JFS-B Standard

(Sectors: E/L)

<Food Manufacturing>

[Guideline]

Ver. 2.0

Japan Food Safety Management Association

October 23, 2019

Contents

Preface

This guideline describes approaches and specific examples that organizations should implement with the JFS-B Standard issued by the Japan Food Safety Management Association (JFSM).

The food safety management system that is established by each food business operator in each of their organizations is dependent on many factors, including the business type, form, scale, and social background. It is assumed that each organization will use this guideline as a reference in order to establish a food safety management system that is suitable for its circumstances.

Figure 1 shows an overview of the JFS Standard (Sector: E/L). This guideline applies to the B Standard of the food manufacturing sector (EI to EIV) and to the chemical product (including biochemicals) manufacturing sector (L). (Figure 2)

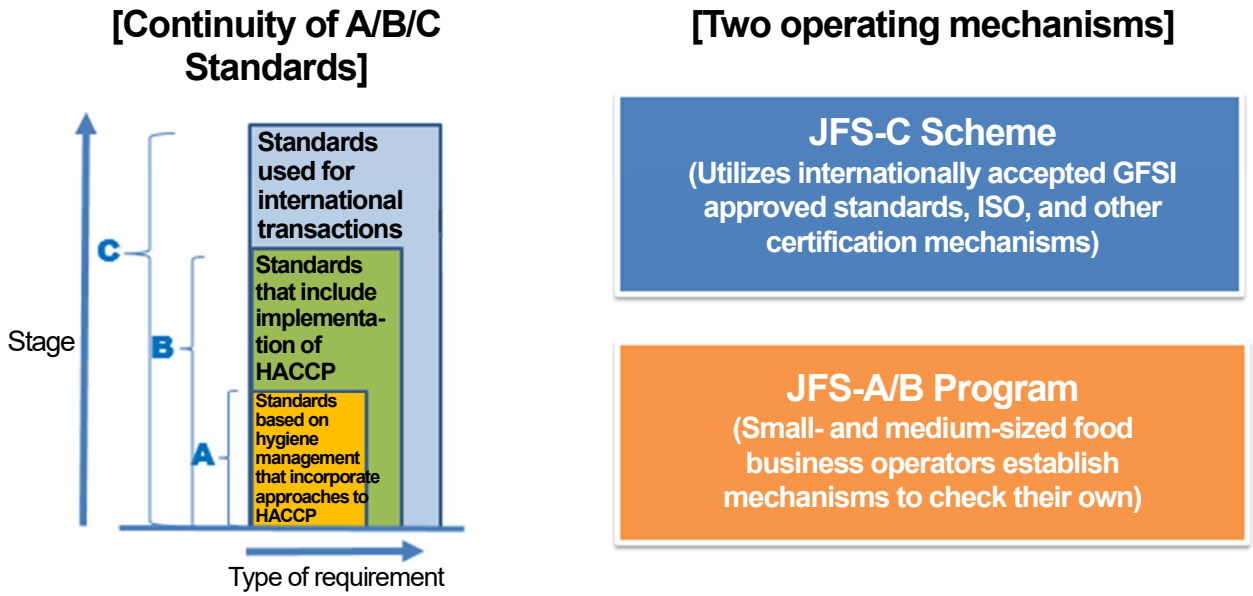


Figure 1. Overview of JFS Standards, certification schemes and programs

This JFS Food Safety Management Standard utilizes the following sector categories.

SECTOR	Sub-sector	CATEGORY
A	AI	Farming of Animals for Meat/ Milk / Eggs / Honey
	AII	Farming of Fish and Seafood
B	BI	Farming of Plants (Other than grain and pulses)
	BII	Farming of Grain and Pulses
C	-	Animal Conversion
D	-	Pre-process handling of plant products, nuts and grain
E	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
F	-	Production of feed
G	-	Catering
H	-	Retail / Wholesale
I	-	Provision of Food Safety Services

J	-	Provision of Storage and Distribution Services
K	-	Manufacture of Food Processing Equipment
L	-	Production of (Bio) Chemical (Additives, Vitamins, Minerals, Bio-cultures, Flavourings, Enzymes and Processing aids)
M	-	Production of Food Packing
N	-	Food Broker / Agent

Figure 2. Sectors in the JFS-A/B/C Standards

Note: Among the sectors cited in the GFSI, the JFS-A/B Standard E/L sectors that apply are framed.

The JFS-B Standard is intended for business operators that implement HACCP in addition to general hygiene management.

The JFS-B standard is a part of the Global Markets Program (a food safety initiatives program for small and medium-sized businesses) of the Global Food Safety Initiative (GFSI) in order to align with international awareness regarding food safety, and refers to requirements and includes intermediate items (Figure 3). This participation makes it possible to comply with food safety management system activities being studied internationally, and when an organization seeks to improve its efforts, such as when the scale of the business or the sales channels are expanding, the food safety stage to be addressed next is clearly defined.

The JFS Standards consist of three layers of requirements, namely, Food Safety Management Systems (FSM), hazard control (Hazard Analysis and Critical Control Point; HACCP) and Good Manufacturing Practice (GMP) (Figure 3).

Note that the order of the Standards does not imply the sequence in which an implementation system should be developed. Actually, it is possible for an organization to develop a system starting from GMP or from FSM, so each organization should proceed in the way that is most suitable for its circumstances.

This guideline presents approaches and specific examples as a reference when utilizing the JFS-B standard. However, as these are only examples, if an organization can technically and scientifically explain that it meets the requirements of the JFS Standard it can choose other approaches and methods. By using this guideline along with research data and food safety theory published by research institutions and industry groups, an organization can also make use of the technical information and expertise in each industry.

Laws and regulations relating to food safety management systems vary depending on the type of business and the region. The JFS Standards and this guideline are based on compliance with such laws and regulations, but as this guideline does not cover all laws and regulations, each organization needs to confirm its own compliance individually.

We hope that this guideline helps you understand the JFS Standard.

<Structure of this guideline>

- Requirements
- Approaches, specific examples
- Legal provisions* relating to food safety that require reference

* Legal provisions refer to mandatory Japanese laws and regulations.

JFS-A Ver.2.0 11 requirements		JFS-B Ver.2.0 19 requirements		JFS-C Ver.2.3 30 requirements	
				FSM 1	Food safety management general requirements
FSM 2	Food safety policy	FSM 2	Food safety policy	FSM 2	Food safety policy
				FSM 3	Food safety manual
FSM 4	Management responsibility	FSM 4	Management responsibility	FSM 4	Management responsibility
FSM 5	Management commitment	FSM 5	Management commitment	FSM 5	Management commitment
				FSM 6	Management review
FSM 7	Resource management	FSM 7	Resource management	FSM 7	Resource management
FSM 8	General documentation requirements	FSM 8	General documentation requirements	FSM 8	General documentation requirements
				FSM 9	Specified requirements
		FSM 10	Procedure	FSM 10	Procedure
				FSM 11	Internal audit
FSM 12	Control of nonconformity	FSM 12	Control of nonconformity	FSM 12	Control of nonconformity
FSM 13	Corrective action	FSM 13	Corrective action	FSM 13	Corrective action
FSM 14	Product release	FSM 14	Product release	FSM 14	Product release
		FSM 15	Purchasing	FSM 15	Purchasing
		FSM 16	Supplier performance	FSM 16	Supplier performance
				FSM 17	Outsourcing
		FSM 18	Complaint handling	FSM 18	Complaint handling
				FSM 19	Serious incident and Crisis Management
FSM 20	Serious incident management	FSM 20	Serious incident management	FSM 20	Serious incident management
FSM 21	Control of measuring and monitoring devices	FSM 21	Control of measuring and monitoring devices	FSM 21	Control of measuring and monitoring devices
		FSM 22	Food defense	FSM 22	Food defense
		FSM 23	Product labelling	FSM 23	Product labelling
		FSM 24	Traceability	FSM 24	Traceability
FSM 24	Traceability	FSM 25	Testing	FSM 25	Testing
				FSM 26	Prevention of the food fraud
				FSM 27	Analysis of verification activities / results
				FSM 28	Renewal of food safety management system
		FSM 29	Allergen management	FSM 29	Allergen management
				FSM 30	Food manufacturing environment monitoring

JFS-A Ver.2.0 HACCP10 items + GMP16 items		JFS-B Ver.2.0 HACCP 12 items + GMP 16 items		JFS-C Ver.2.3 HACCP 12 items + GMP 18 items	
HACCP1:	Formation of HACCP team	HACCP1:	Formation of HACCP team	HACCP1:	Formation of HACCP team
HACCP2:	Checking of product characteristics	HACCP2:	Checking of product characteristics	HACCP2:	Checking of product characteristics
HACCP3:	Checking how to use product	HACCP3:	Checking how to use product	HACCP3:	Checking how to use product
HACCP4:	Creating a flow diagram (process diagram)	HACCP4:	Creating a flow diagram (process diagram)	HACCP4:	Creating a flow diagram (process diagram)
HACCP5:	On-site checking of flow diagram	HACCP5:	On-site checking of flow diagram	HACCP5:	On-site checking of flow diagram
HACCP6/7:	Acceptance of handbook	HACCP6:	Hazard analysis	HACCP6:	Hazard analysis
		HACCP7:	Establishment of Critical Control Points	HACCP7:	Establishment of Critical Control Points
HACCP8/9:	Acceptance of management standards	HACCP8:	Establishment of Critical Limits	HACCP8:	Establishment of Critical Limits
		HACCP9:	Monitoring System	HACCP9:	Monitoring System
HACCP10:	Establishment of corrective actions	HACCP10:	Establishment of corrective actions	HACCP10:	Establishment of corrective actions
HACCP11:	Establishment of verification procedures	HACCP11:	Establishment of verification procedures	HACCP11:	Establishment of verification procedures
HACCP12:	Documentation and record keeping	HACCP12:	Documentation and record keeping	HACCP12:	Documentation and record keeping
				GMP 1:	Location environment
GMP 2:	Local environment	GMP 2:	Local environment	GMP 2:	Local environment
GMP 3:	Facility design, construction, layout and product flow	GMP 3:	Facility design, construction, layout and product flow	GMP 3:	Facility design, construction, layout and product flow
GMP 4:	Management of manufacturing and storage areas and utilities	GMP 4:	Management of manufacturing and storage areas and utilities	GMP 4:	Management of manufacturing and storage areas and utilities
GMP 5:	Equipment	GMP 5:	Equipment	GMP 5:	Equipment
GMP 6:	Maintenance	GMP 6:	Maintenance	GMP 6:	Maintenance
GMP 7:	Staff facilities	GMP 7:	Staff facilities	GMP 7:	Staff facilities
GMP 8:	Specification of contamination risk and control	GMP 8:	Specification of contamination risk and control	GMP 8:	Physical, chemical and biological product contamination risk
GMP 9:	Cross-contamination	GMP 9:	Cross-contamination	GMP 9:	Segregation and cross-contamination
GMP 10:	Stock management	GMP 10:	Stock management	GMP 10:	Stock management
GMP 11:	Housekeeping, cleaning and hygiene	GMP 11:	Housekeeping, cleaning and hygiene	GMP 11:	Housekeeping, cleaning and hygiene
GMP 12:	Water quality (including ice)	GMP 12:	Water quality (including ice)	GMP 12:	Water quality (including ice)
GMP 13:	Waste management	GMP 13:	Waste management	GMP 13:	Waste management
GMP 14:	Pest control	GMP 14:	Pest control	GMP 14:	Pest control
GMP 15:	Transport	GMP 15:	Transport	GMP 15:	Transport
GMP 16:	Personal hygiene and medical screening	GMP 16:	Personal hygiene and medical screening	GMP 16:	Personal hygiene and medical screening
GMP 17:	Education / training	GMP 17:	Education / training	GMP 17:	Education / training
				GMP 18:	Product packaging and storage

[JFS-B Standard Guideline]

JFS-B Standard (Sectors: E/L) <Food Manufacturing>

Ⅰ Food Safety Management System (FSM)

FSM 2 Food Safety Policy

● Requirements

Top management shall have a clearly and concisely documented food safety policy that states how the organization ensures the safety of its products.

● Concepts, specific examples

○ Top management shall formulate a food safety policy that meets safety and appropriate quality standards and ensure that all employees are able to understand and recognize it. The policy shall be created with the following points in mind:
  ① The organization shall base their activities on consumers, and provide consumers with safe and reliable foods.
  ② The organization shall respond appropriately to changes in the social environment and observe laws and fair rules.

○ The food safety policy shall be created with the involvement of top management, and be regularly reviewed to determine its appropriateness.

FSM 4 Top Management Responsibility

● Requirements

Top management shall establish a contact system for directing, reporting and consulting.
Top management shall determine the person(s) responsible for food safety management.

● Approaches, specific examples

Role of top management

○ Top management shall periodically verify and review the effects of the organization's own efforts to ensure food safety and quality and ensure the trust of consumers.

○ Top management shall clarify the organization chart, including the contact system for directing, reporting and consulting.

Contact system for instructing, reporting and consulting

○ For the purpose of clarification of the contact system for instructing, reporting and consulting, it is easier to manage if the activities required for food safety are decided in meetings or morning assemblies. Instructing, reporting and consulting involve the following:
  ・ Instructing: Operations and roles shall be clarified by supervisors and managers.
  ・ Reporting: The worker who performed the operation reports about it to a supervisor, manager, etc.
  ・ Consulting: When it is not possible to determine the appropriateness of an operation or when conducting a new activity, consulting shall be used to confirm the appropriateness.

○ A contact system shall be established that enables safe foods to be shipped even if there is a major change in the manufacturing environment, such as a sudden increase in orders, a moving ahead of the shipping time, or a shortage of staff. (Shipping determinations are also related to the procedure of FSM14.)

Food safety officer
○ The person in charge of food safety management shall be designated as the food safety officer. ○ The food safety officer will be capable of developing an effective system if there is a food safety policy, food safety knowledge, on-site knowledge and experience in the organization. ○ If there is a separate food hygiene manager or food hygiene officer, it is important that they share and coordinate information with the food safety officer. In addition, it is also possible for the same person to serve in both positions concurrently.

● Required reference to legal provisions related to food safety

Role of top management
◎ A food sanitation supervisor or a food hygiene manager who meets the necessary requirements shall be assigned. * Food sanitation supervisor: Shall be assigned under the provisions of Article 48 of the Food Sanitation Act. The applicable foods are whole milk powder, sweetened milk powder, adjusted milk powder, meat products, fish meat ham, fish meat sausage, irradiated food, edible oils and fats, margarine, shortening, and additives. * Food hygiene manager: Based on management standard guidelines of the Ministry of Health, Labor and Welfare to be implemented by food business operators, unless a food sanitation supervisor is assigned, a food hygiene manager shall be assigned at facilities where a business license is required according to the regulations of each prefecture. ◎ The food sanitation supervisor or a food hygiene manager shall direct hygiene management while respecting the opinions of the food safety officer.
Role of food safety officer
◎ The food safety officer shall systematically implement hygiene management, including daily inspections, in accordance with directions from top management. ◎ The food safety officer shall take the required precautions related to hygiene management matters to prevent the occurrence of food hygiene hazards, and convey opinions to top management as necessary. ◎ The food safety officer shall prepare documents related to hygiene management of facilities, products, etc., make them known to food handlers, and confirm them.

FSM 5 Top Management Active Involvement

● Requirements

Top management shall provide a statement of job descriptions（rules for division of duties）for persons who may affect food safety and make it known to the workers. In addition, top management shall keep records that serve as evidence that workers have been informed.

● Concepts, specific examples

○ Top management shall determine the organization and duties in the business after ensuring food safety and legal compliance. ○ A job description (rules for division of duties) is a document that details the business scope, business description, and responsibilities of each department of the organization. ○ The job description document clarifies the work to be performed by the person(s) in charge or the department to which a person belongs, and makes it easier to consider the required skills and the number of staff. ○ “Persons who may affect food safety” refers not only to those directly involved in food manufacturing in the manufacturing department, but also to all persons in departments related to food safety activities. ○ “Evidence that workers have been informed” refers to a record that was provided to workers when indicating a work plan or a notice that is posted on a wall.

FSM 7 Resource Management

• Requirements

Top management shall secure the management resources (people, things and money) necessary to implement the organization's efforts to ensure food safety (hazard control (HACCP)) and good manufacturing practices (GMP) in accordance with this Standard.

● Concepts, specific examples

- ○ Top management shall make management resources (people, things and money) available to ensure food safety.
- ○ Since there are limits to management resources, top management shall set priorities and make efforts to maximize the effectiveness of resources and ensure food safety rationally.
- ○ In order to respond to changes in the manufacturing environment, top management shall constantly check for unrealistic goals or plans, and that on-site workers are well-trained.
- ○ Specific management resources are as follows.
  - ・ People: Workers (numbers and capabilities)
  - ・ Things: Buildings, interiors, machinery, equipment, facilities, etc.
  - ・ Money: Funds used for food safety activities
- ○ Example of rational implementation 1: Training
  - ・ Costs increase when many workers are involved in external training and it becomes difficult to conduct such training regularly. However, if one person receives external training, then involves other workers by training them inside the organization, the entire organization can share the latest information.
- ○ Example of rational implementation 2: Interior
  - ・ When the interior of the facility has deteriorated over long-term use, it effective to plan to remodel the interior environment over a period of several years by giving priority to issues that directly affect food safety instead of renovating everything all at once.

FSM 8 Document and record control

● Requirements

Procedures shall be established and implemented to create, maintain, and preserve documents and records for process control to ensure food safety and to demonstrate effective operations.
Records required as evidence of the implementation of food safety management shall be kept and properly maintained.

● Concepts, specific examples

What is a document?

- ○ Documents include records.
  Documents refers not only to written information on paper, but also to information that may include illustrations, figures, images, sounds, and may be recorded on electronic media.
- ○ Documents are prepared for various reasons such as to ① explain safety management to those outside the company, ② be used to investigate the cause of any problems that occur, ③ standardize work, minimize errors and variations, ④ clarify any points to be noted, and ⑤ serve as a record of the document itself.

Documents for certifying process control to ensure food safety and effective operation

- ○ “Documents for certifying process control to ensure food safety and effective operation” are documents that clearly describe the key points and precautions in process control, and enable proper and effective operation based on them and serve as evidence of such management.
  The content of such documents can be, for example, temperature control such as of heating and cooling, specific measures to prevent contamination, and conveyor speed.
  The required documents will vary according to the business type and conditions, size, and complexity of the organization.

○ Document control shall be implemented so that latest version of a document can always be referenced. This is also useful for determining the rules for correcting and storing documents.
  - An establishment number, abolition number, etc. shall be assigned documents.
  - Documents and records shall be stored for five years.

○ In this Standard, the documents listed in the following table are specifically requested.
Whether these documents are adequate or not depends on an organization's circumstances, and this shall be determined by each organization.

Item	Document content	Checking
FSM 2	Food Safety Policy	
FSM 5	Job description statement (rules for division of duties)	
FSM 8	Document control procedures (records certifying control implementation)	
FSM 10	Work procedures and directions for implementing GMP and HACCP (shown as information visible to workers)	
FSM 13	Nonconformity corrective action	
FSM 14	Product specifications	
FSM 16	Record: Supplier assessments, surveys, follow-up results	
FSM 20	Incident response manual	
FSM 24	Record: ・Identification of all externally sourced materials, products or services. ・Identification of batches, semi-finished products, work in process, remanufactured products, reworked products, finished products and packaging throughout the entire manufacturing process ・Record of buyers and destinations of all products supplied	
FSM 25	Record: Inspection record	
FSM 29	Allergen management plan	
HACCP Procedure 2	Product specifications	
HACCP Procedure 3	Intended use of product (how to use), target consumers	
HACCP Procedure 4	Flow diagram (process diagram)	
HACCP Procedure 12 (Principle 7)	Documents and records required for HACCP planning	
GMP 12	Record: Record of water quality standard conformance	
GMP 15	Mechanisms for keeping containers and transportation vehicles clean, the appropriateness of their intended use, and maintenance	
GMP 16	Appropriate hygiene standards for workers	

○ Having too many documents is not good as it becomes impossible to properly control them, which can easily result in a situation where there is a disparity between the actual conditions and the information in the documents. Make sure to control your documents using the minimum number required for your organization.

Records

○ Records are an effective means of ① explaining that food safety management is being properly implemented, ② analyzing trends over a period of time, and ③ sharing information within the organization. Decide on what records are required for your organization and keep records.
○ The required documents will vary according to the business type and conditions, size, and complexity of the organization.
○ Establish an appropriate storage period for records. For example, storing records until the expiration date makes it possible to learn the cause when a problem occurs.
○ Define the rules for making modifications to records. To prevent a revision from being suspected as being a "deception", for example, one method of making corrections calls for the original to be crossed-out with a double line, and the date of the correction and the name of the person who made the correction written at the corrected part.

● Required reference to legal provisions related to food safety

◎ Product information shall be properly maintained, stored and updated as necessary.

FSM 10 Procedure

● Requirements

The relevant safety requirements shall be taken into consideration when designing products and manufacturing processes. For all processes and operations that affect food safety, good manufacturing practice (GMP) shall be developed, and the work procedures and directions for implementing GMP and HACCP shall be made visible to workers.

● Concepts, specific examples

○ Determine roles and share procedures for all processes and business operations that affect food safety.
Use documents as necessary to make the procedures known to workers, and use methods that are easy for workers to understand.
○ The key points for procedures and documents are shown below.
- Define procedures for all processes that affect food safety.
- Procedures need to be easy to understand for any new workers joining the company or for retraining.
- Procedures are easier to create when you clarify the "when, where, who, what, and how".

FSM 12 Control of nonconformity

● Requirements

Regarding raw materials (including containers and packaging materials), semi-finished products, work in progress, remanufactured products, reworked products, and final products, anything that may cause safety issues shall not be used, and rules shall be created to prevent them from being shipped.

● Concepts, specific examples

○ The role of these requirements is to establish a barrier at each stage in the process up to the final product and stop it when there is a nonconformity.
○ Regarding raw materials (including containers and packaging materials), semi-finished products, work in progress, remanufactured products, reworked products, and final products, treat products that pose safety issues as nonconforming items. The relevant organization determines the person in charge, controls the nonconformity based on procedures, and ensures that nonconforming items will not be used unintentionally or shipped in error.

○ Nonconformities may be found during business activities or due to complaints from customers, as well as during inspections.
○ It is effective to establish manufacturing and inspection procedures in advance in order to find nonconformities in each process.
○ If finding a nonconformity is recognized as something bad, it will be difficult to obtain reporting from the site. For this reason, start with the recognition that nonconformities can be detected by process control.
○ Identify and isolate any nonconforming products that have been found so that they cannot be used in error.
○ Discard or correct (by reprocessing, reworking, etc.) nonconforming products.
○ Thereafter, implement FSM 13 if it is necessary to prevent a recurrence.

FSM 13 Corrective Action

● Requirements

Corrective actions in the event of a nonconformity (correcting the nonconformity, determining the cause of the nonconformity, and eliminating the cause) shall be documented and implemented.

● Concepts, specific examples

○ The organization documents and implements actions to ensure that any detected nonconformities are eliminated as soon as possible and to prevent recurrence.
○ A person who has the capability of performing cause analysis and planning countermeasures formulates and executes corrective actions.
○ In the event of an incident involving non-conforming material, end product or manufacturing process management procedures, learn the root cause of the nonconformity and take corrective actions to prevent recurrence.
○ The flow of corrective actions is as follows.
① Understand the actual situation of the nonconformity (including customer complaints)
② Identify the cause of the nonconformity
③ Implement necessary measures to prevent the nonconformity from recurring
④ Review the effectiveness of the corrective actions taken
⑤ Record a series of corrective actions

FSM 14 Product Release

● Requirements

Appropriate product specifications shall be prepared in accordance with food safety requirements, laws and customer requirements, and appropriate procedures for product release (shipment) shall be established and implemented.

● Concepts, specific examples

Product specifications

It is necessary to clarify what a product is by creating specifications for the products that are handled.
○ The following items shall conform to the requirements in the product specifications.
・ Exterior (packaging form, packaging material, etc.)
・ Product specifications (raw materials, product characteristics, food safety standards, etc.)
・ Display (label, product display, seller information, etc.)
○ The following actions are to be taken when implementing the created product specifications.
・ Designate a qualified person to manage the product specifications and related documents.
・ Manage the content required by business partners and consumers in the product information as customer requirements as necessary.
・ Establish the storage period of the product specification sheet based on a consideration of the sales period of the product.

・Establish a system to notify parties inside and outside the organization of changes in the product specifications.
・Periodically check that the product specifications have not been tampered with when necessary.

Release procedures

○ The product release procedures consist of implementing the following.
・Confirm that the release procedures are up to date and available to workers
・Confirm that the specifications of raw materials, materials, additives, packaging materials, recycled products, reworked products, and final products are clear.
・Confirm that the product to be shipped conforms to the product specifications
・Confirm that not only product specifications but also the process control are being properly performed
・Clarify who will make the final shipping decision.

● Required reference to legal provisions related to food safety

Information management

◎ Product information shall be properly maintained, stored and updated as necessary.

Information for display

◎ Product expiration dates shall be established based on scientific evidence.
◎ A list of product expiration dates shall be created and prepared in necessary places such as the packaging room.

FSM 15 Purchasing

● Requirements

Purchasing procedures shall be developed and implemented to ensure that all outsourced raw materials, materials and services that may affect food safety meet the requirements of the organization.
When outsourcing a process that may affect food safety, the process shall be controlled properly, such as by providing specifications or contracts that specify the control method to the subcontractors.
When purchasing or outsourcing from a previously unused supplier in an emergency (such as a natural disaster), the supplier's facility shall be assessed to confirm that it meets the specifications required for the product and that there are no problems with food safety.

● Concepts, specific examples

○ Each business needs to decide how to confirm what to purchase by outsourcing according to the degree of risk to food safety.
○ Always check the specifications and contracts for raw materials in the purchasing procedures, and include procedures to ensure safety by hiring an alternative supplier in the event of an emergency. An emergency is a situation in which the safety required of the supplier cannot be confirmed due to an incident or disaster.

Subcontractor management

Implement the following as needed to ensure the appropriateness of the outsourcing.
・Confirm the product process management system
・Confirm the in-process inspection accuracy and results
・Perform regular verification of final products

Packaging materials used for food

- ○ Use packaging materials that are manufactured, processed, and properly managed with guaranteed safety in accordance with laws and regulations such as food and additives standards (Ministry of Health and Welfare Notification No. 370 of 1959).
- ○ Select packaging materials that meet the gas barrier performance, tensile strength, piercing strength, etc. appropriate to the characteristics of the product (strong odor, distribution temperature range, etc.), expiration date, size, capacity, etc.
- ○ Select a packaging material that does not allow the display to peel off or the printing to come off due to adhesion and friction of condensation during distribution and storage, or a material with a surface finish.
- ○ Before reusing packaging materials, create a reuse procedure manual in advance and manage it so that the product is not contaminated. If the material is damaged or there is significant dirt, stop using the material and discard it.
- ○ Use packaging containers and packaging gas that are non-toxic and do not impair the safety and appropriateness of the product during storage and use.
- ○ Use reusable packaging materials and containers that are durable, easy to clean and wash, and can be disinfected.
- ○ Handle raw materials that do not meet the acceptance criteria according to documented procedures to ensure that they are not misused.

Development of the Sangen principle (figure at right)

What is the Sangen principle?
It involves three steps: "Go to the site, observe the actual thing there, and understand the real situation." It is important to view other companies as one's own.
This is one of the quality control methods used to grasp the facts correctly when solving a problem.

Supplier data entry form / product standard (Example)

Approved by	Examined by

Product Standard No.

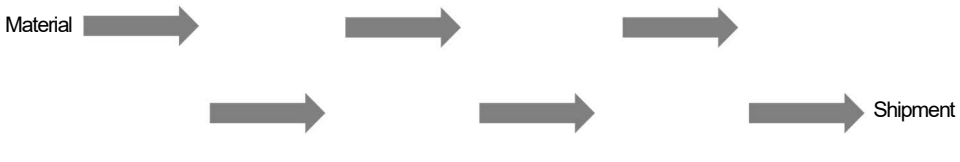
Created on (date) Author

Product name	Product name
Raw material packaging form	Allergen display Not required Required ( )
Product name	Raw materials, direct from production area, manufacturers
Target consumers	
Eating method	
Preservation method Refrigeration required, Frozen, Store at room temperature (temperature setting _____ degrees)	Product label
Shipping method	
Storage method	
Expiration date	
Manufacturing plant	

Standard	Contents	1C/S count	Expiration date	Code	Raw material mixing ratio				Standard quality standards (characteristics)		Nutritional analysis g/100g	
									Sugar		Moisture	
									Salt		Protein	
									pH		Fat	
									Microbial standard		Carbohydrates	
									General viable count		Ash	
									Coliform group		Calories	
											Sodium	

Photos attached

Manufacturing process strategy (see flow diagram for details)



● Required reference to legal provisions related to food safety

Raw material requirements
◎ Packaging materials shall be adequately protected from contamination and damage, and appropriate display shall be possible. ◎ Procurement of properly controlled raw materials. ◎ Management of agricultural, forestry, livestock and fishery products (primary products) used as raw materials shall include the following. ・Dust, soil or sewage pollution at the production stage shall be prevented. ・Waste and toxic substances shall be properly managed at the production stage. ・Measures shall be taken to prevent pollution from pesticides, veterinary drugs, feed, rodents and insects, foreign substances, microorganisms, feces, etc. at the production stage. ・Facilities at the production stage shall be clean and properly maintained by cleaning and appropriate repair. ・Measures shall be taken at the collection, storage, and transport stages to prevent contamination by rodents and insects, chemicals, foreign substances, microorganisms, etc. ・Materials that are clearly unsuitable for food use shall be sorted and removed. ・Food rot and deterioration shall be prevented through temperature and humidity control and other necessary measures. ・Hygiene management of the handlers shall be implemented. ◎ If it is clear that the raw materials contain parasites, pathogenic microorganisms, pesticides, or other foreign substances, the materials shall not be accepted for normal manufacturing processes unless such foreign substances are killed or removed to an acceptable level.

FSM 16 Supplier Performance

● Requirements

The organization shall establish, implement and maintain procedures for continuing to assess, approve and monitor suppliers for effects on food safety. The results of the assessments, surveys and follow-ups on suppliers shall be recorded.

● Concepts, specific examples

○ Establish a procedure for assessing and approving suppliers (suppliers and providers) based on risk assessments for the supplied materials and provided services that affect food safety.

① Assessment method

Perform the following assessment after determining the person in charge.

- Oral hearing
- Document and record confirmation
- On-site visit to confirm or audit

② Assessment items

The person responsible for the assessment collects and assesses the necessary information related to the following.

- Supplier organization: organizational reliability, product supply capacity, manufacturing site confirmation, quality assurance system, past incidents, insurance availability, etc.
- Delivery method: Delivery date, delivery place, delivery condition (at greenhouse temperature or special environment)
- Approval: Method of approval by the responsible person in your organization
- Continual monitoring: Rules for periodic re-assessment
- Have there been any cases of food fraud at the place of origin or supplier?
- Are there circumstances in which fraud is likely to occur (supplier prices are extremely lower than market prices, raw material prices are higher than market prices, supply is tight)?

③ Follow-up

New supplier main data

Classification	
Supplier name	
Representative	
Person in charge	
Location	

Supplier assessment
(5 points each, for a total of 30 points. Pass: 20 points)

Price		Degree of cooperation	
Insurance enrollment		Technology	
Delivery date		Production	
Total			

Management scale and status

Delivered product	Specification	Quality	Price	Assessment
Ika-somen (squid noodles)				
Matsumaezuke pickles				
Shiokara (salted fish)				
Crab				
Number of flavors Ikameshi (rice-filled squid)				

Assessment results

Contract history or recommender

Remarks

Approval	Assessment	Prepared by

Year Month Day
_____ Co., Ltd.

FSM 18 Complaint Handling

● Requirements

A management system that utilizes complaints from business partners and consumers shall be established and implemented, and its data shall be maintained to detect, correct, and manage omissions and oversights from food safety initiatives.

● Concepts, specific examples

○ It is necessary to distinguish between food safety events and other events, for example, quality events. This section deals with events related to food safety.

○ The following can be considered as a procedure for establishing a complaint-handling mechanism.

- Prepare a manual on how to respond to inquiries and complaints from business partners and consumers.
- Have employees recognize their responsibility for processing and investigating inquiries and complaints from business partners and consumers.
- Provide appropriate information in response to inquiries and complaints from business partners and consumers. At that time, if necessary, tell them the date by which they can expect a response.
- Record the content of inquiries and complaints from business partners and consumers.
- Have the person responsible confirm that the response to inquiries and complaints from business partners and consumers has been completed.

○ The key point in resolving complaints promptly is to establish a system that can appropriately grasp complaints from business partners and consumers, and respond promptly.

○ Take corrective actions if nonconformities are discovered based on information from business partners and consumers.

FSM 20 Serious Incident Management

● Requirements

An incident response manual* shall be prepared and implemented in the event of an incident, and shall be maintained at all times. This manual shall also describe the method for removing and recalling products as necessary.
The incident response manual shall be tested at least once a year using products supplied by the organization.
* This manual details appropriate measures and management to prevent problems from worsening when food safety problems arise.

● Concepts, specific examples

- ○ Serious incidents refer to food incidents that may affect food safety, and they do not include incidents may affect quality but do not affect food safety.
- ○ Since it is often unknown at first whether an incident is serious, it is desirable to take action based on a worst case scenario when an incident occurs.
- ○ If a recall incident occurs, report it to the assessment company after the initial response has been completed. (Refer to A/B program documentation.)
- ○ Prepare an incident response manual that documents incident reporting, product removal, and product recall as follows.
  - ・In the event of a serious incident, respond to it based on related management procedures such as those for nonconformity and complaints.
  - ・Assign a person with authority to manage serious incidents.
  - ・Establish an emergency contact network for customers, consumers and relevant government agencies, and keep it up to date.
  - ・To ensure effective communication, assign a person responsible for providing information to customers, consumers and relevant agencies.
  - ・Clarify the organization's internal communication system, such as for providing notifications to workers.
  - ・Conduct simulation training and review at least once a year based on the incident response manual to assess whether a serious incident can be dealt with.
  - ・Record and assess incidents to verify their severity and the risk to the customer. The following information is required for incident records.
    a) Related products, manufacturing location
    b) Amount of affected products
    c) Affected product range (lot, batch, etc.)
    d) Manufacturing records
    e) Shipped quantity and location

● Required reference to legal provisions related to food safety

Emergency response

- ◎ Procedures shall be defined for maintaining and inspecting facilities and equipment, sanitary food handling, etc. in the event of an unexpected incident such as a power outage.
- ◎ Information on consumer health hazards related to manufactured, processed or imported products, and products in violation of the Food Sanitation Act shall be promptly reported to health centers and other places.
- ◎ Water quality inspections shall be conducted every time there is a possibility that water sources have been contaminated due to an unexpected disaster or other causes.

Product recall mechanism

- ◎ A responsibility system shall be established for product recall, recall criteria, specific recall methods, and procedures for reporting to public health centers in control of the area where the facility is located to respond in the event of food hygiene problems caused by manufactured, processed, imported

products, etc., and the affected products shall be promptly and appropriately recalled to prevent health hazards to consumers.

◎ Recalled products shall be clearly distinguished from normal products when stored, and they shall be properly disposed of and other necessary measures shall be taken according to directions from health centers.

◎ The implementation of the recall shall be recorded. When the recall is terminated, the degree of achievement of recall objectives and the reason for the termination shall be clarified.

FSM 21 Control of Measuring and Monitoring Devices

● Requirements

Organizations shall clarify the equipment used for measuring critical parameters to ensure food safety and shall identify which of that measuring equipment needs to be monitored. These devices shall be calibrated in accordance with standards, including national and international standards, or in a reasonably accepted traceable manner.

● Concepts, specific examples

- ○ It is necessary to clarify the equipment used for measuring critical parameters to ensure food safety, and to identify which of that measuring equipment needs to be monitored. Measuring equipment that is not relevant to ensuring food safety does not apply.
- ○ "Calibration" here is one of the means to confirm the validity of the measured numerical parameters, and it is equivalent to verification. It is necessary to determine the appropriate calibration method for the applicable equipment and inspections from available methods that include international calibration, domestic calibration, manufacturer guarantee, in-house verification, etc. Also, if the measuring equipment is guaranteed by the manufacturer, the content of the guarantee can serve as evidence of the appropriateness of the equipment.
- ○ Calibration is required for the equipment and methods used for measuring and monitoring activities.
- ○ Manage the calibrated measuring and monitoring equipment, test equipment, and inspection equipment to prevent damage and mis-adjustments.
- ○ Calibrate the equipment according to the schedule recommended by the equipment manufacturer and the schedule established by the organization.
- ○ When measuring and monitoring equipment, test equipment, or inspection equipment are found to be inaccurate, record this information and establish procedures for assessing and taking appropriate action on potentially affected products.

FSM 22 Food Defense

● Requirements

The risk of intentional food contamination by people inside or outside the organization shall be identified, the magnitude of that risk assessed and prioritized, and measures implemented to reduce or eliminate the risk.

● Concepts, specific examples

- ○ Food defense refers to the means of preventing, avoiding and responding to intentional food contamination by physical, chemical and biological hazards.
- ○ Identifying the risk of intentional food contamination by people inside or outside the organization and assessing the magnitude of that risk is called a food defense vulnerability assessment, and the countermeasures taken are called food defense plans.
- ○ When assessing the food defense vulnerability, it is necessary to anticipate situations in which food may be intentionally contaminated or tampered with, identify places where the probability of such occurrence is high, and establish priorities such as facility access control.
- ○ Prepare and implement procedures for performing a facility vulnerability assessment (analyzing threats and identifying weaknesses).

○ Based on the results of the vulnerability assessment, prepare and implement a food defense plan that includes the methods, responsibilities, and criteria for preventing intentional food contamination and tampering.
○ The food defense plan includes the following elements:
- The person responsible for food defense has been assigned.
- There is a policy and procedure for recording and managing workers, contractors, and visitors entering and exiting the facility area.
- There is a procedure for securing the storage and delivery of raw materials, utensils, containers and packaging materials, drugs and food.
- The physical security (guarding) of the facility is secured.
- There is a procedure for responding to the detection of intentionally contaminated or degraded food, packaging, or equipment.
- There is an effective recall program (see FSM 20).
- The required training is provided to staff in accordance with the food defense plan established by the organization.

Reference

○ More than using surveillance cameras and lock management, the communication between workers serves as a check in food defense.
○ Excessive reliance on hard food defense measures can, in turn, undermine good relationships between workers and managers. As an example, explain that surveillance cameras are not installed because there is a suspicion of workers, but so that the company will have evidence of worker behavior in the unlikely event of a food incident.
○ Food defense should not be limited only to physical measures taken at the facility, but must also assume internal attacks from stakeholders. In particular, it is useful to ensure that there are no short-term workers or workers who are complaining or dissatisfied.
○ It is necessary to establish a system to examine trends such as cases occurring in society, cases at other companies in the same industry, cases that were prevented in advance, and signs.
○ In March 2008 the Ministry of Agriculture, Forestry and Fisheries published a helpful guide to formulating a voluntary action plan to improve reliability in the food industry with five basic principles (in Japanese). Refer to it as needed. The five basic principles are the following:
(Basic principle 1) Clarification of the consumer base
(Basic principle 2) Establishment of compliance awareness
(Basic principle 3) Basic hygiene and quality management
(Basic principle 4) Establishment of a system for proper hygiene management and quality control
(Basic principle 5) Initiatives for collecting, transmitting and disclosing information

FSM 23 Product Labeling

● Requirements

Information shall be displayed or attached to products so that they can be safely handled, displayed, stored, prepared, and used by business partners or consumers.
Procedures for displaying or attaching correct information shall be established and implemented.

● Concepts, specific examples

○ Provide information specified in laws and regulations (allergens, food additives, etc.) using methods and procedures in accordance with laws and regulations.
○ Take note of the following items in food safety when labeling products.
- Clarify users such as sales destinations and target consumers.
- Clarify eating conditions specific to the products such as raw food and cooking.
- Clarify the usage of raw materials and seasonings.
- Clarify the basis for setting the expiration date and best-before date.
- Clarify the handling temperature and method.

○ Information required for the product is printed on or attached to the packaging material based on the product specification.
○ Confirm that the content of the label is correct.
○ Establish a procedure to avoid confusing packaging materials with products.

Precautions for product labeling (example)

■ Confirmation of expiration date labeling
● Make sure the date is correct.
・Have multiple workers confirm the date.
・Check the date on work instructions, calendar, etc.
・Attach the printed packaging material to a confirmation table and record it.

● Points to confirm
・Is the date set correctly?
・Is the printing location correct?
・Is printing fading, fragmented, blurred, or missing?
・ Be careful when the year and month change!

● Reminder sign about printed labeling on a packaging line

Source: "Easily understood interpretation of advanced infrastructure development items" (in Japanese), Japan Food Industry Center

■ Example of information management for raw materials containing allergens [①]
● Digitalization of allergens contained in raw materials
● Enables the allergens in the final product to be identified

Name of raw material	Manufacturer	Specification	Allergens				
			Wheat	Eggs	Milk	……	Gelatine
A			○	△	×		×
Name of raw material	Manufacturer	Specification	Allergens				
			Wheat	Eggs	Milk	……	Gelatine
B			○	△	×		×
Name of raw material	Manufacturer	Specification	Allergens				
			Wheat	Eggs	Milk	……	Gelatine
C			○	△	×		×

Product name	Classification	Raw material	Allergens				
			Wheat	Eggs	Milk	……	Gelatine
Curry udon	Curry	A	○	△	×		×
		B	○	△	×		×
		C	○	△	×		×
	Udon	D	○	△	×		×
		E	○	△	×		×
Allergens in the final product to be identified			○	△	×		

Source: "Easily understood interpretation of advanced infrastructure development

FSM 24 Traceability

• Requirements

a) A traceability system shall be established to enable a) identification of production lots, b) identification of relationships between raw materials, product packaging materials and production lots, and c) identification of processing and distribution, and the system shall be verified at least once a year. The records that comprise the traceability system shall include:
・ Identification of all raw materials (including containers and packaging materials), products, and services
・ Identification of batches, semi-finished products, work in process, remanufactured products, reworked products, finished products and packaging throughout the entire manufacturing process
・ Records of buyers and destinations for all products supplied

• Concepts, specific examples

Record information required for traceability

○ Traceability records are important records for confirming serious product incidents or food fraud.
○ Preparation and provision of the record information necessary for traceability are as follows.

① Improvement of traceability

- Document procedures related to traceability for each product (including notations that can be used to identify raw materials and products, and outsourcing).
- Specify the state of the raw materials in all product stages (including primary processed products).
- Determine the units of lots for products and raw materials if necessary.
- Establish and implement procedures for creating and storing records of receipts and shipments.
- Confirm that traceability is functioning, including work in process, remanufactured items, and reworked items.
- Store product samples for each lot as needed.
- Verify the functioning of traceability at least once a year, and update it as necessary.

② Provision of traceability records

- Establish and implement procedures for preparing and storing records.
- Provide records related to traceability if requested by the government.

Examples of records required for processing and tracing

	Receiving	Manufacturing	Storage	Shipping
Product information	Raw material information Food safety information Acceptance inspection record	Manufacturing daily report Inspection record Process record	Product temperature record Inventory record	Product shipping information Destination information
Environmental information	Delivery vehicle temperature record Delivery vehicle hygiene record	GMP related records Contact information	Internal temperature record	Delivery vehicle temperature record Delivery vehicle hygiene record
Sampling information	Pre-sample product record	Quality control inspection	Quality control thermometer calibration record	—

FSM 25 Analysis of Environments, Inputs and Products

• Requirements

Appropriate inspections shall be conducted for items that affect food safety.
Inspections shall also be performed by a competent testing department or laboratory.

• Concepts, specific examples

○ To ensure food safety for a specified period, plan inspections to ensure that products and raw materials are systematically inspected for food safety, legal requirements, and items that affect customer product requirements.
○ Use a competent testing department or laboratory that conducts tests using procedures consistent with ISO 17025 or industry-recognized methods to ensure that the method is valid. Check the test results periodically for validity.
○ Documents that define the procedures (methods, standards, etc.) related to raw material acceptance inspections, manufacturing processes and product inspections are required.

List of inspection content and records specified in the inspection management rules

Inspection name	Inspection target	Inspection content																			Record
		Supplier	Product	Lot No.	Quantity	Standard	Color/ smell	Appearance	Work content	Temperature	Time	Metallic foreign matter	Vacuum, etc.	Size	Damaged dirt	Foreign matter	Ship date	Destination	Packaging form	Documents	Microorganisms quality control	
Purchase acceptance inspection	Material																				Acceptance inspection table
	Raw material																				
In-house acceptance inspection	Raw material																				
In-plant inspection	Semifinished product																				In-plant inspection table
Final inspection	Final product																				Final inspection table
Shipping inspection	Final product																				Shipping instructions and inspection table

● Required reference to legal provisions related to food safety

Inspection of manufacturing and processing processes and products

◎ The manufacturing and processing processes and products shall be inspected as necessary to confirm that they conform to the standards and standards, and the results shall be recorded.

◎ The method, frequency, and person in charge of the equipment used for inspections shall be determined, and maintenance and inspection records shall be kept.

◎ The status of the maintenance and inspection of equipment used for inspection shall be regularly checked.

FSM 29 Allergen Management

● Requirements

All manufacturing facilities shall develop and implement an allergen management plan. This plan shall include a risk assessment for allergen cross-contamination and control procedures to reduce or eliminate the risk of cross-contamination.

All final products containing or potentially containing allergens shall be identified in accordance with the legislation of the intended destination country.

● Concepts, specific examples

○ Identify allergens to be managed in all manufacturing facilities, and prepare and implement a management plan.

[Required content for allergen management plan]

- Identify allergens to be managed according to the production plan so that they can be confirmed at each production line.
- Develop management procedures to reduce or eliminate the risk of cross-contamination.
- Identify containers and utensils used for manufacturing (plastic bags, scoops, etc.) for each allergen to be managed, and avoid mixed use.
- Develop procedures for handling raw materials, intermediate products, and final products to prevent cross-contamination of allergens throughout all processes from manufacturing to shipping.
- Determine methods for cleaning, washing and verifying manufacturing processes to prevent cross-contamination.

- If different products are manufactured on the same production line, plan to produce allergens in ascending order from the smallest to the largest if possible.
- Ensure that allergen management complies with the laws of the destination country.
- When creating product labels, display the allergens in accordance with the laws of the anticipated destination country.

○ When developing products that contain allergens, conduct validation checks of the allergen management such as by line tests.
○ If verification (analysis, etc.) is required, establish and implement the verification procedure, record and store the verification results.
○ Refer also to FSM 15, 16 (management of raw materials, etc.), FSM 23 (product labeling), and GMP 7, 8, 9, 9, 10 (required items related to contamination in the manufacturing processes, etc.).

Ⅱ Hazard control (HACCP)

Hazard control

Hazard analysis and critical control points, or HACCP is a tool that is used to identify specific hazards and their control measures for food safety and establishes a preventive control system in the process rather than relying on testing final products. The success of HACCP requires that managers and workers work together, and it requires a wide range of expertise, such as in primary production, microbiology, and manufacturing and processing technologies.
The HACCP plan is a plan that clarifies the hazard factors for the target product (group) based on 12 procedures and 7 principles in order to control all hazard factors. The HACCP system is a mechanism that includes the HACCP plan and operates the entire mechanism. HACCP Procedures 1 to 12 are included as reference documents (Figures 5, 6, and 7).

HACCP Procedure 1 Assembly HACCP Team

• Requirements

A HACCP team shall be assembled and consist of qualified personnel.

• Concepts, specific examples

○ Eliminate blind spots in hazard analysis and facilitate communication by having the HACCP team composed of people with various specialized skills as much as possible, such as those in charge of the manufacturing and processing department, quality control department, engineering department of the facilities maintenance and equipment used for manufacturing, etc. Assign the position of the HACCP team leader (food safety officer) to a food sanitation supervisor or food hygiene manager who has product knowledge and specialized skills, knowledge of product characteristics and processes, and has a high level of communication skills and can concisely state their opinions.
When the food safety officer and the HACCP team leader are different individuals, they will need to work together.
○ Depending on the scale of the business, there are often cases in which workers are concurrently performing various duties. As such, top management may be the team leader, or all of the tasks related to food safety may be performed by one person. However, it is important to aim at ensuring the cooperation of the workers in the company as much as possible.
○ If the organization has a small number of employees, the HACCP team does not necessarily need to have more than one person. External human resources can also be utilized.
○ If there is a lack of knowledge and expertise in the organization, an effective approach is to receive external training and to receive the participation and advice of external food hygiene experts.
○ I The HACCP team is responsible for managing food safety initiatives within the organization.
○ Refer to HACCP1 of the "Self-check form for hygiene management using HACCP" (in Japanese) published by the Ministry of Health, Labor and Welfare. Refer to step number 1 in the reference document (Fig. 5).

HACCP Procedure 2 Product Description

● Requirements

Product specifications shall be documented, and shall include all product information required for hazard analysis. The scope of the HACCP system shall be defined for each product or product group, and for each production line or location.

● Concepts, specific examples

○ Describe the specifications and characteristics of the final product as follows, dividing them into the necessary items in order to clarify the characteristics of the product.

- Specifically, for final products, describe the name and type of the product, the characteristics of the product, the name of the raw material, the name of the additive used and the usage standard, the form of packaging, the unit and amount, the material of the container and packaging, the expiration date or the best-by date, how to store the product, and describe the company's internal targets for managing the causes of hazards in products (such as the component standards for bacteria specified by the Food Sanitation Act, including the standards specified by the supplier).
- Whether a product is handled individually or as a group depends on whether the hazards are common.
- If the substance contains allergens, or if there is a possibility of allergen contamination in the facility, describe that fact.

○ Refer to HACCP 2 of the "Self-check form for hygiene management using HACCP" (in Japanese) published by the Ministry of Health, Labor and Welfare. Refer to step number 2 in the reference document (Fig. 5).

HACCP Procedure 3 Identification of Intended Use

● Requirements

The intended use of the product (how it is used) and the intended consumer shall be clearly stated in the document.

● Concepts, specific examples

○ Describe the intended use of the product (how to use it) and the target consumers in the document as follows.

- Clarify the method of eating and using the product and the target consumers. Pay particular attention to the content for people with poor health, infants and the elderly.
- If cooking or precautions after opening the product are required, describe the necessary items.

○ Refer to HACCP3 of the "Self-check form for hygiene management using HACCP" (in Japanese) published by the Ministry of Health, Labor and Welfare. Refer to step number 3 in the reference document (Fig. 5).

HACCP Procedure 4 Construction of Flow Diagram

● Requirements

A flow diagram (a process diagram describing all steps of the process) shall be created.

● Concepts, specific examples

○ Create a flow diagram for a series of manufacturing and processing steps from the receiving of raw materials to the shipping of final products that enables you to understand the details of each step along the flow. Many products that are manufactured using similar processing steps can make use of the same flow diagram.

Creating a flow diagram

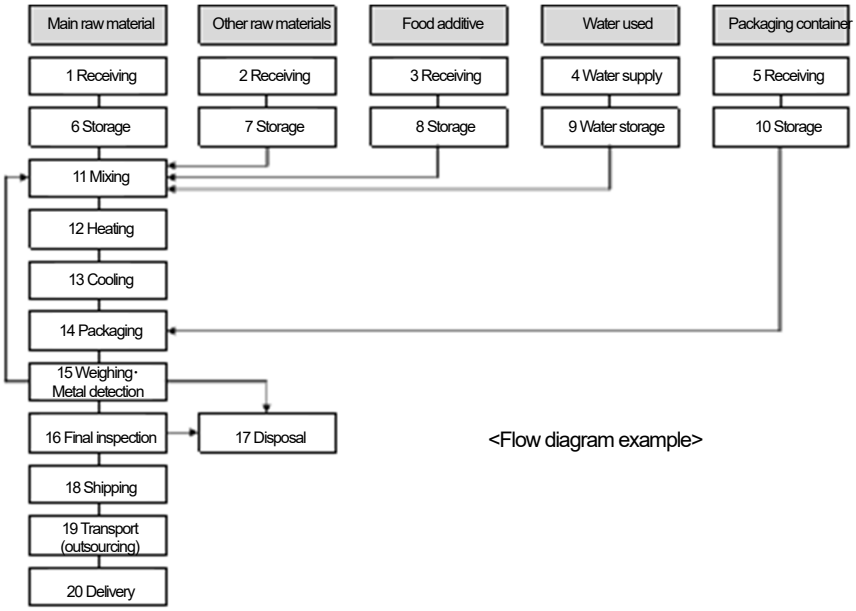
○ Create the flow diagram as follows.

① Briefly list all the processes and operations from receiving raw materials to shipping finished products.

② Enclose the listed raw materials and processes in frames, connect the frames with arrows, and number them in the order of the process. For raw materials, include food additives, packaging containers, water used, etc., and list them in the same column with a frame, and connect them with arrows to the processes used.

③ In raw material processing, if generated waste or processed raw materials are used separately for products, specify that.

④ In the processes, if there are processes with pass/fail judgments or redo processes, specify that so it can be managed.



<Flow diagram example>

○ Creating a drawing of the facility with outlines for each process and a two-dimensional and three-dimensional layout of the facility makes it possible to identify the points in the processes and locations where there is a possibility of cross-contamination and will aid in hazard analysis.

○ Refer to HACCP4 of the "Self-check form for hygiene management using HACCP" (in Japanese) published by the Ministry of Health, Labor and Welfare. Refer to step number 4 in the reference document (Fig. 5).

HACCP Procedure 5 On-site Confirmation of Flow Diagram

● Requirements

The flow diagram (process diagram) shall be confirmed on site to ensure that it matches.

● Concepts, specific examples

○ At the site, confirm that the process that can analyze the hazard factor is properly clarified in the flow diagram as follows. When performing the confirmation, move through the site as follows while comparing it with the layout drawing of the site.

① At the work site, confirm the processes in sequence from the upstream process, and confirm whether the appropriate process is shown in the diagram, including temporary storage and management of semi-finished products.

② If a process or activity is found inconsistent with the flow diagram at the site, confirm the correct management method with the responsible person and correct the diagram.

○ Refer to HACCP5 of the "Self-check form for hygiene management using HACCP" (in Japanese) published by the Ministry of Health, Labor and Welfare. Refer to step number 5 in the reference document (Fig. 5).

HACCP Procedure 6 (Principle 1)　Hazard factor analysis

● Requirements

All available means of identifying, analyzing, and managing potential hazards in each process shall be considered.
Hazard factors shall include allergens, as necessary.

● Concepts, specific examples

○ Hazard analysis is performed to determine the hazard factors to be managed by the HACCP plan and to clarify the control method for each hazard factor. For this purpose, first collect information on hazards that may occur in all processes from raw materials to manufacturing, processing, storage and distribution to consumption, as well as the conditions in which they occur, and understand the likelihood of a hazard occurring and the severity of the consequences.

○ Conducting a hazard analysis makes is possible to create an appropriate management system for the facility according to the degree of potential hazards.

○ In the actual analysis of hazards, it is necessary to list hazards that may lead to a health hazard when the product is eaten for each raw material and process used for the final product.

○ Following the flow diagram from raw materials to the final product, identify the raw materials and processes that may lead to the generation of hazard factors, and identify the hazard factors and the hazard generation factors (contamination, proliferation, survival, mixing, etc.) in each process, and create a hazard factor analysis sheet that lists the control measures to be implemented.

○ During preparation, it is necessary for all members of the HACCP team to share their expertise, and discuss and summarize their capabilities.

《Steps for creating a hazard factor analysis sheet》

○ The steps for creating a hazard factor analysis sheet are as follows.

[Step 1]
List raw materials and manufacturing process steps along the flow diagram

[Step 2]
List the hazards derived from the raw materials and manufacturing processes

[Step 3]
Based on the likelihood of the listed hazard factors occurring and the magnitude of the hazard if they do occur, assess whether it is important that the safety of the final product cannot be guaranteed unless the hazard factors are reduced or eliminated from the food, and describe the basis for the judgment

[Step 4]】
Identify control measures to ensure the safety of the final product for the hazards identified as important

The following is an example of a hazard factor assessment (Step 3) and a hazard factor analysis sheet. Refer to the examples posted on the website of the Ministry of Health, Labor and Welfare for hazard factor analysis sheets for other items.
（http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000098735.html）

For the assessment of the hazard factor in step 3, we recommend filling in the hazard factor analysis sheet with numbers using a table in which the "severity at the time of occurrence" and the "frequency of occurrence" are as shown below (Example of pre-boiled buckwheat noodles). However, this is not required if you can clearly assess using "YES/NO" (example of a catered box lunch).

Hazard assessment matrix (example)

Frequency of occurrence	Severity at occurrence				
	A	B	C	D	E
1	1	2	4	9	11
2	3	5	7	12	16
3	6	8	13	17	20
4	10	14	18	21	23
5	15	19	22	24	25

Red text: Critical hazard

Frequency of occurrence	Severity at occurrence
1 High (often occurs in-house)	A High (lethal)
2 Moderately high (has occurred in-house)	B Moderately high (severe, with aftereffects)
3 Low (has also occurred at other companies)	C Low (transient, recall)
4 Very low (no information available at other companies)	D Very low (almost no injury)
5 Almost inconceivable	E Injury is unlikely

Hazard analysis sheet (example)

Product name: Catered box lunch

(1)	(2)	(3)	(4)	(5)	(6)
Raw materials/process	Hazard expected to occur in (1)	Is it a critical hazard that needs to be reduced or eliminated from the food?	(3) Grounds for the judgment in the column	Critical hazard control measures identified in column (3)	Is this a CCP process?
Refrigerated storage (boiled vegetables)	Organism: Presence of pathogenic microorganisms				
	Harmful microorganisms				
	Salmonella spp.	NO	Possibility of contamination due to unsanitary handling during manufacturing and processing, but can be managed by observing hygienic handling of food		
	Pathogenic E. coli				
	Staphylococcus aureus				
	Heat-resistant spore bacteria				
	Clostridium botulinum	NO	Contamination considered due to unsanitary handling during manufacturing and processing, but it cannot grow during storage due to anaerobic bacteria		
	C. perfringens				
	Bacillus cereus	NO	Contamination considered due to unsanitary handling during manufacturing and processing, but can be managed by observing hygienic handling of food		
	Chemical: None				
	Physical: Presence of foreign matter	YES	Possibility of metallic foreign matter due to unsanitary handling during manufacturing process	Controlled by metal detection (No.9)	NO

Product name: pre-boiled buckwheat noodles

(1)	(2)	(3)	(4)	(5)	(6)
Raw materials/process	Hazard expected to occur in (1)		(3) Grounds for the judgment in the column	Critical hazard control measures identified in column (3)	Is this a CCP process?
Buckwheat flour/receiving	Organism: Presence of pathogenic microorganisms				
	Harmful microorganisms				
	Salmonella spp.	6	Possibility of contamination from soil	Can be controlled in the sterilization process (No.32).	NO
	Pathogenic E. coli	6	Possibility of contamination from soil	Can be controlled in the sterilization process (No.32).	NO
	Heat-resistant spore bacteria				
	Bacillus cereus	7	Possibility of contamination from soil	Can be controlled in cooling process (No.33).	NO
	C. perfringens	19	Thereafter, no possibility of growth because not under anaerobic conditions		
	Clostridium botulinum	15	Thereafter, no possibility of growth because not under anaerobic conditions		
	Chemical: Pesticide residue	17	Qualified products are received and confirmed by inspection certificate once a year		
	Physical: Presence of foreign matter				
	Hard foreign matter	13	It can be eliminated by visual inspection, by weighing and use of sieve (No. 14)		
	Metallic foreign matter	18	It can be eliminated by visual inspection, by weighing and use of sieve (No. 14)		

HACCP Procedure 7 (Principle 2) Establishment of Critical Control Points (CCP)

● Requirements

Critical control points (CCP) shall be determined.

● Concepts, specific examples

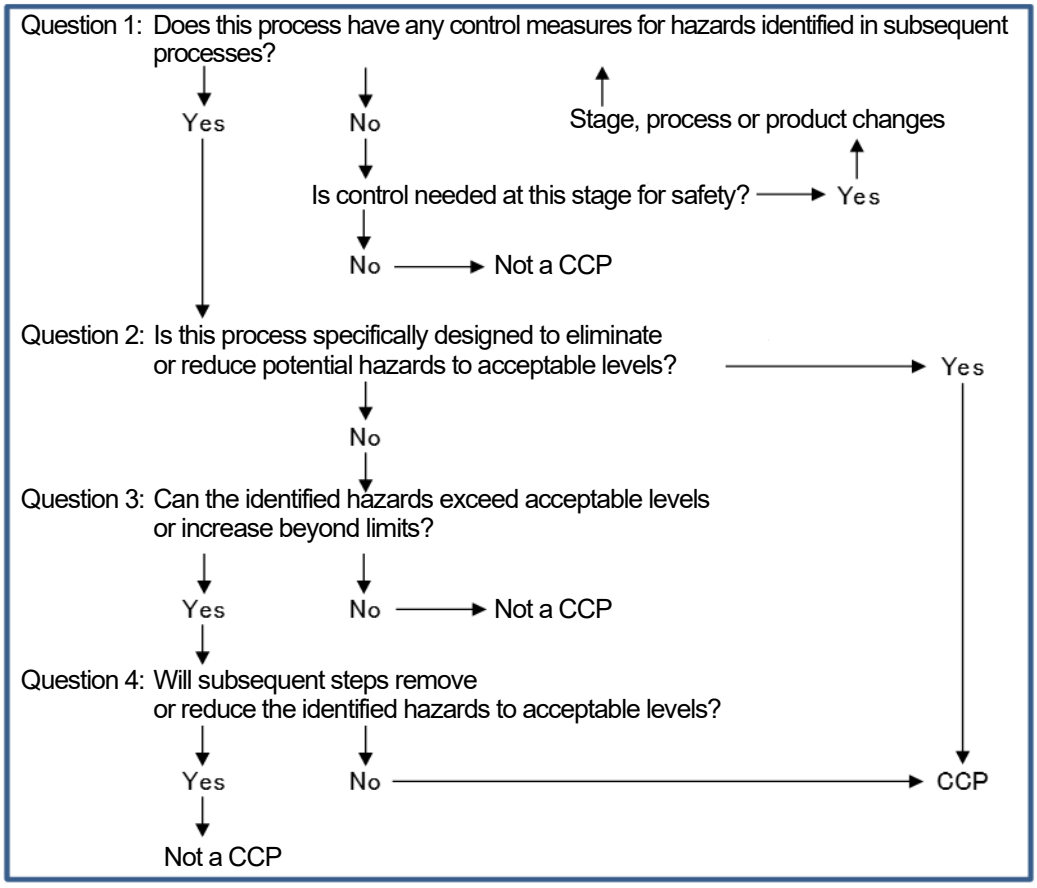
What is a CCP?

- ○ A CCP is a process, operation, or step that is essential during the manufacturing of products to reduce or eliminate hazards from foods, and which needs to be controlled particularly strictly.
- ○ As a result of the harmful factor analysis, it is necessary to establish one or more means of management that can control hazard factors that are regarded as critical hazard factors.
- ○ CCPs require the establishment of allowable limits, as will be described later, and the implementation of measures such as not shipping products that have deviated.

How to determine a CCP

- Fundamentally, define procedures for all processes and perform GMP management. Among these processes, those that directly affect food, such as those related to "not bringing in," "not attaching," "not increasing," and "eliminating (killing)" food poisoning bacteria, which are hazard factors, the process that is the last stronghold is the CCP.
- It is important to manage the hazard factors by GMP, however if particularly strict control is required and a hazard factor cannot be controlled by GMP alone, the process shall be determined as a CCP. If hazards can be controlled by GMP alone in all processes, CCPs may not be established.
- Establish clear methods for determining CCPs. As an example, the Codex Committee has demonstrated a judgment method consisting of four questions (see the CCP decision tree in the figure below).
- If GMP is used to manage processes that should be CCPs, the hazard risk may be out of control. If a process that can be adequately controlled by GMP is determined to be a CCP, efforts will be wasted, and the management of other processes may become inadequate.
- CCP requirements can be monitored continually or at a considerable frequency using a preset monitoring method, and if a parameter deviates from the critical limit (CL), the process can be returned to a controlled state in a short time.
- The value (the limit value) of the monitoring parameter at the boundary between whether product safety can be ensured or not is called a critical limit (CL).

CCP decision tree



Specific examples of CCP

- Examples of CCPs that prevent the occurrence of hazards are as follows.
  - ① Raw material acceptance: prevention of residual antibacterial substances by checking the test report submitted by the supplier
  - ② Cooling: prevention of pathogen growth by appropriate temperature control
  - ③ Refrigerated storage: prevention of pathogen growth by appropriate temperature control
  - ④ Measurement of food additives: prevention of excessive added amounts
- Examples of CCPs that eliminate hazards are as follows.
  - ① Heating process: sterilization of pathogenic bacteria
  - ② Metal detection: detection and elimination of metal fragments using detectors
- Example of multiple CCPs controlling a single hazard are as follows.
  - ① Thickness control of cooked hamburger patties and control of heating time and temperature: kills pathogenic microorganisms
- See the CCP management table (Fig. 8) for reference.

HACCP Procedure 8 (Principle 3) Establishment of Critical Limits

● Requirements

Limits shall be established for critical control points.

● Concepts, specific examples

What is a critical limit (CL)?

- A CL is a monitoring criterion that distinguishes whether or not it is acceptable or not a hazard factor can be acceptably controlled.
- If a CL is set incorrectly, it will lead to the occurrence of hazard factors, so the CL must be established correctly based on scientific data.
- If the CCP deviates from the CL, corrective action is required.
- A CL are required to satisfy the following conditions.
  - ① Optimal parameters for confirming that the hazard factor has been prevented, eliminated, controlled or reduced to an acceptable level, and a value that is proven on a scientific basis
  - ② Standards using parameters that can be judged in real time to the extent possible
    If the control status is found to be inappropriate, prompt corrective action is required, so it is desirable to specify the CL using parameters that can be judged in real time.
- A CL uses the measured values of parameters that include sensory indexes (color, gloss, smell, taste, viscosity, physical properties, foaming, sound, etc.), scientific values such as water activity (Aw), pH, and physical parameters such as temperature and time.

How to establish a CL

- When stipulated by laws and regulations, adopt numerical values for the target hazard factor control. In other cases, establish a CL based on data in the literature and experimental data.
- When managing normal manufacturing processes, it is rare to manage them only using a CL, so to allow more of a margin than a CL, it is common to set criteria that can be managed before the CL is deviated (such as an operational limit (OL)).

HACCP Procedure 9 (Principle 4) Monitoring System

● Requirements

A monitoring method shall be established for each critical control point.

● Concepts, specific examples

What is monitoring?

- ○ Monitoring involves making observations, measurements or laboratory tests to ensure that the CCP is being properly controlled and to provide accurate records that can be used during subsequent verifications.
- ○ For CCP control, monitoring involves observing that there is no deviation from the CL.
- ○ If the CCP deviates from the CL, corrective action is required.
- ○ Monitoring records are also used when verifying the HACCP plan.

How is monitoring performed?

- ○ The monitoring method used is required to satisfy the following conditions.
  ① Continual or at a considerable frequency.
  ② Use a method that enables results to be obtained quickly.
- ○ It is important to monitor that hazard factor control measures conform to all the products. Monitoring needs to be performed continually or at a considerable frequency to be able to monitor that all products, from the first one to the last, or all batches, meet the CL. When a deviation from the CL occurs, it is necessary for the impact to be minimized as much as possible and in a way that can be easily remedied.
- ○ A monitoring method that is defined by [5W1H] means the following.
  - ・ Why: CCP is physically and chemically effective
  - ・ What: CCP is within the CL range or has not deviated from the CL
  - ・ Where: Clarify the applicable process (CCP process)
  - ・ How: By means of fast and accurate physical, chemical or sensory measurements and test methods
  - ・ When: Continual or at a considerable frequency
  - ・ Who: Workers who have been trained in monitoring methods
- ○ Hazard factors cannot be controlled by simply recording the measured values continually. It is necessary for the person responsible for monitoring to check them frequently.
- ○ When creating a HACCP plan, it is necessary to designate a person to be responsible for monitoring.

HACCP Procedure 10 (Principle 5) Corrective Actions

● Requirements

Methods for corrective action (correction, investigation of the cause of occurrence, and elimination of the cause) must be established for deviations from the allowable CL range.

● Concepts, specific examples

What are corrective actions?

- ○ Corrective actions are actions that are taken immediately when monitoring parameters deviate from the CL.
- ○ For CCP processes, which are processes that need to be strictly controlled in order to prevent the occurrence of hazard factors, if the monitoring parameters deviate from the CL, there is a risk that food safety risks may increase, and immediate action is required. At the same time, the target processes and control methods are limited, specific deviations can be identified, and measures to be taken can be easily defined. It is therefore important to define corrective action methods and procedures in advance.

○ The actions to restore the control status of the process, procedures to restart the line, and actions to determine and implement the disposal method of the affected products are specified in the HACCP plan.
○ Investigate the cause and try to prevent recurrence.

Items to be described in the HACCP plan as corrective actions

○ The items to be described in the HACCP plan as corrective actions are as follows.
① Measures to restore the process control status
・Return processes to their normal control status, such as by repair, adjustment, and replacement of machines.
② Measures for products manufactured during the deviation from the CL
・Identify and hold products that do not conform to the standards and assess them.
・Decide the processing method such as reprocessing or disposal of those products.

Person responsible for corrective action

○ The person responsible for implementing the corrective actions needs adequate knowledge about CCP control, understands the processes well, and can make quick decisions.

Corrective action record

○ The corrective action record will include the following items.
・The nature of the deviation from the CL, the manufacturing process or place where it occurred, and the date and time of the occurrence
・The name, lot number, quantity, etc. of the product targeted for treatment
・Results of investigating the cause of the deviation
・Actions taken to return the process to its original state
・Description of the treatment of the products manufactured during the deviation
・Signature of the person in charge of performing and recording the above matters
・Signature of the person inspecting the corrective action and date of inspection

HACCP Procedure 11 (Principle 6) Establishment of verification procedures

● Requirements

Verification procedures shall be established to confirm whether the established handling (HACCP plan) is being performed as planned and whether it needs to be modified.
Verification shall be performed to adapt to changes in equipment design and processing methods as well as technological development in the manufacturing process.

● Concepts, specific examples

Need for verification

○ Assess the effectiveness of the HACCP plan and ensure that the HACCP system is working properly.
○ Revise the HACCP plan to improve it by recognizing the weaknesses in the HACCP system from the results of regular verification.

Verification for each HACCP plan

○ Verification of the HACCP plan for each CCP is performed for the following items.
・Calibration of measurement equipment (meters) used for monitoring
・Testing of raw materials, intermediate products or finished products
・Measurement of manufacturing and processing conditions
・Confirmation of CCP monitoring record, corrective action record and verification record
・Confirmation that workers are working in accordance with the HACCP plan

○ Verification of monitoring involves confirming that the monitoring is correct by using another measuring device or method. For example, for temperature cross-checking with another thermometer and verification of the heating process, microbe tests are performed on samples after the heating process to confirm that no microorganisms remain.

《Matters to be stipulated in the HACCP plan for internal verification》

○ The items to be stipulated in the verification plan are as follows.
- Description
- Frequency
- Actions based on verification results
- Method of recording verification results

Test inspection method

○ Assess and verify that CCPs and CLs are properly configured and controlled to ensure product safety. Perform verification tests in a manner that is valid within the industry. Visual and sensory indicators can also be used as verification tools, but it is necessary to establish documented procedures and objective criteria using photographs and samples.

Verification of the overall HACCP system

○ Perform verification of the HACCP system periodically according to the following flow as required.
- Analysis of the causes of consumer complaints or recalls
- On-site confirmation that monitoring work is being performed according to the prescribed procedures
- Testing and inspection of final products

○ Record the verification results and confirm them.

Validation of the HACCP system

○ Validation is performed once a year and when any of the following occurs.
- Change of raw materials
- Changes in manufacturing processes or systems (including computers and their software)
- Change of packaging
- Change of delivery system for finished products
- Changes in the intended specification of the final product or the intended consumers
- When the verification results indicate a defect or a potential defect in a HACCP plan
- When a new hazard is found in the same food or the same food group
- When new information on product safety is obtained

HACCP Procedure 12 (Principle 7) Documentation and Recordkeeping

● Requirements

The necessary documents shall be created, recorded and maintained.

● Concepts, specific examples

Necessary documents and records

○ Documents and records required by the 12 HACCP procedures Product descriptions, flow diagrams, hazard analysis, HACCP plans, etc.

○ Records of activities according to the HACCP plans
Monitoring records, corrective action records, verification records, personnel training records, etc.

○ Records of HACCP plan implementation
In addition to providing evidence of control, these records are also important for dealing with deviations.

Reference Document: "Voluntary inspection form for hygiene management using HACCP" (original in Japanese), published by Ministry of Health, Labor and Welfare

(Figure 5) HACCP 1-5

HACCP Self-inspection checklist (general food)

Step No.		Item	Assessment (○ = Yes, △ = Partially, × = No)
1	Formation of HACCP team		
	Checking	Detailed item	
	✓	Have you formed a HACCP team? (If you have a small number of workers, the team does not have to be more than one person, and you can use external human resources.)	
		Does the HACCP team have any knowledge of the product or its manufacture? (Persons with product knowledge and specialized skills, knowledge of the product characteristics and processes, food hygiene managers, food sanitation supervisors, etc.)	
		Does the HACCP team include anyone with expert knowledge of HACCP? If not, have you obtained specialized knowledge and advice on HACCP from related organizations, administrative agencies, publications, etc. (e.g., Ministry of Health, Labor and Welfare website)?	
2	Creating product documentation		
	Checking	Detailed item	
		Have you created a product manual that describes the necessary items related to safety? (Example of items to be described: It is not always necessary to describe all items.) ・Composition of raw materials, names of additives, and amount used ・Physical and chemical properties (water activity, pH, etc.) ・Sterilization, bacteriostatic treatment (heat treatment, freezing, salting, smoking, etc.) ・Packaging form (gas replacement, degassing, vacuum, etc.) ・Storability, storage conditions (storage method, expiration date, best-by date, etc.) ・Standards based on laws and regulations (if established) ・Distribution method ・Assumed usage ・Consumer class, etc. (* Refer to the example of the product manual in the "Introduction to HACCP Handbook" (in Japanese) prepared and published by the Ministry of Health, Labor and Welfare.)	
		Do you have product descriptions for all the products that you manage based on HACCP? (Products with similar characteristics or processes can be grouped and described together. It is not necessary to create one product manual for each product.)	
3	Confirmation of intended use		
	Checking	Detailed item	
		Does the product description state that the product is for processing or is it to be consumed directly? If it is to be consumed directly, does the product description indicate the target person (e.g., general consumers, infants, elderly, etc.) and cooking method (e.g., by heat processing)? If the target consumer includes use by a high-risk population (hospital food, nursing homes, etc.), is that stated?	
4	Create a Manufacturing process list		
	Checking	Detailed item	
		Have you created a manufacturing process list? (* Refer to the example of the product manual in the "Introduction to HACCP Handbook" (in Japanese) prepared and published by the Ministry of Health, Labor and Welfare.)	
		Does the manufacturing process list include all the manufacturing processes from the receiving of raw materials to the shipping of products? (In particular, if there are any processes such as temporary storage, outsourcing or return processes, it is necessary to describe them.)	
5	On-site confirmation of manufacturing process list		
	Checking	Detailed item	
		Has the manufacturing process list been confirmed on site against the actual manufacturing process and the facility equipment layout to determine if it is appropriate? If a process was found that did not accurately reflect the actual situation at the site, has the manufacturing process list been corrected?	

(Figure 6) HACCP 6-9

6	Hazard analysis (HA)	
	Checking	Detailed item
		Have you created a list of all the hazardous substances that can occur in each manufacturing process (hazard list)? (* Example of the work of creating a hazard factor analysis table (hazard factor list) is in the "Introduction to HACCP Handbook" (in Japanese) prepared and published by the Ministry of Health, Labor and Welfare. In addition, the appendix contains an example of the form of a hazard factor analysis table (hazard factor list) and a hazard factor extraction manual. This involves filling in the first and second columns of the hazard factor analysis table (hazard factor list). Products that have similar characteristics or processes can be grouped and created as a single list. It is not necessary to create a list for each product.) [Examples of hazardous substances] ・Mixed metal pieces, plastic pieces, etc. (physical hazards) ・Proliferation of pathogenic microorganisms, inadequate sterilization, etc. (microbiological hazards) ・Pesticides and detergents, improper use of additives, etc. (chemical hazards)
		In the list of hazards to be controlled in each manufacturing process, have you identified any substances that could cause a food hygiene hazard? (This involves filling in the third and fourth columns of the hazard factor analysis table (hazard factor list).)
		Regarding the substances identified as causing food-safety hazards, have you listed the substances that cause food-safety hazards and the measures to prevent the occurrence of such hazards (control measures) in each process? (This involves filling in the fifth column of the hazard factor analysis table (hazard factor list).
7	Determination of critical control points (CCP)	
	Checking	Detailed item
		In the manufacturing processes, if substances that cause hazards in subsequent processes cannot be eliminated or reduced to an acceptable level, have you defined critical control points that require continual monitoring or monitoring at a considerable frequency of the implementation status of control measures, and have you prepared documents for them? (This involves filling in the sixth column of the hazard factor analysis table (hazard factor list).) If no critical control points were identified at first after implementing up to step 7, have you returned to steps 6 and 7 to confirm again whether there were any problems with the analysis of the hazard factor or the identification of critical control points? If you still do not need to establish any critical control points, have you prepared and stored a document that specifically records the reason? (* Refer to the examples of critical control points in the "Introduction to HACCP Handbook" (in Japanese) prepared and published by the Ministry of Health, Labor and Welfare.)

8	Setting of control criteria (critical limits (CL))	
	Checking	Detailed item
		Have you established critical limits to eliminate or reduce to an acceptable level substances that cause hazards at critical control points and prepared documents for them? (* Refer to the example of critical limits in the "Introduction to HACCP Handbook" (in Japanese) prepared and published by the Ministry of Health, Labor and Welfare.)
		Have you established critical limits based on indexes that can measure temperature, time, water content, pH, water activity, available chlorine, etc., or sensory indexes such as appearance and texture? (Critical limits do not have to be numerical values.)
9	Establishment of monitoring methods	
	Checking	Detailed item
		Have you established monitoring methods to confirm the status of conformance with the control criteria continually or at a considerable frequency, and have you prepared a document for that? (Refer to the example of monitoring in the "Introduction to HACCP Handbook" (in Japanese) prepared and released by the Ministry of Health, Labor and Welfare. In addition, if control criteria are established using sensory indexes, it is adequate to perform monitoring using those indexes.)
		Have you established an adequate monitoring frequency? (Maintain a record of the reason for the frequency you established.)
		Are all monitoring documents and records signed by the person who implements the monitoring and the person responsible for the monitoring?

(Figure 7) HACCP 10-12

10	Establishment of corrective actions	
	Checking	Detailed item
		Have you determined the method for corrective actions when the control criteria (critical limits) were not adhered to at the critical control points, and prepared a document? Has the person responsible for implementing corrective actions been determined, and who is the person responsible for confirming the corrective actions? (* Refer to the examples of corrective actions in the "Introduction to HACCP Handbook" (in Japanese) prepared and published by the Ministry of Health, Labor and Welfare.)
		Do you have corrective actions in place to prevent problematic products from being shipped if control criteria are not met?
11	Implementation of verification	
	Checking	Detailed item
		Has a document describing the method for verifying that HACCP has properly prevented the occurrence of food hygiene hazards been prepared and verification implemented? [Example of verification items to be described] ・Confirm the on-site confirmation, monitoring and corrective action records that show whether monitoring and corrective actions are being performed properly. ・Perform periodic calibration of instruments. ・Conduct inspections, such as inspections of products and intermediate products, as required to confirm whether the established hygiene controls are actually preventing the occurrence of food hygiene hazards. (* Refer to the example of verification in the "Introduction to HACCP Handbook" (in Japanese) prepared and published by the Ministry of Health, Labor and Welfare.)
		Are verifications being performed frequently enough to ensure that HACCP is working effectively? (Maintain a record of the reason for the frequency you established.)
12	Establishment of recordkeeping and storage methods (* Refer to the example record in the "Introduction to HACCP Handbook" (in Japanese) prepared and published by the Ministry of Health, Labor and Welfare.) Existing records, such as the daily work report, that have been used so far can be arranged to record the necessary items. If critical control points have not been determined, the checks in steps 8 to 11 are not required.)	
	Checking	Detailed item
		Are you maintaining a hazard factor analysis record (step 6)?
		Are you maintaining a record of the determination of critical control points (step 7)?
		Are you maintaining a record of the establishment of control criteria (critical limits) (step 8)?
		Have you prepared and are you maintaining monitoring records (step 9)?
		Have you prepared and are you maintaining corrective action records (step 10)?
		Have you prepared and are you maintaining verification records (step 11)?
		Have you established a retention period for each of the above records?

Figure 8: Example of HACCP Plan (Procedures 7, 8, 9)

Appendix 4

HACCP plan style example 2

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical control point (CCP)	Critical hazard	Critical limit (CL) for each control method	Monitoring				Corrective action	Verification	Record
			What	How	When (frequency)	Who			

Source: "Basics of HACCP Introduction and Operation" (in Japanese)
(Japan Food Hygiene Association) 2014

GMP 2 Site Management

● Requirements

Appropriate standards for the premises of the business shall be established and the premises shall be maintained in accordance with those standards.

● Concepts, specific examples

Around the facility

○ Ensure that the site boundaries are clear.

○ It is necessary to constantly manage the area around the facility and maintain it to be free from hygiene problems. Periodically verify the effectiveness of the corrective actions taken on contamination that adversely affects the products.

○ The following can be considered as the likely causes of rodents and insects.

- Unmaintained greenery
- Locations where drainage is poor and water pools easily
- Garbage and unnecessary materials are left on the premises

Examples of possible adverse effects from the surrounding environment

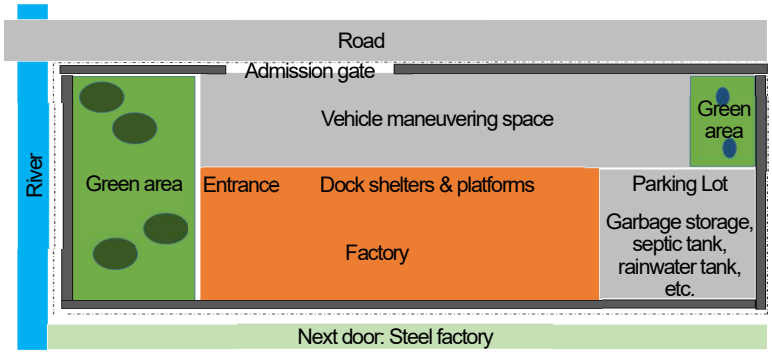
○ Periodically verify the effectiveness of removal measures against contamination around the facility that affects products.

○ Maintain or remove greenery.

○ Design roads, premises and parking lots to prevent puddles, and maintain them.

○ Consider the adverse effects on facilities due to the external environment (corrosion of buildings due to salt damage, strong wind, etc., damage to pipelines due to freezing, etc.).

[Example] Examine the environmental impact from the surroundings of the building (in addition to the on-site facilities, external facilities and the environment (outside the dotted line))



● Legal provisions relating to food safety that require reference

Around the facility

◎ Periodically clean the area around the facility, and during the operation of the facility, it should be maintained without any health problems.

GMP 3 Facility, Equipment and Production

● Requirements

The facilities and equipment within the site, buildings and factories shall be maintained to control the risk of product contamination from the external environment, internal environment and manufacturing flows.

● Concepts, specific examples

Facility location, design, and layout

○ When designing manufacturing and processing facilities, the most important point is to fully understand the impact on manufacturing and processing.
To understand the impact, refer to the following:
- Flow chart showing the manufacturing and processing steps
- Equipment, personnel, transport method of raw materials and products, processing capability, etc.
- Work categories suitable for manufacturing and processing processes

Flow lines of "things" and "people"

○ It is effective to describe the flow lines of manufacturing and the flow lines of workers, and to consider the impact on food safety from the flow of movement through these flow lines.
○ The flow lines are as follows. Among them, the flow lines of "things" and "people" are important. If possible, manage "things" and "people" to prevent their cross-contamination.
- Things: Routes from the receiving of raw materials to the shipping of finished products
- People: Routes for workers to enter and exit the workplace
- Transportation routes between workplaces, access routes for outside workers
- Waste: Routes to carry the remaining materials from the workplace and unnecessary materials outdoors
- Drainage: Workplace drainage route
- Utilities: Utility routes such as for steam, compressed air, carbon dioxide, nitrogen and other gases, air conditioning and ventilation, lighting, water, etc. that are used directly or indirectly for manufacturing and processing.

Lighting

○ Use lighting with specifications that allow it to be easy to maintain and clean, with little deterioration.
○ When installing electric wiring ducts, install them in places where dust and dead insects will not accumulate on their upper surfaces, and when removing them, make sure to pull them out vertically instead of horizontally so that dust will not fall.
○ Install a protective cover (a type that will not accumulate dust) or take shatter-prevention measures using shatter-proof tubes to prevent any damage (physical) from affecting the products even if the lamp is damaged.
○ Select skylights that do not deteriorate easily or shatter when made of resin, or do not easily condense when made of glass, and apply a plastic film to prevent shattering.
○ Use lighting with illuminance and color tone that will not cause errors in the workplace.
- It is necessary to provide a brightness level that allows food handlers to work safely and hygienically.
- If the illuminance is insufficient where work such as a visual inspection is performed, it is necessary to take measures such as installing auxiliary lighting like a desk lamp.
- Consider the color tone of the lamp in addition to the illuminance where work such as color tone inspections is performed.

[Work environment lighting]
- The illuminance of the work environment is specified in Article 604 of the Ordinance on Industrial Safety and Health and JIS. The work categories and standards set forth in Article 604 are: precision work: 300 lux or more; ordinary work: 150 lux or more; rough work: 70 lux or more. According to the JIS illuminance standard, ordinary visual work at a general manufacturing factory is 500 lux.

Drainage system

○ Design and manage the drainage route to minimize the possibility of contamination of products.
○ Have the floors and drainage basins sloped so that water will not collect on them, and so that they can be easily cleaned.

● Required reference to legal provisions related to food safety

Facility specifications: general
◎ The facility shall be located at an appropriate place on the site, and shall have a size and structure suitable for the purpose of use. ◎ Appropriate cleaning equipment shall be installed in the facility.
Facility specifications: Specific locations
◎ The area around the food handling section in the facility shall have a structure that is easy to clean with an appropriate slope to allow it to drain properly. ◎ The surfaces of walls and floors shall not adversely affect the food handling, and the surfaces shall be smooth and can be cleaned and washed. Also, if necessary, unless the walls are made of impermeable materials, wainscoting made of impermeable materials shall be installed at least 1 meter from the floor. ◎ Ensure there is appropriate illuminance for the work.
Facility management: maintenance and inspection
◎ The person responsible for the maintenance and inspection of the facility shall be determined. ◎ The maintenance and inspection status of the facility shall be inspected.
Facility management: hygiene management
◎ Unnecessary items shall not be placed where manufacturing, processing, processing, storage, sales, etc. are performed. ◎ The hygienic condition the facility shall be maintained by regular cleaning, including the interior walls, ceilings and floors. ◎ Windows and doorways shall not be left open. When this is unavoidable, take measures to prevent the invasion of dust, rodents, and insects. ◎ The implementation status of the facility hygiene management shall be confirmed and recorded. ◎ If vomiting occurs at the facility, immediately disinfect it properly using a germicide.

GMP 4 Specifications of Manufacturing and Storage Area, and Utility Management

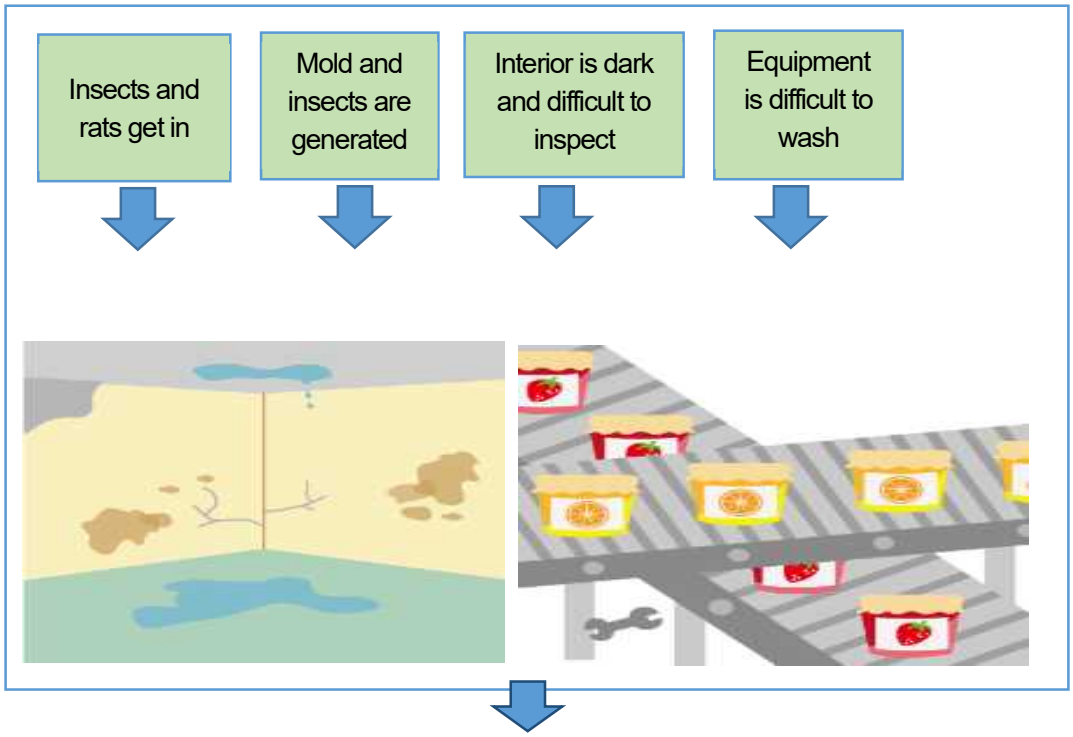
● Requirements

Factory buildings and facilities (receiving areas, raw material and product handling areas, preparation areas, packaging and storage areas) shall have specifications suitable for their intended use. Controls shall be established and implemented, as necessary, for utilities such as air, high-pressure air and other gases that may come into contact with food to prevent contamination and condensation.

● Concepts, specific examples

Specifications in the overall manufacturing area
○ Design the specifications of the facility so that there is no secondary contamination or adverse effects on food. ○ Ensure that the facility is easy to maintain, clean, and wash, and has low deterioration. ○ Take durability into consideration, such handling heavy objects used for work and abrasion. ○ Use materials that can withstand cleaning, washing, sterilization, and disinfection. ○ Design drainage and wastewater systems so that they do not compromise food safety.

■ Key problems in facilities



Hygienic work, products and raw materials
Designed with workers and the environment in mind

[Specification examples for specific locations]

- When installing pipelines, electric and air ducts, etc., install them in locations where dust and dead insects will not accumulate on the top surfaces, and are easy to clean.
- Install electric and air ducts behind the ceiling, and when wiring or ducts are removed try to pull them out vertically instead of horizontally so that dust does not fall out.
- Consider the corrosiveness of the raw materials used when selecting floor, wall and ceiling building materials.

Utilities overall

○ Design and manage the utility storage and supply routes to minimize the possibility of product contamination.

Steam

○ Generate and handle the steam so that it is not contaminated. In particular, ensure that the cleansing agents (chemical agents) used for the boilers that generate steam are approved for food use and are not mixed into the steam.
○ Install a filtration device (filter) near the end of the steam pipe.
○ Use boiler chemicals approved by regulatory authorities.
○ Generate and handle steam to prevent contamination.
○ Confirm that the steam used directly for foods or for equipment that comes into contact with foods does not have an adverse effect on foods.

Compressed air, carbon dioxide, nitrogen and other gases

○ Ensure that the gas equipment used for manufacturing and filling has specifications that do not pose a risk of contamination of food, and are properly maintained.
○ Use approved gas for gases that come in contact with food.

○ Ensure sure that dust, oil, and water are removed from air and gases that come into contact with food.
○ Filter gases as close to the point of use as possible.

Air conditioning and ventilation

○ Establish air requirements so that the air that comes into direct contact with raw materials and food does not adversely affect the food.
○ Establish air-conditioning and ventilation systems to prevent air pollution.
○ Ensure that the air-conditioning and ventilation systems are designed to be easy to clean, wash and replace filters.
○ Regularly check the outside air intake for damage.
○ Consider the air balance between the intake and exhaust air of the facility.
For example, if the facility is only exhausting soot and steam from its exhaust system, the intake and exhaust balance will be lost, causing a negative pressure to be created in the processing room and material room.
○ If necessary, maintain the pressure difference to prevent air from entering clean areas.
○ Since outside air will flow in through windows, doors, and gaps, and insects are attracted, hygiene management becomes difficult.
○ Install inspection ports for cleaning, washing and filter replacement for both intake and exhaust. For small insects (thrips, etc.), 0.5 mm is penetrable.
○ Regularly inspect the outside air intake to prevent clogging due to intake of dust and insects and deterioration due to rust and corrosion.
○ Prevent condensation, mold, etc., by installing equipment to eliminate soot and steam.
○ Establish procedures for monitoring and controlling the cleanliness of air in areas where products are manufactured and it is easy for microorganisms to develop and survive.

● Required reference to legal provisions related to food safety

Air, ventilation, air conditioning

◎ Adequate ventilation and control to the appropriate temperature and humidity shall be provided as necessary.

GMP 5 Equipment

● Requirements

Equipment shall be designed and selected for its intended use, and used, maintained and stored to minimize food safety risks.

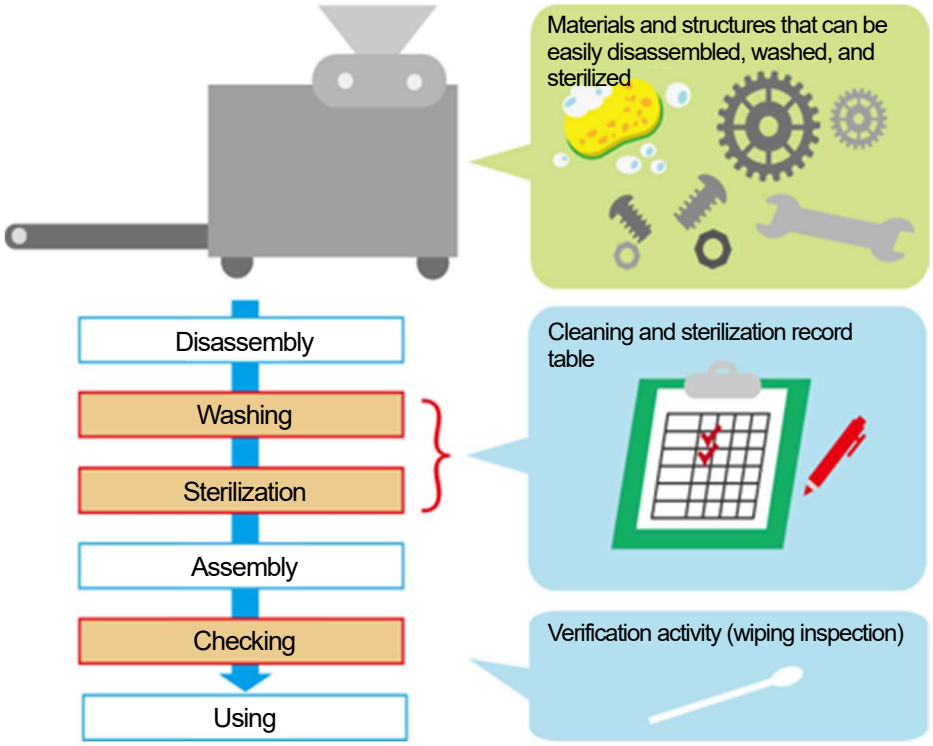
● Concepts, specific examples

Equipment specifications

○ Select manufacturing and processing equipment that is effective against the hazards (biological, chemical, and physical) of the product, paying attention to the following points. In addition, secure the equipment in an adequate number and capacity according to the manufacturing and processing volume, take into account the handling methods and flow lines, and ensure that the equipment is installed properly.
  ・ Install equipment that is easy to clean, wash, disinfect and maintain, and as possible, has a good draining structure.
  ・ Install equipment that does not cause the entry of foreign matter (such as paint).
  ・ Ensure that the piping (pipes and ducts) can be cleaned and washed, will drain well, and that there are no unused branch pipes.
  ・ Use disassembly equipment for maintenance, cleaning, cleaning, disinfection, and monitoring if necessary.

- It is important that the food contacting surfaces are durable, easy to maintain, clean, wash, disinfect and monitor, and are not affected by food or cleaning and washing.
- Ensure that the food contacting surfaces are as impervious as possible and resistant to rust and corrosion, and that rust and corrosion are being monitored.
- It is important that the equipment is made of materials that do not adversely affect the products.
- Confirm that the parts attached to the equipment do not affect the safety of the products.

■ Activities to maintain the hygiene of food handling equipment and utensils



● Required reference to legal provisions related to food safety

Equipment specifications
◎ There shall be sufficient sizes and numbers of the equipment according to the type of product, its manufacturing method and production volume. ◎ Equipment and facilities for heating, cooling or storing products shall have temperature or pressure control devices.
Hygiene management of Equipment
◎ There shall be a place where the equipment can be stored in a hygienic manner. ◎ The equipment shall be cleaned, disinfected and stored in a designated place in a hygienic manner. ◎ The equipment shall be used for its intended purpose in order to maintain hygiene. ◎ The implementation status of activities to maintain the hygiene of the equipment shall be inspected, and records prepared and saved.

GMP 6 Maintenance

● Requirements

A system shall be established to systematically maintain all equipment that is critical to product safety.

● Concepts, specific examples

Equipment maintenance and management

○ Establish and implement procedures for maintenance and management of all equipment that is critical to product safety. The procedures include the following concepts.

① Ex-post maintenance
A management method that performs maintenance after a breakdown or stoppage, or after a decrease in function.

② Preventive maintenance
A management method that focuses on prevention, such as using equipment inspections and regular parts replacement.

③ Improvement maintenance
A management method that focuses on improvement and reinforcement so that failures do not recur.

○ Procedures for maintenance and management of equipment and instruments include the following items.

- Person responsible for maintenance and inspections
- Identification of equipment requiring maintenance and inspections
- Frequency of maintenance and inspections
- Method of confirming and recording the status of maintenance and inspections
- Procedure for putting equipment back in service after repair
- Post-repair cleaning, washing and sterilization procedures

Maintenance precautions

○ Repair the equipment in such a way that will not contaminate the foods.
○ After repairs, perform inspections before production and processing start, and perform cleaning and sterilization as necessary.
○ Replace temporarily attached parts with regular ones during scheduled maintenance.
○ Confirm that the food handling equipment and utensils are not damaged and that there are no missing parts such as screws.
○ Perform preventive maintenance systematically as well as ex-post maintenance.
○ Include equipment in preventive maintenance plans to monitor and control food safety. For example, include sieves, air conditioning filters, magnet traps, metal detectors, etc.
○ When equipment fails or is damaged repair it immediately and maintain it so that it can be used normally.
○ When performing maintenance, be careful not to contaminate the surrounding manufacturing and processing lines and equipment.
○ Be careful not to overlook any temporarily installed equipment when taking food safety measures.
○ Ensure that all materials used for maintenance are suitable for the intended use.
○ Select lubricants and heat transfer media that will not sacrifice safety even if they come into contact with food directly or indirectly.
○ Identify maintenance and inspection workers and conduct training related to maintenance activities.

● Required reference to legal provisions related to food safety

Equipment maintenance and management

◎ Train maintenance and inspection personnel on the preventing hazards from entering products.
◎ When food handling equipment is broken or damaged, repair it immediately and maintain it so that it can always be used properly.

GMP 7 Staff Facilities

● Requirements

Staff facilities shall be designed and operated to minimize food safety risks, including allergens.

● Concepts, specific examples

○ Facilities for food handlers include shoe boxes and shoe lockers for changing from commuting shoes to facility shoes, changing rooms, toilets, cafeterias and break rooms. These must be kept clean at all times to prevent contamination and foreign matter from entering the manufacturing and processing site.

Changing rooms

○ Install a sufficient number of lockers.
○ Install the room in a place where work clothes are not easily contaminated when food handlers move to the manufacturing area.

Hand washing equipment

○ Equipment for hygienic hand washing and drying
- It is important that a sufficient number of this equipment be installed in appropriate locations and that there be sterilization and disinfection equipment and hot water equipment as necessary.
- Maintain a sufficient supply of water, equipped with soap suitable for hand washing, and keep the equipment clean and always available.

Toilets

○ Hygienic toilet structures
- Install a sufficient number.
- Install the toilets in a location that is sufficiently isolated from the food handling areas.

○ Provide hand washing facilities.
○ Always keep the toilets clean, and regularly clean and disinfect them.

Company cafeteria

○ Locate cafeterias and places where food and drinks are stored and eaten to minimize the possibility of cross-contamination with the manufacturing area.

● Required reference to legal provisions related to food safety

Facilities and hand washing equipment for food handlers

◎ Ensure that hand washing and drying can be performed properly and that water can be supplied sufficiently. In addition, provide soap and other items suitable for hand washing, and keep it clean and always ready for use.

Facilities and toilets for food handlers

◎ Provide a sufficient number of toilets with hygienic structures.

GMP 8 Identification and Control of Contamination Risks

● Requirements

The physical (metals, etc.), chemical (drugs, allergens, etc.), and biological (microorganisms, etc.) contamination risks that may affect the products, from receiving of raw materials to shipping of the products shall be identified. In addition, the necessary control methods, procedures and standards for the contamination risk shall be established.

● Concepts, specific examples

The identification of contamination risks and the methods of managing those risks are related to the risks and countermeasures identified in HACCP Procedure 6 (Principle 1). The risks identified in HACCP Procedure 6 (Principle 1) that are considered critical will lead to the step of identifying them as CCPs in HACCP Procedure 7 (Principle 2). Other risks are managed in GMP 8.

Biological hazard factor control

○ Efforts to prevent hazard factors such as pathogenic microorganisms and the toxins, viruses, and parasites they produce by controlling the hygiene of the work environment to prevent contamination of products, removing them through sterilization processes, and controlling their generation by controlling product characteristics are important.

[Hazard factor control points]

- Know the hazard factors ⇒ Bacteria that cause food poisoning
- Find the hazard factors ⇒ Build a system for testing food poisoning bacteria
- Do not mix the hazard factors ⇒ Hygiene management of raw materials and food handlers, manufacturing and processing environment, equipment, etc.
- Do not increase the number of hazard factors ⇒ Temperature, time, formula design (water activity, pH, etc.)
- Eliminate the hazard factors ⇒ Sterilization and cleaning

Chemical hazard factor control

○ Regarding harmful substances derived from living things such as mold venom, food additives that do not conform to the usage standards, allergens, lubricating oils used in facilities, cleaning agents, disinfectants, etc., it is important to select raw materials, receive them, handle them appropriately, mix them in the manufacturing and processing processes, use detergents suitable for equipment and utensils in the cleaning process, and store them in designated places.

[Hazard factor control points]

- Know the hazard factors well ⇒ Poisons contained in fish and shellfish such as mold venom, histamine and blowfish, allergens contained in foods, food additives with usage standards, chemicals used in facilities, lubrication oil, cleaning agent, etc.
- Find the hazard factors ⇒ Component analysis and other means
- Do not mix the hazard factors ⇒ Obtain raw material certificates, manage allergens, etc.
- Do not increase the number of hazard factors ⇒ Temperature and time management to prevent increase of bacteria causing mold venom and histamine
- Eliminate the hazard factors ⇒ Make cleaning methods procedural

Physical hazard factor control

○ Establish a visual inspection system for hazard factors of hard foreign substances such as glass pieces, metal pieces, plastics and stones, and soft foreign substances such as insects, cover equipment and containers that expose raw materials and products, and perform maintenance inspections to make sure that parts used in manufacturing and processing equipment have not dropped off or been damaged. As a method of detecting, sorting and eliminating foreign matter, it is common to install foreign matter sorting equipment, metal detectors, X-ray detectors, etc.

[Hazard factor control points]

- Know the hazard factors well ⇒ Causes of glass flake and metal flake contamination and control measures
- Find the hazard factors ⇒ Build a visual system, install metal detectors, X-ray detectors, etc.
- Do not mix the hazard factors ⇒ Hygienic control of raw materials and food handlers, manufacturing and processing, environment, facilities, etc.
- Do not increase the number of hazard factors ⇒ Replace parts regularly
- Eliminate the hazard factors ⇒ Detection and removal equipment (e.g., metal detector, X-ray detector, powder sieve, etc.)

● Required reference to legal provisions related to food safety

Biological hazard factor control
◎ Harmful microorganisms or the toxins produced by them shall be eliminated or reduced to a safe level during manufacturing or processing so as not to impair the safety and suitability of food. ◎ When controlling time and temperature, give adequate consideration to food characteristics (water activity, pH, levels and types of contaminating and spoiling microorganisms, etc.), expiration date or best-by date of products, packaging forms and manufacturing and processing methods, cooking and processing methods for eating (raw food, heat processing, etc.).
Chemical hazard factor control
◎ Use caution when handling cleaning agents, disinfectants, and other chemical substances. If necessary, mark the name of the content on the container to prevent mixing with the products. ◎ When cleaning equipment, facilities and utensils with detergents, use appropriate detergent types and concentrations.

GMP 9 Cross-contamination

● Requirements

Procedures shall be established to prevent contamination and cross-contamination of raw materials (including containers and packaging materials), semi-finished products, work in process, remanufactured products, rework products and finished products. Sources of contamination shall cover all aspects of food safety, such as microorganisms, drugs and allergens.

● Concepts, specific examples

○ This is related to HACCP procedures 4 and 5.
○ It is also effective to identify areas where cross-contamination occurs due to the flow line movement of people and things, and to take measures to prevent cross-contamination.

Cross-contamination prevention

[Zoning to prevent cross-contamination and improve of flow lines]

○ When making assessments and formulating, prepare a manufacturing and processing process diagram, a supply and exhaust plan, and a product and raw material loading and unloading plan to make it easier to understand the control points of the contamination sources.

○ The flow of zoning and flow line improvement to prevent cross-contamination is as follows.

① Clarify the movement of people and things, and create a flow chart.

⇓

② Assess the possibility of cross-contamination due to the movement of people and things, and take the characteristics of the products and the possibility of contamination into account.

⇓

③ As a result of the assessment, formulate control measures to prevent cross-contamination.

● Required reference to legal provisions related to food safety

Cross-contamination prevention
◎ When determining appropriate control measures for cross-contamination, consider the possibility of contamination and product characteristics.
Allergen management
◎ Take measures to prevent allergens not used as raw materials from being mixed during production and processing.

GMP 10 Stock Management

● Requirements

Establish a system to ensure that raw materials (including containers and packaging materials), semi-finished products, work-in-progress, remanufactured products, reworked products, and finished products shall be used in a prescribed order and within the defined period, be free from contamination, and be stored under non-deteriorating storage conditions.

● Concepts, specific examples

Storage period
○ Ensure that raw materials (including containers and packaging materials), semi-finished products, work in progress, remanufactured products, reworked products, and final products will be used within a predetermined period by using first-in first-out with appropriate management methods.
Storage location
○ Raw materials (including containers and packaging materials), semi-finished products, work in progress, recycled products, reworked products and final products are stored in storage facilities that are not contaminated and do not allow materials to deteriorate due to temperature, humidity, etc.

● Required reference to legal provisions related to food safety

Handling of raw materials
◎ Store unheated or unprocessed raw materials separately from food that is consumed as is to prevent cross-contamination. ◎ Manage raw materials for each lot and record receipts and payments. ◎ Accurately weigh and properly manage food additives.
Storage of raw materials, products, chemicals, etc.
◎ Store foods properly so that there is no cross-contamination or the expiration date has passed. ◎ When storing raw materials, products, chemicals, etc., protect them from dust, condensation, smoke, odors, and other sources of contamination.

GMP 11 Housekeeping, Cleaning and Hygiene

● Requirements

Housekeeping, cleaning and disinfecting where necessary shall be performed throughout all the processes and stages, and a proper hygiene level shall be maintained at all times. Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended use and stored properly.

● Concepts, specific examples

Planning the methods
○ Ensure that housekeeping, cleaning and disinfecting procedures are practical and documented. ○ Train food handlers on standardized methods. It is also effective to provide training while demonstrating actual cleaning, and to post instructions with photos and illustrations. Trained workers will clean, wash and disinfect. ○ In addition to conducting visual checks to confirm that the rules are being followed, use hygiene inspections, such as product inspections and wipe-off inspections, to determine whether the methods are effective. ○ Provide training based on the results of the basic training and hygiene inspections. ○ If the food being handled has low moisture content and the product is manufactured under dry conditions, controlling the amount of water used for cleaning can reduce the risk of microorganisms. ○ Implement the following items for the handling of the detergents and chemicals used for cleaning, sterilization and disinfection. ・ Assign the person responsible for the management

・Stock management of medicines (incoming, outgoing, used amount, stock quantity, user, and first in first out)
・Locking and key management of the drug storage
・Training for the food handlers regarding the handling of drugs

○ Prepare a plan and procedures in order to systematically clean and wash the facility as follows.

① Plan for cleaning and washing the facility
・Describe the frequency of work, the date of work, the person who performed the work, the recording method, etc.

② Procedures for cleaning and washing the facility
・Describe the person responsible for the work, the target, the method, the frequency, the monitoring and verification procedure, the specification of the work equipment, the inspection procedure after the work, the inspection procedure before the start of manufacturing, etc.

Cleaning of cleaning tools and equipment

○ Foreign matter or microorganisms attached to the equipment, facilities, or equipment used for cleaning, washing, sterilization, or disinfection may lead to foreign matter contamination or microbial contamination of the product.
○ Contaminated cleaning tools and equipment may spread the contamination.

[Inspection and maintenance]
・Check the operation and deterioration before and after use, and repair or replace immediately if there is any problem.
・Dirt may remain on the back and bottom of the tools and equipment, so disassemble and check them.

[Storage location]
・Suspend the cleaning tools so that they do not contact the floor and store them dry.
・Determine the storage location so that food handlers can use it immediately, and keep it clean. Posting a notice to that effect will also help to keep it clean.

[Identification]
・Ensure that the cleaning tools and equipment used in the contaminated areas are not mistakenly used in clean areas. It is important to color-code them for the specific use, such as "red" for floors and "blue" for cookware, and separate the storage areas.

● Required reference to legal provisions related to food safety

Overall

◎ Methods of cleaning, cleaning, disinfection and disinfection shall be determined in consideration of the structure, materials, and characteristics of the products to be handled, and documented as necessary.

Equipment and tools used

◎ Keep the equipment and tools used for cleaning, washing, disinfection and sterilization clean and store them in their designated places.

GMP 12 Water and Ice Management

● Requirements

Quality standards classified by application shall be established for water (including steam and ice; the same applies hereafter) used in food manufacturing, and the quality of the water shall be regularly monitored and recorded.
Water added to food and water that may come into contact with food must be food grade.
Facilities, equipment and methods of handling water shall be able to prevent contamination.

● Concepts, specific examples

- ○ When manufacturing food, it is possible to use different kinds of water depending on the application, such as water that is added to food and cooling water that does not contact the food.
- ○ Water that comes into contact with food is water used for food manufacturing.
- ○ Water for food manufacturing refers to water that has passed the 26 items in the water quality inspection listed in the standards for food and additives (notification by the Ministry of Health, Labour and Welfare).
- ○ When using water other than tap water (well water, reused water, etc.), treat it by filtering, sterilization, etc., and conduct water quality tests.

● Required reference to legal provisions related to food safety

Water (water supply equipment)

- ◎ Water for food manufacturing can be supplied at an appropriate position and structure.

Water (water used in manufacturing and processing)

- ◎ Regularly clean the water tank and keep it clean.
- ◎ Water used in food handling facilities is basically water for food manufacturing. If the process is not directly related to manufacturing or does not affect the safety of food, it is not limited to using water for food manufacturing, however do not mix that water with water that comes into direct contact with food.
- ◎ Assign a person responsible for water use hygiene management.

Water (reused water)

- ◎ When reusing water, perform the necessary treatments to prevent any effect on the safety of products, and appropriately manage the treatment processes.

Water (water other than tap water)

- ◎ If water other than tap water is used, install a sterilizing or disinfecting device, confirm that it is operating properly, and record it.

Water (water used for purposes other than manufacturing and processing)

- ◎ The water used for cleaning and washing and the water that is indirectly in contact with the product (e.g., jacketed containers, heat exchangers) must meet the standards according to the application.

Water (water quality test)

- ◎ When using water other than tap water, conduct a water quality test at least once a year, Keep the certificate for at least one year. (If the distribution period of the food to be handled is one year or more, use that period taking into account the expiration date.)
- ◎ As a result of water quality test, if the water is not suitable for food manufacturing, stop using it immediately and take appropriate measures in accordance with directions from an administrative authority.

Ice
◎ Make ice with water for food manufacturing. ◎ Handle and store ice hygienically.

GMP 13 Waste Management

● Requirements

Appropriate procedures for separating, collecting and disposing of waste shall be established. Locations and containers for waste shall be managed to prevent the attraction of pests or the generation of harmful organisms and microorganisms. Waste flow lines shall be established so as to prevent cross-contamination of food.

● Concepts, specific examples

- ○ If waste (including by-products unsuitable for food use) generated as a result of food manufacturing and processing are not properly managed, they can become a breeding ground for pests such as microorganisms, rodents, insects, etc. which will lead to contamination.
- ○ It is necessary to avoid contact between waste and raw materials, materials, and manufacturing and processing equipment.
- ○ Assign a person responsible for waste management (identification, accumulation, quarantine, storage, removal, and disposal), and prepare a procedure manual for waste management. It is important to periodically check the status of waste management, such as whether the work was performed according to the procedure manual.
- ○ Ensure that waste is processed promptly according to the following flow.
  Waste generated in the manufacturing and processing lines → Waste containers → Temporary storage location → Indoor and outdoor waste storage → Collection by designated contractor → Issuance and storage of manifest slip (according to laws and regulations)
- ○ Manage and store waste so that it does not affect products, raw materials, and materials that come into contact with products.
- ○ Prevent cross-contamination between waste and products, in principle, by not storing waste in food handling or storage areas.
- ○ Clearly make containers for waste distinguishable from other containers.

● Required reference to legal provisions related to food safety

Overall
◎ Procedures shall be prepared for waste storage and disposal methods. ◎ A person in charge of waste management shall be appointed. ◎ The status of waste management shall be confirmed.
Storage
◎ Waste shall not be stored in food handling areas or storage areas (including adjacent areas), as long as this does not interfere with the work.
Container
◎ Waste containers shall be clearly distinguishable from other containers, and shall always be kept clean to prevent waste liquid leakage or malodors.

GMP 14 Pest Control

● Requirements

Pest control (inspections and countermeasures) shall be implemented to minimize the risk of pests such as insects, rats, birds, etc. on the premises and in the facilities.
If chemicals are used, handling procedures shall be established so as not to affect food.

● Concepts, specific examples

Pest control

○ The following pest control measures are available.
  ① Inspection plan for pests such as rodents and insects
  Identify the target pests based on past experience, biological basis, product characteristics, etc., and develop an effective plan.
  ② Monitoring and analysis of pests such as rodents and insects
  Monitor pests regularly to ensure that hygiene within the facility is maintained through appropriate monitoring.
  ③ Exterminating and controlling
  If exterminating or controlling is required based on the results of monitoring, have a plan formulated and implemented by qualified personnel that does not affect food or hinder the operation of the facility.

○ It is desirable to not plant flowers and fruits that are attractive to pests such as rodents and insects, and to make sure that the smell of waste and sewage is contained. Establish regular mowing and maintenance practices for greenery.

○ Places where puddles are likely to form, such as in unpaved parking lots, may be a source of midge insects, so take measures such as spreading gravel frequently.

○ In the lighting for entrances and passageways used outside the facility, it is desirable to install yellow or green fluorescent lamps, which are considered difficult for insects to see, or vinyl curtains.

○ Be careful not to allow birds to nest around the eaves of the facility or around the air supply facility. Inspect the mesh and filter regularly.

○ Use nets and water seals at the end of the drainage ditch around the factory, and take measures to prevent rodents and insects from entering the facility through openings.

○ It is desirable that gaps are filled for windows that do not open and close, and that they be removed as necessary. Keep worker and property doors closed when not in use.

○ To prevent dust from scattering and insects from entering due to wind pressure when opening and closing, the windows of the swinging doors should be screened.

○ Do not allow light to leak outside around windows and shutter openings. Applying a light-shielding film or insect-proof sheet to the window is also an effective method.

○ Install an insect trap at the entrance of the workplace inside the building so that no light can be seen from the outside.

Facility measures that are easy to clean

○ Since insects are often found in the gap between the wall and the floor, it is desirable to provide a baseboard at the joint between the wall and the floor.

Chemical management

○ I It is important to determine the procedures for chemical management, spraying procedures, and procedures for starting manufacturing and processing after spraying.

○ I Restrict chemical use to well-trained personnel.

○ I Control the amount of incoming and outgoing chemicals, and store them in a locked place that is isolated from the manufacturing and processing facilities.

○ I It is necessary to record the type of chemical used, the amount used, the concentration used (dilution ratio), the date and time of application, and the location of application.

○ I Since more efficient countermeasures can be expected and chemical management can be omitted, it is preferable to entrust the entire pest control to a specialist.

○ I At least once a week and at least once a month, it is important to check for any pest intrusions or internal occurrences.
○ I Use of poison bait in the manufacturing area is prohibited.

● Required reference to legal provisions related to food safety

Control

◎ Eliminate the breeding sites for pests such as rodents and insects, and take measures to prevent them from entering the facility.
◎ Foods and other edibles shall be stored in containers and kept away from floors and walls to prevent contamination by pests such as rodents and insects.
◎ When raw materials, products, packaging materials, etc. are opened and divided and used multiple times, take measures to prevent contamination, such as by placing them in containers with lids, and storing them.

Extermination

◎ When the presence of pests such as rodents and insects is recognized, exterminate them immediately so as not to affect the products, record the implementation status, and store the record.
◎ Periodically implement extermination (including outsourcing to specialized contractors).
◎ Clarify the expertise of contractors and managers.

GMP 15 Transport

● Requirements

A mechanism shall be documented to ensure that the containers and transport vehicles, including outsourced vehicles, used for transporting raw materials (including packaging materials), semi-finished products, work in progress, refurbished products, reworked products, and final products (including packaging products and final packaged fresh food) are suitable for the intended use, maintained and kept clean.

● Concepts, specific examples

○ Develop and implement documented procedures to maintain the cleanliness suitable for the intended use of the containers and transport vehicles, including outsourced vehicles, used for transporting raw materials (including packaging materials), semi-finished products, work in progress, refurbished products, reworked products, and final products (including packaging products and final packaged fresh food).
○ The following items need to be considered for transport.
- The vehicles and containers that transport products must be clean and structured to prevent external contamination.
- It is necessary to provide refrigeration, freezing, and dehumidification functions when necessary, because temperature and humidity are controlled according to the characteristics of the products being transported.
- Periodically wash and disinfect with a washable material to maintain a state of cleanliness. When any dirt or odor is found, wash it immediately.
- When transporting refrigerated or frozen products, regularly check and record the thermometers in the refrigerator.
- It is important to use vehicles that have sufficient capacity according to the types of food items and the amount handled.
- Cross-check thermometers as necessary to maintain accurate temperatures. (Install two different types of thermometer and confirm that there is no difference in the readings.) .
- Do not allow outsiders to enter the loading area unnecessarily, and do not place any items there that are unnecessary for work.

● Required reference to legal provisions related to food safety

Transport
◎ Vehicles and containers used for transporting food should be maintained in a more appropriate condition, for example, by always being clean and repaired. ◎ After vehicles or containers used for transporting food are used for transporting a different type of food or cargo other than food, clean them using an effective method and disinfect them as necessary. ◎ Manage the food being transported so that it is not contaminated with dust or harmful gases. ◎ Manage the temperature, humidity, time and other necessary conditions during transport. ◎ When food is mixed with a non-food cargo, the food shall be sorted into appropriate containers as necessary. ◎ If necessary, use vehicles and containers that are used exclusively for food, and clearly indicate that they are to be used exclusively for food.

GMP 16 Personnel Hygiene and Health Management

● Requirements

Appropriate hygiene standards for workers shall be documented and implemented in accordance with the laws and regulations of the country in which they are working.
The requirements shall include methods and frequency of hand washing, methods for checking health status, rules for work clothes and footwear, methods for entering and exiting the factory, methods for handling food, and measures against contamination.
These requirements shall be thoroughly communicated to workers and shall also be applied without exception to contractors and visitors.

● Concepts, specific examples

Workers' hygiene conditions are constantly controlled, and care must be taken to prevent contamination.

Health condition

- ○ Workers are given regular medical checkups.
- ○ If a worker is suspected of having an infectious disease or food poisoning with fever, diarrhea, vomiting, etc., or if a skin trauma (burns, cuts, etc.) is suspected, or if there is some problem with a worker's health, it is reported to top management, food safety officer, manufacturing managers, etc., as necessary, to prevent the worker from engaging in product handling and to have a doctor diagnose the condition.
- ○ If a worker complains of illness during work and there is a risk of infection or food poisoning, the facility is sterilized and disinfected as necessary, and also other workers, contractors, and visitors who came in contact will be contacted as necessary.
- ○ For contractors and visitors, it is necessary to obtain their contact information in advance in preparation for the above urgency.

Personal hygiene

- ○ As necessary, food handlers will change to work clothes and footwear that are clean and in good condition according to the purpose.
- ○ Establish laundry and changing rules for the provided work clothes.
- ○ Work clothes worn when handling food may not be used for any purpose other than food protection or hygiene.
- ○ Gloves worn to handle products are to be clean and in good condition.
- ○ Shoes used in the manufacturing and processing areas need to be completely covered and impervious.
- ○ Protective equipment for food handlers maintains hygienic conditions to prevent product contamination.
- ○ Ensure that fingernails are kept clean and tidy.
- ○ Visitors to the facility, such as contractors, suppliers, and construction personnel, are also managed.

Hygienic behavior
○ It is important to clean and disinfect fingers as needed, and to replace disposable gloves. ○ Do not act inappropriately such as touching one's hair, nose, mouth and ears with utensils that handle products or with one's hands. ○ Avoid sneezing and coughing on materials or products. ○ When entering the manufacturing and processing areas, remove hair and dust (using adhesive rollers, air shower, etc.) as necessary. ○ Do not enter contaminated areas, including toilets, while wearing hygienic work clothes, hats and masks, or using special footwear in the workplace. ○ Wear only approved bracelets. ○ It is important to report immediately to a supervisor if any deviations are found while wearing the device. ○ Food and drinks are to be stored and eaten only in the permitted area. ○ Do not store utensils or equipment that come into contact with products in the lockers of food handlers. ○ A written policy shall be established to describe the behavior required of workers in the processing, packaging and storage areas.

● Required reference to legal provisions related to food safety

Food Sanitation Supervisor, Food Hygiene Manager, Manufacturing Manager
◎ Personal hygiene management shall be checked and recorded as needed. ◎ The health status of food handlers shall be checked. If they have any symptoms such as diarrhea or abdominal pain, they shall not be allowed to engage in product handling, and appropriate measures shall be taken, such as having a doctor give an exam and diagnosis.
Food handler health conditions
◎ Food handlers shall be given regular medical checkups. ◎ If a food handler has a health problem such as suspected infection such as fever, diarrhea, vomiting, or food poisoning, or suspected infection among skin trauma (burns, cuts, etc.) it shall be reported to top management, food safety officer, manufacturing managers, etc. to prevent them from engaging in product handling work and receive a doctor's diagnosis. ◎ For cuts and abrasions, food handlers shall use a bandage with a different color from the product and a bandage that can be detected with a metal detector.
Food handler personal hygiene
◎ Food handlers shall change to work clothes and footwear that are clean and in good condition for the purpose as necessary.
Food handlers and hygienic behavior
◎ Food handlers shall clean and disinfect fingers as necessary. When using disposable gloves, they shall replace them. (Before starting to handle the product, after using the toilet, after going to a place where the product may be contaminated, after handling raw products or contaminated raw materials, etc.) ◎ Food handlers shall not act inappropriately such as touching their hair, nose, mouth and ears with utensils that handle products or with their hands. ◎ Food handlers shall not enter contaminated areas including toilets while wearing hygienic work clothes, hats and masks, or using special footwear in the workplace.

GMP 17 Training

● Requirements

All workers shall receive adequate training in food safety principles (including HACCP) and practices, as appropriate for their work.
In addition, a system shall be established for employees to receive appropriate guidance and supervision.
This training shall enable workers to be aware of their roles in food safety and the significance of their efforts.

● Concepts, specific examples

Food safety officer
○ In addition to enhancing their own knowledge and skills, food safety officers establish training programs (contents, implementation timing, methods, frequency (including retraining), etc.), for food handlers, conduct training sessions, and keep training records.
Training
○ It is necessary to provide training for all personnel depending on their food handling roles, including newcomers, to ensure that they obtain the necessary knowledge and skills. ○ The current rules and procedures can be reviewed at any time while incorporating the opinions of food handlers on site. ○ Records created during training can be used for personal assessments and traceability. ○ Conduct re-training (hygiene education) for relevant employees and record them. ○ HACCP training is provided.

● Required reference to legal provisions related to food safety

◎ Food hygiene managers regularly take training courses as stipulated by relevant laws and regulations.
◎ Conduct regular hygiene training for food handlers, and confirm and record the status of the implementation.
◎ Provide food handlers with hygiene education on hygienic handling methods for products, methods for preventing contamination of products, proper hand washing, and health management and other necessary items for food hygiene.
◎ Hygiene education for food handlers should include the following procedures.
- Hygiene management of facilities, equipment and utensils (cleaning, washing and disinfection)
- Response to vomiting at the facility (immediate disinfection using a disinfectant)
- Handling of products
- Product recall
- Storage and disposal of waste

◎ Periodically verify the effects of training, and revise the content as necessary.