

JFS-B Plus Standard Document

(Sector : C I ,C II ,C III ,C IV /K)

**<Manufacture of food products and
Manufacture of chemicals (including
biochemical products)>**

**[Requirements for Organizations]
Ver. 1.0**

Japan Food Safety Management Association

May 29, 2024

1. Introduction

1.1 JFS-B Plus Standard Ver. 1.0

The JFS-B Plus Standard (hereinafter referred to as “this Standard”) is a standard document developed by the Japan Food Safety Management Association (JFSM) and is intended to assist organizations (*1) to improve their systems for manufacturing safety food products. It can also be used to verify and evaluate the organization's efforts by internal auditors and external evaluators.

JFS-B Plus is a standard that adds to the JFS-B standard the requirements for organizations in capacity building programs developed by international industry associations for food-related businesses.

In addition, Codex Alimentarius Commission has published GPFH2020 (GENERAL PRINCIPLES OF FOOD HYGIENE 2020)*2 , which includes HACCP; the contents of GPFH2020 are included in the HACCP and GMP requirements of the JFS-B Plus Standard..

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

In the food manufacturing sector, it is a business, organization, or individual that manufactures food products.

In the chemical manufacturing sector of the scope of this Standard Preface 1.2, it is a business, organization or individual that manufactures chemicals.

(*2) Codex Alimentarius Commission "GENERAL PRINCIPLES OF FOOD HYGIENE," CXC 1-1969, Rev. 2020

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).

Chemical products herein refer to chemical products (including biochemical products) related to food products, and include the production of additives, vitamins, minerals, cultures, flavorings, enzymes and processing aids. (Table 1: List of Sectors by GFSI)

Pet food is included in the following food manufacturing sector

Food Manufacturing Sectors (CI~CIV)

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

Chemical Products (Including Biochemical Products) Manufacturing Sector (K)

K : Manufacture of chemicals (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.

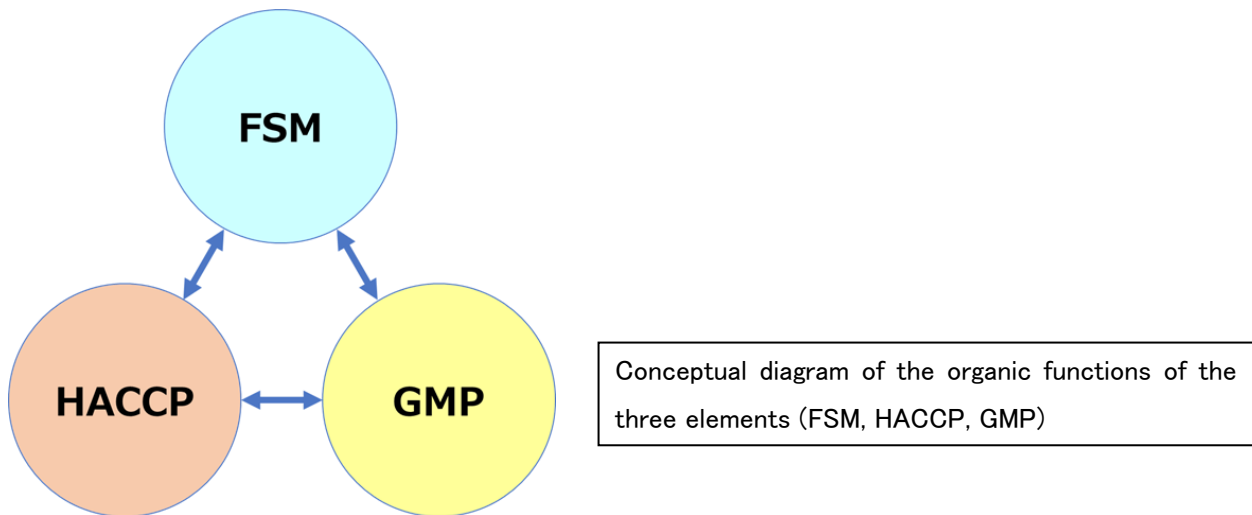
Table 1: List of Sectors by GFSI

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		
CI	Processing of perishable animal products	J1	Hygienic Design of Food Buildings and Processing Equipment (for building constructors and equipment manufacturers)
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) (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

1.3 Structure of this Standard Document

This standard consist of Food Safety Management Systems : FSM, which are requirements for the management of an organization's activities, HACCP, which is a method of controlling hazards, and Good Manufacturing Practices (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. JFSM has also prepares guidelines on the requirements of the Standard 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.

1.5 Checklist

JFSM has provide a checklist that can be used to audit and record (describe points of non-compliance, insufficiencies, and accomplishments, etc.) whether the organization is performing against the requirements.

2. Specific Requirements (Standard Document)

I Food safety management systems (FSM)

Number	Clause Name	Requirements
FSM 1	Management or senior management responsibility	Management or senior management must share and operate an organizational structure that, at a minimum, clarifies the duties and responsibilities of those who affect food safety. There shall also be evidence that employees are made aware of them. Management or senior management must determine who is responsible for food safety management.
FSM 2	Commitment of management or senior management and food safety culture	<p>Management or senior management shall show evidence of its commitment to building, implementing, maintaining and continually improving its food safety management systems.</p> <p>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.</p>
FSM 4	Compliance with food safety laws	<p>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.</p> <p>In addition, records of implementation shall also be maintained.</p>
FSM 6	Food Safety Policy and Goals	Management or senior management shall have a clear, concise, written food safety policy.
FSM 7	Food Defense	<p>The organization shall identify the risk of intentional food contamination by persons within or outside the organization, assess the magnitude of the risk, and prioritize and implement response measures to reduce or eliminate the risk.</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>

Number	Clause Name	Requirements
FSM8	Food Fraud Prevention	<p>The organization shall document, implement and maintain 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>
FSM 9	Document and record management	<p>The organization shall establish documented procedures to create, maintain, and record for control processes to ensure food safety and evidence effective operations.</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 11	Procedures and Instructions	<p>Organizations must consider relevant safety requirements when designing products and manufacturing processes. The organization shall establish, implement and maintain effective procedures and instructions in all processes and activities that affect food safety. These work procedures and instructions must be visible to employees.</p>
FSM 12	Resource Management	<p>Management or senior management must ensure that the organization has the management resources (people, goods, and money) necessary to implement the organization's food safety initiatives (hazard control (HACCP) and Good Manufacturing Practices (GMP) in this standard).</p>
FSM 13.1	Purchasing	<p>The organization must develop and implement purchasing procedures to ensure that all externally procured raw materials, materials, and services that affect food safety comply with the organization's requirements.</p> <p>When processes affecting food safety are subcontracted, control of these processes must be ensured by presenting the control methods to the subcontractor, for example, by describing the control methods in specifications and contracts.</p>

Number	Clause Name	Requirements
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>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. Results of survey, evaluations, approvals, and follow-ups with suppliers shall be maintained.</p>
FSM 14	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 ● Record of purchasers and delivery destinations for all products supplied ● If the procedure has been updated, record it
FSM14.2	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>

Number	Clause Name	Requirements
FSM 16	Allergen Management	<p>The organization shall document and implement allergen management plans.</p> <p>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>All final products containing or potentially containing allergens should be identified 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. Calibration of these instruments and devices must be performed to equivalent standards, including national and international standards, or to reasonably accepted traceable methods.</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	Product labeling	<p>Organizations must label or attach information to their products that will enable a trading partner or consumer to safely handle, display, store, store, prepare, or use the product.</p> <p>It must also establish and implement procedures for labeling or attaching the correct information.</p>

Number	Clause Name	Requirements
FSM 19	Analysis and Inspection	<p>The organization shall conduct appropriate inspections where and as they affect food safety.</p> <p>Such inspections must be performed by a competent laboratory or analytical laboratory.</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 21	Complaint Handling	<p>The organization shall document 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>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.</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 manual	<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	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>

Number	Clause Name	Requirements
FSM 23.2	Product Release	<p>The organization shall document and implement appropriate procedures for product release (shipping).</p> <p>Product release procedures shall include steps to ensure that the final product meets specifications</p>
FSM 24	Control of non-conforming products	<p>The organization shall document and enforce rules for not using or shipping raw materials (including containers and packaging materials), semi-finished products, work-in-process products, recycled products, reworked products, and finished products that may pose a safety hazard.</p> <p>The organization shall also determine who will be responsible for managing nonconforming products.</p>
FSM 25	Corrective Action	<p>The organization shall establish and implement documented corrective actions in the event of nonconformities affecting food safety. (Corrective action is the process of correcting a nonconformity to a condition that is not a nonconformity, determining the cause of the nonconformity and eliminating the cause of the nonconformity.)</p>

II 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.
HACCP Step 7 (Principle 2)	Critical Control Points	Critical Control Points (CCPs) shall be determined.

	Clause Name	Requirements
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	<p>HACCP plan shall be validated prior to implementation.</p> <p>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.</p> <p>Verification shall be carried out considering the design of equipment, change in processing method and technology development in the manufacturing process.</p>
HACCP Step 12 (Principle 7)	Documents and Record	<p>Necessary documents shall be prepared and maintained.</p> <p>These documents shall contain documents related to the standard operating procedures (SOP) and the work instructions (WI) necessary and applicable to the scope of conformity assessment of the organization.</p>

III Good Manufacturing Practice (GMP)

Number	Clause Name	Requirements
GMP 2	Site Management	The organization shall establish and maintain in accordance with appropriate standards for business premises. 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	<p>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.</p> <p>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.</p> <p>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.</p>
GMP 4.1	Cross-contamination (including allergen cross-contact) and isolation	<p>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.</p> <p>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.</p>
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.

Number	Clause Name	Requirements
GMP 5	Personnel Facilities	<p>The organization shall provide changing rooms and hand washing facilities.</p> <p>Facilities for employees, including these, must be properly managed to minimize food safety risks, including allergens.</p> <p>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.</p>
GMP 6	Hygiene, workwear and Health management of personnel, etc.	<p>The organization must document and enforce appropriate hygiene standards for employees in accordance with the laws and regulations of the country in which the employees are working.</p> <p>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.</p> <p>These requirements must be made known to employees and applied without exception to contractors and visitors.</p> <p>The organization shall also determine who will be responsible for managing personnel with health conditions.</p>
GMP 7	Training	<p>The organization must ensure that all employees, including new employees, receive adequate education and training in food safety principles (including HACCP) and practices appropriate to their jobs. In addition, a system must be established to ensure that employees receive appropriate guidance and supervision.</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>This education and training should enable employees to recognize their role in food safety and the significance of their efforts.</p>

Number	Clause Name	Requirements
GMP 8	Housekeeping, cleaning, sterilization and disinfection	<p>The organization shall document and implement a management procedure of maintain an appropriate level of hygiene at all times by conducting tidying and cleaning operations throughout all processes and phases, and disinfecting where necessary.</p> <p>This procedure should include procedures for verifying that sanitary conditions are ensured.</p> <p>Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended purpose, clearly identified and stored in areas separated from food production areas.</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>
GMP 12	Waste Management	<p>The organization shall establish adequate systems for segregation, collection and disposal of waste.</p> <p>Waste placement and containers must be controlled to prevent the attraction of pests and the development of harmful organisms and microorganisms.</p> <p>Containers for storing waste materials (including by-products not suitable for food use) shall be clearly distinguished from other containers.</p> <p>Waste flow lines must be set up so as not to cause cross-contamination of food.</p>
GMP 13	Pest control	<p>The organization shall monitor pests and implement controls (surveys and countermeasures) to minimize the risk of insects, rodents, birds, and other pests occurring or entering the premises and facilities.</p> <p>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>

Number	Clause Name	Requirements
GMP 15	Transport	<p>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.</p>
GMP 17	Stock Management	<p>The organization shall establish 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.</p> <p>Storage facilities and equipment shall be designed to allow food to be stored under appropriate storage conditions.</p>
GMP 18	Devices and Tools	<p>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.</p>
GMP 19	Maintenance	<p>The organization shall document and implement a system for systematic maintenance of all equipment critical to product safety.</p> <p>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.</p> <p>All materials used for maintenance shall be suitable for the intended purpose.</p>

Annex

●Definition

	Term	Definition
1.	Access control	Control access by persons inside and outside the organization. Examples include restricting and recording who enters and exits, and controlling locks.
2.	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)
3.	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.)
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.	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.
6.	Corrective action	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. 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.

	Term	Definition
7.	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)
8.	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)
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.	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)
11.	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)
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.	Flow diagram	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)

	Term	Definition
14.	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)
15.	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)
16.	Food fraud mitigation plan	食品偽装の脆弱性評価によって特定された、偽装行為をいつ、どこ 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.
17.	Food incident management procedure	A procedure for appropriate response and management in the event of food safety problems to prevent it from escalating.
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.	HACCP Plan	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)
20.	HACCP system	Develop a HACCP plan and implement procedures according to that plan. (Reference) Japan Food Hygiene Association 2021 Translation First Edition)

	Term	Definition
21.	Hazard	<p>A biological, chemical, or physical agent in food with the potential to cause an adverse health effect.</p> <p>(Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)</p>
22.	Intended use	<p>Methods of use and consumption methods established at the time of planning and design for products, buildings and equipment.</p>
23.	Management	<p>Coordinated activities to direct and control an organization.</p> <p>Note to entry: Management can include establishing policies and objectives, and processes to achieve these objectives.</p>
24.	Management system	<p>Set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve these objectives.</p> <p>(Cited from the definition of ISO 22000:2018 3.25)</p>
25.	Monitoring	<p>Definitions related to CCP</p> <p>A planned observation procedure or measurement of control parameters performed to assess whether the CCP is under control.</p> <p>(Cited from Codex Alimentarius Commission CAC/RCP 1-1969 Annex: Hazard analysis and critical control point (HACCP) system and guideline for its application)</p> <p>Definitions other than CCP</p> <p>Determination of the status of a system, process or activity</p> <p>Note 1: Inspection, supervision or careful observation may be required to determine the situation.</p> <p>Note 2: Monitoring in food safety involves a series of planned observations or measurements to assess whether a process is operating as intended.</p> <p>Note 3: ISO 22000:2018 makes a distinction between validation, monitoring and verification.</p> <ul style="list-style-type: none"> - 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. <p>(Cited from ISO 22000:2018)</p>

	Term	Definition
26.	Nonconformities	Non-fulfilment of a requirement. (Cited from the definition of ISO 22000:2018 3.28)
27.	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.
28.	Packaging materials	Materials used for packaging food products, such as papers, plastics, wooden boxes, cardboards, PET bottles, and tin cans.
29.	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)
30.	Raw materials and ingredients	Ingredients refer to those used as part of product including packaging materials and water as well.
31.	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)

	Term	Definition
32.	Record	<p>Document stating results achieved or providing evidence of activities performed.</p> <p>Note 1 to entry: Records can be used, for example, to formalize traceability and to provide evidence of verification, preventive action and corrective action.</p> <p>Note 2 to entry: Generally records need not be under revision control. (Cited from the definition in ISO 9000:2015)</p>
33.	Rework	<p>[When indicating an act].</p> <p>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.</p> <p>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].</p> <p>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.</p> <p>(Adapted from Codex Alimentarius Commission CXC 80-2020 (Adopted in 2020) CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS)</p>
34.	Sector, sub-sector	Scope of conformity assessment.
35.	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.
36.	Significant hazard	<p>Hazard identified by a hazard analysis that, in the absence of controls, are reasonably likely to occur to an unacceptable level and whose control is essential for the intended use of the food.</p> <p>(Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)</p>

	Term	Definition
37.	Top management	<p>Person or group of people who directs and controls an organization at the highest level.</p> <p>Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.</p> <p>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.</p> <p>(Cited from the definition of ISO 22000:2018 3.41)</p>
38.	Updating	<p>Immediate and/or planned activity to ensure application of the most recent information.</p> <p>(Cited from the definition in ISO 22000:2018)</p>
39.	Validation of control measures	<p>Obtain evidence that the control measures or combination of control measures, if properly implemented, will control the hazards to the identified results.</p> <p>(Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)</p>
40.	Validation of the HACCP Plan	<p>Ensure that the food business operator is capable of controlling the appropriate critical hazards by the following elements: identification of hazards, CCP, CL, control measures, frequency and type of CCP monitoring, remedial actions, frequency and type of verification, and type of information to be recorded.</p> <p>(Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)</p>
41.	Verification	<p>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.</p> <p>(Cited from Codex General Principles of Food Hygiene 2020: (Reference) Japan Food Hygiene Association 2021 Translation First Edition)</p>
42.	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>

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Supplementary provision

Revision history

Document Number	Revision Number	Revision Date	Details
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