TNV Certification Pvt. Ltd.

Food Safety Management System

ISO 22000:2018

www.isoindia.org

Food safety management system principles

Food safety is related to the presence of food safety hazards at the time of consumption (intake by the consumer). As the introduction of food safety hazards can occur at any stage of the food chain, adequate control throughout the food chain is essential. Thus, food safety is ensured through the combined efforts of all the parties in the food chain. This document specifies the requirements for a food safety management system that combines the following generally recognized key elements

- Interactive communication;
- System management;
- Prerequisite programmes;
- Hazard analysis and critical control points (HACCP) principles.

ISO 22000 FAMILY

- ISO 22000:2005 - Food safety management systems - Requirements for any organization in the food chain.
- ISO 22001 - Guidelines on the application of ISO 9001:2000 for the food and drink industry (replaces: ISO 15161:2001).
- ISO/TS 22002-1:2009 Prerequisite programmes on food safety—Part 1: Food Manufacturing
- ISO/TS 22002-2:2013 Prerequisite programmes on food safety—Part 2: Catering
- ISO/TS 22002-3:2011 Prerequisite programmes on food safety—Part 3: Farming
- ISO/TS 22002-4:2013 Prerequisite programmes on food safety—Part 4: Food Packaging
- ISO TS 22003:2013 - Food safety management systems for bodies providing audit and certification of food safety management systems.
- ISO TS 22004:2014 - Food safety management systems - Guidance on the application of ISO 22000:2005.
- ISO 22005:2007 - Traceability in the feed and food chain - General principles and basic requirements for system design and implementation.
- ISO 22006 - Quality management systems - Guidance on the application of ISO 9002:2000 for crop production.

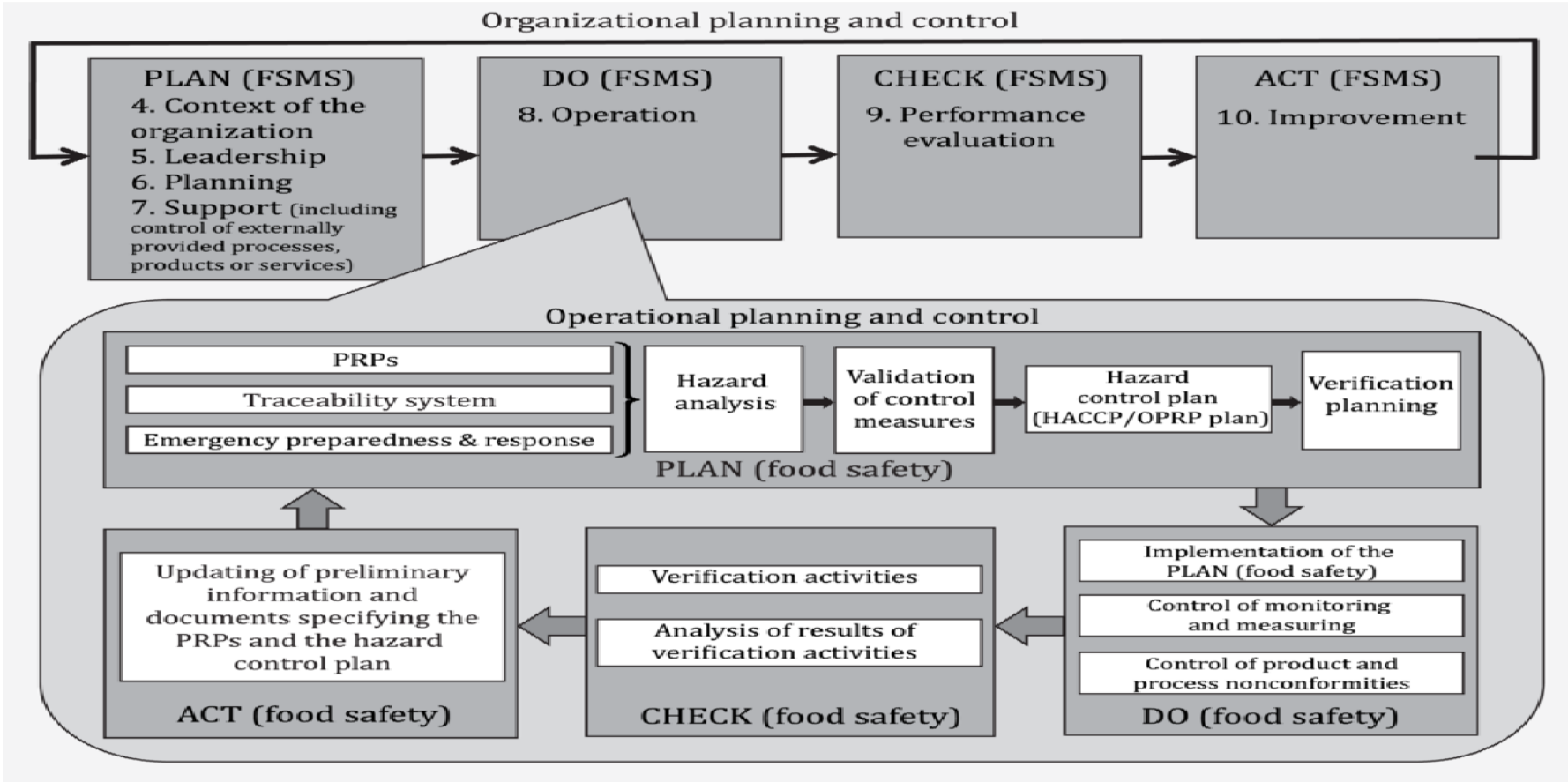
ISO 22000 is also used in the Food Safety Systems Certification (FSSC) Scheme FS22000. FS22000 is a Global Food Safety Initiative (GFSI) approved scheme.

Plan-Do-Check-Act cycle

- The PDCA cycle can be described briefly as follows:
- **Plan: establish the objectives of the system and its processes and provide the resources needed to deliver the results and identify and address risks and opportunities;**
- **Do: implement what was planned;**
- **Check: monitor and (where relevant) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;**
- **Act: take actions to improve performance, as necessary.**

Plan-Do-Check-Act cycle

The process approach embraces two PDCA cycles. One cycle covers the overall frame of the food safety management system (Clause 4 to Clause 7 and Clause 9 to Clause 10). The other cycle covers the operational processes within the food safety system as described in Clause 8. This means that communication between the two cycles is essential.



Food Safety Management Systems

- Cultural and social differences in the global market demand flexibility
- Different hazards are associated with different products and different technologies
- Companies both the standard structure to effectively manage food safety and the latitude to implement the specific controls that work in their system

Risk Management Framework: Risk Communication

Risk Management Framework

Risk Management Framework: Risk Communication Much of the work performed by the Joint FAO/WHO Committees is performing food risk management/risk assessments in order to define safe exposure levels or allowable limits where no adverse health affects are noted. Risk communication begins with the gathering of information on the risk issue of concern and continues throughout the assessment process, so the output can be communicated among all stakeholders : World-wide to assist FAO and WHO member countries in order to protect consumers from microbiological and chemical hazards Internationally to assist Codex Alimentarius Commission, in the development of standards, guidelines and recommendations for food safety Open communication among all stakeholders during all stages in food safety management is crucial to obtain the most reliable current information

Risk Management Framework

Risk analysis : Defined by CAC as a process consisting of three components: risk assessment, risk management, and risk communication

Risk Management: Weighing policy alternatives with all stakeholders considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed, selecting appropriate prevention and control options

Risk communication: interactive exchange of information and opinions throughout the risk analysis process concerning risks and hazards, risk-related factors and perceptions, among all parties in the food chain including explanation of risk assessment findings and the basis of risk management decisions.

Risk Management Framework

Risk Assessment

- **"A scientifically based process consisting of the following steps…"**
- **Hazard Identification: Identification of the chemical, physical, and/or microbiological agents which can be potentially present in a food that is capable of causing adverse health effects**
- **Hazard Characterization: Qualitative or quantitative evaluation of the nature of the adverse health effects associated with the hazard that may be present in the food. A dose-response assessment should be performed for chemical agents and if the data is obtainable for microbiological and physical agents.**
- **Exposure Assessment: Qualitative or quantitative evaluation of the likely intake of the hazard via food as well as from other relevant sources**
- **Risk Characterization: Qualitative or quantitative estimation of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, characterization, and exposure assessment.**

Risk Management

- **Risk Evaluation**
- **Identify food safety problem**
- **Establish risk profile (description, product or commodity involved, values at risk, example: health, potential consequences, consumer perception of risk, and distribution of risks and benefits**
- **Ranking of the hazard for risk assessment and risk management priority**
- **Establishing of risk assessment policy for conduct of risk assessment (guidelines for value judgment and policy choices applied at specific decision points, example: establishing the population(s) at risk, establishing criteria for ranking of hazard, and guidelines for application of safety factors)**
- **Commissioning of risk assessment**
- **Consideration of risk assessment result**
- **Risk Management Option Assessment**
- **Identification of available management options.**

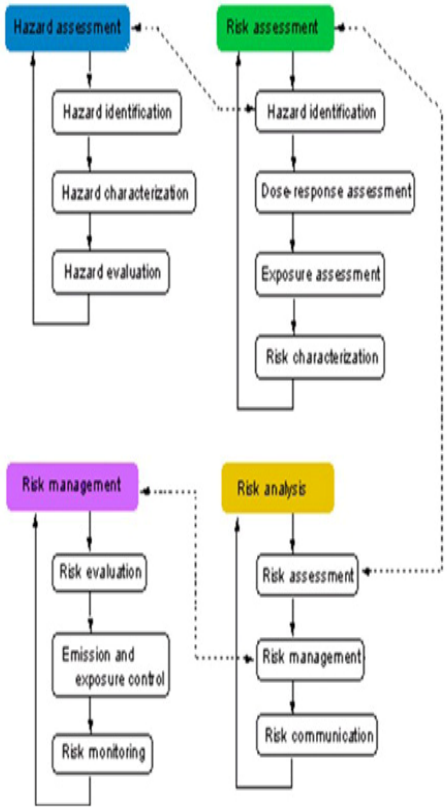
Risk Management

- **Selection of preferred management option including consideration of an appropriate safety standard do Safety standard defined as level of acceptable risk example:**
- **“balancing” standard used in cost-benefit, cost-effectiveness ALARA as low as reasonable achievable, “procedural” standards (acceptable level of risk is determined by an agreed process, such as a negotiation or referendum, “threshold” standards (a nonzero level of risk is stipulated as acceptable), “zero-risk” standards such as ADI levels, allowable daily intake levels**
- **Final management decision**
- **Implementation of management decision**
- **Monitoring and review**
- **Assessment of effectiveness of measures taken**
- **Review risk management and/or assessment as necessary**
- **Outcome of the risk evaluation process should be combined with**
- **evaluation of available risk management options in order to reach a decision on management of risk**
- **Human health should be primary concern**

Risk Management

- **Other factors: economic costs, benefits, technical feasibility, risk perceptions considered appropriately**
- **Implementation should be followed by monitoring both effectiveness of control measure and impact on risk to the exposed consumer population to ensure that the food safety objective is met**
- **All interested parties, stakeholders, should have opportunity for input into the risk management process if likely to be affected by the decision**
- **examples: consumer organizations, industry representatives, regulatory bodies**

Risk Management



HACCP

- **Hazard Analysis Critical Control Points**
- **HACCP provides a proactive systematic approach for identifying food safety hazards categorized as biological, chemical, and physical hazards.**
- **Applied through seven principles which facilitate prevention, elimination, or reduction of food safety hazards to an acceptable level and is effective and economical**

Biological Hazards

- Most food borne illnesses are caused by microbiological safety hazards Include: pathogenic bacteria, fungal organisms and toxins, viruses, prions (BSE) and parasites
- A pathogen or toxin must be present to cause a food borne illness
- Generally infants, elderly, and immuno-compromised persons aremost susceptible
- Top 5 food borne pathogens: Escherichia coli 0157, E. coli, Campylobacter, Listeria monocytogenes, and Salmonella
- Most pathogens must grow to high enough numbers to cause an
- infection or produce a toxin- E. coli 0157:H7 has a low infectious dose
- Viruses account for 10 %
- Examples: Norovirus, Hepatitis A
- Cannot multiply in food
- Results from fecal contamination
- Parasites In US most common: Cryptosporidium parvum (unpasteurized
- apple cider and poor personnel hygiene by an infected person) ,
- Cyclospora cayetanensis (berries such as raspberries and blackberries, and mesclun lettuce, basil) Trichinella spiralis (undercooked bear meat and pork), Giardia lambia (waterborne parasites, so contamination occurs during washing of fruits and vegetables)

Biological Hazards

- Factors Causing Biological Contamination
- Should be assumed that the raw material potentially contains a biological hazard
- Improper Storage/Holding Temperatures
- Bacteria growth in food at temps 31ºF - 122ºF and rapid growth
- 77ºF - 104ºF
- Inadequate Cooking or Reheating
- examples: poultry must reach an internal temp of at least 160ºF
- Poor Personal Hygiene
- Major contributing factor (fecal-oral route)
- Cross-Contamination and Poor Storage Practices
- Raw vs. finished handling and storage
- Prevention/Controls
- Three distinct methods
- 1. Prevent contamination of foods
- Following Good Agricultural Practices
- Following Good Husbandry Practices in animal production
- Harvesting of shellfish (filter feeders)
- Following good personal hygiene and avoiding cross contamination

Biological Hazards

- 2. Destroy food borne disease agents
- Following the appropriate time and temperature kill step (dependent
- on food material and biological hazard)
- Irradiation
- Pasteurization or high pressure processing in avocados
- Ultraviolet Light used to pasteurize apple cider
- New technologies: pulsed light, pulsed electronic fields, etc.
- Chemical rinses ex. Propylene oxide to kill salmonella in almonds and
- spices
- 3. Prevent growth of food borne disease agents
- Using a preservative or high salt concentrations
- Decreasing pH and/or water activity
- Holding food at low or high temps and rapid cooling

Chemical Hazards

- Food can become contaminated with a chemical hazard during any stage in the food chain.
- Chemical hazards vary widely. They can be naturally occurring, or chemical hazards can be introduced into a plant or animal tissue by the use of agrichemicals. Foods may also become chemically contaminated from leaching of chemicals or metals introduced through the environment, processing equipment and/or packaging
- The presence and allowable limits of a chemical in a food is typically established by regulatory agencies
- **Naturally Occurring Chemicals**
- Usually allowed at certain levels or food can be toxic and must be avoided
- Naturally occurring toxins found in certain types of plants (mushrooms), shellfish, or can be created by microorganisms (molds and bacteria)
- Histamine, produces an allergenic response, is associated with certain species of fish (caused by inadequate time/temp control causing growth of microorganisms, which produce the enzyme histidine)
- Mycotoxins are by products from the growth of mold
- Occur during pre-harvesting or storage
- Cause acute and chronic toxicity in humans & animals
- Associated with fruits and their juices, grains and nuts

Chemical Hazards

- Acrylamides produced as a by-product of food processing and cooking (undefined doses are thought to be toxic to nervous system and to cause cancer)
- Allergens
- Proteins that cause an immunological response ranging from a sensitivity such as asthma or a rash to anaphylaxis shock, death
- US focuses on the “Big 8”: peanuts, tree nuts, milk, soy, wheat, shellfish, egg, and fish
- Considered a chemical hazard, because if not properly controlled can be introduced into a food product not labeled as containing the allergen
- Labeling requirements are established by The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)
- **Intentionally Added Chemicals**
- Chemicals added during growing, harvesting, storing, processing, packaging, or distribution
- If chemicals are not used in accordance with regulatory guidelines, chemicals become potential hazards
- Examples include: pesticides, herbicides, Dioxin/PCB, antibiotics/veterinary drug residues, fertilizers, preservatives, coloring agents, sanitation chemicals, indirect food additives such
- as lubricants, and materials used in food contact packaging
- **Controls**
- Harvesting fish and shellfish from waters that have been approved by health authorities or water quality meets standards
- Use chemicals in accordance to regulatory requirements
- Following Good Agricultural Practices and Animal husbandry practices
- Prevent cross-contamination by following Current Good
- Manufacturing Practices and establishing programs that control approval, storage, and usage of chemicals
- Knowledgeable about the food product and potential sources of chemical contamination, source of product (imported), acceptable limits, and any new information on regulations and toxicity of chemicals

Physical Hazards

- Can enter into the food supply chain at any stage
- Mortimore and Wallace classify physical hazards as extraneous sharp, hard items that could potentially:
- Penetrate skin or gastrointestinal tract
- Damage teeth
- Block respiratory tract and cause chocking
- Typical examples: glass, metal, plastic, bone, insect fragments, sand, etc.
- FDA has established allowable defect limits, ADL, for unavoidable contaminants that pose no health risk
- Potential sources
- Raw material
- Poorly maintained equipment
- Personnel practices
- Storage conditions
- Facility environment
- **Controls/Prevention**
- Following current Good Manufacturing Practices and employee training
- Use of detection equipment such as magnets, filters, screens, metal detectors, x-ray equipment
- Inspection practices and maintenance of equipment and facility
- Programs to control glass, brittle plastic and ceramics

ISO 22000:2018

Food Safety Management System Requirements

Scope

This document specifies requirements for a food safety management system (FSMS) to enable an organization that is directly or indirectly involved in the food chain:

a) to plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance with their intended use;

b) to demonstrate compliance with applicable statutory and regulatory food safety requirements;

c) to evaluate and assess mutually agreed customer food safety requirements and to demonstrate conformity with them;

d) to effectively communicate food safety issues to interested parties within the food chain;

e) to ensure that the organization conforms to its stated food safety policy;

f) to demonstrate conformity to relevant interested parties;

g) to seek certification or registration of its FSMS by an external organization, or make a self assessment or self-declaration of conformity to this document. All requirements of this document are generic and are intended to be applicable to all organizations in the food chain, regardless of size and complexity

Organizations that are directly or indirectly involved include, but are not limited to, feed producers, animal food producers, harvesters of wild plants and animals, farmers, producers of ingredients, food manufacturers, retailers, and organizations providing food services, catering services, cleaning and sanitation services, transportation, storage and distribution services, suppliers of equipment, cleaning and disinfectants, packaging materials and other food contact materials. This document allows any organization, including small and/or less developed organizations (e.g. a small farm, a small packer-distributor, a small retail or food service outlet) to implement externally developed elements in their FSMS. Internal and/or external resources can be used to meet the requirements of this document.

Normative references

There are no normative references in this document.

Terms and definitions

3.1 acceptable level of a food safety hazard (3.22) not to be exceeded in the end product (3.15) provided by the organization (3.31)

3.2 Action criterion measurable or observable specification for the monitoring (3.27) of an OPRP (3.30) Note 1 to entry: An action criterion is established to determine whether an OPRP remains in control, and distinguishes between what is acceptable (criterion met or achieved means the OPRP is operating as intended) and unacceptable (criterion not met nor achieved means the OPRP is not operating as intended)

3.3 audit systematic, independent and documented process (3.36) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party) , and it can be a combined audit (combining two or more disciplines) .

Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf. Note 3 to entry: Audit evidence and audit criteria are defined in ISO 19011. Note 4 to entry: Relevant disciplines are, for example, food safety management, quality management or environmental management.

3.4 competence ability to apply knowledge and skills to achieve intended results

3.5 conformity fulfilment of a requirement (3.38)

3.6 contamination introduction or occurrence of a contaminant including a food safety hazard (3.22) in a product (3.37) or processing environment

3.7 continual improvement recurring activity to enhance performance (3.33)

3.8 control measure action or activity that is essential to prevent a significant food safety hazard (3.22) or reduce it to an acceptable level (3.1) Note 1 to entry: See also significant food safety hazard (3.40) . Note 2 to entry: Control measure(s) is (are) identified by hazard analysis.

Terms and definitions

3.9 correction action to eliminate a detected nonconformity (3.28) Note 1 to entry: A correction includes the handling of potentially unsafe products and can therefore be made in conjunction with a corrective action (3.10) . Note 2 to entry: A correction may be, for example, reprocessing, further processing and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling) .

3.10 corrective action action to eliminate the cause of a nonconformity (3.28) and to prevent recurrence Note 1 to entry: There can be more than one cause for a nonconformity. Note 2 to entry: Corrective action includes cause analysis.

3.11 critical control point CCP step in the process (3.36) at which control measure(s) (3.8) is (are) applied to prevent or reduce a significant food safety hazard (3.40) to an acceptable level, and defined critical limit(s) (3.12) and measurement (3.26) enable the application of corrections (3.9)

3.12 critical limit measurable value which separates acceptability from unacceptability Note 1 to entry: Critical limits are established to determine whether a CCP (3.11) remains in control. If a critical limit is exceeded or not met, the products affected are to be handled as potentially unsafe products. [SOURCE: CAC/RCP 1-1969, modified — The definition has been modified and Note 1 to entry has been added.]

3.13 documented information

- information required to be controlled and maintained by an *organization (3.31) and the medium on which it is contained*
- Note 1 to entry: Documented information can be in any format and media, and from any source.
- Note 2 to entry: Documented information can refer to:
- — the management system (3.25), including related processes (3.36);
- — information created in order for the organization to operate (documentation);
- — evidence of results achieved (records).

Terms and definitions

- 3.14 effectiveness extent to which planned activities are realized and planned results achieved
- 3.15 end product *(3.37) that will undergo no further processing or transformation by the organization (3.31)*
- Note 1 to entry: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.
- 3.16 feed single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to food-producing animals
- Note 1 to entry: Distinctions are made in this document between the terms *food (3.18), feed (3.16) and animal food (3.19):*
- — food is intended for consumption by humans and animals, and includes feed and animal food**;**
- — feed is intended to be fed to food-producing animals;
- — animal food is intended to be fed to non-food-producing animals, such as pets.
- [SOURCE: CAC/GL 81-2013, modified — The word “materials” has been changed to “products” and “directly” has been deleted.]
- 3.17 flow diagram schematic and systematic presentation of the sequence and interactions of steps in the process

Terms and definitions

- 3.18 Food substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances (ingredients) used only as drugs
- Note 1 to entry: Distinctions are made in this document between the terms *food (3.18), feed (3.16) and animal food (3.19):*
- — food is intended for consumption by humans and animals, and includes feed and animal food;
- — feed is intended to be fed to food-producing animals;
- — animal food is intended to be fed to non-food-producing animals, such as pets.
- [SOURCE: CAC/GL 81-2013, modified — The word “human” has been deleted.]
- 3.19 animal food single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to non-food-producing animals
- Note 1 to entry: Distinctions are made in this document between the terms *food (3.18), feed (3.16) and animal food (3.19):*
- — food is intended for consumption by humans and animals, and includes feed and animal food;
- — feed is intended to be fed to food-producing animals;
- — animal food is intended to be fed to non-food-producing animals, such as pets.
- [SOURCE: CAC/GL 81-2013, modified — The word “materials” has been changed to “products”, “non” has been added and “directly” has been deleted.]
- 3.20 food chain sequence of the stages in the production, processing, distribution, storage and handling of a *food (3.18) and its ingredients, from primary production to consumption*

Terms and definitions

- Note 1 to entry: This includes the production of *feed (3.16) and animal food (3.19).*
- Note 2 to entry: The food chain also includes the production of materials intended to come into contact with food or raw materials.
- Note 3 to entry: The food chain also includes service providers.
- 3.21 food safety assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use
- Note 1 to entry: Food safety is related to the occurrence of *food safety hazards (3.22) in end products (3.15) and does not include other health aspects related to, for example, malnutrition.*
- Note 2 to entry: It is not to be confused with the availability of, and access to, food ("food security").
- Note 3 to entry: This includes feed and animal food.
- [SOURCE: CAC/RCP 1-1969, modified — The word "harm" has been changed to "adverse health effect" and notes to entry have been added.]
- 3.22 food safety hazard biological, chemical or physical agent in *food (3.18) with the potential to cause an adverse health effect*
- Note 1 to entry: The term "hazard" is not to be confused with the term "*risk" (3.39) which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (e.g. death, hospitalization) when exposed to a specified hazard.*
- Note 2 to entry: Food safety hazards include allergens and radiological substances.

Terms and definitions

- Note 3 to entry: In the context of feed and feed ingredients, relevant food safety hazards are those that can be present in and/or on feed and feed ingredients and that can through animal consumption of feed be transferred to food and can thus have the potential to cause an adverse health effect for the animal or the human consumer. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, disinfectants), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended (see 8.5.1.4).
- Note 4 to entry: In the context of animal food, relevant food safety hazards are those that are hazardous to the animal species for which the food is intended.
- [SOURCE: CAC/RCP 1-1969, modified — The phrase “or condition of” has been deleted from the definition and notes to entry have been added.]
- 3.23 interested party (preferred term) stakeholder (admitted term) person or *organization (3.31) that can affect, be affected by, or perceive itself to be affected by a decision or activity*
- 3.24 lot defined quantity of a *product (3.37) produced and/or processed and/or packaged essentially under the same conditions*
- Note 1 to entry: The lot is determined by parameters established beforehand by the organization and may be described by other terms, e.g. batch.
- Note 2 to entry: The lot may be reduced to a single unit of product.
- [SOURCE: CODEX STAN 1, modified — Reference to “and/or processed and/or packaged” has been included in the definition and notes to entry have been added.]

Terms and definitions

- 3.25 management system set of interrelated or interacting elements of an *organization (3.31) to establish policies (3.34) and objectives (3.29) and processes (3.36) to achieve those objectives*
- Note 1 to entry: A management system can address a single discipline or several disciplines.
- Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation.
- Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.
- Note 4 to entry: Relevant disciplines are, for example, a quality management system or an environmental management system.
- 3.26 Measurement *process (3.36) to determine a value*
- 3.27 monitoring determining the status of a system, a *process (3.36) or an activity*
- Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.
- Note 2 to entry: In the context of food safety, monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended.
- Note 3 to entry: Distinctions are made in this document between the terms *validation (3.44), monitoring (3.27) and verification (3.45):*
- — validation is applied prior to an activity and provides information about the capability to deliver intended results;
- — monitoring is applied during an activity and provides information for action within a specified time frame;
- — verification is applied after an activity and provides information for confirmation of conformity.

Terms and definitions

- **3.28 nonconformity** non-fulfilment of a *requirement (3.38)*
- **3.29 objective** result to be achieved
- Note 1 to entry: An objective can be strategic, tactical, or operational.
- Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and *process (3.36)).*
- Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a FSMS objective, or by the use of other words with similar meaning (e.g. aim, goal, or target).
- Note 4 to entry: In the context of FSMS, objectives are set by the organization, consistent with the food safety policy, to achieve specific results.
- **3.30 operational prerequisite programme OPRP** *control measure (3.8) or combination of control measures applied to prevent or reduce a significant food safety hazard (3.40) to an acceptable level (3.1), and where action criterion (3.2) and measurement (3.26) or observation enable effective control of the process (3.36) and/or product (3.37)*
- **3.31 organization** person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives (3.29)*
- Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Terms and definitions

- **3.32 outsource, verb** make an arrangement where an external *organization (3.31) performs part of an organization's function or process (3.36)*
- Note 1 to entry: An external organization is outside the scope of the *management system (3.25), although the outsourced function or process is within the scope.*
- **3.33 performance** measurable result
- Note 1 to entry: Performance can relate either to quantitative or qualitative findings.
- Note 2 to entry: Performance can relate to the management of activities, *processes (3.36), products (3.37) (including services), systems or organizations (3.31).*
- **3.34 policy** intentions and direction of an *organization (3.31) as formally expressed by its top management (3.41)*
- **3.35 prerequisite programme PRP** basic conditions and activities that are necessary within the *organization (3.31) and throughout the food chain (3.20) to maintain food safety*
- Note 1 to entry: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. Examples of equivalent terms are: good agricultural practice (GAP), good veterinary practice (GVP), good manufacturing practice (GMP), good hygiene practice (GHP), good production practice (GPP), good distribution practice (GDP) and good trading practice (GTP).
- **3.36 process** set of interrelated or interacting activities which transforms inputs to outputs
- **3.37 product** output that is a result of a *process (3.36)*
- Note 1 to entry: A product can be a service.

Terms and definitions

- **3.38 requirement** need or expectation that is stated, generally implied or obligatory
- Note 1 to entry: “Generally implied” means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.
- Note 2 to entry: A specified requirement is one that is stated, for example in documented information.
- **3.39 Risk** effect of uncertainty
- Note 1 to entry: An effect is a deviation from the expected – positive or negative.
- Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
- Note 3 to entry: Risk is often characterized by reference to potential “events” (as defined in ISO Guide 73:2009, 3.5.1.3) and “consequences” (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.
- Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated “likelihood” (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.
- Note 5 to entry: Food safety risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to (a) hazard(s) in *food (3.18), as specified in the Codex Procedural Manual[11].*
- **3.40 significant food safety hazard** *food safety hazard (3.22), identified through the hazard assessment, which needs to be controlled by control measures (3.8)*

Terms and definitions

- **3.41 top management** person or group of people who directs and controls an *organization (3.31) at the highest level*
- Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.
- Note 2 to entry: If the scope of the *management system (3.25) covers only part of an organization, then top management refers to those who direct and control that part of the organization.*
- **3.42 traceability** ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution
- Note 1 to entry: Movement can relate to the origin of the materials, processing history or distribution of the *food (3.18).*
- Note 2 to entry: An object can be a *product (3.37), a material, a unit, equipment, a service, etc.*
- [SOURCE: CAC/GL 60-2006, modified — Notes to entry have been added.]
- **3.43 update** immediate and/or planned activity to ensure application of the most recent information
- Note 1 to entry: Update is different from the terms “maintain” and “retain”:
- — “maintain” is to keep something on-going/to keep in good condition;
- — “retain” is to keep something that is retrievable.
- **3.44 validation** <food safety> obtaining evidence that a *control measure (3.8) (or combination of control measures) will be capable of effectively controlling the significant food safety hazard (3.40)*

Terms and definitions

- Note 1 to entry: Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures.
- Note 2 to entry: Distinctions are made in this document between the terms *validation (3.44), monitoring (3.27) and verification (3.45):*
- — validation is applied prior to an activity and provides information about the capability to deliver intended results;
- — monitoring is applied during an activity and provides information for action within a specified time frame;
- — verification is applied after an activity and provides information for confirmation of conformity.
- **3.45 verification** confirmation, through the provision of objective evidence, that specified *requirements (3.38) have been fulfilled*
- Note 1 to entry: Distinctions are made in this document between the terms *validation (3.44), monitoring (3.27) and verification (3.45):*
- — validation is applied prior to an activity and provides information about the capability to deliver intended results;
- — monitoring is applied during an activity and provides information for action within a specified time frame;
- — verification is applied after an activity and provides information for confirmation of conformity.

4 Context of the organization

ISO	Key Content	Comment
4.1 Understanding the organization and its context	determine external and internal issues Include intended result(s) of its FSMS	Issues can include positive and negative factors or conditions for consideration Understanding the context can be facilitated by considering external and internal issues, including, but not limited to, legal, technological, competitive, market, cultural, social and economic environments, cyber security and food fraud, food defence and intentional contamination, knowledge and performance of the organization, whether international, national, regional or local

parties	Determine the needs and expectations of interested parties Determiner the compliance obligations	parties. It is the requirements that help us understand what compliance obligations to take into account.
4.3 Determining the scope of the food safety management system	• Determine the scope of the FSMS • Take into account the external and internal issues • Take into account the compliance obligations •Take into account the units, functions and physical boundaries • Take into account the authority, control and influence of the organization • Include in the FSMS the scope, the activities, products and services • Maintain a documented information on the scope	Understand the products and services, processes and production site(s) that included in the FSMS Understand influence on the food safety of its end products

4.4 Food safety management system

ISO	Key Content	Comment
4.4 Food safety management system	establish, implement, maintain, update and continually improve a FSMS including the processes needed and their interactions, Maintain a documented information	Incorporate the requirements of the FSMS in business functions, processes and their interactions

5 Leadership

ISO	Key Content	Comment
5.1 Leadership and commitment	• Assume responsibility for the effectiveness of the FSMS • Establish an Food Safety policy and associated objectives • Integrate FSMS requirements in the internal process requirements • Provide the necessary resources for the FSMS • Raise awareness on the importance of an effective and compliant FSMS • Support the staff contribution to the effectiveness of the FSMS • Promote continual improvement • Support the leadership of managers	• Top management demonstrates leadership (assumes its responsibility and commitment) • The policy and objectives are consistent with the strategic direction and business context • And ensure that these resources are really available. • Confirm in the management review • Thanks to the acquired skills • Essential commitment of top management

5 Leadership

ISO	Key Content	Comment
5.2 Policy 5.2.1 Establishing the food safety policy	establish, implement and maintain a food safety policy setting and reviewing the objectives of the FSMS includes a commitment to satisfy applicable food safety requirements includes a commitment to continual improvement addresses the need to ensure competencies related to food safety	Fits with the role the organization plays in the food chain Conforms with requirements of statutory, regulatory, and the mutually agreed food safety requirements of customer

FOOD SAFETY POLICY

EXAMPLE

XYZ TEA FACTORY

ISO 22000 FOOD SAFETY MANAGEMENT SYSTEM

ORTHODOX BLACK TEA MANUFACTURE

FOOD SAFETY POLICY

We will make sure to provide our customers hygienically safe black tea and added value in their teacup.

We will ensure to provide pure orthodox black tea made at our factory is free from physical, chemical and microbiological hazards which are conforming to the relevant statutory and regulatory requirements.

We will train and motivate our employees continuously to upgrade and maintain ISO 22000 FSMS effectively.

Prepaid B :…..ABC Issue : ----- Rev : -------

Approved B : ….XYZ Date : ----------

5 Leadership

ISO	Key Content	Comment
5.2.2 Communicating the food safety policy	food safety policy available and maintained as documented information communicated, understood and applied at all levels within the organization available to relevant interested parties	documented and communicated by top management inspire teams to make effective use of their food safety management system
5.3 Organizational roles, responsibilities and authorities	Assign responsibilities and authorities of roles	Internally. Clarity of roles, responsibilities and authorities and expected results In order to ensure that the FSMS meets the requirements of the ISO 22000 standard In order to report on the performance of the FSMS to top management

6 Planning

ISO	Key Content	Comment
6.1 Actions to address risks and opportunities	determine the risks and opportunities that need to be addressed to: assurance that the FSMS can achieve its intended result(s) enhance desirable effects prevent, or reduce, undesired effects achieve continual improvement. Plan include actions to address these risks and opportunities. integrate and implement the actions into its FSMS processes. evaluate the effectiveness of these actions.	the concept of risks and opportunities is limited to events and their consequences relating to the performance and effectiveness of the FSMS. Public authorities are responsible for addressing public health risks. Organizations are required to manage food safety hazards Actions to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or accepting the presence of risk by

6 Planning

ISO	Key Content	Comment
6.2 Objectives of the food safety management system and planning to achieve them	establish objectives for the FSMS at relevant functions and levels how to achieve its objectives for the FSMS retain documented information on the objectives for the FSMS	be consistent with the food safety policy be measurable (if practicable); take into account applicable food safety requirements, including statutory, regulatory and customer requirements; be monitored and verified; be communicated; be maintained and updated as appropriate. Resource , responsible , evaluation

6 Planning

ISO	Key Content	Comment
6.3 Planning of changes	determines the need for changes to the FSMS, including personnel changes communicated in a planned manner	the purpose of the changes and their potential consequences the allocation or re-allocation of responsibilities and authorities the availability of resources integrity of the FSMS

7 Support

ISO	Key Content	Comment
7.1 Resources **7.1.1** General	determine and provide the resources needed for the establishment, implementation, maintenance, update and continual improvement of the FSMS	capability of internal resources; need for external resources
7.1.2 People	ensure that persons necessary to operate and maintain an effective FSMS are competent evidence of agreement or contracts defining the competency, responsibility and authority of external experts Retain documented information on the competence of persons	Training and support (external providers if necessary) on the Food Safety and the FSMS Evaluate the effectiveness of the actions

7 Support

ISO	Key Content	Comment
7.1.3 Infrastructure	provide the resources for the determination, establishment and maintenance of the infrastructure necessary	Infrastructure can include: land, vessels, buildings and associated utilities; equipment, including hardware and software; transportation; information and communication technology
7.1.4 Work environment	determine, provide and maintain the resources for the establishment, management and maintenance of the work environment	A suitable environment can be a combination of human and physical factors such as: a) social (e.g. non-discriminatory, calm, non-confrontational); b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective); c) physical (e.g. temperature, heat, humidity, light, air flow, hygiene, noise). These factors can differ substantially depending on the products and services provided.

7 Support

ISO	Key Content	Comment
7.2 Competence	determine the necessary competence of person(s) ensure that these persons, including the food safety team and those responsible for the operation of the hazard control plan Competency on the basis of appropriate education, training and/or experience ensure that the food safety team has a combination of multi-disciplinary knowledge Retain documented information on the competence of persons	work under its control that affects its food safety performance and effectiveness of the FSMS provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7 Support

ISO	Key Content	Comment
7.3 Awareness	Ensure persons are aware of the Food Safety policy Ensure persons are aware of the objectives of the FSMS relevant to their task Ensure persons are aware of their contribution Ensure persons are aware of the consequences of not conforming	Including external persons performing work under the organization's control. And the impact on the workplace. In order to improve the performance of the FSMS
7.4 Communication 7.4.1 General	Plan and implement a communication process - on what • when • with whom • how • Take into account compliance obligations • Ensure that communication is adequate • Respond to communications on its EMS • Retain documented information on communication	Communication is transparent, in good faith, appropriate, factual and understandable Quick response to complaints and claims but also to recommendations and proposals for improvement Internally and externally via those responsible for communication In writing, orally, Intranet, Internet, video, presentation, report Communication is clear, transparent, appropriate, factual, in good faith

7 Support

ISO	Key Content	Comment
7.4.2 External communication	ensure that sufficient information is communicated externally available for interested parties of the food chain. external providers and contractors defined responsibility and authority for the external communication of any information concerning food safety	product information related to food safety, to enable the handling, display, storage, preparation, distribution and use of the product within the food chain or by the consumer identified foods safety hazards that need to be controlled by other organizations in the food chain and/or by consumers; contractual arrangements, enquiries and orders, including their amendments; customer and/or consumer feedback, including complaints

7 Support

ISO	Key Content	Comment
7.4.3 Internal communication	establish, implement and maintain an effective system for communicating issues having an impact on food safety. ensure that the food safety team is informed in a timely manner of changes ensure that this information is included when updating the FSMS ensure that relevant information is included as input to the management review	products or new products; raw materials, ingredients and services; production systems and equipment; production premises, location of equipment and surrounding environment; cleaning and sanitation programmes; packaging, storage and distribution systems; competencies and/or allocation of responsibilities and authorizations; applicable statutory and regulatory requirements; knowledge regarding food safety hazards and control measures; Customer, sector and other requirements that the organization observes; relevant enquiries and communications from external interested parties; complaints and alerts indicating food safety hazards associated with the end product; other conditions that have an impact on food safety

7 Support

ISO	Key Content	Comment
7.5 Documented information **7.5.1 General**	documented information determined by the organization as being necessary for the effectiveness of the FSMS documented information and food safety requirements required by statutory, regulatory authorities and customers.	The extent of documented information for a FSMS 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 interactions; the competence of persons.
7.5.2 Creating and updating	ensure creating and updating documented information	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 Support

ISO	Key Content	Comment
7.5.3 Control of documented information	Control the availability of the documented information Control the protection of the documented information Control the distribution, access and use of the documented information Control the storage of the documented information Control the changes of the documented information Control the retention and disposition of the documented information Control the documented information of external origin	Where and when required in a form that is suitable for use Loss of confidentiality, loss of integrity, misuse Who is responsible, method to use, rule to follow Including protection Use updated versions, limited access to outdated versions Retention period, disposal method Unique codification, access, protection

8 Operation

ISO	Key Content	Comment
8.1 Operational planning and control	plan, implement, control, maintain and update the processes needed to meet requirements for the realization of safe products. establishing criteria for the processes implementing control of the processes ensure that outsourced processes are controlled	control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects

8 Operation

ISO	Key Content	Comment
8.2 Prerequisite programmes (PRPs)	establish, implement, maintain and update PRP(s) appropriate to the organization and its context with regard to food safety appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled; implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or process; approved by the food safety team. ensure that applicable statutory, regulatory and mutually agreed customer requirements	prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment the applicable part of the ISO/TS 22002 series;

ISO/TS 22002-1
Food Manufacturing

4 Construction and layout of buildings

4.1 General requirements

- Buildings shall be designed, constructed and maintained in a manner appropriate to the nature of the processing operations to be carried out, the food safety hazards associated with those operations and the potential sources of contamination from the plant environs. Buildings shall be of durable construction which presents no hazard to the product.
- NOTE An example of "durable construction" is self-draining roofs which do not leak.

4.2 Environment

- Consideration shall be given to potential sources of contamination from the local environment.
- Food production should not be carried out in areas where potentially harmful substances could enter the product.
- The effectiveness of measures taken to protect against potential contaminants shall be periodically reviewed.

ISO/TS 22002-1
Food Manufacturing

4.3 Locations of establishments

- The site boundaries shall be clearly identified.
- Access to the site shall be controlled.
- The site shall be maintained in good order. Vegetation shall be tended or removed. Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained.

5 Layout of premises and workspace

5.1 General requirements

- Internal layouts shall be designed, constructed and maintained to facilitate good hygiene and manufacturing practices. The movement patterns of materials, products and people, and the layout of equipment, shall be designed to protect against potential contamination sources.

5.2 Internal design, layout and traffic patterns

- The building shall provide adequate space, with a logical flow of materials, products and personnel, and physical separation of raw from processed areas.
- NOTE Examples of physical separation include walls, barriers or partitions, or sufficient distance to minimize risk.
- Openings intended for transfer of materials shall be designed to minimize entry of foreign matter and pests.

ISO/TS 22002-1
Food Manufacturing

5.3 Internal structures and fittings

- Process area walls and floors shall be washable or cleanable, as appropriate for the process or product hazard. Materials of construction shall be resistant to the cleaning system applied.
- Wall floor junctions and corners shall be designed to facilitate cleaning.
- It is recommended that wall floor junctions be rounded in processing areas.
- Floors shall be designed to avoid standing water.
- In wet process areas, floors shall be sealed and drained. Drains shall be trapped and covered.
- Ceilings and overhead fixtures shall be designed to minimize build-up of dirt and condensation.
- External opening windows, roof vents or fan, where present, shall be insect screened.
- External opening doors shall be closed or screened when not in use.

5.4 Location of equipment

- Equipment shall be designed and located so as to facilitate good hygiene practices and monitoring.
- Equipment shall be located to permit access for operation, cleaning and maintenance.

5.5 Laboratory facilities

- In-line and on-line test facilities shall be controlled to minimize risk of product contamination.
- Microbiology laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products. They shall not open directly on to a production area.

ISO/TS 22002-1
Food Manufacturing

5.6 Temporary or mobile premises and vending machines

- Temporary structures shall be designed, located and constructed to avoid pest harbourage and potential
- contamination of products.
- Additional hazards associated with temporary structures and vending machines shall be assessed and
- controlled.

5.7 Storage of food, packaging materials, ingredients and non-food chemicals

- Facilities used to store ingredients, packaging and products shall provide protection from dust, condensation,
- drains, waste and other sources of contamination.
- Storage areas shall be dry and well ventilated. Monitoring and control of temperature and humidity shall be applied where specified.
- Storage areas shall be designed or arranged to allow segregation of raw materials, work in progress and
- finished products.
- All materials and products shall be stored off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out.
- The storage area shall be designed to allow maintenance and cleaning, prevent contamination and minimize deterioration.
- A separate, secure (locked or otherwise access controlled) storage area shall be provided for cleaning
- materials, chemicals and other hazardous substances.
- Exceptions for bulk or agricultural crop materials shall be documented in the food safety management system.

ISO/TS 22002-1
Food Manufacturing

6 Utilities ~~-a~~ir, water, energy

- 6.1 General requirements
- The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination. Utilities'quality shall be monitored to minimize product contamination risk.

6.2 Water supply

- The supply of potable water shall be sufficient to meet the needs of the production process(es). Facilities for storage, distribution and, where needed, temperature control of the water shall be designed to meet specified water quality requirements.
- Water used as a product ingredient, including ice or steam (including culinary steam), or in contact with products or product surfaces, shall meet specified quality and microbiological requirements relevant to the product.
- Water for cleaning or applications where there is a risk of indirect product contact (e.g. jacketed vessels, heat exchangers) shall meet specified quality and microbiological requirements relevant to the application.
- Where water supplies are chlorinated, checks shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specifications.
- Non-potable water shall have a separate supply system that is labelled and not connected to the potablewater system. Take measures to prevent non-potable water refluxing into the potable system.
- It is recommended that water that can come into contact with the product should flow through pipes that can be disinfected.

ISO/TS 22002-1
Food Manufacturing

- 6.3 Boiler chemicals
- Boiler chemicals, if used, shall be either:
- a) approved food additives which meet relevant additive specifications; or
- b) additives which have been approved by the relevant regulatory authority as safe for use in water intended
- for human consumption.
- Boiler chemicals shall be stored in a separate, secure (locked or otherwise access-controlled) area when not
- in immediate use.
- 6.4 Air quality and ventilation
- The organization shall establish requirements for filtration, humidity (RH%) and microbiology of air used as an
- ingredient or for direct product contact. Where temperature and/or humidity are deemed critical by the
- organization, a control system shall be put in place and monitored.
- Ventilation (natural or mechanical) shall be provided to remove excess or unwanted steam, dust and odours,
- and to facilitate drying after wet cleaning.
- Room air supply quality shall be controlled to minimize risk from airborne microbiological contamination.
- Protocols for air quality monitoring and control shall be established in areas where products which support the
- growth or survival of microorganisms are exposed.
- Ventilation systems shall be designed and constructed such that air does not flow from contaminated or raw
- areas to clean areas. Specified air pressure differentials shall be maintained. Systems shall be accessible for
- cleaning, filter changing and maintenance.
- Exterior air intake ports shall be examined periodically for physical integrity.

ISO/TS 22002-1
Food Manufacturing

6.5 Compressed air and other gases

- Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.
- Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil and water.
- Where oil is used for compressors and there is potential for the air to come into contact with the product, the oil used shall be food grade.
- Use of oil free compressors is recommended.
- Requirements for filtration, humidity (RH%) and microbiology shall be specified.
- Filtration of the air should be as close to the point of use as is practicable.

6.6 Lighting

- The lighting provided (natural or artificial) shall allow personnel to operate in a hygienic manner.
- The intensity of the lighting should be appropriate to the nature of the operation.
- Light fixtures shall be protected to ensure that materials, product or equipment are not contaminated in the case of breakages.

7 Waste disposal

7.1 General requirements

- Systems shall be in place to ensure that waste materials are identified, collected, removed and disposed of in a manner which prevents contamination of products or production areas.

ISO/TS 22002-1
Food Manufacturing

7.2 Containers for waste and inedible or hazardous substances

- Containers for waste and inedible or hazardous substances shall be:

a) clearly identified for their intended purpose;

b) located in a designated area;

c) constructed of impervious material which can be readily cleaned and sanitized;

d) closed when not in immediate use;

e) locked where the waste may pose a risk to the product.

7.3 Waste management and removal

- Provision shall be made for the segregation, storage and removal of waste.
- Accumulation of waste shall not be allowed in food-handling or storage areas. Removal frequencies shall be managed to avoid accumulations, with a minimum daily removal.
- Labelled materials, products or printed packaging designated as waste shall be disfigured or destroyed to ensure that trademarks cannot be reused. Removal and destruction shall be carried out by approved disposal contractors. The organization shall retain records of destruction.

7.4 Drains and drainage

- Drains shall be designed, constructed and located so that the risk of contamination of materials or products is avoided. Drains shall have capacity sufficient to remove expected flow loads. Drains shall not pass over processing lines.
- Drainage direction shall not flow from a contaminated area to a clean area.

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Food Manufacturing

8 Equipment suitability, cleaning and maintenance

8.1 General requirements

- Food contact equipment shall be designed and constructed to facilitate cleaning, disinfection and maintenance. Contact surfaces shall not affect, or be affected by, the intended product or cleaning system.
- Food contact equipment shall be constructed of durable materials able to resist repeated cleaning.

8.2 Hygienic design

- Equipment shall be able to meet established principles of hygienic design, including:

a) smooth, accessible, cleanable surfaces, self draining in wet process areas;

b) use of materials compatible with intended products and cleaning or flushing agents;

c) framework not penetrated by holes or nuts and bolts.

- Piping and ductwork shall be cleanable, drainable, and with no dead ends.
- Equipment shall be designed to minimize contact between the operator's hands and the products.

8.3 Product contact surfaces

- Product contact surfaces shall be constructed from materials designed for food use. They shall be impermeable and rust or corrosion free.

ISO/TS 22002-1
Food Manufacturing

8.4 Temperature control and monitoring equipment

- Equipment used for thermal processes shall be able to meet the temperature gradient and holding conditions given in relevant product specifications.
- Equipment shall provide for the monitoring and control of the temperature.

8.5 Cleaning plant, utensils and equipment

- Wet and dry cleaning programmes shall be documented to ensure that all plant, utensils and equipment are cleaned at defined frequencies.
- The programmes shall specify what is to be cleaned (including drains), the responsibility, the method of cleaning (e.g. CIP, COP), the use of dedicated cleaning tools, removal or disassembly requirements and methods for verifying the effectiveness of the cleaning.

8.6 Preventive and corrective maintenance

- A preventive maintenance programme shall be in place.
- The preventive maintenance programme shall include all devices used to monitor and/or control food safety hazards.
- NOTE: Examples of such devices include screens and filters (including air filters), magnets, metal detectors and X-ray detectors.
- Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.

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Food Manufacturing

- Maintenance requests which impact product safety shall be given priority.
- Temporary fixes shall not put product safety at risk. A request for replacement by a permanent repair shall be included in the maintenance schedule.
- Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or indirect contact with the product.
- The procedure for releasing maintained equipment back to production shall include clean up, sanitizing, where specified in process sanitation procedures, and pre-use inspection.
- Local area PRP requirements shall apply to maintenance areas and maintenance activities in process areas. Maintenance personnel shall be trained in the product hazards associated with their activities.

9 Management of purchased materials

9.1 General requirements

- Purchasing of materials which impact food safety shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements. The conformance of incoming materials to specified purchase requirements shall be verified.

9.2 Selection and management of suppliers

- There shall be a defined process for the selection, approval and monitoring of suppliers. The process used shall be justified by hazard assessment, including the potential risk to the final product, and shall include:

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Food Manufacturing

a) assessment of the supplier's ability to meet quality and food safety expectations, requirements and specifications;

b) description of how suppliers are assessed;

- NOTE Examples of a description of how suppliers are assessed include:

1) audit of the supplying site prior to accepting materials for production;

2) appropriate third party certification.

c) monitoring the performance of the supplier to assure continued approval status.

- NOTE: Monitoring includes conformity with material or product specifications, fulfilment of COA requirements, satisfactory audit outcomes.

9.3 Incoming material requirements (raw/ingredients/packaging)

- Delivery vehicles shall be checked prior to, and during, unloading to verify that the quality and safety of the material has been maintained during transit (e.g. integrity of seals, freedom from infestation, existence of temperature records).
- Materials shall be inspected, tested or covered by COA to verify conformity with specified requirements prior to acceptance or use. The method of verification shall be documented.
- NOTE: The inspection frequency and scope can be based on the hazard presented by the material and the risk assessment of the specific suppliers.
- Materials which do not conform to relevant specifications shall be handled under a documented procedure which ensures they are prevented from unintended use.

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Food Manufacturing

- Access points to bulk material receiving lines shall be identified, capped and locked. Discharge into such systems shall take place only after approval and verification of the material to be received.

10 Measures for prevention of cross-contamination

10.1 General requirements

- Programmes shall be in place to prevent, control and detect contamination. Measures to prevent physical, allergen and microbiological contamination shall be included.

10.2 Microbiological cross-contamination

- Areas where potential for microbiological cross-contamination exists (airborne or from traffic patterns) shall be identified and a segregation (zoning) plan implemented. A hazard assessment shall be carried out to determine potential contamination sources, susceptibility of the product and control measures suitable for these areas as follows:

a) separation of raw from finished or ready to eat (RTE) products;

b) structural segregation ~~-p~~hysical barriers, walls or separate buildings;

c) access controls with requirements to change into required workwear;

d) traffic patterns or equipment segregation ~~-p~~eople, materials, equipment and tools (includin use of dedicated tools);

e) air pressure differentials.

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Food Manufacturing

10.3 Allergen management

- Allergens present in the product, either by design or by potential manufacturing cross-contact, shall be declared. The declaration shall be on the label for consumer products, and on the label or the accompanying documentation for products intended for further processing.
- Products shall be protected from unintended allergen cross-contact by cleaning and line change-over practices and/or product sequencing.
- NOTE: Manufacturing cross-contact can arise from either:

1) traces of product from the previous production run which cannot be adequately cleaned from the product line due to technical limitations; or

2) when contact is likely to occur, in the normal manufacturing process, with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas.

- Rework containing allergen(s) shall be used only:

a) in products which contain the same allergen(s) by design; or

b) through a process which is demonstrated to remove or destroy the allergenic material.

- NOTE: For general rework requirements, see Clause 14.
- Employees handling food should receive specific training in allergen awareness and associated manufacturing practices.

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Food Manufacturing

10.4 Physical contamination

- Where brittle materials are used, periodic inspection requirements and defined procedures in case of breakage shall be put in place.
- Brittle materials, such as glass and hard plastic components in equipment, should be avoided where possible.
- Glass breakage records shall be maintained.
- Based on hazard assessment, measures shall be put in place to prevent, control or detect potential contamination.
- NOTE 1 Examples of such measures include:

a) adequate covers over equipment or containers for exposed materials or products;

b) use of screens, magnets, sieves or filters;

c) use of detection or rejection devices such as metal detectors or X-ray.

- NOTE 2 Sources of potential contamination include wooden pallets and tools, rubber seals, and personal protective clothing and equipment.

11 Cleaning and sanitizing

11.1 General requirements

- Cleaning and sanitizing programmes shall be established to ensure that the food-processing equipment and environment are maintained in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

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Food Manufacturing

11.2 Cleaning and sanitizing agents and tools

- Facilities and equipment shall be maintained in a condition which facilitates wet or dry cleaning and/or sanitation.
- Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturer's instructions.
- Tools and equipment shall be of hygienic design and maintained in a condition which does not present a potential source of extraneous matter.

11.3 Cleaning and sanitizing programmes

- Cleaning and sanitizing programmes shall be established and validated by the organization to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment.
- Cleaning and/or sanitizing programmes shall specify at a minimum:

a) areas, items of equipment and utensils to be cleaned and/or sanitized;

b) responsibility for the tasks specified;

c) cleaning/sanitizing method and frequency;

d) monitoring and verification arrangements;

e) post-clean inspections;

f) pre start-up inspections.

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Food Manufacturing

11.4 Cleaning in place (CIP) systems

- CIP systems shall be separated from active product lines.
- Parameters for CIP systems shall be defined and monitored (including type, concentration, contact time and temperature of any chemicals used).

11.5 Monitoring sanitation effectiveness

- Cleaning and sanitation programmes shall be monitored at frequencies specified by the organization to ensure their continuing suitability and effectiveness.

12 Pest control

12.1 General requirements

- Hygiene, cleaning, incoming materials inspection and monitoring procedures shall be implemented to avoid creating an environment conducive to pest activity.

12.2 Pest control programmes

- The establishment shall have a nominated person to manage pest control activities and/or deal with appointed expert contractors.
- Pest management programmes shall be documented and shall identify target pests, and address plans, methods, schedules, control procedures and, where necessary, training requirements.
- Programmes shall include a list of chemicals which are approved for use in specified areas of the establishment.

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Food Manufacturing

12.3 Preventing access

- Buildings shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed.
- External doors, windows or ventilation openings shall be designed to minimize the potential for entry of pests.

12.4 Harbourage and infestations

- Storage practices shall be designed to minimize the availability of food and water to pests.
- Material found to be infested shall be handled in such a way as to prevent contamination of other materials, products or the establishment.
- Potential pest harbourage (e.g. burrows, undergrowth, stored items) shall be removed.
- Where outside space is used for storage, stored items shall be protected from weather or pest damage (e.g. bird droppings).

12.5 Monitoring and detection

- Pest-monitoring programmes 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 designed and located so as to prevent potential contamination of materials, products or facilities.
- Detectors and traps shall be of robust, tamper-resistant construction. They shall be appropriate for the target pest.

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Food Manufacturing

- The detectors and traps shall be inspected at a frequency intended to identify new pest activity. The results of inspections shall be analysed to identify trends.

12.6 Eradication

- Eradication measures shall be put in place immediately after evidence of infestation is reported.
- Pesticide use and application shall be restricted to trained operatives and shall be controlled to avoid product safety hazards.
- Records of pesticide use shall be maintained to show the type, quantity and concentrations used; where, when and how applied, and the target pest.

13 Personnel hygiene and employee facilities

13.1 General requirements

- Requirements for personal hygiene and behaviours proportional to the hazard posed to the process area or product shall be established and documented. All personnel, visitors and contractors shall be required to comply with the documented requirements.

13.2 Personnel hygiene facilities and toilets

- Personnel hygiene facilities shall be available to ensure that the degree of personal hygiene required by the organization can be maintained. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated.

ISO/TS 22002-1
Food Manufacturing

- Establishments shall:

a) provide adequate numbers, locations and means of hygienically washing, drying and, where required, sanitizing hands (including wash-basins, supply of hot and cold or temperature controlled water, and soap and/or sanitizer);

b) have sinks designated for hand washing, whose taps should not be hand operated, separate from sinks for food use and equipment-cleaning stations;

c) provide an adequate number of toilets of appropriate hygienic design, each with hand-washing, drying and, where required, sanitizing facilities;

d) have employee hygiene facilities that do not open directly on to production, packing or storage areas;

e) have adequate changing facilities for personnel;

f) have changing facilities sited to enable personnel handling food to move to the production area in such a way that risk to the cleanliness of their workwear is minimized.

13.3 Staff canteens and designated eating areas

- Staff canteens and designated areas for food storage and consumption shall be situated so that the potential for cross-contamination of production areas is minimized.
- Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods. Storage conditions and storage, cooking and holding temperatures, and time limitations, shall be specified.
- Employees'own food shall be stored and consumed in designated areas only.

ISO/TS 22002-1
Food Manufacturing

13.4 Workwear and protective clothing

- Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean and in good condition (e.g. free from rips, tears or fraying material).
- Clothing mandated for food protection or hygiene purposes shall not be used for any other purpose.
- Workwear shall not have buttons. Workwear shall not have outside pockets above waist level. Zips or press stud fastenings are acceptable.
- Workwear shall be laundered to standards and at intervals suitable for the intended use of the garments.
- Workwear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.
- Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints unless hazard analysis indicates otherwise.
- Where gloves are used for product contact, they shall be clean and in good condition. Use of latex gloves should be avoided where possible.
- Shoes for use in processing areas shall be fully enclosed and made from non-absorbent materials.
- Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

ISO/TS 22002-1
Food Manufacturing

13.5 Health status

- Subject to legal restrictions in the country of operation, employees shall undergo a medical examination prior to employment in food contact operations (including site catering), unless documented hazard or medical assessment indicates otherwise.
- Additional medical examinations, where permitted, shall be carried out at intervals defined by the organization.

13.6 Illness and injuries

- Where permitted by law, employees shall be required to report the following conditions to management for possible exclusion from food-handling areas: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin lesions (boils, cuts or sores) and discharges from the ear, eye or nose.
- People known or suspected to be infected with, or carrying, a disease or illness transmissible through food shall be prevented from handling food or materials which come into contact with food.
- In food-handling areas, personnel with wounds or burns shall be required to cover them with specified dressings. Any lost dressing shall be reported to supervision immediately.
- NOTE: Dressings should be brightly coloured and metal detectable where appropriate.

ISO/TS 22002-1
Food Manufacturing

13.7 Personal cleanliness

- Personnel in food production areas shall be required to wash and, where required, sanitize hands:

a) before starting any food-handling activities;

b) immediately after using the toilet or blowing the nose;

c) immediately after handling any potentially contaminated material.

- Personnel shall be required to refrain from sneezing or coughing over materials or products. Spitting (expectorating) shall be prohibited.
- Fingernails shall be kept clean and trimmed.

13.8 Personal behaviour

- A documented policy shall describe the behaviours required of personnel in processing, packing and storage areas. The policy shall at a minimum cover:

a) permissibility of smoking, eating, chewing in designated areas only;

b) control measures to minimize hazards presented by permitted jewellery, such as that worn by personnel in processing and storage areas, taking into account religious, ethnic, medical and cultural imperatives;

c) permissibility of personal items, such as smoking materials and medicines, in designated areas only;

d) prohibition of the use of nail polish, false nails and false eyelashes;

ISO/TS 22002-1
Food Manufacturing

e) prohibition of carrying of writing implements behind the ears;

f) maintenance of personal lockers so that they are kept free from rubbish and soiled clothing;

g) prohibition of storage of product contact tools and equipment in personal lockers.

14 Rework

14.1 General requirements

- Rework shall be stored, handled and used in such a way that product safety, quality, traceability and regulatory compliance are maintained.

14.2 Storage, identification and traceability

- Stored rework shall be protected from exposure to microbiological, chemical or extraneous matter contamination.
- Segregation requirements for rework (e.g. allergen) shall be documented and met.
- Rework shall be clearly identified and/or labelled to allow traceability. Traceability records for rework shall be maintained.
- The rework classification or the reason for rework designation shall be recorded (e.g. product name, production date, shift, line of origin, shelf-life).

14.3 Rework usage

- Where rework is incorporated into a product as an ĺn-process”step, the acceptable quantity, type and conditions of rework use shall be specified. The process step and method of addition, including any necessary pre-processing stages, shall be defined.

ISO/TS 22002-1
Food Manufacturing

- Where rework activities involve removing a product from filled or wrapped packages, controls shall be put in place to ensure the removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.

15 Product recall procedures

15.1 General requirements

- Systems shall be in place to ensure that products failing to meet required food safety standards can be identified, located and removed from all necessary points of the supply chain.

15.2 Product recall requirements

- A list of key contacts in the event of a recall shall be maintained.
- Where products are withdrawn due to immediate health hazards, the safety of other products produced under the same conditions shall be evaluated. The need for public warnings shall be considered.

16 Warehousing

16.1 General requirements

- Materials and products shall be stored in clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.

16.2 Warehousing requirements

- Effective control of warehousing temperature, humidity and other environmental conditions shall be provided where required by product or storage specifications.

ISO/TS 22002-1
Food Manufacturing

- It is recommended that where products are stacked, consideration is given to measures necessary to protect the lower layers.
- Waste materials and chemicals (cleaning products, lubricants, and pesticides) shall be stored separately.
- A separate area or other means of segregating materials identified as non-conforming shall be provided.
- Specified stock rotation systems (FIFO/FEFO) shall be observed.
- Gasoline- or diesel-powered fork-lift trucks shall not be used in food ingredient or product storage areas.
- 16.3 Vehicles, conveyances, and containers
- Vehicles, conveyances, and containers shall be maintained in a state of repair, cleanliness, and condition consistent with requirements given in relevant specifications.
- Vehicles, conveyances, and containers shall provide protection against damage or contamination of the product. Control of temperature and humidity shall be applied and recorded where required by the organization.
- Where the same vehicles, conveyances, and containers are used for food and non-food products, cleaning shall be carried out between loads.
- Bulk containers shall be dedicated to food use only. Where required by the organization, bulk containers shall be dedicated to a specified material.

ISO/TS 22002-1
Food Manufacturing

17 Product information and consumer awareness

- Information shall be presented to consumers in such a way as to enable them to understand its importance and make informed choices.
- Information may be provided by labelling or other means, such as company websites and advertisements, and may include storage, preparation and serving instructions applicable to the product.

18 Food defence, biovigilance, and bioterrorism

18.1 General requirements

- Each establishment shall assess the hazard to products posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures.

18.2 Access controls

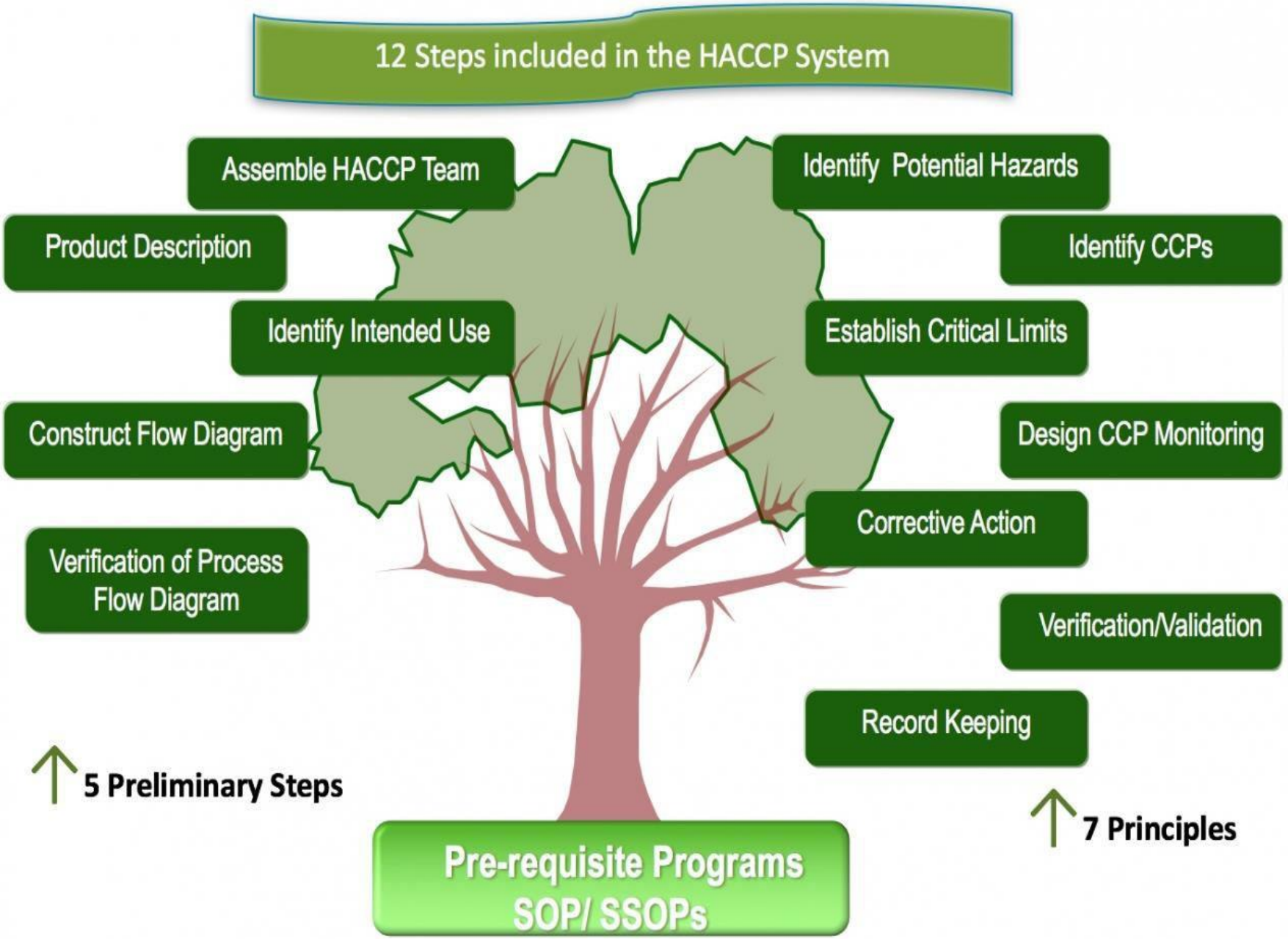
- Potentially sensitive areas within the establishment shall be identified, mapped, and subjected to access control.
- Where feasible, access should be physically restricted by use of locks, electronic card key or alternative systems.

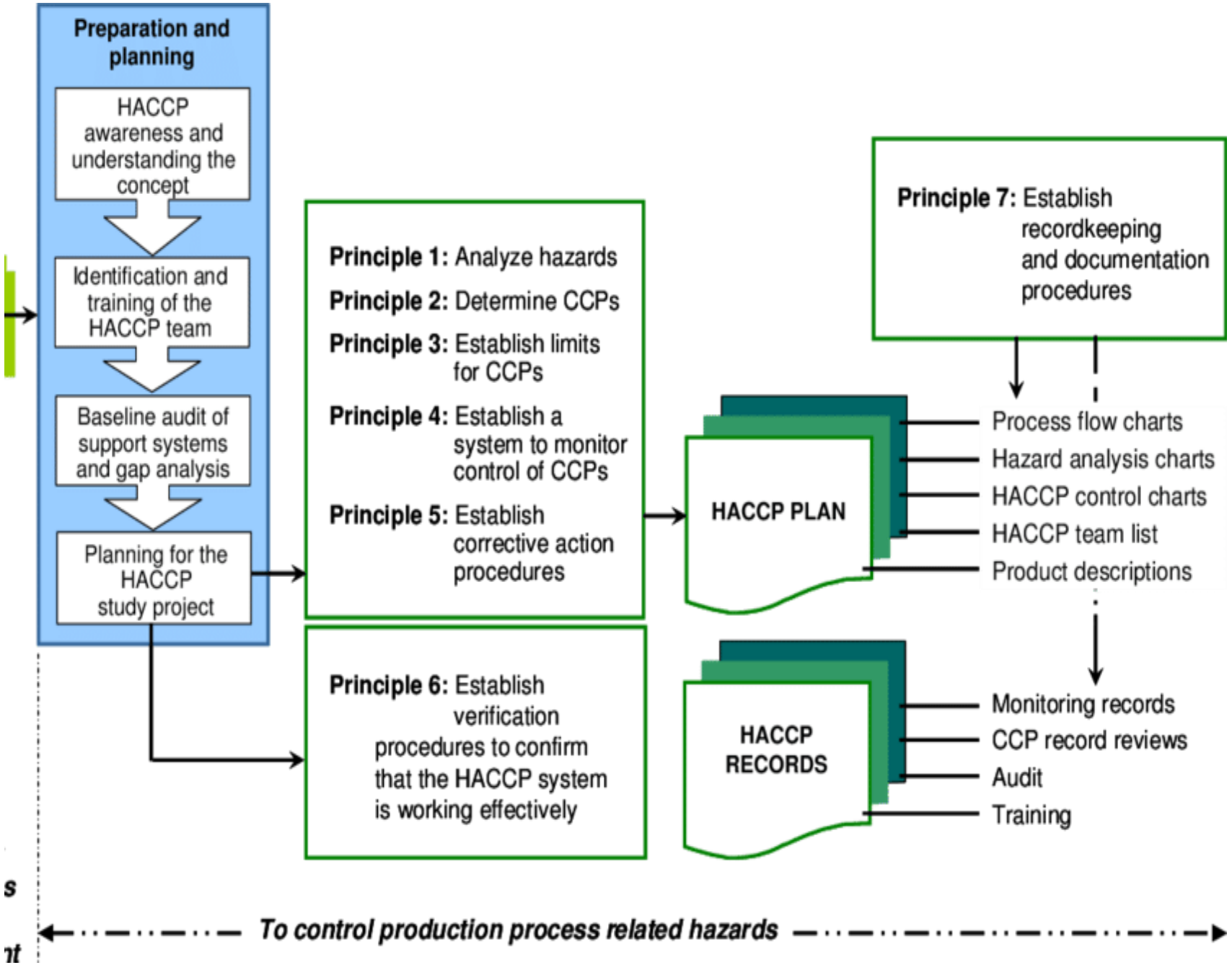
8 Operation

ISO	Key Content	Comment
8.3 Traceability system	able to uniquely identify incoming material from the suppliers and the first stage of the distribution route of the end product ensure that applicable statutory, regulatory and customer requirements are identified. Documented information retained for a defined period to include, as a minimum, the shelf life of the product. verify and test the effectiveness of the traceability system.	relation of lots of received materials, ingredients and intermediate products to the end products; reworking of materials/products; distribution of the end product. the verification of the system is expected to include the reconciliation of quantities of end products with the quantity of ingredients as evidence of effectiveness.

8 Operation

ISO	Key Content	Comment
8.4.1 General	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.	Define role of the organization in the food chain.
8.4.2 Handling of emergencies and incidents	respond to actual emergency situations and incidents to reduce the consequences of the emergency situation review and, where necessary, update the documented information	emergency situations that can affect food safety and/or production are 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.


12 Steps included in the HACCP System
Assemble HACCP Team
Identify Potential Hazards
Product Description
Identify CCPs
Identify Intended Use
Establish Critical Limits
Construct Flow Diagram
Design CCP Monitoring
Corrective Action
Verification of Process Flow Diagram
Verification/Validation
Record Keeping
5 Preliminary Steps
7 Principles
Pre-requisite Programs
SOP/ SSOPs


Preparation and planning
HACCP awareness and understanding the concept
Identification and training of the HACCP team
Baseline audit of support systems and gap analysis
Planning for the HACCP study project
Principle 1: Analyze hazards
Principle 2: Determine CCPs
Principle 3: Establish limits for CCPs
Principle 4: Establish a system to monitor control of CCPs
Principle 5: Establish corrective action procedures
Principle 6: Establish verification procedures to confirm that the HACCP system is working effectively
Principle 7: Establish recordkeeping and documentation procedures
HACCP PLAN
Process flow charts
Hazard analysis charts
HACCP control charts
HACCP team list
Product descriptions
HACCP RECORDS
Monitoring records
CCP record reviews
Audit
Training
To control production process related hazards

8 Operation

ISO	Key Content	Comment
8.5 Hazard control. **8.5.1 Preliminary steps to enable hazard analysis** **8.5.1.1 General** **8.5.1.2 Characteristics of raw materials, ingredients and product contact materials**	the food safety team carry out the hazard analysis, preliminary documented information to collected, maintained and updated	applicable statutory, regulatory and customer requirements the organization's products, processes and equipment; food safety hazards relevant to the FSMS.
8.5.1.2 Characteristics of raw materials, ingredients and product contact materials	ensure that all applicable statutory and regulatory food safety requirements identified for all raw materials, ingredients and product contact materials maintain documented information concerning all raw materials, ingredients and product contact materials to the extent needed to conduct the hazard analysis	a) biological, chemical and physical characteristics; b) composition of formulated ingredients, including additives and processing aids; c) source (e.g. animal, mineral or vegetable); d) place of origin (provenance); e) method of production; f) method of packaging and delivery; g) storage conditions and shelf life; h) preparation and/or handling before use or processing; i) acceptance criteria related to food safety or specifications of purchased materials and ingredients appropriate to their intended use.

8 Operation

ISO	Key Content	Comment
8.5.1.3 Characteristics of end products	ensure that all applicable statutory and regulatory food safety requirements are identified for all the end products intended to be produced concerning the characteristics of end products to the extent needed to conduct the hazard analysis	product name or similar identification; composition; biological, chemical and physical characteristics relevant for food safety; intended shelf life and storage conditions; packaging; labelling relating to food safety and/or instructions for handling, preparation and intended use; method(s) of distribution and delivery.

8 Operation

ISO	Key Content	Comment
8.5.1.4 Intended use	expected handling of the end product any unintended use but reasonably expected mishandling and misuse of the end product groups of consumers/users identified for each product	Addressed groups of consumers/users for products
8.5.1.5 Flow diagrams and description of processes **8.5.1.5.1 Preparation of the flow diagrams**	establish, maintain and update flow diagrams by Food Safety Team clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis via Flow diagrams the sequence and interaction of the steps in the operation; any outsourced processes; where raw materials, ingredients, 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.	Flow diagrams provide a graphic representation of the process hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of food safety hazards.

Product Description, Distribution, Consumers and Intended Use	
Product Name(s)	Chicken Sausage (Fully cooked, not shelf stable)
Product Description, including Important Food Safety Characteristics	Refrigerated, chicken sausage pH 5.0-5.3, water activity>0.99 , with preservatives
Ingredients	Chicken, water, salt, modified food starch, potassium chloride, spices, sodium phosphate sodium erythorbate, sodium nitrite, collagen casings
Packaging Used	Vacuum-packaged in plastic film; bulk-packed in plastic bag in cardboard box.
Intended Use	The product is considered ready-to-eat, but is typically heated to hot holding temperature (135°F (57°C)) or above for palatability. Heating is typically conducted using microwaves or convection oven. End user may thaw at refrigeration temperatures overnight to reduce cooking time. Sold for foodservice applications. Potential abuse: Some establishments may hold thawed product for longer than the recommended 24 hrs
Intended Consumers	Retail consumers
Shelf Life	40-60 days with proper refrigeration (< 40°F)
Labeling Instructions	Keep frozen and serve within 7 days after opening. Thaw under refrigeration (<40°F (5°C)) for <24 hours before cooking
Storage and Distribution	Shipped in refrigerated trucks. Product should remain in refrigerated or frozen state (< 40°F)

8 Operation

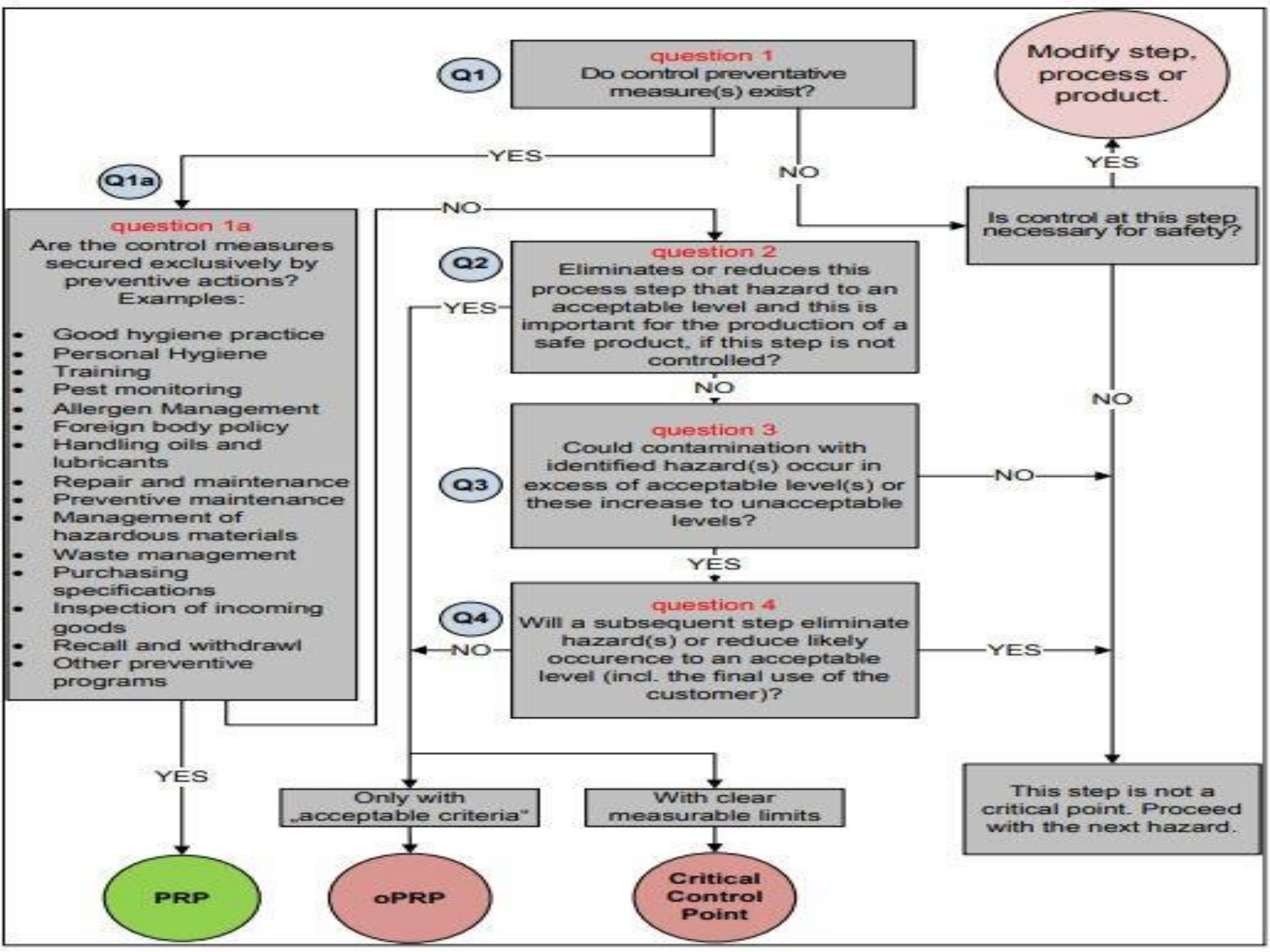
ISO	Key Content	Comment
8.5.1.5.2 On-site confirmation of flow diagrams	confirm on-site the accuracy of the flow diagrams update the flow diagrams retain as documented information	food safety team confirm Flow diagrams
8.5.1.5.3 Description of processes and process environment	existing PRPs, process parameters, control measures (if any) and/or the strictness with which they are applied, or procedures that can influence food safety ; describe the extent needed to conduct the hazard analysis the layout of premises, including food and non-food handling area processing equipment and contact materials, processing aids and flow of materials; external requirements (e.g. from statutory and regulatory authorities or customers) that can impact the choice and the strictness of the control measures.	expected seasonal changes or shift patterns

8 Operation

ISO	Key Content	Comment
8.5.2 Hazard analysis **8.5.2.1 General**	conduct a hazard analysis, based on the preliminary information to determine the hazards that need to be controlled.	Food Safety team conduct hazard analysis & defined controlled
8.5.2.2 Hazard identification and determination of acceptable levels	identify and document all food safety hazards expected to occur in relation to the type of product, type of process and process environment identification based on the preliminary information and data collected , Experience, internal and external information including, to the extent possible, epidemiological, scientific and other historical data; information from the food chain on food safety hazards related to the safety of the end products, intermediate products and the food at the time of consumption, statutory, regulatory and customer requirements.	Experience can include information from staff and external experts who are familiar with the product and/or processes in other facilities. Statutory and regulatory requirements can include food safety objectives (FSOs). The Codex Alimentarius Commission defines FSOs as “The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)”. Hazards should be considered in sufficient detail to enable hazard assessment and the selection of appropriate control measures.

8 Operation

ISO	Key Content	Comment
8.5.2.2.2	identify step(s) (e.g. receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase or persist. the stages preceding and following in the food chain the stages preceding and following in the food chain the process equipment, utilities/services, process environment and persons	Food Safety Team verify each process equipment, utilities/services, process environment and persons
8.5.2.2.3	determine the acceptable level in the end product of each food safety hazard identified ensure that applicable statutory, regulatory and customer requirements are identified consider the intended use of end products consider any other relevant information maintain documented information determination of acceptable levels and the justification for the acceptable levels	Food Safety team verify statutory, regulatory and customer requirements , intended use of end products & acceptable levels and its justification


Q1
question 1
Do control preventative measure(s) exist?
YES
NO
Modify step, process or product.
YES
Q1a
question 1a
Are the control measures secured exclusively by preventive actions?
Examples:
Good hygiene practice
Personal Hygiene
Training
Pest monitoring
Allergen Management
Foreign body policy
Handling oils and lubricants
Repair and maintenance
Preventive maintenance
Management of hazardous materials
Waste management
Purchasing specifications
Inspection of incoming goods
Recall and withdrawl
Other preventive programs
NO
Is control at this step necessary for safety?
Q2
question 2
Eliminates or reduces this process step that hazard to an acceptable level and this is important for the production of a safe product, if this step is not controlled?
YES
NO
NO
Q3
question 3
Could contamination with identified hazard(s) occur in excess of acceptable level(s) or these increase to unacceptable levels?
NO
YES
Q4
question 4
Will a subsequent step eliminate hazard(s) or reduce likely occurence to an acceptable level (incl. the final use of the customer)?
NO
YES
YES
Only with „acceptable criteria"
With clear measurable limits
This step is not a critical point. Proceed with the next hazard.
PRP
oPRP
Critical Control Point

8 Operation

ISO	Key Content	Comment
8.5.2.3 Hazard assessment	conduct a hazard assessment for each identified food safety hazard prevention or reduction to an acceptable level evaluate each food safety hazard with regard to: the likelihood of its occurrence in the end product prior to application of control measures the severity of its adverse health effects in relation to the intended use identify any significant food safety hazards described used methodology	Food Safety Team described used methodology and maintain hazard assessment records

8 Operation

ISO	Key Content	Comment
8.5.2.4 Selection and categorization of control measure(s)	Based on the hazard assessment select an appropriate control measure or combination of control measures capable of preventing or reducing the identified significant food safety hazards to defined acceptable levels categorize the selected identified control measure(s) to be managed as OPRP(s) For each of the control measures selected an assessment of the following the likelihood of failure of its functioning; the severity of the consequence in the case of failure of its functioning the effect on identified significant food safety hazards the location in relation to other control measure(s) whether it is specifically established and applied to reduce the hazards to an acceptable level whether it is a single measure or is part of combination of control measure(s).	Food Safety Team select an appropriate control which should be cable to preventing or reducing the identified significant food safety hazards to defined acceptable levels

8 Operation

ISO	Key Content	Comment
8.5.2.4.2	for each control measure an assessment of the feasibility of: establishing measurable critical limits and/or measurable/observable action criteria; monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria; applying timely corrections in case of failure. documented information of decision-making process and results of the selection and categorization of the control measures and External requirements (e.g. statutory, regulatory and customer requirements)	Food Safety Team establishing measurable critical limits and/or measurable/observable action criteria

8 Operation

ISO	Key Content	Comment
8.5.3 Validation of control measure(s) and combinations of control measures	The food safety team validate that the selected control measures are capable of achieving the intended control of the significant food safety hazard(s) When the result of validation shows that the control measures(s) is (are) not capable of achieving the intended control, the food safety team modify and re-assess the control measure(s) and/or combination(s) of control measure(s). maintain the validation methodology and evidence of capability of the control measure(s) to achieve the intended control as documented information.	Modification can include changes in control measure(s) (i.e. process parameters, rigour and/or their combination) and/or change(s) in the manufacturing technologies for raw materials, end product characteristics, methods of distribution and intended use of the end products.

8 Operation

ISO	Key Content	Comment
8.5.4 Hazard control plan (HACCP/OPRP plan) **8.5.4.1 General**	establish, implement and maintain a hazard control plan hazard control plan include the following information for each control measure at 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; records of monitoring.	Food Safety team maintain hazard control plan include CCP & OPRP with monitoring, correction and responsibilities and authorities
8.5.4.2 Determination of critical limits and action criteria	Specify CCPs and action criteria for OPRPs Ensure that the acceptable level is not exceeded(Critical limits at CCPs) Action criteria for OPRPs (measurable or observable)	Food Safety team ensure that the acceptable level is not exceeded and record should be maintained

8 Operation

ISO	Key Content	Comment
8.5.4.3 Monitoring systems at CCPs and for OPRPs	established monitoring system for each CCP , control measure or combination of control measure(s) to detect any failure to remain within the critical limits include all scheduled measurements relative to the critical limit(s). established monitoring system for each OPRP , the control measure or combination of control measure(s) to detect failure to meet the action criterion At each CCP, the monitoring method and frequency capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product For each OPRP, the monitoring method and frequency proportionate to the likelihood of failure and the severity of consequences. OPRP is based on subjective data from observations (e.g. visual inspection) the method supported	measurements or observations that provide results within an adequate time frame; monitoring methods or devices used; applicable calibration methods or, for OPRPs, equivalent methods for verification of reliable measurements or observations monitoring frequency; monitoring results; responsibility and authority related to monitoring; responsibility and authority related to evaluation of monitoring results.

8 Operation

ISO	Key Content	Comment
8.5.4.4 Actions when critical limits or action criteria are not met	specify corrections and corrective actions to be taken when critical limits or action criterion are not met 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; recurrence is prevented	make corrections and corrective actions in accordance with defined Corrective actions process
8.5.4.5 Implementation of the hazard control plan	implement and maintain the hazard control plan, and retain evidence of the implementation as documented information.	Food Safety Team maintain hazard control plan and records

8 Operation

ISO	Key Content	Comment
8.6 Updating the information specifying the PRPs and the hazard control plan	Update hazard control plan the following information, if necessary: characteristics of raw materials, ingredients and product-contact materials; characteristics of end products; intended use; flow diagrams and descriptions of processes and process environment.	Food Safety Team ensure that hazard control plan and/or the PRP(s) are up to date via regular review of system .
8.7 Control of monitoring and measuring	specified monitoring and measuring methods and equipment in use are adequate for the monitoring and measuring activities related to the PRP(s) and the hazard control plan. The results of calibration and verification retained as documented software updated in a timely manner validity of the previous measurement results when the equipment or process environment is found not to conform to requirements	monitoring and measuring equipment used calibrated or verified at specified intervals prior to use adjusted or re-adjusted as necessary identified to enable the calibration status safeguarded from adjustments protected from damage and deterioration. Software used in monitoring and measuring within the FSMS validated by the organization

8 Operation

ISO	Key Content	Comment
8.8 Verification related to PRPs and the hazard control plan **8.8.1 Verification**	establish, implement and maintain verification activities define purpose, methods, frequencies and responsibilities for the verification activities ensure that verification activities are not carried out by the person responsible for monitoring the same activities. Verification results documented and communicated. verification is based on testing of end product samples or direct process samples	the PRP(s) are implemented and effective; the hazard control plan is implemented and effective; hazard levels are within identified acceptable levels; input to the hazard analysis is updated; other actions determined by the organization are implemented and effective test samples show nonconformity with the acceptable level of the food safety hazard handle the affected lot(s) of product as potentially unsafe and apply corrective actions
8.8.2 Analysis of results of verification activities	conduct an analysis of the results of verification	used as an input to the performance evaluation of the FSMS (

8 Operation

ISO	Key Content	Comment
8.9 Control of product and process nonconformities	ensure that data derived from the monitoring of OPRPs and at CCPs are evaluated by designated persons	Ensure competent and have the authority to initiate corrections and corrective actions.
8.9.2 Corrections	ensure that when critical limits at CCP(s) and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release. When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products action criteria for an OPRP are not met describe corrections made on nonconforming products and processes, documented	a method of identification, assessment and correction for affected products to ensure their proper handling; arrangements for review of the corrections carried out. determination of the consequences of that failure with respect to food safety; determination of the cause(s) of failure; identification of the affected products and handling in accordance with Handling of potentially unsafe products

8 Operation

ISO	Key Content	Comment
8.9.3 Corrective actions	Evaluated corrective actions when critical limits at CCP(s) and/or action criteria for OPRPs are not met. identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to return the process to control after a nonconformity is identified retain documented information on all corrective actions.	reviewing nonconformities identified by customer and/or consumer complaints and/or regulatory inspection reports; reviewing trends in monitoring results that can indicate loss of control; determining the cause(s) of nonconformities; determining and implementing actions to ensure that nonconformities do not recur; documenting the results of corrective actions taken; verifying corrective actions taken to ensure that they are effective.

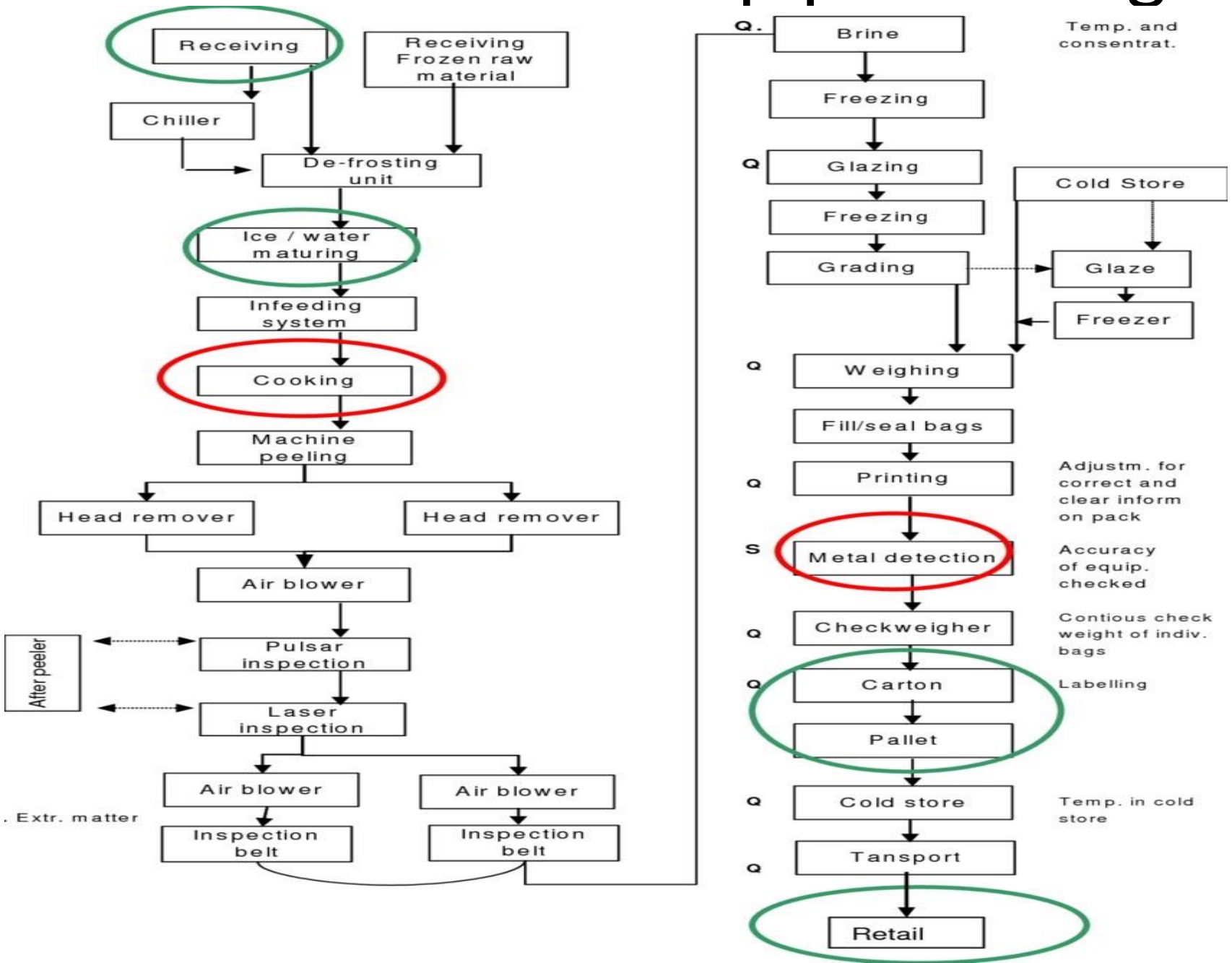
8 Operation

ISO	Key Content	Comment
8.9.4 Handling of potentially unsafe products **8.9.4.1 General**	take action(s) to prevent potentially unsafe products from entering the food chain retain products that have been identified as potentially unsafe under its control until the products have been evaluated and the disposition has been determined If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal/recall The controls and related responses from relevant interested parties and authorization for dealing with potentially unsafe products	the food safety hazard(s) of concern is (are) reduced to the defined acceptable levels; 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 hazard(s) of concern despite the nonconformity.

8 Operation

ISO	Key Content	Comment
8.9.4.2 Evaluation for release	Evaluation Each lot of products affected by the nonconformity Products affected by failure to meet action criterion for OPRPs only be released as safe when any of the following conditions apply: evidence other than the monitoring system demonstrates that the control measures have been effective; evidence shows that the combined effect of the control measures for that particular product conforms to the performance intended (i.e. identified acceptable levels); the results of sampling, analysis and/or other verification activities	Products affected by failure to remain within critical limits at CCPs has not be released

Flow chart for shrimp processing



HACCP Plan Form

Firm Name: ABC Shrimp Company

Product Description: IQF cooked, headless, peeled and de-veined shrimp

Firm Address:

Method of Storage and Distribution: Frozen

Intended Use and Consumer: Cooked, ready-to-eat Shrimp for sale to the general public

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Verification	Records
			What	How	Frequency	Who			
Cooker	Bacterial pathogen survival	Cook at 212°F for 3 minutes	Cooker temp and cook time	Continuous temperature recorder and conveyor belt time checks with a marked block	Continuous temperature monitoring with hourly checks of continuous temperature log and conveyor belt speed using a marked block	The cooker operator	If cooker temperature <212°F the cook time <3 minutes, then processing line is stopped until temperature is 212°F or > or cook time is > 3 minutes. Affected product is re-cooked or destroyed.	Thermometer calibrated quarterly. Records reviewed daily. Cooked shrimp tested semi-annually for pathogens. Time and temperature critical limits and cooker equipment performance validated as needed. HACCP system verification annually and as needed.	

Signature of Company Official: Date:

Hazard-Analysis Worksheet

Firm Name: ABC Shrimp Company

Firm Address: One Water Lane

Product Description: IQF cooked, headless, peeled and de-veined shrimp

Method of Storage and Distribution: Frozen

Intended Use and Consumer: Cooked, ready-to-eat Shrimp for sale to the general public

(1) Ingredient/ Processing Step	(2) Identify potential hazards introduced, controlled, or enhanced at this step	(3) Are any potential food safety hazards significant? (Yes/No)	(4) Justify your decision for column 3	(5) What control measure(s) can be applied to prevent significant hazards	(6) Is this step a critical control point? (Yes/No)
Receiving	**BIOLOGICAL** **Species Hazards:** None **Process Hazards:** *Pathogen Growth*	YES	Pathogens are likely to be present in raw shrimp and can grow if the product is time and temperature abused during transport	The cooking step will eliminate this hazard.	NO
	CHEMICAL **Species Hazards:** None **Process Hazards:** *Sulfites (Food Additive)*	YES	Sulfites are likely to be present in raw shrimp when they are received	The only effective control measure available is to ensure that all products that contain sulfites are properly labeled	NO
	PHYSICAL **Species Hazards:** None **Process Hazards:** None				

Examples of critical limit support documentation may include:

- Data to establish the adequacy of a cooking process used to destroy bacterial pathogens.
- Data to establish the adequacy of other barriers for bacterial pathogen growth such as time and temperature limits during storage.
- Data used to establish batch process parameters such as the salt concentration, product size, brining time, and brine temperature necessary to achieve the correct water phase salt in smoked fish products.
- Letters, reports, or correspondence from processing authorities, food science experts, consultants, laboratories or other sources that were used to establish critical limits.

Other support documents for your HACCP system could also include:

- A list of the HACCP team members and their responsibilities.
- Prerequisite programs such as your company's Sanitation Standard Operating Procedures.
- A summary of preliminary steps taken in the development of the HACCP plan.
- The Process Flow diagram.
- A Process Flow Narrative.
- The FDA Hazards and Controls Guide.

Records of CCP Monitoring Results

haccp monitoring records are primarily kept to demonstrate that significant food safety hazards have been controlled at CCPs. These records provide the information needed to determine if critical limits have been met or violated. Timely review of these records by a HACCP trained individual ensures that the CCPs are being controlled in accordance with the HACCP plan Monitoring records also provide a means by which regulators can determine whether a firm is in compliance with its HACCP plan.

Monitoring records can also help firms identify and track trends in their process. By tracking the values recorded on monitoring records, an operator or manager can determine if a process is approaching its critical limit. Trends can be identified through record review to make necessary process adjustments. If adjustments are made before the critical limit is violated, processors can reduce or eliminate the labor and material costs associated with corrective actions.

Monitoring information should be recorded at the time the observation is made. False or inaccurate records filled out before the operation takes place or ones that are completed later are illegal and inappropriate for a HACCP system.

Shrimp Cooker Log for Cooker CCP

ABC Shrimp has chosen to conduct continuous temperature monitoring using a recording thermometer, and to conduct manual time and temperature checks every hour. The cooker operator checks the continuous recording chart every hour to confirm that the critical limit was continually met since the last manual check. Time checks are performed by using a stop watch to determine how long it takes a block to move through the steam tunnel.

Shrimp Cooker Log
ABC Shrimp Co.

Date: _____ **Critical Limits:** 212°F for 3 minutes

Line: Number 1 **Product:** IQF cooked shrimp

Label Room Supervisor: _____

Line Number	Lot Number	Time of Day	Steam Temp. MIG (F)	Temp. from Recorder (F)	Cook Time (Min.)	Critical Limits Met	Comments
1	034	2:34 pm		214	3.2	Yes	
1	043	3:30 pm		214	3.2	Yes	
1	053	4:28 pm		**210**	3.1	No	See corrective actions
1	053	4:29 pm		212		Yes	Steam valve adjusted
1	053	5:01 pm	213	212	3.1	Yes	

Temperature/time to be checked hourly during operation

Reviewer: _____ **Date of Review:** _____

If critical limits are not met, notify the shift supervisor, and separate and identify the batch involved

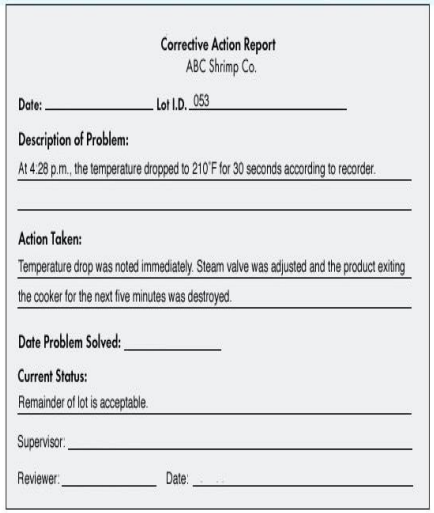
Records of Corrective Action

Processors must also develop a corrective action record to document critical limit deviations and describe:

1. how control of the process was re-established, and
2. how the affected products were evaluated, and
3. the results of this evaluation, and
4. the disposition of the affected products.

Corrective action records should reflect the nature of the deviation, the firm name and location, date of the report, and the individuals responsible for the corrective action and for reviewing it.

An example and one possible format for a Corrective Action Report for the ABC Shrimp Company is shown below. It contains all of the elements that should be included in this type of record. This Corrective Action Report was completed as a result of critical limit deviation that was recorded on the Shrimp Cooker Log record at 4:28 pm on Line 1 for Lot Number 053.



Corrective Action Report
ABC Shrimp Co.

Date: _____ **Lot I.D.** 053

Description of Problem:

At 4:28 p.m., the temperature dropped to 210°F for 30 seconds according to recorder.

Action Taken:

Temperature drop was noted immediately. Steam valve was adjusted and the product exiting the cooker for the next five minutes was destroyed.

Date Problem Solved: _____

Current Status:

Remainder of lot is acceptable.

Supervisor: _____

Reviewer: _____ Date: _____

Examples of Verification Records *(continued)*

The type of verification records needed will vary depending on the process and the procedures identified in the HACCP plan. For some processors, laboratory tests are used to periodically verify that effective controls are in place at certain CCPs. In this situation, these laboratory reports are a verification record. Examples of laboratory report records for ABC Shrimp Company are shown below.

A-One Laboratory Report
ABC Shrimp Co.

Date: _____ **Sample No.:** ABC Shrimp Lot #0112

Vendor: East Bay **Analyst:** _____

The results of the analyses of samples 0112 consisting of 6/8 oz. samples of shrimp identified as batch 1 to 6 are as follows

Batch	T.P.C./ g	Coliforms/ 10g	E. Coli/ 10g	Staph/ g	Salmonella/ sample
1	40	0	0	Negative	Positive
2	48	0	0	Negative	Negative
3	20	0	0	Negative	Negative
4	56	0	0	Negative	Negative
5	40	0	0	Negative	Negative
6	20	2	0	Negative	Negative

Remarks: The above sample was analyzed using methods found in the FDA Bacteriological Analytic Manual, 7th Edition.

Records of Verification Activities

A variety of different verification and validation records may be needed depending on the procedures identified in your HACCP plan. Again, you will need to develop your own verification records. Each of these records should contain the same elements necessary for monitoring and corrective action records including the firm name and location, date, actual verification measurement or observation, and who conducted the verification procedure, who reviewed it, and the date of the review.

Examples of the types of verification records that may be needed includes records that document:

- Modifications to the HACCP plan (e.g., changes in ingredients, formulations, processing, packaging and distribution methods etc.);
- Calibration of all monitoring equipment (e.g. thermometers, salometers, pH meters etc);
- Processor audit records verifying supplier compliance with guarantees or certifications;
- Results of periodic in-process and finished product microbiological, chemical and physical tests if applicable;
- Results of in-house inspections or on-site inspections by experts;
- Results of equipment evaluation or challenge tests.
- Results of process validation studies such as temperature distribution studies for thermal processes.

8.9.4.3 Disposition of nonconforming products

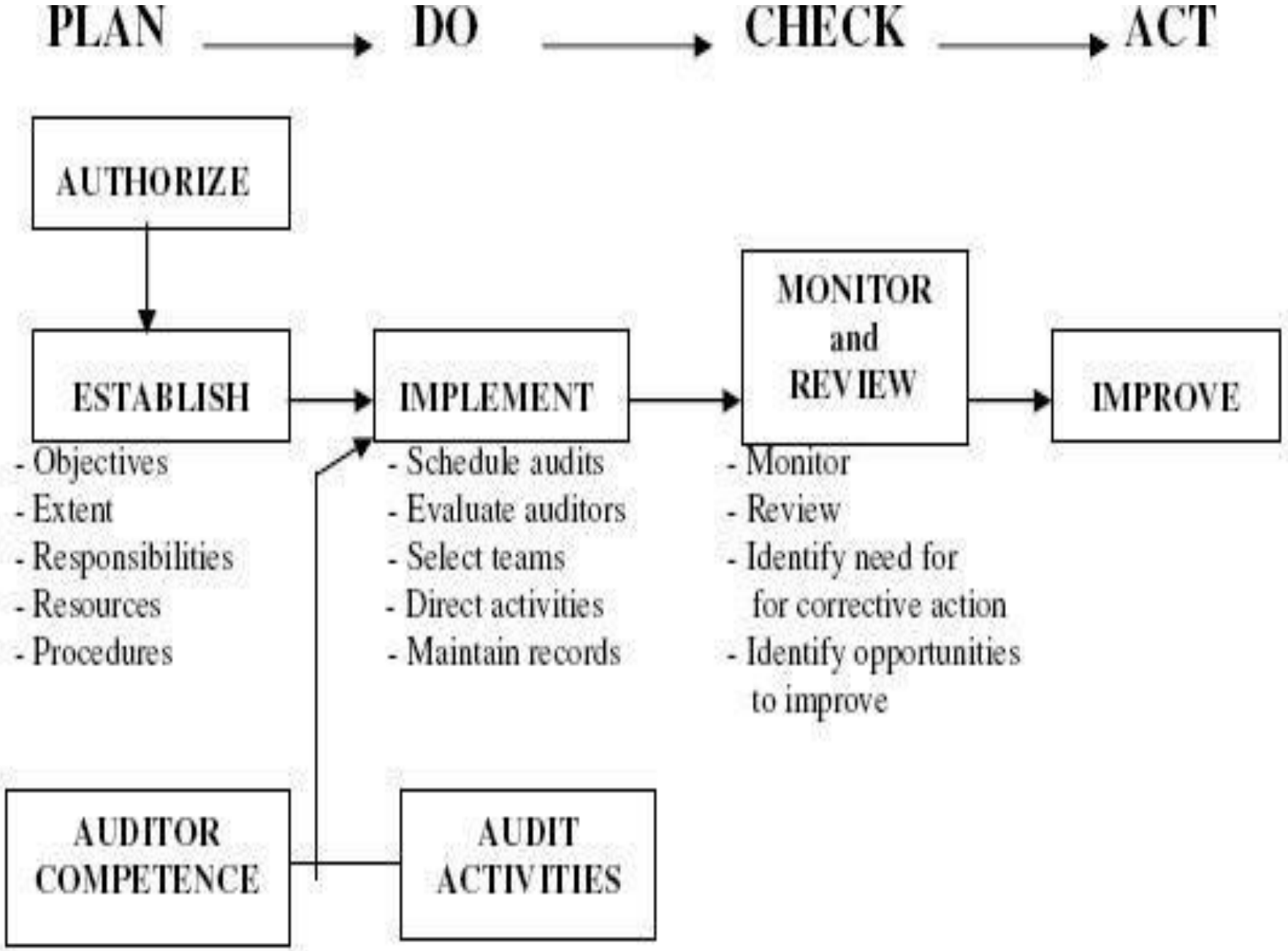
ISO	Key Content	Comment
8.9.4.3 Disposition of nonconforming products	Products that are not acceptable for release reprocessed or further processed within or outside the organization to ensure that the food safety hazard is reduced to acceptable levels; or redirected for other use as long as food safety in the food chain is not affected; or destroyed and/or disposed as waste.	Retained Documented information on the disposition of nonconforming products, including the identification of the person(s) with approving authority
8.9.5 Withdrawal/recall	ensure the timely withdrawal/recall of lots of end products that have been identified as potentially unsafe, by appointing competent person(s) having the authority to initiate and carry out the withdrawal/recall. use of appropriate techniques (e.g. mock withdrawal/recall or practice withdrawal/recall) and retain documented information verify the implementation and effectiveness of withdrawals/recalls	establish and maintain documented information for: a) notifying relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers); handling withdrawn/recalled products as well as products still in stock; performing the sequence of actions to be taken.

9 Performance evaluation

ISO	Key Content	Comment
9.1 Monitoring, measurement, analysis and evaluation	Determine what needs to be monitored and measured; the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results; when the monitoring and measuring shall be performed; when the results from monitoring and measurement shall be analysed and evaluated; who shall analyse and evaluate the results from monitoring and measurement.	Choose the inspection method Monitor and measure the essential steps The use and maintenance of equipment is appropriate and consistent for reliable and reproducible results The results of analysis and evaluation are reliable and reproducible. These results are inputs for the management review on the effectiveness of the FSMS
9.1.2 Analysis and evaluation	analyse and evaluate appropriate data and information arising from monitoring and measurement, including the results of verification activities related to PRPs and the hazard control plan , the internal audits and	•Periodically review all PRPs and the hazard control plan through : visits / inspections / interviews / project / reviews / sample review • The evaluation frequency is appropriate •And if necessary take action to restore compliance to the legal

9 Performance evaluation

ISO	Key Content	Comment
9.2 Internal audit **9.2.1**	conduct internal audits at planned intervals Is effectively implemented and maintained	•In order to determine whether the FSMS conforms to internal requirements of the organization. • In order to determine whether the FSMS conforms to the requirements of the ISO 22000 standard • In order to determine whether the FSMS is efficient and updated
9.2.2	• Plan, establish, implement and update an audit programme • Take into account the environmental importance of processes • Define the scope and audit criteria • Select auditors • Communicate audit results to top management • Retain documented information on audit programme and audit	Include the frequency, methods, responsibilities and accountability of results. Take into account: the importance of processes for the FSMS / the actions to address the significant CCP/OPRP the compliance obligations / the results of inspections / the emergency situations / the HACCP Plan the changes having taken place / the results of internal and external previous audits / the effectiveness of actions implemented

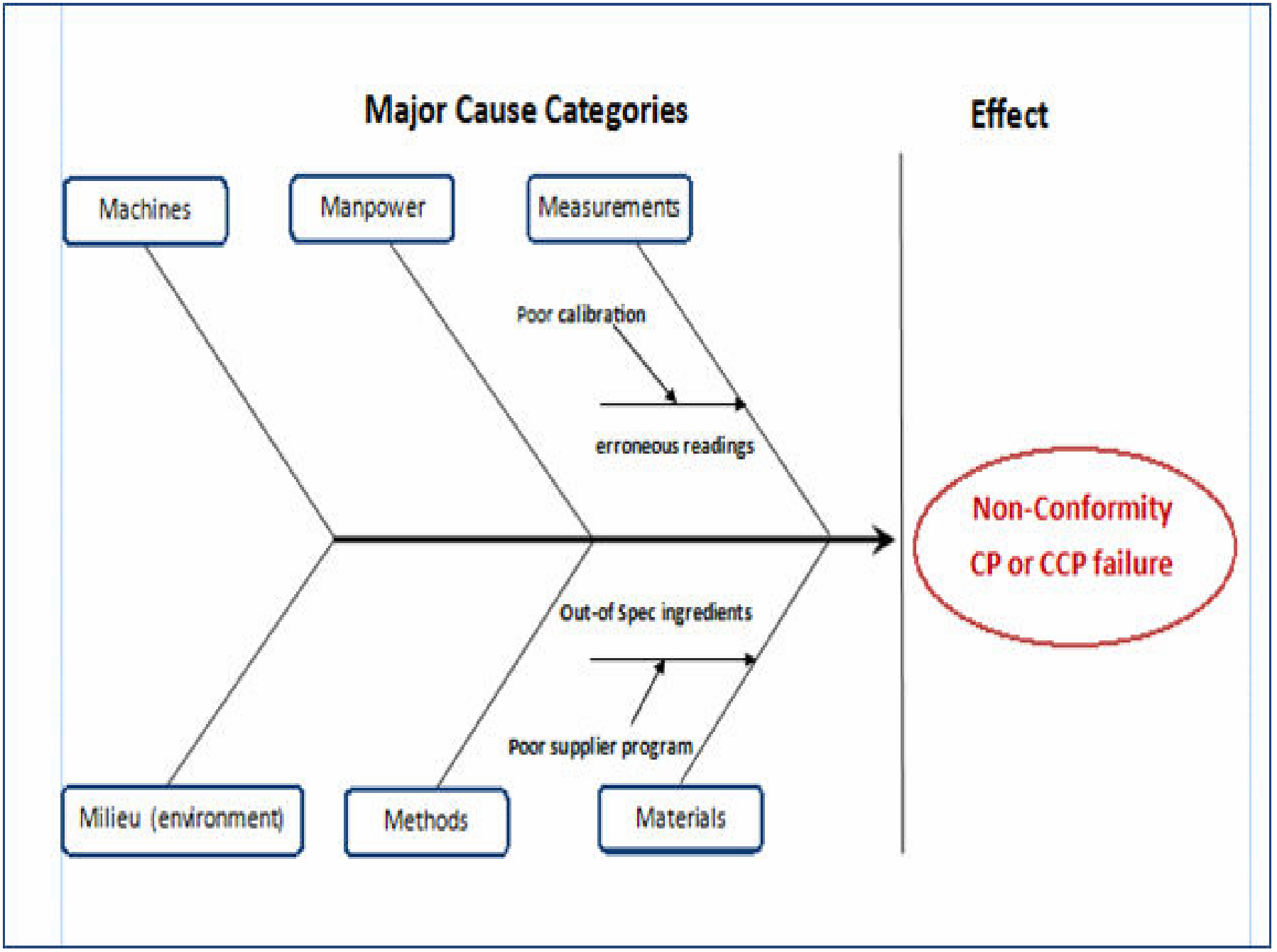

PLAN
DO
CHECK
ACT
AUTHORIZE
ESTABLISH
- Objectives
- Extent
- Responsibilities
- Resources
- Procedures
IMPLEMENT
- Schedule audits
- Evaluate auditors
- Select teams
- Direct activities
- Maintain records
MONITOR and REVIEW
- Monitor
- Review
- Identify need for for corrective action
- Identify opportunities to improve
IMPROVE
AUDITOR COMPETENCE
AUDIT ACTIVITIES

9 Performance evaluation

ISO	Key Content	Comment
9.3 Management review **9.3.1 General**	review the organization's FSMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.	Perform the management review at least once a year - **(**To confirm that the FSMS is still relevant, adequate (meeting the requirements of ISO 22000) and effective (achieved the desired results). **)**
9.3.2 Management review input **9.3.3 Management review output**	Consider the status of actions from previous management reviews; changes in external and internal issues that are relevant to the FSMS, including changes in the organization and its context (information on the performance and the effectiveness of the FSMS the adequacy of resources; any emergency situation, incident) or withdrawal/recall that occurred; relevant information obtained through external and internal communication, including requests and complaints from interested parties; opportunities for continual improvement. decisions and actions related to continual improvement opportunities; any need for updates and changes to	

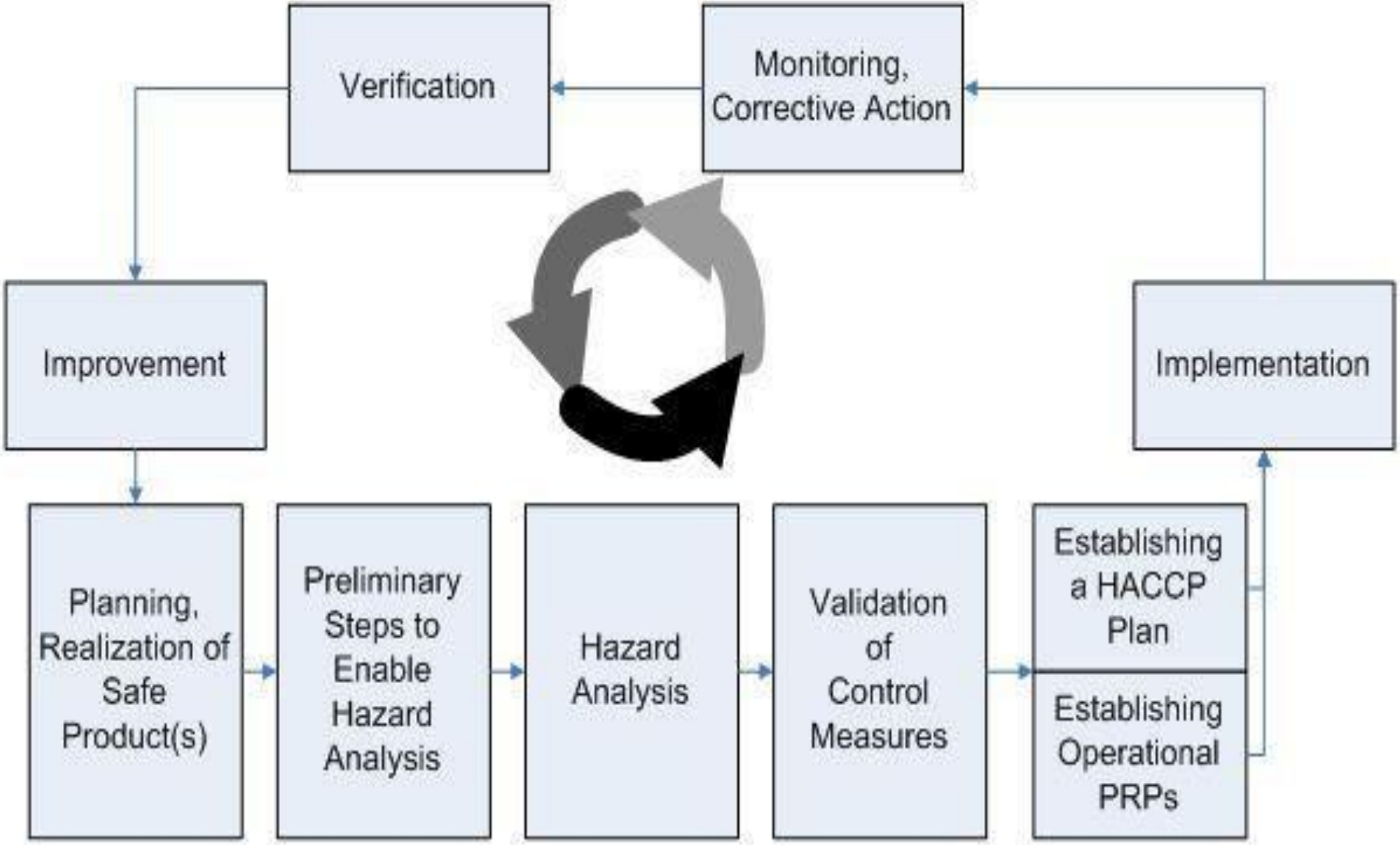
10 Improvement

ISO	Key Content	Comment
10.1 Nonconformity and corrective action	React to the nonconformity and correct it •Evaluate whether action is needed by performing a nonconformity review • Investigate the root causes • Find if similar nonconformities have been listed • Implement the necessary actions • Review the effectiveness of the corrective action • Make changes to the FSMS • Choose corrective actions proportionate to the importance of the nonconformities • Retain documented information on the nature of nonconformities • Retain documented information on the results of the corrective actions	Carry out a corrective action Take into account the context of the organization and perform actions to address the risks • The goal is to find and eliminate the root causes and prevent a recurrence of the nonconformity Realize an analysis of the root causes To prevent a recurrence of the nonconformity To check if the action is finalized And actions carried out.. Actions, results and review of the effectiveness of actions


Major Cause Categories
Effect
Machines
Manpower
Measurements
Poor calibration
erroneous readings
Non-Conformity
CP or CCP failure
Out-of Spec ingredients
Poor supplier program
Milieu (environment)
Methods
Materials

10 Improvement

ISO	Key Content	Comment
10.2 Continual improvement	Improve continually the Food Safety performance of the FSMS	With beneficial action to the FSMS , processes and Food Safety -related activities
10.3 Update of the food safety management system	ensure that the FSMS is continually updated the food safety team evaluate the FSMS at planned intervals it is necessary to review the hazard analysis , the established hazard control plan and the established PRPs	input from communication, external as well as internal input from other information concerning the suitability, adequacy and effectiveness of the FSMS; output from the analysis of results of verification activities output from management review reported as input to the management review and documented

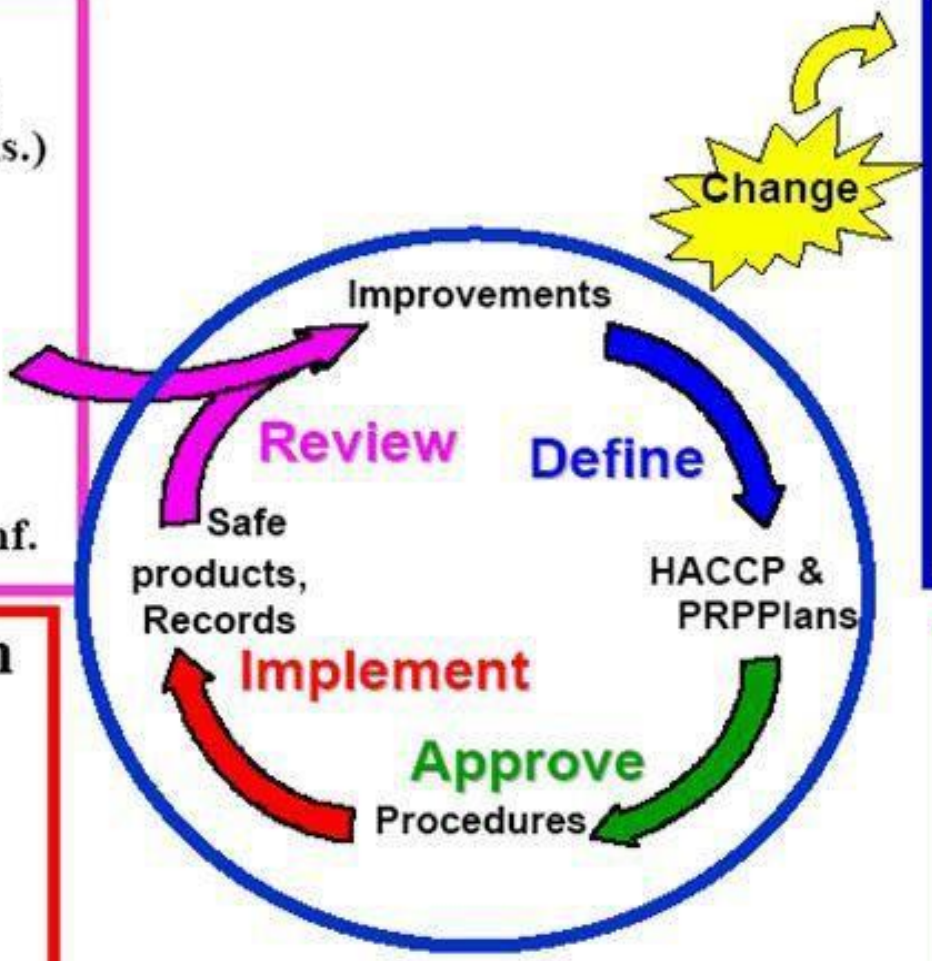


Concept of Continuous Improvement Applied to a Food Safety Management System (taken from ISO 22004)

FSMS Overview

Verification
- Confirm compliance (HACCP & Prerequis.)
- Review the study
- Review results
- Review records
- Review changes
- Review of validation data
- Gather Int. & Ext. Inf.

Study
- List pot. hazards
- Hazard Analysis
- List significant haz.
- CCP (& CPs)
- Monitoring
- Critical Limits
- Corrective actions
- Validation
- List verification act.



Implementation
- Training
- Awareness
- Information
- Prerequisites
- Control Measures
- Monitoring
- Corrective actions
- Recording

Approval:
(NOT VALIDATION)
- Monitoring (Prerequisites)
- Contr. meas.
- Modifications
- Corr. actions
- Verification

Continuous Improvement