JFS-C Standard Document
(Sector: CI,CII,CIII,CIV/K)

[Requirements for Organizations]
Version 3.0

Japan Food Safety Management Association

October 2, 2020

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)
  (Manufacture of additives, vitamins, minerals, cultures, flavors, enzymes, processing aids, etc.)
  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, “Annex of 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.

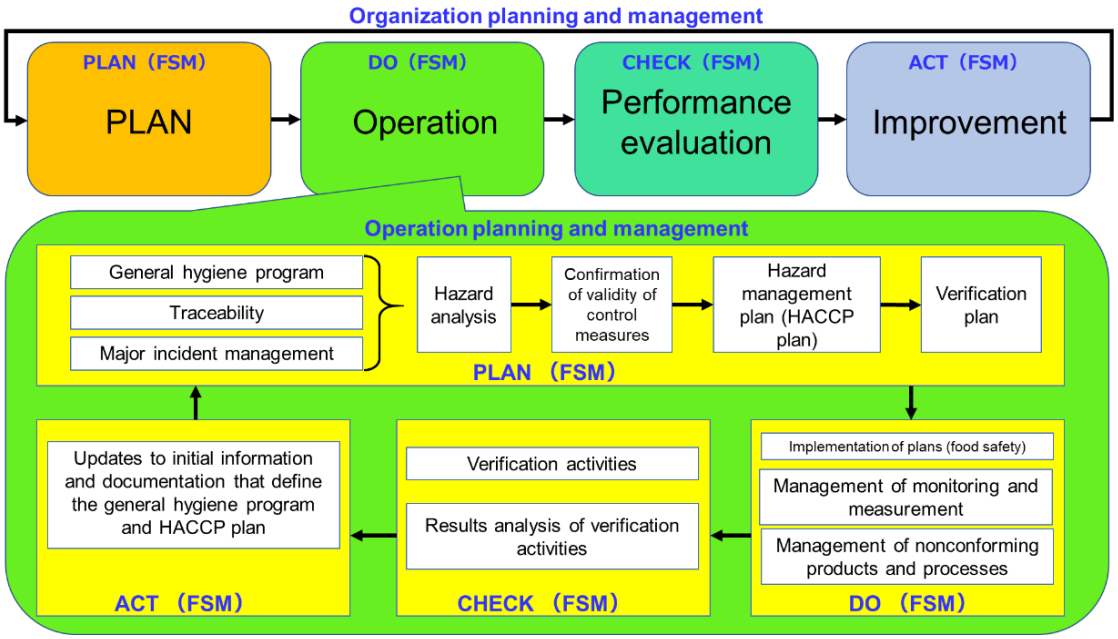
This Standard Document is consistent with the benchmark requirement version 2020.1 (*3 hereafter, BR 2020.1) published by GFSI in June 2020. On the other hand, since BR 2020.1 adopts ISO22000:2018 (*4) in its scope structure and numbering structure, this Standard Document has a structure consistent with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

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.



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	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 Inspection
FSM 12	Resource Management	FSM 19.2	Environmental Monitoring for Food Manufacturing
FSM 13.1	Purchasing	FSM 22	Serious Incident Management
FSM 13.2	Supplier Performance	FSM 23	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 20	Internal Audit
		FSM 21	Complaint Handling
		ACT（FSM）Improvement	
		FSM 25	Corrective Action
		FSM 26	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.

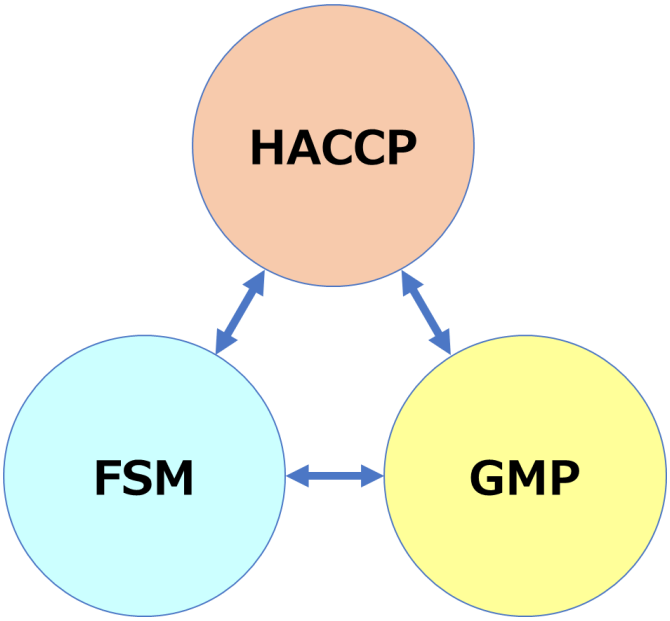


Fig. 2 Conceptual diagram of the organic functions of the three elements (FSM, HACCP, GMP)

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

(*2) Codex Alimentarius Commission
"RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE" CAC/RCP 1-1969, Rev.4(2003)

(*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.

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:

List of JFS Standard Document Sectors

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

Code	Sector/Subsector	Code	Sector/Subsector
AI	Farming of Animals for Meat/ Milk/ Eggs/ Honey	FI	Retail / Wholesale
AII	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	JII	Hygienic Design of Food Buildings and Processing Equipment (for building and equipment users)
CIII	Processing of perishable animal and plant products (mixed products)		
CIV	Processing of ambient stable products	K	Manufacture of chemical products (including biochemical products) (Manufacture of additives, vitamins, minerals, cultures, flavors, enzymes, processing aids, etc.)
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 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. 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.

Number	Clause Name	Requirements
FSM 5	Food Safety Management System and General Requirements	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. In addition, the Food Safety Management Systems shall be continuously improved by properly adapting to changes in the surrounding social environment.
FSM 6	Food Safety Policy and Goals	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.
FSM 7	Food Defense	The organization shall document, implement, and record assessment procedures to identify potential and overt threats to food defense and prioritize response to those threats. The organization shall document and implement a food defense plan that specifies the actions that the organization implements to mitigate the identified food defense threat. This plan shall cover GMP and shall be incorporated into the food safety management system.
FSM 8	Food Fraud Prevention	The organization shall document, implement, and record assessment procedures to identify potential and overt tampering with records and labeling of products and intentional dilution, and prioritize food fraud mitigation measures. The organization shall develop a documented plan that specifies the measures the organization implements to mitigate the identified threats of food fraud. This plan shall cover the GMP and shall be incorporated into the food safety management system.

Number	Clause Name	Requirements
FSM 9.1	Documentation procedures	The organization shall have documented procedures in place to formulate, implement and maintain the documented information (including records) needed to demonstrate the effective operation of its food safety management systems and process controls.
FSM 9.2	Control and storage of documented information	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.
FSM 10	Specification Control of Purchased or Provided Items and Services	For all purchased or provided input items and services (including raw materials and ingredients, 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. 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. 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.
FSM 11	Procedures and Instructions	The organization shall establish, implement and maintain effective procedures and instructions in all processes and activities that affect food safety. In addition, these procedures and instructions shall be understandable by personnel in different languages.
FSM 12	Resource Management	Top management shall determine and provide, in a timely manner, the qualified resources (including human resources, facilities and work environment, equipment, systems for operating business 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.

Number	Clause Name	Requirements
FSM 13.1	Purchasing	The organization shall control purchasing procedures to ensure that all externally sourced raw materials, packaging materials, and services that have an effect on food safety conform to stipulated specifications, as well as legal and regulatory requirements related to food safety. In addition, these purchasing procedures shall also apply to raw materials, packaging materials, and services purchased from the organization's group companies.
FSM 13.2	Supplier Performance	The organization shall establish, implement and maintain procedures for the evaluation, approval and continual monitoring of suppliers, which have an effect on food safety. Supplier evaluation shall include measures for food defense and to prevent food fraud. 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. The organization shall maintain evaluation, approval and monitoring records for suppliers.
FSM 13.3	Outsourcing	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. Control of such outsourced processes shall be identified, documented and monitored as a part of the food safety management system. Changes to the contract content shall be approved by both parties and communicated to the relevant personnel.
FSM 14	Traceability	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. Documented procedures shall be verified at least once a year by trace testing to ensure that they are working effectively, and the verification results shall also be recorded.

Number	Clause Name	Requirements
FSM 15	Product development	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. 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.
FSM 16	Allergen Management	The organization shall develop and implement allergen management plans and maintain them appropriately. The plans shall include a risk assessment of allergen cross-contamination and control measures to be implemented to reduce or eliminate the risk of cross-contamination. In addition, the plans shall ensure that products that are shipped and sold are labeled according to the allergen labeling regulations in the country where they are to be sold.
FSM 17	Control of Measuring and Monitoring Devices	The organization shall identify measuring and monitoring devices that are parameters critical to ensure food safety. In addition, the specified equipment and devices shall be calibrated regularly. The calibration shall be traceable by the relevant national or international standards and methods.
FSM 18.1	Product labeling (B-to-C products)	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.
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.

Number	Clause Name	Requirements
FSM 19.1	Analysis and Inspection	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. The inspection shall be conducted by a competent inspection department or analysis institution using appropriate sampling and analytical methods. Inspections that have a significant effect on food safety shall be conducted in accordance with the applicable requirements of ISO/IEC 17025.
FSM 19.2	Environmental Monitoring	The organization shall establish, implement and maintain a microbial environmental monitoring program to reduce the risk of food contamination. This program shall consider microbial risks specific to the manufacturing process and facility environment and include evaluation methods tailored to the risks.
FSM 20	Internal Audit	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). The procedures shall include at least the following content. 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. The organization shall maintain a record of the performance of the internal audit as evidence. The organization shall specify the competence required for internal auditors and provide training for internal auditors.
FSM 21	Complaint Handling	The organization shall establish, implement, and maintain complaint handling and complaint data management procedures. Control procedures shall include analyzing complaints, evaluating the magnitude of the impact threatening food safety, and implementing corrective action as necessary.

Number	Clause Name	Requirements
FSM 22	Serious Incident Management	The organization shall establish, implement and maintain an effective management procedure of serious incidents. The incident management procedure shall cover planning for product withdrawal and product recall as required, and be regularly tested for all products it supplies. The effectiveness of the incident management procedure shall be verified at least once a year, and the results shall be recorded.
FSM 23	Product Release	The organization shall establish and implement appropriate procedures for product release.
FSM 24	Identification of nonconformities and control of nonconforming products	The organization shall establish, implement and maintain effective procedures to identify nonconformities that have an effect on food safety and to clearly identify, control, discard and rework nonconforming products resulting from nonconformities in order to prevent misuse and mis-shipment.
FSM 25	Corrective Action	The organization shall establish procedures for the determination and implementation of corrective actions in the event of any nonconformities arising relating to food safety. 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.
FSM 26	Utilization of Kaizen suggestions from personnel	The organization shall establish and implement a system to properly utilize food safety Kaizen suggestions from personnel.

2.2 Hazard Analysis and Critical Control Point (HACCP)

	Clause Name	Requirements
HACCP Step 1	HACCP Team Assembly	A HACCP team shall be assembled with competent staff.
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 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 of the hazards that are reasonably likely to occur in each process steps, conduct an analysis, and identify any necessary measures to control them. Hazards shall include allergens where required.
HACCP Step 7 (Principle 2)	Critical Control Points	Critical Control Points (CCPs) shall be determined.
HACCP Step 8 (Principle 3)	Establishment of Critical Limits	Critical limit(s) shall be stipulated for each CCP.

	Clause Name	Requirements
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)	Verification	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	Site Management	The organization shall establish and maintain appropriate standards for the grounds of their workplaces to prevent pollution and produce safe products.
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 and the flow lines of people, goods, and work shall be designed to meet the intended purpose and minimize food safety risks.
GMP 4	Physical, chemical and biological product contamination risks and isolation	The organization shall clarify that all hazard factors (physical, chemical (including allergens), and biological) for each process have been identified based on consistency checks between the process flow created by the HACCP team and the site. The frequency of occurrence and the magnitude of the consequences of the identified hazards shall be evaluated and appropriate control measures shall be set for each. Procedures shall be established and documented to control identified hazards other than critical control points (CCPs) that are difficult to manage effectively with a general hygiene control program to prevent contamination of raw materials (including packaging materials), semi-finished products, work-in-process, rework and finished products, and cross-contamination. The organization shall regularly review these procedures and keep them in effect.
GMP 5	Personnel Facilities	Personnel facilities, including washbasins and toilets, and applicable shared facilities shall be provided, designed, and utilized to minimize food safety risks.

Number	Clause Name	Requirements
GMP 6.1	Personal hygiene criteria for personnel	The organization shall develop, implement and maintain hygiene criteria that evaluate and document product-specific risks to minimize food safety risks. 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. These hygiene criteria shall also be understandable by personnel in different languages.
GMP 6.2	Personnel workwear	The organization shall evaluate product-specific risks and provide appropriate work clothing to minimize food safety risks.
GMP 6.3	Health management of personnel	The organization shall develop, implement and maintain health care procedures that evaluate and document product-specific risks to minimize food safety risks. 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.
GMP 6.4	Application to non-business personnel and visitors	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 contractors and visitors without exception.
GMP 7	Training	All personnel shall be trained in their appropriate language on food safety (including management, culture, HACCP, GMP), and there shall be a system for each personnel to deepen their understanding, implement, and maintain food safety in their respective work. In addition, there shall be a system to improve comprehension by repeating the training as necessary after evaluating competence.

Number	Clause Name	Requirements
GMP 8	Housekeeping, cleaning, sterilization and disinfection	The organization shall identify product-specific risks based on a hazard analysis and establish, implement and maintain documented organization, cleaning, sterilization and disinfection procedures. In addition, the organization shall also verify that procedures that can minimize product-specific risks are working effectively. Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended use and stored appropriately. Food safety information on potentially harmful chemicals shall be obtained and confirmed.
GMP 9	Rework	The organization shall control product rework in a traceable manner with minimal food safety risk. The food safety risks involved in rework shall be evaluated and included in HACCP flow diagrams. Records shall be maintained as evidence of control.
GMP 10	Patrol and inspection of the site	The organization shall establish a patrol plan and regularly inspect the environment, facilities, and process design (people, goods, work flow lines) of the entire site. Records shall be maintained as evidence of the inspection. The patrol plan shall ensure that the workplace is maintained in an appropriate state according to its activities and that food safety is ensured.
GMP 11	Air and water management	The organization shall define the required quality criteria according to the application, and regularly monitor and record the air, high-pressure gas, and water (including ice and steam) used in food production in order to minimize the effect on food safety. If water that has been used but is acceptable in contact with food is applied to food production, it shall be controlled to prevent it from being contaminated with dedicated production water.

Number	Clause Name	Requirements
GMP 12	Waste Management	The organization shall establish adequate systems for segregation, collection and disposal of waste (including waste water). The flow lines of waste shall be established so as not to cause cross-contamination of food. Locations and containers for placing waste shall be controlled to prevent attraction of pests or growth of harmful organisms/micro-organisms.
GMP 13	Pest control	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. 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. The organization shall establish procedures for eliminating pests and vermin as necessary.
GMP 14	Acceptance of purchased items	The organization shall establish, implement and maintain acceptance procedures for all externally sourced raw materials, packaging materials and services that have an effect on 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.
GMP 15	Transport	The organization shall establish a system to ensure that containers and vehicles, including contracted vehicles, used for the transportation of raw materials and ingredients (including packaging materials), partially processed products, works in progress, reworks, and finished products (including packed fresh products in final packaging) are suitable for the intended use, maintained in good repair and clean.

Number	Clause Name	Requirements
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, 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.
GMP 18	Devices and Tools	Devices and tools shall be suitably designed and selected for the intended uses and shall be used, maintained and stored so as to minimize food safety risks.
GMP 19	Maintenance	A system of planned maintenance covering all items of equipment which are critical to product safety shall be established.

Annex

●Definitions

	Term	Definition
1.	intended use	Methods of use and consumption methods established at the time of planning and design for products, buildings and equipment.
2.	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.
3.	categories	Range of application of certification.
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 material in, or condition of, food with the potential to cause an adverse health effect. (Cited from the definition in the Codex General Principles of food hygiene)
6.	critical limit	Criterion which separates acceptability from unacceptability. (Cited from Codex Alimentarius Commission CAC/RCP 1-1969 Annex: Hazard analysis and critical control point (HACCP) system and guideline for its application)
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	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents. Note 2 to entry: The activities carried out for verification are sometimes called a qualification process. Note 3 to entry: The word “verified” is used to designate the corresponding status. (Cited from the definition in ISO 9000:2015)
9.	raw materials and ingredients	Ingredients refer to those used as part of product including packaging materials and water as well.
10.	updating	Immediate and/or planned activity to ensure application of the most recent information. (Cited from the definition in ISO 22000:2018)
11.	CCP （critical control point）	Controls can be applied and are essential steps to prevent or eliminate food safety hazards, or bring 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)
12.	employee, personnel	All personnel in an organization who are involved in work related to food safety, including part-timers, contractors, and dispatched personnel.
13.	correction	Action to eliminate a detected nonconformity. Note 1 to entry: A correction can be made in advance of, in conjunction with or after a corrective action. Note 2: As terms with the same notation but different meanings in this Standard Document: Modification, which is the act of revising documents, records, and items to be stated, and Rework, which is the act of remedying a product in process. (Refer to the definition in ISO 9000:2015)
14.	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.
15.	food	All substances that are processed, semi-processed or unprocessed with the intention of human consumption. Note to entry: Food includes all substances used for manufacturing, preparation and processing of beverages, chewing gums and foods. However, it does not include substances used solely for cosmetics, cigarettes and drugs.

	Term	Definition
16.	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)
17.	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)
18.	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)
19.	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.
20.	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)
21.	product	Output of an organization that can be produced without any transaction taking place between the organization and the customer. 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. Note 2 to entry: The dominant element of product is that it is generally tangible. 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). (Cited from the definition in ISO 9000:2015)
22.	corrective action	Action to eliminate the cause of a nonconformity and to prevent recurrence. Note to entry: There can be more than one cause for a nonconformity. (Cited from the definition in ISO 9000:2015)

	Term	Definition
23.	product withdrawal	Removal of products from the supply chain that are considered unsafe before they are sold to the end consumer. (Cited from the definition of GFSI Benchmarking Requirement ver. 2020.1)
24.	rework	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.
25.	top management	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 in ISO 9000:2015. Note 3 to entry is not included in the definition of “top management” in this document.)
26.	food chain	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)
27.	flow diagram	Diagrams constructed to show all the process steps for specified product.
28.	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 in ISO 9000:2015. Notes 2 and 3 to entry are not included in the definition of “document” in this document.)
29.	nonconformities	Non-fulfilment of a requirement. (Cited from the definition in ISO 9000:2015)

	Term	Definition
30.	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. (Cited from the definition in ISO 9000:2015. Note 2 to entry is not included in the definition of “management” in this document.)
31.	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 in ISO 9000:2015)
32.	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)
33.	packaging materials	Materials used for packaging food products, such as papers, plastics, wooden boxes, cardboards, PET bottles, and tin cans.
34.	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
35.	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)
36.	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)