determination of the causes of failure;				
	• Determination of the consequences of that failure with respect to food safety.				
	The result of evaluation shall be retained as documented information.				
	Documentation information shall be retained to describe corrections taken on conformities products and processes including:				
	• The nature of nonconformity;				
	• The cause(s) of the nonconformity;				
	• The consequences as a results of the nonconformity and				
	• The traceability information related to the lots of nonconforming products.				
8.9.4	**Handling of potential unsafe products**				
8.9.4.1	**General**				
	The organization shall take action to prevent potentially unsafe products from entering the food chain unless its is possible to demonstrate that:				
	• The food safety hazard)s) concern is (are) reduced to the defined acceptable level;				
	• The food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering the food chain; or				
	The product still meets the defined acceptable level(s) of the food safety hazards of concern despite the nonconformity.				
	products that have been identified as potentially unsafe shall be held under control of the organization until they have been evaluated.				
	If products that have control of the organization are subsequently determined to be unsafe the organizations hall notify relevant interested parties and initiate a withdrawal/recall (see8.9.5).				

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	The controls and related response from relevant interested parties and authorization for dealing with potentially unsafe products shall be retained as documented information.				
8.9.4.2	**Evaluation for release**				
	Each lot of products affected by the nonconformity shall be evaluated.				
	Products affected by failure to meet critical limits at CCPs shall not be released but be handled in accordance with 8.9.4.3. products affected by failure to meet action criteria for OPRPs shall only release as when any of the following condition apply:				
	• Evidence other than monitoring system demonstrate that the control measure have been effective;				
	• Evidence that shows that the combined effect of control measure for that particular product conforms with the performance intended (i.e. identified acceptable levels)				
	• The results of sampling analysis and/or other verification activities demonstrate that the affected products conforms with the identified acceptable levels for food safety hazard(s) concerned.				
	Results of evaluation for release of products shall be retained as documented information.				
8.9.4.3	**Disposition of nonconforming products**				
	Products that are not acceptable for release shall either be:				
	• Reprocessed or further processed within or outside the organization to ensure that the food safety hazard is prevented or reduced to acceptable levels; or				
	• Redirecting for other use as long as food safety in the food chain is not affected; or				
	• Destroy and/or disposed as waste				
	Documented information of nonconforming products including the identification of designated approving authority shall be retained.				
8.9.5	Withdrawal/recall				
	The organizational shall be able to ensure and timely withdrawal/recall of lots of end products that have been identified as potentially unsafe:				
	• Appointing competent person(s) having the authority to initiate and carry out the withdrawal/recall; and				

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	• Establishing and maintaining documented information for:				
	○ Notifying relevant interest parties (e.g. statutory/regulatory authorities, customers and/or consumers);				
	○ Handling withdrawn/recalled products as products still in stock; and				
	○ Preforming the sequence of actions to be taken.				
	Withdrawn/recalled products and end products still in stock shall be secured or held under control of the organization until they are managed in accordance with (9.9.43).				
	The cause extent and result of a withdrawal/recall shall be retained as document information and reported to the management as input for the management review (9.3)				
	The organization shall verify implementation and effectiveness of withdrawal/recalls through the use of appropriate technique (e.g. mock withdrawal/recall) and retain documented information.				
9	**Performance evaluation of food safety management system**				
9.1	**Monitoring, measuring, analysis and evaluation**				
9.1	**General**				
	The organization shall determine:				
	• What need to be monitored and measured;				
	• The method for monitoring the measurements, analysis and evaluation, as applicable, to ensure valid results:				
	• When the monitoring shall be performed;				
	• When the results from the monitoring and measurements shall be analysed and evaluated				
	• Who shall analysed and evaluate the results from monitoring and measurements.				
	The organization shall retain appropriate documented information as evidence of the results.				
	The organization shall evaluate performance and the effectiveness of the food safety management system (see Clause 8)				
9.1.2	Analysis and evaluation				
	The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurements including				

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	the results of verification activities related to PRPs and the hazards control plan(see8.8), the internal audits (see9.2) and eternal audits.				
	The analysis shall be carried out in order to:				
	• Confirm that the overall performance of system meets the planned arrangements and the food safety management system requirements established by organization;				
	• Identify the need for updating or improving the food safety management system;				
	• Identify trends which indicate a higher incidence of potentially unsafe products or process failures;				
	• Establish information for planning of the internal audit programme related to the status and importance of areas to be audited, and				
	• Provide evidence that may corrections and corrective actions that have been taken are effective.				
	The results of the analysis and any resulting activities shall be retained as documented information and shall be reported to management review (see9.3) and the updating of food safety management system(see10.2)				
9.2	**Internal audit**				
	The organization shall conduct internal audits at planned intervals to provide information on whether the food safety management system:				
	• Confirms to:				
	○ The organization own requirements for its food safety management system;				
	○ The requirements of the document;				
	• Is effectively implemented and maintained.				
9.2.2	The organization shall plan, establish, implement and maintain and audit programme(s) including the frequency, methods, responsibilities , planning requirements and reporting, which shall take into consideration the importance of the process concerned changes in the food safety management system , and a results of monitoring measurements and previous audits;				
	• Define the audit criteria and scope for each audit;				
	• Select competent auditors and conduct audit to ensure objectivity and the impartiality of the audit process;				

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	• Ensure that the results of audit to ensure objectivity and the impartiality of the audit process;				
	• Retain documented information as evidence of the implementation of the audit programme and the audit results;				
	• Take necessary correction and corrective action within agreement timelines;				
	• Determine if the food safety management system meets the intent of the food safety policy (see 5.2), and the food safety management system (see 6.2)				
	Follow -up activities shall include the verification of the actions taken and the reporting of the verification results.				
With reference to the note 1 & 2 in 9.2.2:					
	• The organization may audit the entire food safety management system annually. The organization can choose to audit parts of the food safety management system at predetermine times according to audit program. • ISO 19011 provides guidance for management system audits.				
9.3	**Management review**				
9.3.1	**General**				
	Top management shall review the organization food safety management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.				
9.3.2	**Management review shall include consideration of:**				
	• The status of actions from previous management reviews;				
	• Changes in external and internal issue that are relevant to the food safety management system including changes in the organization and its context (see4.1)				
	• Information on the performance and effectiveness of the food safety management system including trends in:				
	○ Result of system updating activities (see 4.4 and 10.2); ○ Monitoring and measurements results;				
	○ Analysis of the results of verification activities related to PRPs and the hazard control plan (see 8.8.2);				
	○ Nonconformities and corrective actions;				

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	○ Audit results (internal and external);				
	○ Inspections (e.g, regulatory, customer);				
	○ Performance of external providers;				
	○ Review of risk and opportunities and effectiveness of action taken to address them (see6.1); and				
	○ Extent to which objectives of the food safety management system have been met				
	• The adequacy situation, incidents (see 8.4.2) or withdrawal/recall (see8.9.5) that occurred;				
	• Opportunities for continual improvement.				
	The data shall be presented in a manner that enables top management to relate the information to stated objectives of the food safety management system.				
9.3.3	**Management review output**				
	The outputs of management review shall include:				
	Decision and actions related continual improvement opportunities; and				
	Any need for updates and changes to the food safety management, including resource needs and revision of the food safety policy and objective of the food safety management system.				
	• React to the nonconformity and, as applicable:				
	○ Take action control and correct it; ○ Deal with consequences;				
	• Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:				
	○ Reviewing the nonconformity; ○ Determining the causes of the nonconformity; ○ Determining if similar nonconformities exist, or could potentially occur;				
	• Implement any action needed;				
	• Review the effectiveness of any corrective action taken;				
	• Make change to the food safety management system, if necessary.				
	• Corrective actions shall be appropriate to the effects of the nonconformities encountered.				
10.1.2	The organization shall retain documented information as evidence of:				

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	• The nature nonconformities and any subsequent action taken;				
	• The result of any corrective action.				
10.2	**Updating the food safety management system**				
	Top management shall ensure that is continually updated. To achieve this, the food safety team shall evaluate the food safety management system at planned intervals. The team shall then consider whether it necessary to review the hazard analysis (see8.5.2), the establish hazard control plan (see 8.5.4). the establish PRPs (see 8.2). the updating activities shall be based on :				
	• Input form communication external as well as internal (see 7.4):				
	• Input from other information concerning the suitability, adequacy and effectiveness of the food safety management system;				
	Output from the analysis result of verification activities (see Clause 9); and output from the analysis of results of verification activities (see Clause 9); and				
	• Output from management review (see9.3)				
	System updating activities shall be retained as documented information and reported as input to the management review (see 9.3).				
10.3	**Continual improvement**				
	The organizational shall continually improve the suitability, adequacy and effectiveness of the food safety management system to enhance the operation of the organization .				
	Top management shall ensure that the organization continually improve the effectiveness of the food safety management system through the use of communication (see 7.4), management system through the use of communication (see9.3), and internal audit (see 9.2), analysis of result of verification activities (see 8.8.2), validation of control measure(s) and combination (s) of control measure(s) (see 8.5.3), corrective actions (see 8.9.2) and food safety management system updating (see 10.2).				