

JFS-E-C Standard

[Requirements for Organizations]

Ver.1

Japan Food Safety Management Association
July 26, 2016

1. Introduction

1.1 JFS-E-C Standard

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

(*1) “Organization” refers to business operator, group or individual to whom the requirements of this Standard apply. In the manufacturing sector, it refers to business operator, group or individual who manufactures food products.

1.2 Scope of Application

This Standard applies to the “manufacturing sector” consisting of businesses below. (See the Reference)

- EI Processing of perishable animal products
- EII Processing of perishable plant products
- EIII Processing of perishable animal and plant products (mixed products)
- EIV Processing of ambient stable products

1.3 Structure of this Standard

This Standard consists of three layers of requirements, namely, Food Safety Management Systems (FSM), hazard control (Hazard Analysis and Critical Point Control; HACCP), and Good Manufacturing Practice (GMP).

This Standard only specifies common requirements for the manufacturing sector, and does not cover individual hygiene requirements for each product. Organizations shall use information appropriate for the organization (e.g., laws and regulations on food safety, standards specified by the relevant industry group etc., “General Principles of Food Hygiene” by the Codex Alimentarius Commission (*2), specific code of conduct), in addition to the requirements stipulated in this Standard. Further, organizations are advised to refer to the guidelines on the requirements that is to be prepared by JFSM.

(*2) Codex Alimentarius Commission

“RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE” CAC/RCP 1-1969, Rev.4 (2003)

1.4 Exclusion from Application of Requirements

All the requirements in this Standard shall be applied in principle. However, if all the requirements in this Standard do not apply for reasons arising from the business scale, business form, etc., of an organization, the organization shall prepare a document listing up non-applicable requirement items and demonstrating the proper maintenance of food safety management without applying the listed requirement items.

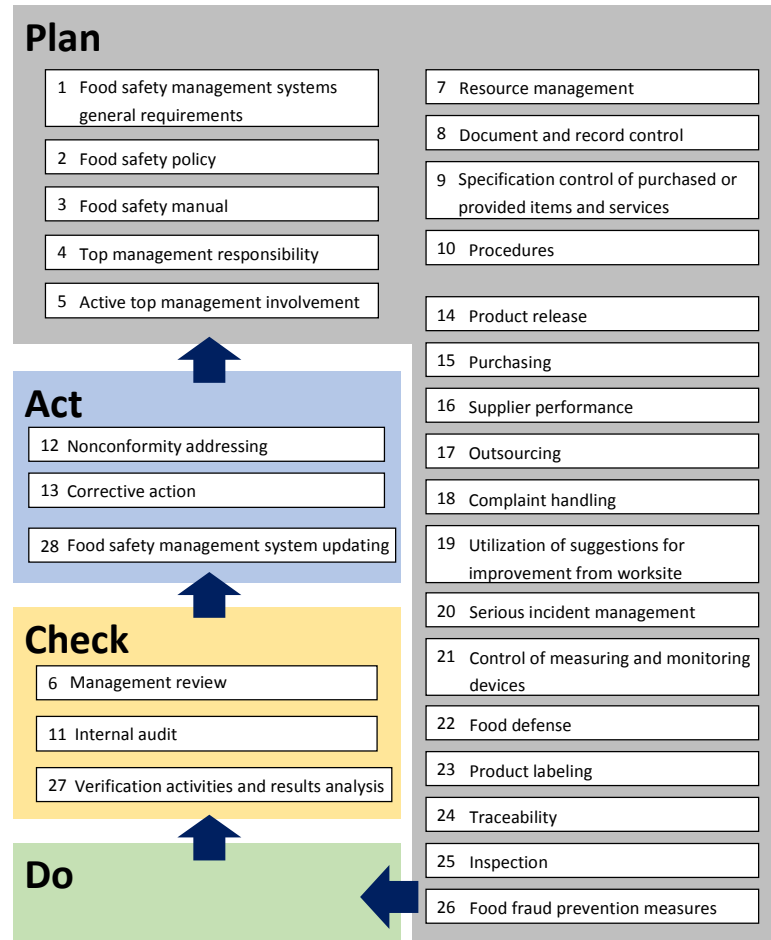
1.5 Continuous Improvement

Organizations are required to fulfill requirements for organizations, make continuous improvement to the organization's food safety management, and to maintain and improve the level of the food safety management. Therefore, requirements for organizations are formulated on the basis of repeating Plan-Do-Check-Act (PDCA) cycles.

Each item of requirements for organizations specified by the Scheme is closely linked to one another within a PDCA cycle. Additionally, a PDCA cycle exists within each requirement item. Organizations are required to understand the whole image of requirements and fulfill each individual requirement item.

Requirements for organizations in PDCA cycle are summarized in the figure below.

FSM



HACCP, GMP

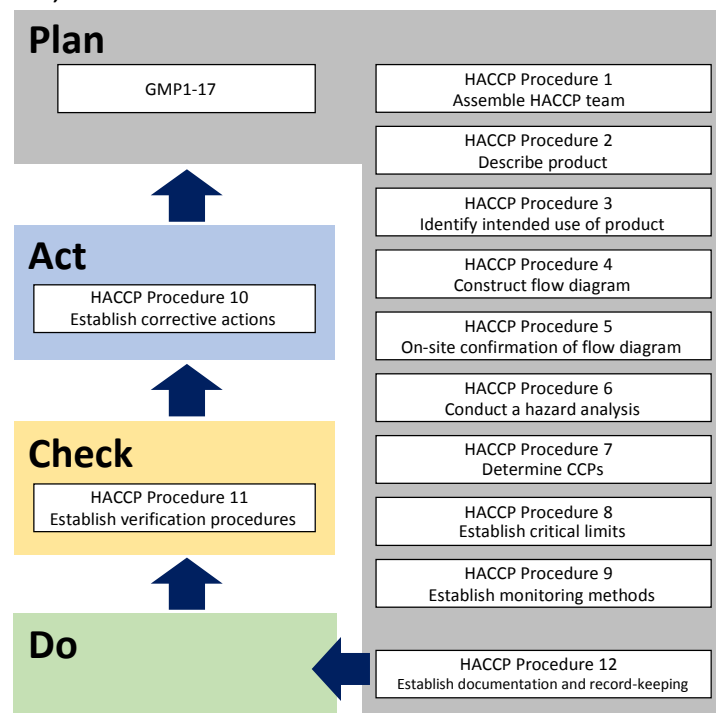


Figure. Concept of PDCA

(Reference) Sector categorization is as shown in the table below;

List of JFS Standard Sectors

The categories below are used in this JFS Standard.

The “manufacturing sector” refers to EI-EIV.

Code	Category	Code	Category
AI	Farming of Animals for Meat/ Milk/ Eggs/ Honey	F	Production of feed
AII	Farming of Fish and Seafood	G	Catering
BI	Farming of Plants (other than grains and pulses)	H	Retail / Wholesale
BII	Farming of Grains and Pulses	I	Provision of Food Safety Services
C	Animal Conversion	J	Provision of Storage and Distribution Services
D	Pre-process handling of plant products, nuts and grain	K	Manufacture of Food Processing Equipment
EI	Processing of perishable animal products	L	Production of (Bio) Chemicals (Additives, Vitamins, Minerals, Bio-cultures, Flavorings, Enzymes and Processing aids)
EII	Processing of perishable plant products		
EIII	Processing of perishable animal and plant products (mixed products)	M	Production of Food Packaging
EIV	Processing of ambient stable products	N	Food Broker / Agent

Extracted from Annex 1: GFSI Scope of Recognition, GFSI Guidance Document Version 6.4

2. Specific Requirements (Standard)

2.1 Food safety management systems (FSM)

Number	Clause Name	Requirements
FSM 1	Food safety management systems general requirements	<p>The organization shall document, implement and maintain the elements of the organization's Food Safety Management Systems. Additionally, the organization shall continually improve the organization's Food Safety Management Systems properly adapting to changes in the surrounding social environment. The food safety management systems shall:</p> <ul style="list-style-type: none"> a) clarify the scope of application of the food safety management systems, b) comply with laws and regulations on food safety, c) identify the processes needed for the food safety management systems, d) determine the sequence and interaction of these processes, e) determine the criteria and methods required to ensure the effective operation and control of these processes, f) secure information necessary to maintain the operation and monitoring of these processes, g) measure, monitor and analyze these processes and implement actions necessary to achieve planned results and continuous improvement. <p>Changing of a food safety management system shall be conducted systematically. On changing, considerations shall be given to maintaining the completeness of the food safety management system.</p>
FSM 2	Food safety policy	<p>The top management 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. The top management shall ensure the organization to establish determinable objectives consistent with the organization's food safety policy, formulate plans to achieve the objectives, monitor the objectives, and to update the objectives as necessary.</p>
FSM 3	Food safety manual	<p>The organization shall have a documented Food Safety Manual having a scope appropriate to the range of business activities to be covered, including documented procedures or specific reference to them and describing the interaction of the related process steps.</p>
FSM 4	Top management responsibility	<p>The top management shall establish a clear organizational structure, which unambiguously defines and documents the job functions, responsibilities, reporting relationships and information sharing of at least those staff whose activities affect food safety.</p> <p>The top management shall appoint person(s) responsible for the operation of the organization's food safety management system.</p>
FSM 5	Top management commitment	<p>The top management shall provide evidence of their commitment to establish, implement, maintain and improve the food safety management system.</p>

Number	Clause Name	Requirements
FSM 6	Management review	<p>The top management shall review the verification of the food safety management system and HACCP Plan, at planned intervals, to ensure their continuing suitability, adequacy and effectiveness.</p> <p>The HACCP Plan shall also be reviewed in the event of any change that impacts food safety. Such a review shall evaluate the need for changes to the entire food safety management system, including the food safety policy and food safety objectives.</p>
FSM 7	Resource management	<p>The top management shall determine and provide, in a timely manner, all the resources needed to implement, maintain and improve the food safety management system.</p>
FSM 8	Document and record control	<p>The organization shall formulate document control procedures to demonstrate compliance with this Standard.</p> <p>All records that demonstrate the effective operation and control of its processes and its management of food safety shall be securely retained for a time period required to meet customer or legal requirements, effectively controlled and readily accessible when needed.</p>
FSM 9	Specification control of purchased or provided items and services	<p>The organization shall ensure that, for all inputs to the process, items and services (including materials and ingredients, utilities and services (e.g., electricity, water, transport, maintenance)) that are purchased or provided and have an effect on the safety of final product, documented specifications are prepared, maintained, securely retained and readily accessible when needed.</p>
FSM 10	Procedures and instructions	<p>The organization shall design its products taking into account all relevant safety requirements. The organization shall prepare and control work procedures and instructions for all processes and operations having an effect on food safety, through establishment of GMP and implementation of HACCP.</p>
FSM 11	Internal audit	<p>The organization shall plan and implement internal audits covering the scope of the food safety management system, including the HACCP Plan.</p> <p>The results of internal audits and corrective action shall be recorded.</p> <p>The organization shall specify the competence required for internal auditors and provide training for the internal auditors.</p>
FSM 12	Nonconformity control	<p>The organization shall establish effective processes to ensure that any product, which does not conform to food safety requirements, is clearly identified, controlled, discarded, modified, reprocessed and/or corrected to prevent unintended use or delivery.</p> <p>These processes shall be defined in a documented procedure that is securely retained and readily accessible when needed.</p>
FSM 13	Corrective action	<p>The organization shall establish procedures for the determination and implementation of corrective action in the event of any nonconformities relating to food safety.</p> <p>In the case of deviance or violation, the organization shall identify the root cause, endeavor to prevent recurrence, and confirm the effectiveness of corrective action.</p>
FSM 14	Product release	<p>The organization shall prepare and implement appropriate product release procedures.</p>

Number	Clause Name	Requirements
FSM 15	Purchasing	The organization shall control purchasing processes to ensure that all externally sourced materials and ingredients, supplies and services, which have an effect on food safety, conform to requirements.
FSM 16	Supplier performance	The organization shall establish, implement and maintain procedures for the evaluation, approval and continued monitoring of suppliers, which have an effect on food safety. The results of evaluations, investigations and follow up actions shall be recorded.
FSM 17	Outsourcing	The organization shall, where the organization chooses to outsource any process that may affect food safety, shall ensure control over such processes. Control of such outsourced processes shall be identified, documented and monitored within the food safety management system.
FSM 18	Complaint handling	The organization shall establish, implement and maintain an effective system for the management of complaints and complaint data to control and correct shortcomings in food safety.
FSM 19	Utilization of suggestions for improvement from workers	The organization shall establish and implement a system to properly utilize suggestions for improvement of food safety from workers.
FSM 20	Serious incident management	The organization shall establish, implement and maintain an effective incident management procedure. The incident management procedure shall be regularly tested for all products it supplies and cover planning for product withdrawal and product recall as required. The effectiveness of the incident management procedure shall be verified at least once per year, and the results shall be recorded.
FSM 21	Control of measuring and monitoring devices	The organization shall identify the measurement of parameters critical to ensure food safety, identify the measuring and monitoring devices required, and carry out calibration of these measuring and monitoring devices by a method in compliance with a national, international or equivalent standard.
FSM 22	Food defense	The organization shall established a documented assessment procedure to address risks of intentional food contamination by persons inside or outside the organization, and establish, implement and maintain a system to mitigate or eliminate the identified risks. The system shall cover GMP and shall be incorporated into the food safety management system.
FSM 23	Product labeling	The organization shall ensure that all product bears or is accompanied by information to enable the safe handling, display, storage, preparation and use of the product within the food supply chain or by the consumer. Procedures for ensuring correct labeling or appending shall be established and implemented.

Number	Clause Name	Requirements
FSM 24	Traceability	<p>The organization shall establish, implement and maintain appropriate procedures and systems to ensure:</p> <ul style="list-style-type: none"> a) Identification of any outsourced materials and ingredients (including packaging materials), products or services, b) Product identification that includes, as a minimum, the name and address of the producer, c) Identification of batches, half-finished products, work in progress, regenerated goods, repaired goods, final products, and packaging throughout the production process, d) A record of purchaser and delivery destination for all products supplied. <p>The procedures and systems shall be verified at least once a year, and the results shall be recorded.</p>
FSM 25	Analysis of input materials	<p>The organization shall establish and implement a system to ensure analysis of input materials and ingredients (including water) that have an effect on food safety. The inspection shall be conducted in compliance with a standard deemed equivalent to ISO 17025.</p>
FSM 26	Food fraud prevention	<p>The organization shall identify potential falsification of product record or labeling, deliberate contamination of product, etc., implement food fraud vulnerability assessment, and record the results.</p> <p>The organization shall prepare a documented plan clearly describing measures implemented by the organization to mitigate food safety risks arising from the identified food fraud Vulnerabilities The plan shall fully cover the scope of the relevant food fraud prevention system.</p>
FSM 27	Verification activities and result analysis	<p>The organization shall verify the implementation status of FSM, GMP and HACCP, and analyze the results of verification activities. Results of analysis and associated activities shall be recorded in an appropriate form. These results shall be reported to the top management at the management review.</p>
FSM 28	Food safety management system updating	<p>The top management shall ensure that the organization continually updates the organization's food safety management system. The organization shall, in order to achieve that, evaluate the organization's food safety management system at planned intervals.</p> <p>The organization shall report the system updating activities to the top management at the management review, and record the activities.</p>

2.2 Hazard control (HACCP)

	Clause Name	Requirements
HACCP Procedure 1	Assemble HACCP team	A HACCP team shall be assembled with competent staff.
HACCP Procedure 2	Describe product	Product specifications shall be described in written document. The document shall describe all product information necessary to conduct hazard analysis.
HACCP Procedure 3	Identify intended use	The intended use of product and target consumers shall be clearly described in written document.
HACCP Procedure 4	Construct flow diagram	The flow diagram that covers all steps in the operation shall be constructed.
HACCP Procedure 5	On-site confirmation of flow diagram	The flow diagram shall be reviewed whether it correctly reflects the existing process steps of the operation.
HACCP Procedure 6 (Principle 1)	Conduct a hazard analysis	The HACCP team shall list all of the hazards that are reasonably likely to occur at each process steps, conduct an analysis, and identify any necessary means to control them. Hazard shall include allergens where required.
HACCP Procedure 7 (Principle 2)	Determine Critical Control Points	Critical Control Points (CCPs) shall be determined.
HACCP Procedure 8 (Principle 3)	Establish critical limits for each CCP	Critical limits shall be specified for each CCP.
HACCP Procedure 9 (Principle 4)	Establish monitoring system for each CCP	Monitoring methods shall be established for each CCP.
HACCP Procedure 10 (Principle 5)	Establish corrective actions	Methods of corrective action (correction, cause unfolding and cause removal) shall be established for deviations from critical limit.
HACCP Procedure 11 (Principle 6)	Establish verification procedures	Verification procedures to confirm (1) whether the defined instructions (HACCP Plans) are kept and (2) whether the defined instructions are working as intended, shall be established. Verification shall be carried out considering the design of equipment, change in processing method and technology development within the manufacturing process.
HACCP Procedure 12 (Principle 7)	Establish documentation and record-keeping	Necessary documents shall be prepared and maintain and records shall be taken and retained.

2.3 Good Manufacturing Practice (GMP)

Number	Clause Name	Requirements
GMP 1	Facility environment	The site shall be located and maintained so as to prevent contamination and enable the production of safe products.
GMP 2	Site management	An appropriate standard for all grounds within the site shall be established and kept.
GMP 3	Design, construction and layout of facility, equipment and production	Site, building, and facility and equipment in plant shall be laid out, designed, constructed and maintained, to enable controlling the risk of product contamination caused by external and internal environment.
GMP 4	Manufacturing/storage area specifications, and utility management	Specifications of manufacturing and storage areas shall meet the intended Purpose. Procedures to control contamination and condensation shall be established and implemented, as necessary, for utilities such as air, compressed air and other gases, which may come into contact with food.
GMP 5	Devices and tools	Devices and tools shall be suitably designed for the intended use and shall be used, maintained and stored so as to minimize food safety risks.
GMP 6	Maintenance	A system of planned maintenance covering all items of equipment, which are critical to product safety, shall be established.
GMP 7	Staff facilities	Staff facilities shall be designed and used so as to minimize food safety risks.
GMP 8	Physical, chemical and biological product contamination risks	Appropriate facilities and procedures to control the risks of physical, chemical and biological contamination of product shall be established.
GMP 9	Segregation and cross-contamination	Procedures to prevent contamination and cross-contamination shall be established for raw materials and ingredients (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks, and finished products, covering all aspects of food safety including micro-organisms, chemicals and allergens.
GMP 10	Stock management	A system to use raw materials and ingredients (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks, and finished products by a designated order and within the expiry defined period shall be established.
GMP 11	Housekeeping, cleaning and hygiene	Housekeeping and cleaning shall be carried out throughout all the process steps and stages, and an appropriate hygiene level shall be maintained at all times by disinfecting where necessary. Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended use and stored appropriately.

Number	Clause Name	Requirements
GMP 12	Water and ice management	<p>Application-dependent quality standards shall be established for water (including steam and ice; the same applies hereinafter) used in food manufacturing, and the quality of water shall be regularly monitored and recorded.</p> <p>Water added to food and water that potentially come into contact with food shall be potable.</p> <p>Facilities, tools and procedures used for handling water shall be checked to prevent contamination.</p>
GMP 13	Waste management	<p>Adequate systems for the segregation, collection and disposal of waste material shall be established.</p> <p>Locations and containers for placing waste material shall be managed to prevent attraction of pests or generation of harmful organisms/micro-organisms. The traffic line of waste material shall be established so as to prevent cross-contamination for food.</p>
GMP 14	Pest control	<p>A system for controlling or eliminating the food safety risk caused by pest in the site or in the facilities shall be established.</p> <p>In the cases where chemicals are used, handling procedures not to affect food shall be established.</p>
GMP 15	Transport	<p>A documented system to ensure that containers and vehicles, including contracted out vehicles, used for the transportation of materials and ingredients (including packaging materials), partially processed products, work in progress, products being reprocessed, reworks, and finished products (including packed, fresh product in final packaging) are suitable for the intended use, maintained in good repair and clean shall be established.</p>
GMP 16	Personnel hygiene and health management	<p>Documented personal hygiene standards based on risk of contamination in accordance with product characteristics shall be established and implemented.</p> <p>The requirements shall include hand washing methods and frequency, health status confirmation methods, rules on workwear and shoes, methods of entry to and exit from the production area, food handling methods and prevention of foreign material contamination. These requirements shall be made fully known to employees, and shall also apply to contractors and visitors without exception.</p>
GMP 17	Education and training	<p>A system to ensure all employees are adequately educated and trained on food safety principles (including HACCP) and practices, commensurate with their activity, shall be established.</p> <p>A system to ensure all employees are adequately instructed and supervised shall be established.</p> <p>This education and training shall ensure all employees become aware of their own roles in food safety and the significance of their activity.</p>

Annex

• Definitions

	Term	Definition
1.	categories	Range of application of certification.
2.	CCP (critical control point)	Step at which control can be applied and is essential or eliminate a food safety hazard or reduce it to an acceptable level. (Cited from the definition in ISO 22000:2005)
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	The state wherein correct procedures are being followed and criteria are being met. (Cited from the definition in CAC/RCP 1-1969, Rev. 4-2003 - Annex)
5.	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 to entry: A correction can be, for example, rework or regrade. (Cited from the definition in ISO 9000:2015)
6.	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)
7.	critical limit	Criterion which separates acceptability from unacceptability. Note to entry: Critical limits are established to determine whether a CCP remains in control. If a critical limit is exceeded or violated, the products affected are deemed to be potentially unsafe. (Cited from the definition in ISO 22000:2005)
8.	document	Information and the medium on which it is contained. Example: Record, specification, procedure document, drawing, report, standard 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.)
9.	employee, personnel	All personnel in an organization who are involved in work related to food safety, including part-timers, contractors, and dispatched workers.
10.	flow diagram	Diagrams constructed to show all the process steps for specified product.
11.	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.
12.	food chain	Sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption. (Cited from the definition in ISO 22000:2005)
13.	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 22000:2005)

	Term	Definition
14.	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 22000:2005)
15.	hazard	A biological, chemical or physical agent 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, Codex Alimentarius Commission (CAC/RCP 1-1969, Rev. 4-2003))
16.	intended use	Way of use or consumption of product or building/equipment designated at the time of planning and designing.
17.	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.)
18.	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)
19.	materials and ingredients	Ingredients refer to those used as part of product and do not retain the original form when the product is finished. Examples are sugar, powdered milk, additives, and spices. Materials is a general term referring to packaging materials, processing aids, cleaning/cleansing agents, lubricants, etc.
20.	monitoring	Conducting a planned sequence of observations or measurements to assess whether action taken to control the food safety is operating as intended. (Referenced to ISO 22000:2005)
21.	nonconformities	Non-fulfilment of a requirement. (Cited from the definition in ISO 9000:2015)
22.	packaging materials	Materials used for packaging food, such as papers, plastics, wooden boxes, cardboard, PET bottles, and tin cans.
23.	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. tyres). 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 programme, mobile phone app, instruction manual dictionary content, musical composition copyright, driver’s license). (Cited from the definition in ISO 9000:2015)
24.	recall	Cessation of supply of product and recovering of all the products including those kept by consumers, retail stores, and stocks under distribution.
25.	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
26.	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)
27.	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.
28.	supplier, customer	Business operators from whom materials and ingredients, utilities, services, etc., are provided, and business operators to whom manufactured food is sold.
29.	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.)
30.	updating	Immediate and/or planned activity to ensure application of the most recent information. (Cited from the definition in ISO 22000:2005)
31.	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)