

JFS-C Standard Document

(Sector: CI, CII, CIII, CIV/K)

Requirements for Organizations

Version 3.1

Japan Food Safety Management Association

May 20, 2024

1. Introduction

1.1 JFS-C Standard Document

The JFS-C Standard Document (hereinafter referred to as “this Standard Document”) is a standard document developed by the Japan Food Safety Management Association (JFSM) and is intended to assist organizations to establish, operate and improve its management systems for manufacturing safe food products. In addition, this Standard Document can also be utilized to have the system of the organization (*1) evaluated by external agencies including Certification Bodies. This Standard Document is utilized by organizations that endeavor to realize a food safety management system applicable worldwide.

(*1) “Organization” refers to a business entity, group or individual to whom the requirements of this Standard Document apply.

1.2 Scope of application

This Standard Document applies to the following “Food Manufacturing Sectors (CI, CII, CIII, CIV)” and “Chemical Products (Including Biochemical Products) Manufacturing Sector (K)”. (See JFS Standard Document sector list on page 5)

*Pet food is included in the following food manufacturing sector (C).

Food manufacturing sector (C)

- CI: Processing of perishable animal products
- CII: Processing of perishable plant products
- CIII: Processing of perishable animal and plant products (mixed products)
- CIV: Processing of ambient stable products

Manufacturing sector of chemical products (including biochemical products) (K)

- K: Manufacture of chemical products (including biochemical products)
(Production of chemical products (including biochemical products) and cultures used as food ingredients or processing aids in food production.)
In addition, chemical products here means a chemical product (including a biochemical product) related to food.

1.3 Structure of this Standard Document

This Standard Document consists of three elements, namely, Food Safety Management Systems (FSM), Hazard Analysis and Critical Control Point (HACCP), and Good Manufacturing Practice (GMP). This Standard Document only specifies common requirements for the manufacturing sector, and does not cover individual hygiene requirements for individual product. Organizations shall use information appropriate for the organization (e.g. laws and regulations on food safety, standards specified by the relevant industry group, “General Principles of Food Hygiene Code of Practices” by the Codex Alimentarius Commission (*2), specific code of conduct), in addition to the requirements stipulated in this Standard Document.

This Standard Document is consistent with the benchmark requirement version 2020.1 (*3 hereafter, BR 2020.1) published by GFSI in June 2020. On the other hand, since BR 2020.1 adopts ISO22000:2018 (*4) in its scope structure and numbering structure, this Standard Document has a structure consistent with both the scope structure and numbering structure.

In addition, this Standard Document uses a process approach that incorporates the plan-do-check-act (PDCA) cycle of ISO22000:2018 and a risk-based approach as a benchmark. This Standard Document establishes and implements a food safety management system to ensure the provision of safe food and services while meeting each applicable requirement and adopts a process approach for improving its effectiveness.

The process approach indicates that each process used for providing food and services is regarded as a system and is managed as such. In the process approach, the purpose of each process is clarified and managed in consideration of process interactions to aid the organization to achieve the intended results effectively and efficiently.

Risk (*5) in this Standard Document refers to all the factors that may hinder the achievement of the organization's food safety objectives and targets. Risk-based thinking involves "focusing on what factors may compromise the achievement of goals and objectives, identifying those factors, clarifying their effects, and considering necessary measures." By establishing a hypothesis based on risk, executing it, and performing verification based on the facts that are obtained, it becomes possible to aim to improve the accuracy of achieving the objectives and goals of the organization.

As shown in Figure 1, in this Standard Document the process approach adopts the concept of a plan-do-check-act (PDCA) cycle at two levels. The first level involves the FSM framework. The second level is targeted at the Do process within the food safety management system. For this reason, communication between the two levels is extremely important.

(*2) Codex Alimentarius Commission

"GENERAL PRINCIPLES OF FOOD HYGIENE," CXC 1-1969, Rev. 2022

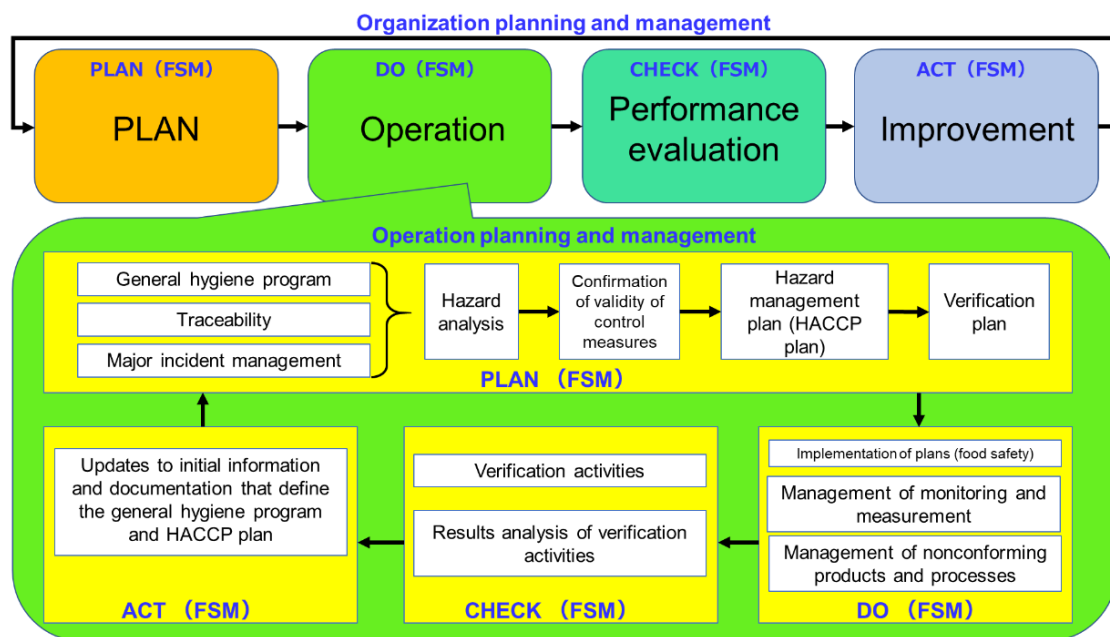
(*3) GFSI "The GFSI Benchmarking Requirements version 2020.1"

(*4) The International Organization for Standardization

"Food safety management systems – Requirements for any organization in the food chain"

ISO22000 : 2018

(*5) Unlike the risk defined in ISO22000:2018 (ISO22000:2018 3.39), the term risk is used in the JFS-C Standard Document as something limited more to food safety.



PLAN (FSM)		DO (FSM)	
FSM 1	Top Management Responsibility	FSM 7	Food Defense
FSM 2	Top Management Commitment and Food Safety Culture	FSM 8	Food Fraud Prevention
FSM 4	Compliance with food safety laws	FSM 11	Procedures and Instructions
FSM 5	Food Safety Management System and General Requirements	FSM 14.1	Traceability
FSM 6	Food Safety Policy and Goals	FSM 15	Product development
FSM 9.1	Documentation procedures	FSM 16	Allergen Management
FSM 9.2	Control and storage of documented information	FSM 17	Control of Measuring and Monitoring Devices
FSM 10	Specification Control of Purchased or Provided Items and Services	FSM 19.1	Analysis and Testing
FSM 12	Resource Management	FSM 19.2	Environmental Monitoring for Food Manufacturing
FSM 13.1	Purchasing	FSM 22.1	Serious Incident Management
FSM 13.2	Supplier Performance	FSM 23.2	Product Release
FSM 13.3	Outsourcing	FSM 24	Identification of nonconformities and control of nonconforming products
FSM 18.1	Product labeling (B-to-C products)	CHECK (FSM) Performance evaluation	
FSM 18.2	Product labeling (B-to-B products, work in progress, semi-finished products)	FSM 3	Management Review
FSM 23.1	Management of product specifications	FSM 14.2	Traceability verification
FSM 26	Change management	FSM 20	Internal Audit
		FSM 21	Complaint Handling
		FSM 22.2	Verification of food incident management procedure
		ACT (FSM) Improvement	
		FSM 25	Corrective Action
		FSM 27	Utilization of Kaizen suggestions from personnel

Figure 1 Conceptual diagram of two PDCA cycles in the JFS-C Standard Document Food Safety Management System

At the beginning of this chapter, it was noted that this Standard Document consists of three elements: Food Safety Management Systems (FSM), Hazard Analysis and Critical Control Point (HACCP), and Good Manufacturing Practice (GMP). Instead of working independently, each of these elements influences the other. Each element has an organic function within this relationship that spirals up while interlocking. Figure 2 shows a conceptual diagram of the three elements. An understanding of this conceptual diagram will be effective for organizations that use this Standard Document for building and operating a food safety management system.

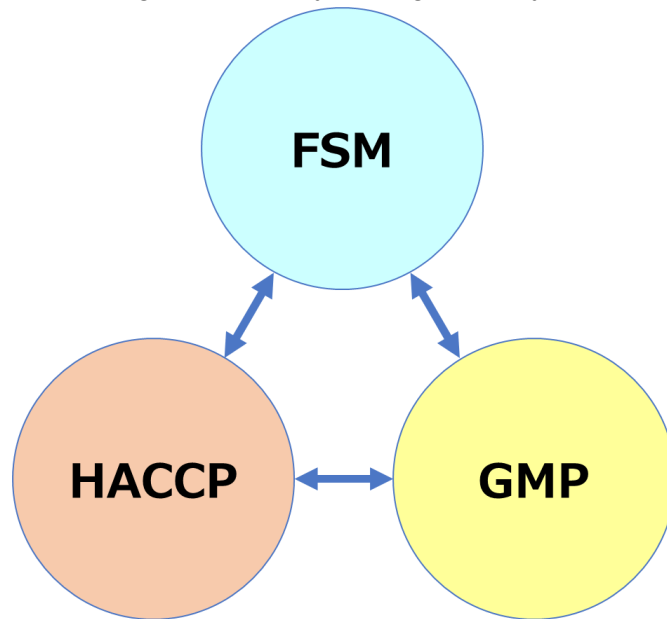


Fig. 2 Conceptual diagram of the organic functions of the three elements (FSM, HACCP, GMP)

The association also prepares guidelines on the requirements of the Standard Document and recommends that organizations refer to them.

1.4 Exclusion from Application of Requirements

All the requirements in this Standard Document shall be applied in principle. However, in case any of the requirements in this Standard Document is not able to apply for reasons arising from the business scale, business form and so on of an organization, the organization shall provide a document which indicates proof of non-applicability with explanations demonstrating the proper maintenance of food safety management system.

(Reference) Category is as shown in the table below:

Sector list by GFSI

The following sectors apply to this JFS (Food Safety Management) Standard Document.

※Of the sectors presented by GFSI, the sectors covered by this standard document are enclosed in a box.

Code	Sector/Subsector	Code	Sector/Subsector
AI	Farming of Animals for Meat/ Milk/ Eggs/ Honey	FI	Retail / Wholesale
All	Farming of Fish and Seafood	FII	Food Broker / Agent
BI	Farming of Plants (other than grains and pulses)	H	Provision of Food Safety Services
BII	Farming of Grains and Pulses	G	Provision of Storage and Distribution Services
BIII	Pre-process handling of plant products	I	Production of Food Packaging
C0	Animal primary conversion	JI	Hygienic Design of Food Buildings and Processing Equipment (for building constructors and equipment manufacturers)
CI	Processing of perishable animal products		
CII	Processing of perishable plant products		
CIII	Processing of perishable animal and plant products (mixed products)	JII	Hygienic Design of Food Buildings and Processing Equipment (for building and equipment users)
CIV	Processing of ambient stable products	K	Manufacture of chemical products (including biochemical products) (Production of chemical products (including biochemical products) and cultures used as food ingredients or processing aids in food production.)
D	Production of feed		
E	Catering		

Reference: The GFSI Benchmarking Requirements version 2020 PART I

2. Specific Requirements (Standard Document)

2.1 Food safety management systems (FSM)

Number	Clause Name	Requirements
FSM 1	Top Management Responsibility	Top management shall establish and operate a clear organizational structure which unambiguously defines the job functions, responsibilities, directing and reporting structure and information sharing of at least the personnel whose activities affect food safety. There shall also be evidence that employees are made aware of them. Top management shall appoint personnel responsible for the operation of the organization's food safety management system.
FSM 2	Top Management Commitment and Food Safety Culture	Top management shall show evidence of its commitment to building, implementing, maintaining and continually improving its food safety management systems. This commitment shall include elements of a food safety culture, and this means, at a minimum, communicating with employees, responding to Kaizen suggestions, training to improve food safety, and assessing the performance of food safety activities. In addition, these efforts shall be incorporated and implemented in the food safety management systems of the entire organization.
FSM 3	Management Review	Top management shall conduct management reviews on a regular basis and record them in an appropriate manner to review all elements of the overall food safety management system, including HACCP plans for managing food safety hazards and risks. In the event of changes that have an effect on food safety, top management shall ensure that the food safety management system remains relevant and effective.
FSM 4	Compliance with food safety laws	When developing a food safety management system, the organization shall develop, implement and maintain detailed procedures to ensure that all processes and operations that have an effect on food safety are in compliance with the laws of both the country of manufacture and the intended country of sale. In addition, records of implementation shall also be maintained.

Number	Clause Name	Requirements
FSM 5	Food Safety Management System and General Requirements	<p>The organization shall document the elements of the Food Safety Management Systems and shall establish, implement and maintain them appropriate to the scope of the products covered by its business activities.</p> <p>In addition, the Food Safety Management Systems shall be continuously improved by properly adapting to changes in the surrounding social environment.</p>
FSM 6	Food Safety Policy and Goals	<p>The organization shall have a clear, concise and documented food safety policy statement and objectives specifying the extent of the organization's commitment to meet the safety needs of its products. Top management shall ensure the organization to establish measurable objectives consistent with the organization's food safety policy, formulate plans to achieve the objectives, monitor the progresses against the objectives, and to update the objectives as necessary.</p>
FSM 7	Food Defense	<p>The organization shall document, implement, and record assessment procedures to identify potential and overt threats to hazards of intentional food contamination by persons within or outside the organization and prioritize response to those threats.</p> <p>The organization shall document and implement a food defense plan that specifies the actions that the organization implements to mitigate or exclude the identified food defense threat.</p> <p>This plan shall include GMP and shall be incorporated into the food safety management system.</p> <p>The organization shall also establish access controls for areas where food defense vulnerabilities have been identified.</p> <p>The organization shall establish and implement procedures for responding to possible intentional contamination of product.</p>
FSM 8	Food Fraud Prevention	<p>The organization shall document, implement, and record assessment procedures to identify potential and overt food fraud vulnerabilities such as tampering with records and labeling of products and intentional dilution, and prioritize food fraud mitigation measures.</p> <p>The organization shall develop a documented plan that specifies the measures the organization implements to mitigate the identified threats of food fraud.</p> <p>This plan shall cover the GMP and shall be incorporated into the food safety management system.</p>

Number	Clause Name	Requirements
FSM 9.1	Documentation procedures	<p>The organization shall document, implement, and maintain documentation procedures to manage the documented information (including records) necessary for effective operation of the food safety management system and explicit control of the process.</p> <p>In addition, the organization shall keep records necessary to prove the implementation of food safety management, determine an appropriate storage period, and store them.</p>
FSM 9.2	Control and storage of documented information	<p>The organization shall provide the documented information required to demonstrate its effective operation of the food safety management system and control of processes. Documented information shall be stored for the period required by the customer or legal and regulatory requirements, or if there are no applicable requirements, for a period exceeding the shelf life of the food. In addition, the documented information shall be effectively controlled so that it is always available when it is required.</p>
FSM 10	Specification Control of Purchased or Provided Items and Services	<p>For all purchased or provided input items and services (including raw materials and ingredients (including containers and packaging materials), equipment and tools, utilities, and services (e.g. electricity, water, transportation, maintenance)) that have an effect on the safety of final product, the organization shall ensure that documented specifications are prepared, maintained, securely retained and readily accessible when needed.</p> <p>The organization shall evaluate the risks and set the confirmation items (confirmation of inspection certificate, condition, temperature, display, etc.) on the items to be purchased or provided.</p> <p>In addition, the organization shall define and implement a review process that includes the handling of changes in specifications and the frequency of regular reviews.</p>
FSM 11	Procedures and Instructions	<p>The organization shall establish, implement and maintain effective procedures and instructions in all processes and activities that affect food safety.</p> <p>In addition, these procedures and instructions shall be understood by personnel who use different languages.</p>

Number	Clause Name	Requirements
FSM 12	Resource Management	<p>Top management shall determine and provide, in a timely manner, the qualified resources (including human resources, facilities and work environment, equipment, systems for operating sites (including communication technology and transportation), means of measurement and traceability, intellectual property management, etc.) that meet the standards required to implement, maintain, and improve the food safety management system.</p>
FSM 13.1	Purchasing	<p>The organization shall control purchasing procedures to ensure that all externally sourced raw materials, packaging materials, services, and equipment and tools that have an effect on food safety conform to stipulated specifications, as well as legal and regulatory requirements related to food safety.</p> <p>In addition, these purchasing procedures shall also apply to raw materials, packaging materials, services, and equipment and tools purchased from the organization's group companies.</p>
FSM 13.2	Supplier Performance	<p>The organization shall document, implement, and maintain procedures for the evaluation, approval, and continual monitoring of suppliers, which have an effect on food safety.</p> <p>Supplier evaluation shall include measures for food defense and to prevent food fraud.</p> <p>When accepting raw materials, packaging materials, and services from unapproved suppliers in an emergency (such a natural disaster), the organization shall confirm that the products meet the required specifications by an evaluation, inspection, visit, etc. before use.</p> <p>Results of survey, evaluations, approvals, and follow-ups with suppliers shall be maintained.</p>
FSM 13.3	Outsourcing	<p>The organization shall ensure, when the organization chooses to outsource any process that that may have an effect on food safety (including contract manufacturers, service providers for existing process, and other service providers), that it complies with the customer requirements and takes into account the JFS-C standard requirements required for food safety risk management.</p> <p>Control of such outsourced processes shall be identified, documented and monitored as a part of the food safety management system.</p> <p>Changes to the contract content shall be approved by both parties and communicated to the relevant personnel.</p>

Number	Clause Name	Requirements
FSM 14.1	Traceability	<p>The organization shall establish, implement, and maintain appropriate tracing procedures covering all processes from supplier (at least one step before) to recipient (at least one step after) to ensure product identification. These procedures must include procedures (e.g., labeling) to continuously identify the product throughout the manufacturing process and throughout distribution.</p> <p>To ensure traceability, at least the following shall be recorded:</p> <ul style="list-style-type: none"> ● Record of all externally procured raw materials (including containers and packaging materials), products, or services ● Records to identify batches, semi-finished products, work-in-progress, recycled products, reworked products, finished products and packaging throughout the manufacturing process ● Records of all product suppliers and recipients ● If the procedure has been updated, record it
FSM 14.2	Traceability verification	<p>The organization shall verify the documented procedures for implementing and maintaining traceability through traceability test at least once a year to ensure that they are functioning effectively. The results of verification shall also be recorded.</p>
FSM 15	Product development	<p>The organization shall establish, implement and maintain product design and development procedures to ensure that new products or products whose specifications and manufacturing processes have changed are manufactured safely and in accordance with legal and regulatory requirements.</p> <p>These development procedures shall clearly confirm that the products and services provided conform to specifications, and after identifying all the hazards of food safety, shall include a review to evaluate and approve the adequacy of food safety assurance in the design and development.</p>

Number	Clause Name	Requirements
FSM 16	Allergen Management	<p>The organization shall document and implement allergen management plans and maintain them appropriately. The allergen management plans shall include:</p> <ul style="list-style-type: none"> ● Control procedures to properly assess the risk of allergen cross-contact and, based on that assessment, reduce, or eliminate the risk of cross-contact. ● Procedures for handling raw materials (including containers and packaging materials), semi-finished products, work in progress, reworked products, and final products to prevent cross-contact with allergens during all processes from manufacturing to shipping. ● Cleaning procedures and verification procedures for areas that come into contact with food ● Procedures for identifying and displaying allergens that shall be controlled in all processes from manufacturing to shipping <p>The plan shall also ensure that all products containing or potentially containing allergens that are shipped and offered for sale are labeled in accordance with the laws and regulations of the country to which they are expected to be shipped, and appropriate customer requirements.</p>
FSM 17	Control of Measuring and Monitoring Devices	<p>The organization shall identify measuring and monitoring devices that are parameters critical to ensure food safety.</p> <p>In addition, the specified equipment and devices shall be calibrated regularly.</p> <p>This calibration shall be performed in accordance with national or international standards concerned, or by a reasonably accepted traceable method.</p> <p>The organization shall take appropriate action when equipment and devices are found to be inaccurate, and these actions shall be recorded.</p>
FSM 18.1	Product labeling (B-to-C products)	<p>The organization shall ensure that all product labels or attached information to enable the safe handling, display, storage, preparation and use of the product in the food supply chain or by the consumer. The finished product shall be labeled according to the applicable food regulations in the intended country of sale.</p>

Number	Clause Name	Requirements
FSM 18.2	Product labeling (B-to-B products, work in progress, semi-finished products)	The organization shall define and implement procedures to provide information, such as on primary processed foods, commercial ingredients, or intermediates in the processing process, so that customers or consumers can be informed about product safety, even if the information is not labeled on or attached to the product.
FSM 19.1	Analysis and Testing	<p>The organization shall establish, implement, and maintain procedures to ensure the analysis of raw materials, semi-finished products, finished products, manufacturing environments, etc. that affect food safety.</p> <p>The analysis and testing shall be conducted by a competent analysis institution or testing laboratory institution using appropriate sampling and analytical / testing methods.</p> <p>The testing that has a significant effect on food safety shall be conducted in accordance with the applicable requirements of ISO/IEC 17025.</p> <p>In addition, the organization shall establish and implement analysis and testing procedures (methods, standards, etc.) to confirm that the product meets product specifications within its shelf life.</p>
FSM 19.2	Environmental Monitoring	<p>The organization shall establish, implement and maintain a microbial environmental monitoring program to reduce the risk of food contamination.</p> <p>This program shall consider microbial risks specific to the manufacturing process and facility environment and include evaluation methods tailored to the risks.</p>
FSM 20	Internal Audit	<p>The organization shall establish, implement and maintain documented internal audit procedures for all applicable food safety management systems (including HACCP plans, food defense plans, and food fraud prevention plans).</p> <p>The procedures shall include at least the following content.</p> <ul style="list-style-type: none"> a) Timing of internal audits. Schedules including frequency of at least once a year. b) Corrective action for nonconformity. c) Rules that ensure the objectivity and fairness of internal audits. <p>The organization shall maintain a record of the performance of the internal audit as evidence.</p> <p>The organization shall specify the competence required for internal auditors and provide training for internal auditors.</p>

Number	Clause Name	Requirements
FSM 21	Complaint Handling	<p>The organization shall document, implement, and maintain a system of management to respond to complaints and utilize complaint data to identify, correct, and manage omissions and deficiencies in food safety efforts.</p> <p>Control procedures shall include analyzing complaints, evaluating the magnitude of the impact threatening food safety, and implementing corrective action as necessary.</p> <p>Additionally, organization must record and maintain complaints, investigation results, and corrective actions.</p>
FSM 22.1	Serious Incident Management	<p>The organization shall document serious food incident management procedure, implement it in the event of an incident, and maintain it in effect at all times to ensure that they can respond in the event of a serious incident. This procedure shall also describe the methods for product withdrawal and product recall and include tests to ensure that product recalls are carried out reliably.</p> <p>It shall also include systems and procedures for providing necessary information to customers, consumers, and relevant authorities.</p> <p>Incidents that occur shall be recorded and evaluated.</p>
FSM 22.2	Verification of food incident management procedure	<p>The organization shall verify the effectiveness of its food incident management procedure by conducting tests at least annually on products supplied by the organization to ensure that product recalls are implemented, and maintain records of the verifications.</p>
FSM 23.1	Management of product specifications	<p>The organization shall document and maintain specifications for raw materials (including packaging materials), semi-finished products, work in progress, remanufactured products, reworked products, and finished products.</p> <p>The organization shall have a system for communicating changes to product specifications both internally and externally.</p> <p>The organization shall designate a person responsible for managing product specifications.</p>
FSM 23.2	Product Release	<p>The organization shall document, implement and maintain appropriate procedures for product release (shipping).</p> <p>Product release procedures shall include steps to ensure that the final product meets specifications.</p>

Number	Clause Name	Requirements
FSM 24	Identification of nonconformities and control of nonconforming products	<p>The organization shall document, implement, and maintain effective procedures for raw materials (including containers and packaging materials), semi-finished products, work in progress, recycled products, reworked products, and final products to identify nonconformities affecting its food safety and to clearly identify, control, dispose of, and rework nonconforming products resulting from such nonconformities in order to prevent misuse and mis-shipment of nonconforming products affecting food safety.</p> <p>The organization shall also determine who will be responsible for managing nonconforming products.</p>
FSM 25	Corrective Action	<p>The organization shall define, implement, and maintain the document of procedures for the determination and implementation of corrective actions in the event of any nonconformities arising relating to food safety.</p> <p>In case of deviation or violation, the organization shall identify the root cause, take measures to prevent recurrence, and review the effectiveness for the series of corrective actions.</p>
FSM 26	Change management	<p>The organization shall document, implement, and maintain procedures to evaluate the impact to the necessary extent in advance when changes occur in all processes and operations (including equipment and devices) that affect the safety of the final product.</p> <p>The organization shall also determine who will be responsible for change management.</p>
FSM 27	Utilization of Kaizen suggestions from personnel	<p>The organization shall establish and implement a system to properly utilize food safety Kaizen suggestions from personnel.</p>

2.2 Hazard Analysis and Critical Control Point (HACCP)

	Clause Name	Requirements
HACCP Step 1	HACCP team assembly and identification of the scope of application	HACCP team shall be assembled with competent staff, and the scope of application of the HACCP system and applicable GMPs shall be identified. The scope shall be documented what products and processes are covered by which HACCP plan.
HACCP Step 2	Product Description	Product specifications shall be documented. The document shall describe all product information necessary to conduct hazard analysis. Scope of the HACCP system shall be defined per product or product group and per process line or process location. This system should be systematic and comprehensive and take into account legal and regulatory requirements related to food safety.
HACCP Step 3	Identification of Intended Use	Intended use of the product and target users (consumers) shall be clearly described in a written document.
HACCP Step 4	Construction of Flow Diagram	The flow diagram that covers all steps in the operation shall be constructed.
HACCP Step 5	On-site Confirmation of Flow Diagram	The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.
HACCP Step 6 (Principle 1)	Hazard Analysis	The HACCP team shall list all the hazards that are reasonably likely to occur in each process steps. Potential hazards in each process shall be identified, the critical hazards shall be identified, and all measures to control them must be considered. Hazards shall include allergens, if necessary.

	Clause Name	Requirements
HACCP Step 7 (Principle 2)	Critical Control Points	Critical Control Points (CCPs) shall be determined.
HACCP Step 8 (Principle 3)	Critical Limits	Validated critical limit(s) shall be stipulated for each CCP.
HACCP Step 9 (Principle 4)	Monitoring System	Monitoring procedures shall be established for each CCP.
HACCP Step 10 (Principle 5)	Corrective Actions	A procedure of corrective actions (correction, and investigation and removal of root cause) shall be established for deviations from a critical limit.
HACCP Step 11 (Principle 6)	Establish HACCP plan validation and verification procedures	HACCP plan shall be validated prior to implementation. Verification procedures shall be established to confirm whether the defined handling (HACCP Plans) is carried out as specified and to judge whether it is necessary to modify the defined handling. Verification shall be carried out considering the design of equipment, change in processing method and technology development in the manufacturing process.
HACCP Step 12 (Principle 7)	Documents and Record	Necessary documents shall be prepared and maintained. These documents shall contain documents related to the standard operating procedures (SOP) and the work instructions (WI) necessary and applicable to the scope of certification of the organization.

2.3 Good Manufacturing Practice (GMP)

Number	Clause Name	Requirements
GMP 1	Facility Environment	The organization shall locate and maintain their business site in a location where pollution can be prevented and products can be safely received, stored, manufactured and delivered.
GMP 2	Factory premise environment	The organization shall establish and maintain appropriate standards for the area around and on the premises of the business so that contamination can be prevented, and safe products can be made accordingly. These Standards shall include the management of waste and unnecessary materials on the premises.
GMP 3	Design, construction, layout of business site and work and product flow lines	The organization shall design, construct and maintain the factory buildings and facilities (storage area, raw material and product handling area, preparation area, packaging and storage area, etc.) of the business site both outside and inside the plant to minimize food safety risks. In addition, the equipment layout (including drainage system and lighting) and the flow lines of people, goods, and work shall be designed to meet the intended purpose and minimize food safety risks. The organization shall set the lighting necessary for food safety to an appropriate level of illuminance. Additionally, the organization shall ensure that facilities and equipment that come into contact with food are constructed and made of materials that allow for appropriate maintenance, cleaning, and disinfection.
GMP 4.1	Cross-contamination (including allergen cross-contact) and isolation	The organization shall prevent physical, chemical (including allergens), biological contamination, and cross-contamination (including allergen cross-contact) of raw materials (including containers and packaging materials), semi-finished products, work in progress, reworked products, and finished products. The necessary control measures, including isolation, shall be established to cover all aspects of food safety, and these procedures shall be documented and maintained effectively through periodic review.

Number	Clause Name	Requirements
GMP 4.2	Control of hazards that require enhancement	The organization must establish control measures for hazards that require particularly enhanced controls, other than CCPs, document those procedures as necessary, and maintain them effectively through periodic review.
GMP 5	Personnel Facilities	The organization shall design, install, and manage personnel facilities, including changing rooms, washbasins and toilets, and applicable shared facilities to minimize food safety hazards including allergens. The organization shall separate toilets and areas where food and drinks are stored and consumed such as cafeterias, and break rooms, from areas where food is manufactured, packaged, and stored.
GMP 6.1	Personal hygiene criteria for personnel	The organization shall establish, implement, and maintain appropriate hygiene standards that be assessed and documented product-specific hazards to minimize food safety hazards, for its employees in accordance with the laws and regulations of the countries in which they work. The criteria shall include provisions of hand washing and toilet facilities, ways and frequency of hand washing, medical screening procedure to identify conditions impacting food safety, proper protective clothing, rules on the clothing and shoes, rules on accessing production area, ways of food handling, and control measures for foreign materials, and management procedures and reporting system in the event of an infected person that poses food safety risks. These hygiene criteria shall also be understood by personnel who use different languages.
GMP 6.2	Personnel workwear	The organization shall evaluate product-specific risks and provide appropriate work clothing to minimize food safety risks.

Number	Clause Name	Requirements
GMP 6.3	Health management of personnel	<p>The organization shall develop, implement and maintain health care procedures that evaluate and document product-specific risks to minimize food safety risks.</p> <p>These shall include procedures for personnel suspected of illness to promptly report illness or symptoms to their superiors according to the laws and regulations of the country in which personnel are working.</p> <p>The organization shall also determine who will be responsible for managing personnel with health conditions.</p>
GMP 6.4	Application to subcontractors and visitors	<p>The organization shall ensure that GMP 6.1, 6.2, and 6.3 are well known to personnel who have an impact on food safety, and apply them to subcontractors and visitors without exception.</p>
GMP 7	Training	<p>The organization shall ensure that all personnel, including new personnel, be trained in their appropriate language on food safety (including management, culture, HACCP, GMP), and be a system for each personnel to deepen their understanding, implement, and maintain food safety in their respective work.</p> <p>The organization shall keep records of the implementation of education and training. Additionally, the system for retraining as necessary shall be documented and implemented.</p> <p>This education and training shall enable employees to recognize their role in food safety and the significance of their efforts.</p> <p>In addition, there shall be a system to improve comprehension by repeating the training as necessary after evaluating competence.</p>

Number	Clause Name	Requirements
GMP 8	Housekeeping, cleaning, sterilization, and disinfection	<p>The organization shall identify product-specific risks based on a hazard analysis throughout all processes and stages and establish, implement, and maintain documented organization, cleaning, sterilization, and disinfection procedures.</p> <p>In these procedures, the organization shall include steps to verify that product-specific risks have been minimized.</p> <p>Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended purpose, clearly identified and stored in areas separated from areas where food is manufactured, packaged, and stored.</p> <p>Food safety information on potentially harmful chemicals shall be obtained and confirmed.</p>
GMP 9	Rework	<p>The organization shall control product rework in a traceable manner with minimal food safety risk.</p> <p>The food safety risks involved in rework shall be evaluated and included in HACCP flow diagrams.</p> <p>Records shall be maintained as evidence of control.</p>
GMP 10	Patrol and inspection of the site	<p>The organization shall establish a patrol plan and regularly inspect the environment, facilities, and process design (people, goods, workflow lines) of the entire site.</p> <p>Records shall be maintained as evidence of the inspection.</p> <p>The patrol plan shall ensure that the workplace is maintained in an appropriate state according to its activities and that food safety is ensured.</p>
GMP 11	Air and water management	<p>The organization shall establish application-specific standards and regular monitoring procedures for air, high-pressure gas, and water (including ice and steam) used in food production to minimize impacts on food safety, and the records shall be kept.</p> <p>If water not intended for use in food production and water that has been used and is still acceptable in contact with food is applied to food production, it shall be controlled to prevent it from being contaminated with water for food production.</p>

Number	Clause Name	Requirements
GMP 12	Waste Management	<p>The organization shall establish adequate systems for segregation, collection and disposal of waste (including wastewater). The flow lines of waste shall be established so as not to cause cross-contamination of food.</p> <p>Locations and containers for placing waste shall be controlled to prevent attraction of pests or growth of harmful organisms/micro-organisms. Containers for storing waste materials (including by-products not suitable for food use) shall be clearly distinguished from other containers.</p>
GMP 13	Pest control	<p>The organization shall establish, implement and maintain procedures to control or remove food safety risks caused by pests (pests and vermin) on the premises and in the facilities. These procedures shall be implemented using the following cycle.</p> <ol style="list-style-type: none"> 1. Understanding of the pest outbreak situation and formulation of monitoring plans. 2. Implementation of pest control and invasion prevention. 3. Pest monitoring and dissemination of results to personnel. <p>The organization shall establish procedures for eliminating pests and vermin as necessary. If chemicals are used, handling procedures shall be established to ensure that food is not affected.</p> <p>Pest control shall be carried out by persons with the necessary competence.</p>
GMP 14	Acceptance of purchased items	<p>The organization shall establish, implement, and maintain acceptance procedures for all externally sourced raw materials, packaging materials and services that influence food safety. In addition, in order to ensure that the safety of the final product is not compromised and that the materials are suitable for the intended use, verification of raw materials, containers and packaging materials shall be carried out.</p>

Number	Clause Name	Requirements
GMP 15	Transport	The organization shall establish a system to ensure that containers and transportation vehicles, including contracted vehicles, used for the transportation of raw materials and ingredients (including packaging materials), partially processed products, works in progress, recycled products, reworks, and finished products (including packed fresh products in final packaging) are suitable for the intended use, maintained in good repair and clean, protected from contamination, and transported within its intended temperature range.
GMP 16	Storage	The organization shall hold or store foods (raw materials, semi-finished products, work in progress, reworked products, and final products) at designated locations, and manage them under appropriate conditions to minimize food safety risks.
GMP 17	Stock Management	The organization shall establish, implement and maintain a system to use raw materials and ingredients (including packaging materials), partially processed products, work in progress, recycled products, reworks, and finished products in a designated order and within the defined expiry period, and shall store these materials under the proper conditions to avoid contamination and deterioration. Storage facilities and equipment shall be designed to allow food to be stored under appropriate storage conditions.
GMP 18	Equipment and Tools	The organization shall suitably design and select equipment and tools for the intended uses and shall use, maintain, and store so as to minimize food safety hazards.

Number	Clause Name	Requirements
GMP 19	Maintenance	<p>The organization shall document and implement a system for systematic maintenance of all facility and equipment critical to product safety. Maintenance activities shall be performed in such a way that they do not pose a food safety risk.</p> <p>This system shall include procedures (such as cleaning, washing, and sterilization procedures) for returning the food production facility to a state capable of producing food after maintenance activities.</p> <p>Maintenance activities shall not represent food safety hazards. All materials used for maintenance shall be suitable for the intended purpose.</p>

Annex 1

● List of documented information explicitly required by the standard (Refer to FSM 5)

Clause	Content of documented information
FSM 1	Records that top management has made employees aware of the defined organizational structure (at least the duties, responsibilities, instruction/reporting system, and information sharing for employees in charge of activities that affect food safety).
FSM 3	Management review by top management
FSM 4	Records of implementation of food legal compliance procedures
FSM 5	Elements of the food safety management system that are deemed necessary by the organization
FSM 6	Food Safety Policy and Goals
FSM 7	<ul style="list-style-type: none"> ● Assessment procedures for prioritizing responses to threats to food defense ● Food Defense Plan
FSM 8	<ul style="list-style-type: none"> ● Evaluation procedures for assigning predominance to food deception reduction measures ● Food Deception Prevention Plan
FSM 9.1	<ul style="list-style-type: none"> ● Information documentation procedure ● Records required to prove the implementation of food safety management
FSM 10	Specifications of what is being purchased or supplied
FSM 13.2	Supplier evaluation/approval/monitoring records
FSM 13.3	Documents related to the management of outsourced processes
FSM 14.1	<ul style="list-style-type: none"> ● Documented procedures for implementing and maintaining product tracing ● The following records are required to ensure traceability: <ul style="list-style-type: none"> · Identification of all externally procured raw materials (including containers and packaging materials), products, or services · Records to identify batches, semi-finished products, work in progress, refurbished products, reworked products, finished products and packaging throughout the manufacturing process · Record of purchasers and shipping destinations for all products supplied · If the procedure has been updated, record it
FSM 14.2	Trace test verification results
FSM 16	Allergen management plan
FSM 17	Records of actions taken if equipment or devices is found to be inaccurate
FSM 21	Management mechanism for handling complaints and utilizing complaint data
FSM 22.1	<ul style="list-style-type: none"> ● Food incident management procedure ● Record of incidents that have occurred
FSM 22.2	Product recall test verification results
FSM 23.1	Specifications of products (raw materials (including containers and packaging materials), semi-finished products, work in progress, recycled products, reworked products, and final products)
FSM 23.2	Product release (shipping) procedures
FSM 24	Procedures for identifying nonconformities that impact food safety and for clearly identifying, managing, disposing of, and reworking resulting nonconforming products

FSM 25	Procedures for determining and implementing corrective actions when nonconformities impacting food safety occur
FSM 26	Procedures to assess, to the extent necessary, the impact of changes that may impact food safety in advance
HACCP Step 12 (Principle 7)	Documents and records required for HACCP plan (Step 12 requires documentation of all documents and records required for the HACCP plan.)
GMP 4.1	Necessary control measures/methodological procedures, including isolation, aimed at preventing contamination and cross-contamination (including cross-contact)
GMP 4.2	Procedures for control measures/methods for hazards that require enhanced control (as appropriate)
GMP 6.1	Personal hygiene standards for employees, etc.
GMP 6.3	Health management procedures for employees, etc.
GMP 6.4	Documents related to GMP 6.1 and GMP 6.3 applied to contracted businesses and visitors
GMP 7	<ul style="list-style-type: none"> ● Record of education/training implementation ● System for re-education (if necessary)
GMP 8	Documented procedures for organizing, cleaning, and sanitizing/disinfecting
GMP 9	Records of product rework
GMP 10	Business site patrol/inspection results
GMP 11	Monitoring records of air, high pressure gas, and water (including ice and steam) used in food production
GMP 19	Systems for systematically maintaining all equipment and devices important to product safety

Annex 2

●Definitions

	Term	Definition
1.	Allergen cross-contact	The unintentional incorporation of an allergenic food, or ingredient, into another food that is not intended to contain that allergenic food or ingredient. (Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)
2.	Intended use	Methods of use and consumption methods established at the time of planning and design for products, buildings and equipment.
3.	Outsourced processes	Outsourcing refers to an organization commissioning its own processes to be performed by an external party. This commissioning includes not only the services provided by a contractor, but also the provision of the services by the contractor. Services provided by contractors include provision of lunch for personnel, cleaning of work clothes, insect, vermin and sanitation consultants, sanitation of facilities at business sites, maintenance of facilities and equipment, etc.
4.	Control measure	Any action or activity that can be used to prevent, eliminate, or reduce food safety hazards to acceptable levels. (Cited from Codex Alimentarius Commission CAC/RCP 1-1969 Annex: Hazard analysis and critical control point (HACCP) system and guideline for its application) This is also defined as a control measure in the glossary of the “Guide to Implementing HACCP in Food Manufacturing” (in Japanese) published by the Ministry of Health, Labor and Welfare.
5.	Hazard	A biological, chemical, or physical agent in food with the potential to cause an adverse health effect. (Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)
6.	Critical limit	A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the food. (Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)
7.	Record	Document stating results achieved or providing evidence of activities performed. Note 1 to entry: Records can be used, for example, to formalize traceability and to provide evidence of verification, preventive action and corrective action. Note 2 to entry: Generally records need not be under revision control. (Cited from the definition in ISO 9000:2015)

	Term	Definition
8.	Verification	The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended. (Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)
9.	Cross-contamination	When people or objects (raw materials, packaging materials, semi-finished products, finished products, carts, etc.) are moved between different sanitary areas, they can bring in bacteria or other contaminants that can contaminate food.
10.	Raw materials and ingredients	Ingredients refer to those used as part of product including packaging materials and water as well.
11.	Updating	Immediate and/or planned activity to ensure application of the most recent information. (Cited from the definition in ISO 22000:2018)
12.	CCP (Critical control point)	A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system. (Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)
13.	Employee, Personnel	All personnel in an organization who are involved in work related to food safety, including part-timers, contractors, and dispatched personnel.
14.	Correction	Action to eliminate a detected nonconformity. (Cited from the definition of ISO 22000:2018 3.9) Note 1: Corrections may occur prior to, in conjunction with, or after corrective action. Note 2: Modifications include, for example, rework and rerating.
15.	Serious incident	Food incident that may have an effect on food safety. Does not include incidents that do not have an effect on food safety but may have an effect on the quality.
16.	Disinfection	Reduction by means of biological or chemical agents and/or physical methods in the number of viable microorganisms on surfaces, in water or in air to a level that does not compromise food safety and/or suitability. (Cited from Codex Alimentarius Commission CXC 1-1969 (Revised in 2022.) GENERAL PRINCIPLES OF FOOD HYGIENE)
17.	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. (Cited from the definition of ISO 22000:2018 3.18)

	Term	Definition
18.	Food safety policy	Overall intentions and direction of an organization related to food safety as formally expressed by top management. (Cited from the definition in ISO 22000:2018)
19.	A culture of food safety	Shared values, beliefs and norms that affect mind-set and behavior toward food safety in, across and throughout an organization. (Cited from A Culture of Food Safety, a position paper from the Global Food Safety Initiative (GFSI) 4/11/18 V1.0)
20.	Food safety management system	A system to specify policies and objectives and to achieve these objectives so that food does not harm the consumer for when the food is cooked and/or consumed in accordance with the intended use. (Referenced to ISO 9000:2015 and ISO 22000:2018)
21.	Food fraud	A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients, feed, food packaging or labelling, product information or false or misleading statements made about a product for economic gain that could impact consumer health. (GFSI BENCHMARKING REQUIREMENTS VERSION 2020.1 / PART IV GLOSSARY OF TERMS)
22.	Food fraud mitigation plan	The process of defining requirements regarding when, where, and how to mitigate deceptive practices identified by the food mitigation vulnerability assessment. The plan developed defines the measures and checks necessary to effectively mitigate the identified hazards.
23.	Food incident management procedure	A procedure for appropriate response and management in the event of food safety problems to prevent it from escalating.
24.	Scope	GFSI defined certification scope. A code with a specific classification is assigned to each food, feed, and food-related service industry, and a detailed business category for each classification is indicated.
25.	Control	The state wherein correct procedures are being followed and criteria are being met. (Cited from Codex Alimentarius Commission CAC/RCP 1-1969 Annex: Hazard analysis and critical control point (HACCP) system and guideline for its application)

	Term	Definition
26.	Product	<p>Output of an organization that can be produced without any transaction taking place between the organization and the customer.</p> <p>Note 1 to entry: Production of a product is achieved without any transaction necessarily taking place between provider and customer, but can often involve this service element upon its delivery to the customer.</p> <p>Note 2 to entry: The dominant element of product is that it is generally tangible.</p> <p>Note 3 to entry: Hardware is tangible and its amount is a countable characteristic (e.g. tires). Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft drinks). Hardware and processed materials are often referred to as goods. Software consists of information regardless of delivery medium (e.g. computer program, mobile phone app, instruction manual dictionary content, musical composition copyright, driver's license).</p> <p>(Cited from the definition in ISO 9000:2015)</p>
27.	Sector, Sub-sector	Scope of certification.
28.	Corrective action	<p>Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product, if any, and prevent or minimize reoccurrence of the deviation.</p> <p>(Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)</p>
29.	Product withdrawal	<p>Removal of products from the supply chain that are considered unsafe before they are sold to the end consumer.</p> <p>(Cited from the definition of GFSI Benchmarking Requirement ver. 2020.1)</p>

	Term	Definition
30.	Rework	<p>[When indicating an act]. Indicates the action to be taken when returning to the manufacturing flow a product that complies with the requirements for products that have deviated from the regular series of processes, including final products, semi-finished products, work-in-process, and raw materials in all processes. Rework includes the action of returning a product from a series of processes to an upstream process for reworking, and the action of returning a product to a process again without processing.</p> <p>[When indicating an item]. Indicates clean, unadulterated food that has been removed from processing at any point up to and including final packaging for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food or a food component. (Adapted from Codex Alimentarius Commission CXC 80-2020 (Adopted in 2020) CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS)</p>
31.	Top management	<p>Person or group of people who directs and controls an organization 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 covers only part of an organization, then top management refers to those who direct and control that part of the organization. (Cited from the definition of ISO 22000:2018 3.41)</p>
32.	HACCP plan	<p>Documentation or set of documents, prepared in accordance with the principles of HACCP, to ensure control of significant hazards in the food business. (Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)</p>
33.	Food chain	<p>A series of steps from primary production to consumption that involve the production, processing, distribution, storage and handling of food and its ingredients. Note 1: Production also includes the production of feed and food for animals. Note 2: The food chain also includes the production of ingredients intended to come into contact with food or ingredients. Note 3: The food chain also includes service providers. (Cited from the definition of ISO 22000:2018)</p>
34.	Flow diagram	<p>A systematic representation of the sequence of steps used in the production or manufacture of food. (Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)</p>

	Term	Definition
35.	Document	Information and the medium on which it is contained. Example: Record, specification, procedure document, drawing, report, Standard Document Note to entry: The medium can be paper, magnetic, electronic or optical computer disc, photographic or master sample, or combination thereof. (Cited from the definition of ISO 22000:2018 3.13)
36.	Nonconformities	Non-fulfilment of a requirement. (Cited from the definition of ISO 22000:2018 3.28)
37.	Management	Coordinated activities to direct and control an organization. Note to entry: Management can include establishing policies and objectives, and processes to achieve these objectives.
38.	Management system	Set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve these objectives. (Cited from the definition of ISO 22000:2018 3.25)
39.	Monitoring	Definitions related to CCP A planned observation procedure or measurement of control parameters performed to assess whether the CCP is under control. (Cited from Codex Alimentarius Commission CAC/RCP 1-1969 Annex: Hazard analysis and critical control point (HACCP) system and guideline for its application) Definitions other than CCP Determination of the status of a system, process or activity Note 1: Inspection, supervision or careful observation may be required to determine the situation. Note 2: Monitoring in food safety involves a series of planned observations or measurements to assess whether a process is operating as intended. Note 3: ISO 22000:2018 makes a distinction between validation, monitoring and verification. - Validation is applicable prior to the activity and provides information on the ability to produce the intended result. - Monitoring is applicable during the activity and provides information on the activity within a specified period of time. - Verification is applicable after the activity and provides information to confirm conformance. (Cited from ISO 22000:2018)
40.	Packaging materials	Materials used for packaging food products, such as papers, plastics, wooden boxes, cardboards, PET bottles, and tin cans.
41.	Competence	Ability to apply knowledge and skills to achieve intended results. Note to entry: Demonstrated competence is sometimes referred to as qualification. (Cited from the definition in ISO 9000:2015. Note 2 to entry is not included in the definition of “competence” in this document.)

	Term	Definition
42.	Product recall	Products that have been or are being sold to the end consumer and are considered unsafe are removed from the supply chain by the supplier. (Cited from the definition of GFSI Benchmarking Requirement ver. 2020.1)
43.	Review	Determination of the suitability, adequacy or effectiveness of an object to achieve established objectives EXAMPLE: Management review, design and development review, review of customer requirements, review of corrective action and peer review. Note to entry: Review can also include the determination of efficiency. (Cited from the definition in ISO 9000:2015)

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