

JFS-A Standard Document

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

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

Version 3.0

[Guidelines]

Edition 1.0

Japan Food Safety Management Association

July 25 , 2022

Table of Contents

Introduction.....	3
I Food Safety Management Systems (FSM).....	10
FSM 1 Management or senior management responsibility.....	10
FSM 2 Commitment of management or senior management.....	12
FSM 6 Food Safety Policy and Goals.....	12
FSM 9 Document and record management.....	13
FSM 12 Resource Management.....	14
FSM 13 Purchasing.....	14
FSM 14 Traceability	17
FSM17 Control of Measuring and Monitoring Devices	18
FSM 22 Serious Incident Management.....	20
FSM 23 Product Release	21
FSM24 Control of non-conforming products	22
FSM25 Corrective Action.....	22
II Hazard Analysis and Critical Control Point(HACCP).....	24
HACCP Step 1 Formation of HACCP team	24
HACCP Step 2 Product Information Description.....	25
HACCP Step 3 Identification of Intended Use.....	25
HACCP Step 4 Construction of Flow Diagram	25
HACCP Step 5 On-site Confirmation of Flow Diagram.....	28
HACCP Step 6,7 (Principle 1 and 2) Establishment of methods for analyzing hazards and controlling critical hazards.....	28
HACCP Step 8, 9 (Principle 3, 4) Establishment of control criteria and monitoring methods.....	30
HACCP Step 10 (Principle 5) Establishment of corrective actions (improvement measures).....	31
HACCP Step11 (Principle 6) Setup of verification procedures.....	32
HACCP Step 12 (Principle 7) Record keeping	33
III Good Manufacturing Practice (GMP).....	34
GMP 2 Site Management.....	34

GMP 3	Design, construction and layout of facilities and equipment, and work and product flow lines ..	36
GMP 4	Control of critical hazards that cannot be controlled by the control measures in HACCP procedures 6 and 7 (prevention of cross-contamination).....	38
GMP 5	Personnel Facilities.....	41
GMP 6	Sanitation, work clothes and health management of employees, etc.	42
GMP 7	Training.....	45
GMP 8	Housekeeping, cleaning, sterilization and disinfection.....	46
GMP 11	Air and water management.....	48
GMP 12	Waste Management.....	51
GMP 13	Pest control.....	52
GMP 15	Transport.....	54
GMP 17	Stock Management.....	56
GMP 18	Devices and Tools.....	56
GMP 19	Maintenance	59

Disclaimer: This translated document is machine translated by JFSM and is provided for information purposes only. In the event of a difference of interpretation or a dispute, the original Japanese version of this document is binding.

Introduction

This guideline provides ideas and specific examples of what organizations should implement with regard to the JFS-A Standard Ver. 3.0 For food business operators (organizations) to comply with JFS-A standard.

Food safety management systems vary depending on many factors such as the type of industry, business category, business scale, and social background of the food business operator (organization). It is envisioned that each organization will use these guidelines as a guide for establishing a food safety management system suited to their own needs.

The overall JFS standard is shown in Figure 1. These guidelines are for the JFS-A for the food manufacturing sector (CI - CIV) and for the "chemical products (including biochemical products) manufacturing sector (K). (Table 1)

The JFS-A standard is intended for food business operators (organizations) aiming to improve the level of food safety, mainly in general hygiene management, and to operate HACCP in a flexible manner. In this guideline, illustrative examples in the form of figures and tables are included where necessary to make it easier for food business operators (organizations) to understand.

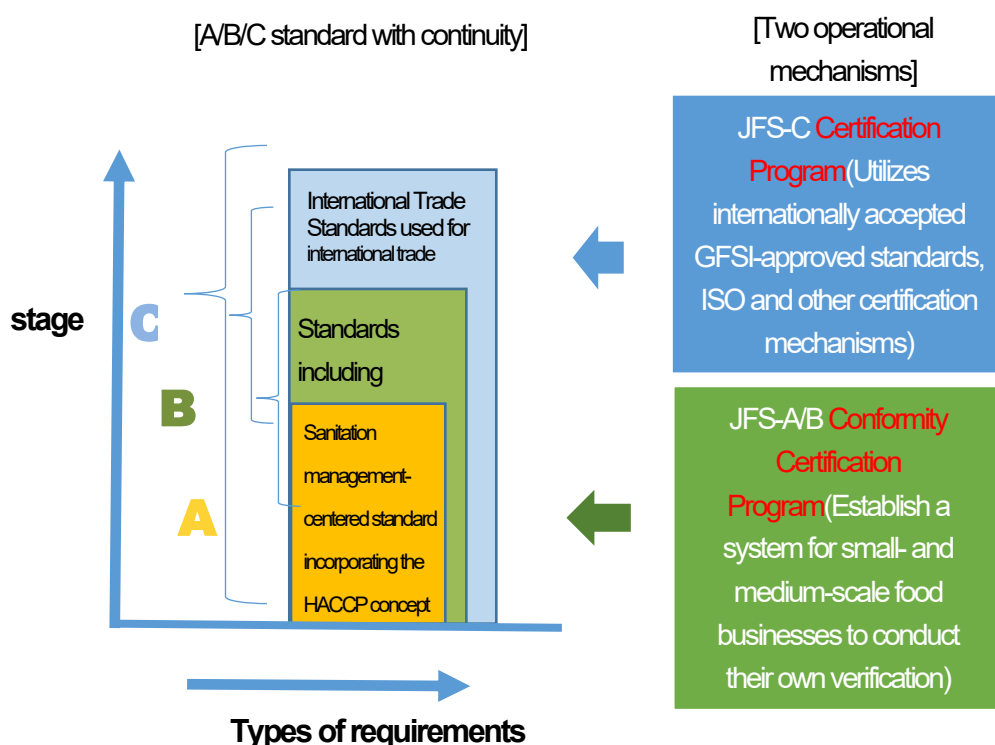


Figure 1: Overall view of the JFS Standards and Certification/Certification of Conformity Program

Table 1: List of Sectors by GFSI

Code	Sector/Subsector	Code	Sector/Subsector
AI	Farming of Animals for Meat/ Milk/ Eggs/ Honey	FI	Retail / Wholesale
All	Farming of Fish and Seafood	FII	Food Broker / Agent
BI	Farming of Plants (other than grains and pulses)	H	Provision of Food Safety Services
BII	Farming of Grains and Pulses	G	Provision of Storage and Distribution Services
BIII	Pre-process handling of plant products	I	Production of Food Packaging
C0	Animal primary conversion		
CI	Processing of perishable animal products	J1	Hygienic Design of Food Buildings and Processing Equipment (for building constructors and equipment manufacturers)
CII	Processing of perishable plant products	JII	Hygienic Design of Food Buildings and Processing Equipment (for building and equipment users)
CIII	Processing of perishable animal and plant products (mixed products)		
CIV	Processing of ambient stable products	K	Manufacture of chemical products (including biochemical products) (Manufacture of additives, vitamins, minerals, cultures, flavors, enzymes, processing aids, etc.)
D	Production of feed		
E	Catering		

Reference: The GFSI Benchmarking Requirements version 2020 PART I

* : Sectors presented by GFSI that are covered by this standard document are framed.

The JFS-A standard is intended for businesses that implement HACCP in addition to general hygiene control.

This Standard Document applies to the following “Food Manufacturing Sectors(CI, CII, CIII, CIV)” and “Chemical Products (Including Biochemical Products) Manufacturing Sector(K)” (Table 1)

※Pet food is included in the following food manufacturing sector

Food Manufacturing Sectors(C I ~CIV)

CI : Processing of perishable animal products

CII : Processing of perishable plant products

CIII : Processing of perishable animal and plant products (mixed products)

CIV : Processing of ambient stable products

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

K : Manufacture of chemicals (including biochemical products)

(Production of chemical products (including biochemical products) and cultures used as food ingredients or processing aids in food production)

Chemical products herein refer to chemical products (including biochemical products) related to food products.

《Features of JFS-A Standard Ver. 3.0》.

JFS-A Standard is intended for relatively small food business operators (organizations) to establish a foundation for food safety management.

(Feature 1) Even small-scale food business operators can aim for international standard food safety. To ensure consistency with international food safety initiatives, the GFSI (Global Food Safety Initiative) Global Market Program Fundamentals (a program to improve food safety initiatives for small- and medium-scale operators) is referenced.

It also incorporates the seven principles and 12 procedures of hazard control (HACCP) proposed by the Codex Alimentarius Commission and allows for their flexible application.

(Feature 2) Easy-to-understand and easy-to-apply HACCP

JFS-A standard enables flexible application of HACCP so that even small-scale organizations can work on HACCP. For example, it allows for commonly published information and data to be referred to in identifying risk factors (HACCP procedures 6 and 7), and for monitoring to be recorded using a logbook (HACCP procedure 12).

(Feature 3) Food safety level can be improved step by step.

Food business operators (organizations) can work on food safety management in accordance with international food safety management systems. In order to further improve their efforts, they can step up to the higher level JFS-B and JFS-C standards. For reference, a comparison of the requirements of JFS-A, B, and C standards is shown in Table 2.

(Feature 4) Complying with Japan's Revised Food Sanitation Law

Japan's Law for Partial Revision of the Food Sanitation Law, etc. (Law No. 46, 2008) requires small-scale business operators to implement "sanitation management appropriate to the characteristics of food handled" (so-called "sanitation management incorporating the HACCP concept"), which is necessary to prevent the occurrence of food sanitation hazards (Food Sanitation Law, Article 50-2, Paragraph 2).

The requirements of the JFS-A standard are structured so that they can respond to this "sanitation control incorporating the concept of HACCP." By appropriately implementing food safety management based on the JFS-A standard, it will be easier to explain their efforts to food sanitation inspectors at health centers.

《How to use the JFS-A Standard Ver. 3.0 Guidelines》

- This guideline is intended to provide guidelines for understanding the meaning and purpose of the requirements of the JFS-A standard and what exactly should be implemented.
- Desirable food safety management practices differ among food business operators (organizations). In order to assist all food business operators who intend to work on the JFS-A standard to establish

a food safety management system (FSMS) that meets the requirements of the standard, this guideline includes basic concepts and various examples related to the requirements. The JFS-A standard requires food business operators (organizations) to work on food safety management through on-site creativity and ingenuity, and does not require capital investment to comply with the JFS-A standard. We hope that each food business operator (organization) will make maximum use of these guidelines and incorporate information from the government and industry associations to implement food safety management initiatives in line with the JFS-A standards.

These Guidelines are organized as follows.

- Requirements
- Concepts, specific examples
- Items to be referred to in the legal provisions related to food safety*

※Legal provisions are taken from the Food Sanitation Law Enforcement Regulations of Japan.

○ Points to be noted in this guideline

- The specific examples in this guideline are not requirements, but are presented only as examples.
- It is not necessary to establish an implementation system according to the sequence of requirements in the standard. It is also possible to build from Good Manufacturing Practices (GMP) and Food Safety Management (FSM).
- The legal provisions in these Guidelines are based on Japanese laws and regulations.

《Elements and Composition of JFS Standards (Sectors: CI - CIV/K)》

JFS standards consist of Food Safety Management Systems:FSM, which are requirements for the management of an organization's activities, HACCP, which is a method of controlling hazards, and Good Manufacturing Practices (GMP), which are requirements for general hygiene management, and are interrelated. (Figure 2)

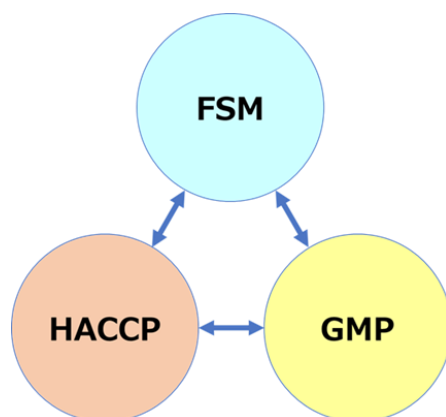


Figure 2: Basic structure of the JFS standard

On the other hand, the order of standards is not the order in which implementation systems are established. In practice, it is possible to start from GMP or FSM, and each organization should take appropriate measures. This guideline provides ideas and specific examples to serve as a reference when utilizing the JFS-A standards. However, these are examples only, and other ideas and methods may be selected if it can be explained technically and scientifically that the requirements of the JFS standards are met. They can also be used together with research data and food safety theory from research institutes and industry associations that have been published in the past, making use of technical information and know-how possessed by individual industries.

The legal and regulatory requirements for food safety management systems vary by industry and region, and while the JFS Standards and these Guidelines assume compliance with those legal and regulatory requirements, they are not all encompassed in these Guidelines and should be reviewed by each organization on an individual basis. Therefore, it is necessary for each organization to individually confirm the compliance.

We hope that these guidelines will help you understand JFS standards.

Table 2 Comparison of JFS-A/B/C

JFS-Astandard Version 3.0

No.	item (FSM 12 items)
FSM 1	Management or senior management responsibility
FSM 2	Commitment of management or senior management

FSM 6	Food Safety Policy and Goals
-------	------------------------------

FSM 9	Document and record management
-------	--------------------------------

FSM 12	Resource Management
--------	---------------------

FSM 13	Purchasing
--------	------------

FSM 14	Traceability
--------	--------------

FSM 17	Control of Measuring and Monitoring Devices
--------	---

FSM 22	Serious Incident Management
--------	-----------------------------

FSM 23	Product Release
--------	-----------------

FSM 24	Identification of nonconformities and control of nonconforming products
--------	---

FSM 25	Corrective Action
--------	-------------------

JFS-Bstandard Version 3.0

No.	item (FSM 20 items)
FSM 1	Management or senior management responsibility
FSM 2	Commitment of management or senior management

FSM4	Compliance with food safety laws
------	----------------------------------

FSM 6	Food Safety Policy and Goals
-------	------------------------------

FSM 7	Food Defense
-------	--------------

FSM 9	Document and record management
-------	--------------------------------

FSM 11	Procedures and Instructions
--------	-----------------------------

FSM 12	Resource Management
--------	---------------------

FSM 13.1	Purchasing
----------	------------

FSM 13.2	Supplier Performance
----------	----------------------

FSM 14	Traceability
--------	--------------

FSM 16	Allergen Management
--------	---------------------

FSM 17	Control of Measuring and Monitoring Devices
--------	---

FSM 18	Product labeling
--------	------------------

FSM 19	Analysis and Inspection
--------	-------------------------

FSM 21	Complaint Handling
--------	--------------------

FSM 22	Serious Incident Management
--------	-----------------------------

FSM 23	Product Release
--------	-----------------

FSM 24	Identification of nonconformities and control of nonconforming products
--------	---

FSM 25	Corrective Action
--------	-------------------

JFS-Cstandard Version 3.0 supplementary requirements

No.	item (FSM 31 items)
FSM 1	Top Management Responsibility

FSM 2	Top Management Commitment and Food Safety Culture
-------	---

FSM 3	Management Review
-------	-------------------

FSM 4	Compliance with food safety laws
-------	----------------------------------

FSM 5	Food Safety Management System and General Requirements
-------	--

FSM 6	Food Safety Policy and Goals
-------	------------------------------

FSM 7	Food Defense
-------	--------------

FSM 8	Food Fraud Prevention
-------	-----------------------

FSM 9.1	Documentation procedures
---------	--------------------------

FSM 9.2	Control and storage of documented information
---------	---

FSM 10	Specification Control of Purchased or Provided Items and Services
--------	---

FSM 11	Procedures and Instructions
--------	-----------------------------

FSM 12	Resource Management
--------	---------------------

FSM 13.1	Purchasing
----------	------------

FSM 13.2	Supplier Performance
----------	----------------------

FSM 13.3	Outsourcing
----------	-------------

FSM 14	Traceability
--------	--------------

FSM 15	Product development
--------	---------------------

FSM 16	Allergen Management
--------	---------------------

FSM 17	Control of Measuring and Monitoring Devices
--------	---

FSM 18.1	Product labeling(B-to-C products)
----------	-----------------------------------

FSM 18.2	Product labeling(B-to-B products, work in progress, semi-finished products)
----------	---

FSM 19.1	Analysis and Testing
----------	----------------------

FSM 19.2	Environmental Monitoring
----------	--------------------------

FSM 20	Internal Audit
--------	----------------

FSM 21	Complaint Handling
--------	--------------------

FSM22	Serious Incident Management
-------	-----------------------------

FSM 23	Product Release
--------	-----------------

FSM 24	Identification of nonconformities and control of nonconforming products
--------	---

FSM 25	Corrective Action
--------	-------------------

FSM 26	Utilization of Kaizen suggestions from persone
--------	--

JFS-Astandard Ver.3.0

No.	item (HACCP 1 0 item)
HACCP step 1	Formation of HACCP team
HACCP step 2	Product Information Description
HACCP step 3	Identification of Intended Use
HACCP step4	Construction of Flow Diagram
HACCP step 5	On-site Confirmation of Flow Diagram
HACCP step 6, 7 (principle1, 2)	(Principle 1) Hazard Analysis (Principle 2) Critical Control Points

HACCP, step 8, 9 (principle3, 4)	(Principle 3) Establishment of Critical Limits (Principle 4) Monitoring System
----------------------------------	---

HACCP step10 (principle5)	Corrective Actions
HACCP step11 (principle6)	Establish HACCP plan validation and verification procedures
HACCP step12 (principle7)	Documents and Record

JFS-Astandard Ver.3.0

No.	item (GMP 1 4 item)
-----	---------------------

GMP 2	Site Management
GMP 3	Design, construction, layout of business site and work and product flow lines
GMP 4	Control of critical hazard factors that cannot be controlled by critical control points (CCPs) (Prevention of cross-contamination)
GMP 5	Personnel Facilities
GMP 6	Hygiene, workwear and Health management of personnel, etc.
GMP 7	Training
GMP 8	Housekeeping, cleaning, sterilization and disinfection

GMP 11	Air and water management
GMP 12	Waste Management
GMP 13	Pest control

GMP 15	Transport
--------	-----------

GMP 17	Stock Management
GMP 18	Devices and Tools
GMP 19	Maintenance

JFS-Bstandard Ver.3.0

No.	item (HACCP 1 2 item)
HACCP step 1	Formation of HACCP team
HACCP step 2	Product Information Description
HACCP step 3	Identification of Intended Use
HACCP step4	Construction of Flow Diagram
HACCP step 5	On-site Confirmation of Flow Diagram
HACCP step 6 (principle 1)	Hazard Analysis
HACCPstep 7 (principle2)	Critical Control Points
HACCP step 8 (principle3)	Establishment of Critical Limits
HACCP step 9 (principle4)	Monitoring System
HACCP step10 (principle5)	Corrective Actions
HACCP step11 (principle6)	Establish HACCP plan validation and verification procedures
HACCP step12 (principle7)	Documents and Record

JFS-Bstandard Ver.3.0

No.	item (GMP 1 4 item)
-----	---------------------

GMP 2	Site Management
GMP 3	Design, construction, layout of business site and work and product flow lines
GMP 4	Control of critical hazard factors that cannot be controlled by critical control points (CCPs) (Prevention of cross-contamination)
GMP 5	Personnel Facilities
GMP 6	Hygiene, workwear and Health management of personnel, etc.
GMP 7	Training
GMP 8	Housekeeping, cleaning, sterilization and disinfection

GMP 11	Air and water management
GMP 12	Waste Management
GMP 13	Pest control

GMP 15	Transport
--------	-----------

GMP 17	Stock Management
GMP 18	Devices and Tools
GMP 19	Maintenance

JFS-Cstandard Version 3.0 supplementary requirements

No.	item (HACCP 1 2 item)
HACCP step1	HACCP Team Assembly
HACCP step2	Product Description
HACCP step3	Identification of Intended Use
HACCP step4	Construction of Flow Diagram
HACCP step5	On-site Confirmation of Flow Diagram
HACCP step6 (principle1)	Hazard Analysis
HACCP step7 (principle2)	Critical Control Points
HACCP step8 (principle3)	Establishment of Critical Limits
HACCP step9 (principle4)	Monitoring System
HACCP step10 (principle5)	Corrective Actions
HACCP step11 (principle6)	Verification
HACCP step12 (principle7)	Documents and Record

JFS-Cstandard Version 3.0 supplementary requirements

No.	item (GMP 2 2 item)
-----	---------------------

GMP 1	Facility Environment
GMP 2	Site Management
GMP 3	Design, construction, layout of business site and work and product flow lines
GMP 4	Physical, chemical and biological product contamination risks and isolation
GMP 5	Personnel Facilities
GMP 6.1	Personal hygiene criteria for personnel
GMP 6.2	Personnel workwear
GMP 6.3	Health management of personnel
GMP 6.4	Application to nonbusiness personnel and visitors
GMP 7	Training
GMP 8	Housekeeping, cleaning, sterilization and disinfection
GMP 9	Rework
GMP 10	Patrol and inspection of the site
GMP11	Air and water management
GMP 12	Waste Management
GMP 13	Pest control
GMP 14	Acceptance of purchased items
GMP 15	Transport
GMP 16	Storage
GMP 17	Stock Management
GMP 18	Devices and Tools
GMP 19	Maintenance

JFS-A Standard (Sector: CI~CIV/K)
< Manufacture of food products >
<Manufacture of chemicals (including biochemical products)>

I Food Safety Management Systems (FSM)

FSM 1 Management or senior management responsibility

●Requirements

Management or senior management must share and operate an organizational structure that, at a minimum, clarifies the duties and responsibilities of those who affect food safety. Management or senior management must determine who is responsible for food safety management.

●Concepts, specific examples

1. Role of management or senior management
 - 1) Periodically verify and review the effectiveness of the company's own efforts to ensure food safety and quality and to secure consumer confidence.
 - 2) Clearly define an organizational chart that includes a communication system for instructions, reporting, and consultation, and share it with employees.
2. Communication system for instructions, reporting, and consultation
 - 1) In order to clarify the communication system for instructions, reporting, and consultation, it is easier to manage by using meeting bodies and morning meetings to determine the activities necessary for food safety. Instructions, reporting, and consultation are as follows.
 - (1) Instructions: The clarification of tasks and roles by a supervisor, manager, or other person.
 - (2) Reporting: The person who performed the work communicates the facts to a supervisor, manager, or other person.
 - (3) Consultation: Confirmation of appropriateness should be obtained when it is not possible to determine whether the work is appropriate, or when new activities are undertaken.
 - 2) A communication system should be in place to ensure that safe food products can be shipped even in the event of major changes in the manufacturing environment, such as a sudden increase in order volume, accelerated shipping times, or personnel shortages. (Shipment decisions are also related to procedures in FSM 23 (Product Release)).
3. Food safety officer
 - 1) Determine a food safety officer as the person responsible for food safety management.
 - 2) The food safety manager's knowledge of food safety policies, food safety knowledge, and field knowledge and experience in the organization will enable him or her to create an effective system.
 - 3) If there is a separate food safety manager or food safety officer, it is important to share information and collaborate. They may also serve concurrently.

- Items to be referenced in legal provisions related to food safety

Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))

(i) Appointment of food sanitation supervisors, etc.

(a) Appointment of a person who conducts business prescribed in Article 51, paragraph (1) of the Act (including the cases where it is applied mutatis mutandis pursuant to Article 68 and Article 62, paragraph (3) of the Act) Hereinafter referred to as a "business person" in this table) shall appoint a person responsible for food sanitation. Article 68 A person engaged in a business prescribed in Article 1, paragraph (1) of the Act (including cases where it is applied mutatis mutandis under Article 62, paragraph (3) of the Act) shall specify a person responsible for food sanitation. However, this shall not apply to business persons prescribed in each item of Article 66-2, paragraph (4). In addition, a food sanitation supervisor prescribed in Article 48 of the Act may also serve as a person responsible for food sanitation.

(d) A business person shall respect the opinions of the person responsible for food sanitation.

(e) A person responsible for food sanitation shall take necessary precautions to ensure compliance with the measures prescribed in Article 66-2, paragraph (3) and endeavor to state necessary opinions to a business person.

Appended Table 17 (Re: Article 66-2, paragraph (1)) of the Ordinance for Enforcement of the Food Sanitation Act

(i) c. Food sanitation supervisors shall comply with the following matters

(1) Attend seminars held by prefectural governors, etc. or seminars approved by prefectural governors, etc. on a regular basis, and endeavor to acquire new knowledge concerning food sanitation (limited to business under Article 54 of the Act (including cases where it is applied mutatis mutandis under Article 68, paragraph (3) of the Act)) (limited to businesses under Article 54 of the Act (including cases where it is applied mutatis mutandis under Article 68, paragraph (3) of the Act)) (i) To make efforts to learn new knowledge concerning food sanitation (limited to businesses under Article 54 of the Act (including cases where it applies mutatis mutandis to Article 68, paragraph (3) of the Act))

(ii) follow the instructions of a business person and take charge of sanitation control.

(e) A person responsible for food sanitation shall take necessary precautions to ensure compliance with the measures prescribed in Article 66-2, paragraph (3), and shall endeavor to state necessary opinions to the business person.

■Reference: "Food Hygiene Manager" and "Food Hygiene Manager"

	food sanitation manager	food sanitation supervisor
Laws and regulations governing	Article 48 of the Food Sanitation Law	To be specified by prefectures, designated cities, etc. under Article 50, paragraph 2 of the Food Sanitation Act.
Qualifications	national qualification	official certification
Report to	prefectural governor	health care centre
Target	For each licensed facility that manufactures or processes the subject food, additive, etc.	Per business license facility
Whether qualifications are renewed or not	Basically none. Regular attendance at practical training courses is recommended.	Basically none. Regular attendance at designated training sessions is recommended.

FSM 2 Commitment of management or senior management

●Requirements

Management or senior management shall show evidence of its commitment to building, implementing, maintaining and continually improving its food safety management systems. The organizational structure for the implementation of the food safety management system must be clearly defined and the duties must be made known to all employees. Evidence must also be maintained that employees have been made aware of them.

●Concepts, specific examples

1. Management or senior management is responsible for the establishment, implementation, maintenance, and continuous improvement of the food safety management system and demonstrates its commitment to the establishment, implementation, maintenance, and continuous improvement of the system through the implementation of the following.
 - 1) Develop a food safety policy.
 - 2) All organizations involved in food safety and their respective roles are clearly defined and made known to all employees.
 - 3) Communicate to employees in a timely manner the importance of compliance with laws and regulations, social norms, and rules set by the organization.
 - 4) Establish business goals that support food safety.
 - 5) Review the food safety management system in a timely manner.
 - 6) Provide necessary resources in a timely manner.
 - 7) Continuous improvement is required from verification of HACCP procedures 11 and FSM 14 and 22.
 - 8) Other matters necessary for the establishment, implementation and maintenance of food safety management systems
2. Evidence of employee awareness" includes documentation of communication through food safety-related employee communication opportunities and training, as well as wall postings.

FSM 6 Food Safety Policy and Goals

●Requirements

Management or senior management must have a clear, concise, written food safety policy.

●Concepts, specific examples

1. Management or senior management should create a food safety policy that meets safe and appropriate quality standards and that all employees understand and recognize. The policy should be developed with the following in mind.
 - 1) The organization provides safe and trusted food products to consumers based on the consumer.
 - 2) Respond appropriately to changes in the social environment and comply with laws, ordinances, fair rules and social norms.
2. To ensure that all employees understand and recognize the food safety policy, for example;
 - 1) Always teach it during employee training.
 - 2) Posting the policy in a place where employees can see it on a regular basis.
 - 3) Communicating the policy at morning meetings. etc.
3. Food safety policies should be developed with the involvement of management or senior management, and food safety policies should be reviewed periodically for adequacy.

FSM 9 Document and record management

●Requirements

The organization shall establish and implement procedures to control processes to ensure food safety and to create, maintain, and preserve documents and records to evidence effective operations.

●Concepts, specific examples

1. Record

- 1) Record keeping will enable the following actions to be taken.
 - (1) Clearly demonstrate appropriate food safety management systems to third parties
 - (2) Able to analyze trends in activity over a period of time
 - (3) Information can be shared within the organization
- 2) The records required will vary depending on the industry, type of business, size, and complexity of the organization's operations.
- 3) Some documents, mainly records, require long-term storage. Therefore, "appropriate storage period" should be set in consideration of the shelf life of products and other factors. Therefore, "appropriate storage period" should be set in consideration of the shelf life of products, etc., and the documents should be managed so that they will not be disposed of by mistake during that period.
- 4) Establish "rules for amending records" so that corrections such as erroneous entries will not be suspected of being "falsification." For example, "Corrections should be made with double lines, and the date of correction and the name of the person who made the correction should be written on the corrected part, etc. It is desirable to establish a method that can be clearly understood by a third party.

●Items to be referenced in legal provisions related to food safety

Procedure Manual for Cleaning, Washing and Sanitizing

Food Sanitation Act Enforcement Regulations, Article 66-2, paragraph 3

- (ii) Taking into consideration the structure and materials of facilities and equipment, machinery and appliances, and the processes of manufacturing, processing, cooking, transporting, storing, or selling food, a procedure manual (hereinafter referred to as a "procedure manual") to properly implement measures necessary for public health in these processes
- (iv) Verify the effectiveness of the sanitation management plan and procedure manuals, and review their contents as necessary.

Record Keeping

Article 66-2, paragraph (3) of the Ordinance for Enforcement of the Food Sanitation Act

- (iii) The status of implementation of sanitation management shall be recorded and preserved. The period for keeping records shall be reasonably set based on the period until the food or additives handled are used or consumed.

Appended Table 17 (Re: Article 66-2, paragraph (1)) of the Ordinance for Enforcement of the Food Sanitation Act

- (iii) Sanitation control of facilities, etc.
 - (d) For instruments such as thermometers, pressure gauges, and flow meters, and for equipment used for sterilization, disinfection, sanitization, or water purification, their functions shall be periodically inspected, and the inspection results shall be recorded.
- (iv) Control of water used, etc.
 - (e) When water suitable for drinking is used and sterilization or water purification equipment is installed, periodically check that the equipment is working properly and record the results.

(v) Rats and insect control

Rats and insects shall be exterminated at least twice a year, and records shall be kept for a period of one year.

(xiv) Others

(a) To the extent necessary to prevent the occurrence of food sanitation hazards, efforts should be made to prepare and preserve records concerning the source of purchase, state of manufacture or processing, shipping or sales destination, and other necessary matters concerning the food or additives handled.

(b) When self-inspections have been conducted on manufactured or processed products, efforts shall be made to preserve the records.

FSM 12 Resource Management

●Requirements

Management or senior management must ensure that the organization has the management resources (people, goods, and money) necessary to implement the organization's food safety initiatives (hazard control (HACCP) and Good Manufacturing Practices (GMP) in this standard).

●Concepts, specific examples

1. Management or management should make management resources (people, goods, and money) available to ensure food safety.
2. Since management resources are limited, management should determine priorities and devise ways to maximize effectiveness and ensure that food safety is implemented in a rational manner.
3. Management or senior management must constantly check to ensure that goals and plans are not in line with reality and that front-line employees are well educated and trained to respond to changes in the manufacturing environment.
4. Specific management resources are as follows
 - (1) Human resources: employees (number and competence), etc.
 - (2) Goods: buildings, interiors, machinery, equipment, facilities, etc.
 - (3) Money: funds used for food safety activities
5. Example 1 of Rational Implementation: Training
External training, for example, can be difficult to conduct on a regular basis due to the high cost of training a large number of workers, but if one person receives training and internal training is conducted and deployed horizontally, it is possible to share the latest information throughout the organization.
6. Example of Reasonable Practice 2: Interior
When a facility has deteriorated due to long-term use, it is effective to prioritize items in order of their direct impact on food safety and to prepare the manufacturing environment over a period of several years, rather than repairing everything at once.

FSM 13 Purchasing

●Requirements

The organization must establish and implement acceptance procedures to ensure that all externally procured raw materials, materials, and services that affect food safety comply with the organization's requirements.

●Concepts, specific examples

【 Purchasing】

1. This standard requirement requires that each organization establish and implement procedures to verify what it purchases from outside sources according to the magnitude of the risk it poses to food safety.
Procedures related to acceptance confirm that there are no discrepancies with the specifications and contracts for the raw materials.
2. Confirmation method means to determine whether or not what is purchased from outside conforms to the specifications established by the company, and specifically includes the following.
 - 1) Inspection of a sample representative of the lot of what is to be purchased
 - 2) Acceptance inspection of items to be purchased
(e.g., temperature of acceptance, expiration/expiration dates, appearance, etc.)
 - 3) Compliance with specifications in Certificate of Quality and Certificate of Analysis
3. The organization should periodically verify that the raw materials it purchases meet its standards and that verification methods are implemented in accordance with its procedures
4. Where appropriate, an audit of the food safety management system of the manufacturer of what is being purchased or a review of the results of an audit by a third party is also an example of verification.

Example of Supplier Data Entry Form
(Product Specification)

product specification No

approval	examination

creation-day author

Product Name	Product Name
Material Packaging Form	Allergy Labeling not required required()
Product Name	Ingredients, Direct Producers, Manufacturers
Target Consumers	
way of eating	
Preservation refrigerated freezing normal (setting °C)	
Shipping refrigerated freezing normal (setting °C)	
Storage refrigerated freezing normal (setting °C)	
best before date	product label
manufacturing plant	

standard	volume	ICS number	best before date	code	Raw material mixing ratio	Standard Quality Standards (Characteristics)		Nutritional analysis g/100g	
						sugar		water	
						salt		protein	
						pH		fat	
						Microbiological Standards		carbohydrate	
						General bacterial count		ash	
						E. coli		energy	
								sodium	

Photo attached



Outline of manufacturing process (see flow diagram for details)



●Requirements

The organization must establish procedures for implementing and maintaining tracing, covering all processes from the supplier (at least one step before) to the recipient (at least one step after) to ensure product identification.

●Concepts, specific examples

【Traceability in the FSM14】

1. Traceability records are important to confirm the manufacturing process of the subject product and to assure the safety of the food in the event of a serious product accident.
2. "Recipient" in this requirement basically refers to the purchaser one step further in the food chain, and does not necessarily include the final consumer of the product. "Recipient" may also refer to wholesalers, retailers, etc., who handle the shipped product.
3. Shipped products are not always delivered to the purchaser, but may be delivered to a warehouse designated by the purchaser. Therefore, this requirement requires that the owner of the product and the "recipient" where the product is actually placed be known so that speedy action can be taken when a problem occurs. Raw materials, containers and packaging materials, services, and outsourced processes purchased from outside (hereinafter referred to as "raw materials, etc.") are also basically subject to traceability up to one step before.
4. Each organization is required to reliably identify the supplier (at least one step before) to the recipient (at least one step after). By linking these organizations, the entire supply chain can be traced.

【Recorded information required for traceability】

1. The maintenance and provision of record information necessary for traceability is as follows
 - 1) Maintenance of traceability
 - (1) Establish procedures related to traceability, depending on the product (including identifiable labels for raw materials and products, as well as external procurement).
 - (2) Identify the status of raw materials at the main product stage (including primary processed products).
 - (3) Establish lot units for products and raw materials as necessary.
 - (4) Establish and implement procedures for preparing and maintaining records of incoming and outgoing shipments.
 - (5) Confirm that traceability is functioning, including work in process, recycled products, and reworked products.
 - (6) If necessary, product samples for each lot are stored.
 - 2) Provide records related to traceability
 - (1) Establish and implement procedures for the preparation of records and the retention of records.
 - (2) When requested by the government, submit records related to traceability.

Examples of records required for process and tracing

	accessioning	manufacture	custody	shipping
Product Information	Ingredient Information Food Safety Information Receiving Inspection Records	Daily Production Report Inspection records Process records	Product temperature records Inventory records	Product Shipping Information Destination Information
Environmental Information	Delivery Vehicle Temperature Record Delivery vehicle hygiene records	GMP-Related Records Person in charge information	Internal temperature record	Delivery Vehicle Temperature Record Delivery vehicle hygiene records
Sampling Information	pre-sampled product record	Quality Control Inspection and Acceptance	Quality Control Thermometer Calibration Record	—

FSM17 Control of Measuring and Monitoring Devices

●Requirements

The organization must manage to ensure that the devices and equipment it measures and monitors to ensure food safety remain reliable at all times.

●Concepts, specific examples

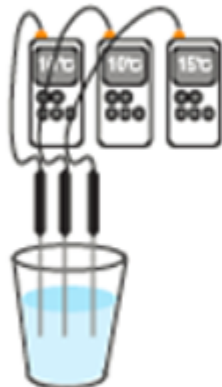
1. It is necessary to check the accuracy of devices and equipment used in measurement and monitoring activities to ensure food safety (calibration).
2. Creation of a list
Make a list of all devices and equipment used for all measurements and monitoring that need to be checked for accuracy (fairness), clarify the frequency and methods of calibration and maintenance, implement them to ensure that there are no omissions in the accuracy check, and record them. Records may be kept in a logbook.
Scales for weighing food additives, etc. (K sorbate, nitrite, etc.) for which use standards are set under the Food Sanitation Law should also be added to the list. (For details on the standards for use, check "Standards for Foods, Additives, etc. (Ministry of Health and Welfare Notification No. 370, December 28, 1959)", etc.)
The list should clearly state the allowable error range (e.g., $\pm 2^{\circ}\text{C}$, ± 5 seconds, etc.) for each device.
3. Accuracy check (calibration) method
Timers should be checked to confirm that they match the time signal by using a telephone or other means.
For thermometers, refer to "Accuracy Check (Calibration) of Equipment" on page 50 of the "Guide for Introduction to HACCP in Food Production" (available on the Ministry of Health, Labor and Welfare website).

3. Improvement of Instrument Accuracy (Calibration)

Thermometers are essential measuring instruments for HACCP. If they are out of calibration, safe food cannot be produced. It is necessary to check (calibrate) the accuracy periodically.



(1) Check the temperature indicated by three or more thermometers. If all thermometers display the same temperature, there is "no problem"; if they are out of alignment, there is a problem.



This can be done right away, so let's give it a try!



(2) Use boiling water and ice water. Fill the electric kettle with water and bring it to a boil. When the water boils, point the thermometer sensor at the spout and confirm that the displayed temperature reaches 100° C after standing still (about 1 minute). Next, prepare crushed ice. Place the thermometer sensor in the ice and check that the temperature readout reaches 0° C after about 1 minute of standing still. If all the thermometers display the same temperature, we assume "no problem," and if they are off, we assume "problem."



(Note: Use an electric kettle because kettles are affected by direct heat. If the temperature indication is different by - 5° C, the actual temperature will be 85° C if the control standard for heating is 90° C or higher, which may result in insufficient heating.



From "A Guide for Introduction to HACCP in Food Production" (Ministry of Health, Labour and Welfare)

4. Frequency of accuracy checks (calibration)

For precision instruments other than thermometers and timers (e.g., metal detection detectors), the frequency should be set based on the schedule recommended by the instrument manufacturer.

5. After accuracy verification (fairness) is completed, measuring/monitoring equipment, test equipment, and inspection equipment should be managed to prevent damage and adjustment errors.
6. If it becomes apparent that measuring, monitoring, testing, or inspection equipment is not appropriate (i.e., has errors beyond acceptable limits), a record (including a logbook) should be kept, posted at the site, and the equipment itself should be marked. Define procedures for evaluating potentially affected products and taking appropriate action.

●Items to be referenced in legal provisions related to food safety

Sanitation of facilities, etc.

Appended Table 17 (Re: Article 66-2, paragraph (1)) of the Ordinance for Enforcement of the Food Sanitation Act

(iii) Sanitation control of facilities, etc.

(d) For instruments such as thermometers, pressure gauges, and flow meters, and for equipment used for sterilization, disinfection, sanitization, or water purification, their functions shall be periodically inspected, and the inspection results shall be recorded.

FSM 22 Serious Incident Management

●Requirements

The organization must develop an incident response manual*, implement it in the event of an incident, and maintain it in effect at all times. This manual should also describe how to remove or recall (recall) products, if necessary.

The products supplied by the organization must be tested at least once a year in accordance with the Incident Response Manual.

※This manual is designed to ensure that when a food safety issue arises, appropriate actions and controls are taken to prevent the problem from escalating.

●Concepts, specific examples

1. A critical incident is a food accident that has the potential to affect food safety, but does not include accidents that do not affect food safety but may affect quality.
2. Since it is often not known at first whether an accident is serious or not, it is advisable to work on the assumption of a worst-case scenario when an accident occurs.
3. In the event of a recall accident that has a serious impact on food safety, the incident should be reported to the audit company after the initial response is complete. In addition, once a voluntary recall is initiated, it should be reported to the Ministry of Health, Labour and Welfare through the health center with jurisdiction.
4. An accident response manual documenting accident reporting, product removal, and product recall shall be prepared as follows
 - 1) In the event of a major accident, the response shall be based on relevant management procedures such as nonconformity handling and complaint handling.
 - 2) Appoint an authorized person in charge for critical incident management.
 - 3) Establish and maintain an up-to-date emergency contact network for customers, consumers, and relevant authorities.
 - 4) Appoint a person responsible for providing information to customers, consumers, and relevant authorities to ensure effective communication.
 - 5) Clearly define internal communication mechanisms, such as notifications to employees.
 - 6) Conduct mock drills and reviews at least once a year based on the accident response manual to evaluate the company's ability to respond to serious accidents.
 - 7) To establish the severity of the accident and whether or not there is a risk to customers, the accident should be documented and evaluated. Accident records should include the following
 - (1) The product involved and the location of manufacture
 - (2) Quantity of product affected
 - (3) The extent of the affected product (lot, batch, etc.)
 - (4) Records of manufacturing

(5) Quantity and location of shipments made

●Items to be referenced in legal provisions related to food safety

Emergency response

Appended Table 17 (Re: Article 66-2, paragraph (1)) of the Ordinance for Enforcement of the Food Sanitation Act

(ix) Provision of information

- (b) A business person shall provide information on health hazards (limited to those diagnosed by a physician and diagnosed as being caused or suspected to be caused by said food or additive; hereinafter the same shall apply in this item) from consumers concerning the product. The same shall apply hereinafter in this item). (ii) When obtaining information on the health hazards of a product (limited to those that have been diagnosed by a physician and that are or are suspected to be caused by said food or additive) and information on violations of the Law, a business person shall endeavor to provide said information to the prefectural governor, etc.
- (c) When a business person obtains information about a product from a consumer or a person who handles the product that is undeniably likely to lead to the occurrence of a strange taste or odor, contamination with a foreign substance, or other health hazard, the business person shall endeavor to provide said information to the prefectural governor, etc.

Collection Mechanism

Appended Table 17 (Re: Article 66-2, paragraph (1)) of the Ordinance for Enforcement of the Food Sanitation Act

(x) Recovery and disposal

- (a) In the event of food sanitation hazards or the threat of such hazards arising from a product, a business person shall, from the viewpoint of preventing health hazards to consumers, establish a system for responsibility for recall, methods for alerting consumers, specific methods for recall, and procedures for reporting to the prefectural governor, etc. having jurisdiction over the area where said food or additive is handled, so that said food or additive can be quickly and appropriately recovered. The procedures for reporting to the prefectural governor, etc. with jurisdiction over the area where the facility handling the food or additive is located should be established.

FSM 23 Product Release

●Requirements

The organization must establish and implement appropriate procedures for product release (shipment).

●Concepts, specific examples

Product Release Procedures

1. the procedures for releasing a product include the following
 - 1) Verify that the product to be shipped conforms to the product specifications.
 - 2) Verify that not only the product specification but also the process control is appropriate.
2. The following items must be confirmed prior to release
 - 1) Release procedures are up-to-date and available to personnel
 - 2) Specifications of raw materials, ingredients, additives, packaging materials, recycled products, rework and finished products are clearly identified
 - 3) The final shipping decision makers are clearly identified.
 - 4) Procedures are in place to verify that products to be shipped conform to product specifications and that process controls have been properly implemented.

FSM24 Control of non-conforming products

●Requirements

The organization must create and enforce rules for not using or shipping raw materials (including containers and packaging materials), semi-finished products, work-in-process products, recycled products, reworked products, and finished products that may pose a safety hazard.

●Concepts, specific examples

1. These requirements set up barriers at each stage on the way to the final product, and play the role of stopping nonconformity when it occurs.
2. Raw materials (including containers and packaging materials), semi-finished products, work-in-process products, recycled products, reworked products, and finished products that pose a safety problem are treated as nonconformities. The organization determines the responsible person and manages according to procedures to prevent unintended use or erroneous shipment of nonconforming items.
 - 1) It is effective to have well-defined manufacturing and inspection procedures in advance to detect nonconformities in each process.
 - 2) In addition to detection through manufacturing and inspection procedures, nonconformities may also be detected through customer complaints.
 - 3) Nonconforming products found are to be clearly identified and segregated so that they cannot be mistakenly used. In identifying the scope of nonconforming products, appropriate judgment should be made to ensure that nonconforming products are not mixed in with compliant products.
 - 4) Non-conforming products are disposed of or corrected (reprocessed, reworked, etc.).
 - 5) After that, if recurrence prevention is necessary, FSM25 is implemented.
3. It is important to recognize that process control is capable of detecting nonconformities, because if we recognize that the discovery of nonconformities is a bad thing, it will be difficult to get reports from the field.

●Items to be referenced in legal provisions related to food safety

Nonconformity Management
Appended Table 18 (Re: Article 66-2, paragraph (2)) of the Ordinance for Enforcement of the Food Sanitation Act
(v) Establishment of improvement measures
At individual critical control points, improvement measures shall be established when monitoring results reveal deviations from the control standards.

FSM25 Corrective Action

●Requirements

The organization shall establish and implement written corrective actions in the event of nonconformities affecting food safety. (Corrective action is the process of correcting a nonconformity to a condition that is not a nonconformity, determining the cause of the nonconformity and eliminating the cause of the nonconformity.)

●Concepts, specific examples

1. The organization establishes and implements procedures to ensure that causes of detected nonconformities affecting food safety are eliminated as soon as possible and to prevent recurrence
2. corrective actions are developed and implemented by those who have the competence to analyze the causes and develop countermeasures.
3. The flow of corrective actions shall be handled according to the following procedures.
 - 1) Grasp the actual situation of nonconformity (including customer complaints).
 - 2) Identify the causes of nonconformity.
 - 3) Implement necessary measures to prevent recurrence of nonconformity.
 - 4) Review the effectiveness of the corrective actions taken.
 - 5) It is desirable to document the sequence of actions related to corrective actions.

II Hazard Analysis and Critical Control Point(HACCP)

Hazard Analysis and Critical Control Point(Control of Hazardous Factors)

HACCP is a tool for establishing a preventive control system in a process that identifies specific hazards (hazards) and their control measures for food safety and does not rely on testing and inspection of the final product.

The success of HACCP requires management and engaged personnel to work together and expertise in a wide range of areas, including primary production, microbiology, and manufacturing and processing techniques.

A HACCP plan is a document or set of documents prepared in accordance with HACCP principles (Codex General Principles of Food Hygiene 2020: from the first edition of 2021 by the Japan Food Sanitation Association) to ensure control of critical hazards in food operations. A HACCP system refers to the development of a HACCP plan and the implementation of procedures according to that plan (from Codex General Principles of Food Hygiene 2020: Japan Food Sanitation Association, first edition 2021).

HACCP Step 1 Formation of HACCP team

●Requirements

A HACCP team shall be assembled with competent staff.

●Concepts, specific examples

1. The HACCP team should be composed of people with various professional skills to the extent possible, such as those in charge of the manufacturing and processing departments, quality assurance, quality control, and engineering departments including facilities, maintenance, and maintenance of machinery and equipment used in manufacturing, to eliminate blind spots in hazard factor analysis and to facilitate communication. The HACCP team leader (food safety manager) should be a food sanitation manager or food sanitation supervisor who has knowledge of the product, specialized skills, and knowledge of the product characteristics and processes, and who has good communication skills and can organize opinions within the company.

When the food safety manager and the HACCP team leader are different personnel, coordination must be ensured.

2. Depending on the size of the business, there are many cases in which various tasks are performed concurrently, and for this reason, the manager himself may be the team leader, or one person may be responsible for all food safety-related actions, etc. However, it is important to try to ensure the cooperation of employees within the company to the extent possible.

3. If there is a lack of knowledge or expertise within the organization, it may be useful to receive outside training or to engage the participation and advice of outside food sanitation experts. A guide for industry associations by the Ministry of Health, Labor and Welfare can be used as a reference.

4. The HACCP team is responsible for managing food safety initiatives within the organization.

5. The HACCP team will identify the scope of application of the HACCP system and appropriate GMPs. Within the scope, the team identifies what products and processes are covered by the HACCP plan.

HACCP Step 2 Product Information Description

●Requirements

Product specifications shall be documented.

The document shall describe all product information necessary to conduct hazard analysis.

Scope of the HACCP system shall be defined per product or product group and per process line or process location.

●Concepts, specific examples

1. In order to clarify the characteristics of the product, the specifications and characteristics shall be described for the final product in necessary items as follows

- 1) Specifically, for the final product, describe the name and type of product, product characteristics, names of raw materials, names of additives and standards for use, form of packaging, units and quantities, materials of containers and packaging, expiration date or best before date and storage method, internal targets for controlling hazards in the product (including standards specified by the supplier, such as ingredient standards for bacteria specified by the Food Sanitation Law). (including standards specified by the supplier, such as ingredient standards for bacteria specified in the Food Sanitation Law).
- 2) In facilities that manufacture multiple products, it may be effective to group foods by similar characteristics and processing steps for the purpose of creating a HACCP plan.
- 3) If the food contains allergens or there may be cross-contact of allergens within the facility, this should also be noted.

2. Identify the scope of the HACCP system and the appropriate GMP (PRP in Codex).

HACCP Step 3 Identification of Intended Use

●Requirements

Intended use of the product and target consumers shall be clearly described in a written document.

●Concepts, specific examples

1. Describe the intended use (manner of use) and target consumers of the product in the documentation as follows

- 1) Clarify the method of consumption or use and the intended consumers. Particular attention should be paid to the contents in the case of vulnerable persons, young children, and the elderly.
 - 2) If the intended use includes the need for cooking or precautions after opening the package, the necessary information should be described.
2. For foods intended for susceptible populations, enhanced process controls, more frequent monitoring, product testing to verify the effectiveness of controls, or other activities may be necessary to assure a high level of assurance that the food is safe.

HACCP Step 4 Construction of Flow Diagram

●Requirements

The flow diagram that covers all steps in the operation shall be constructed.

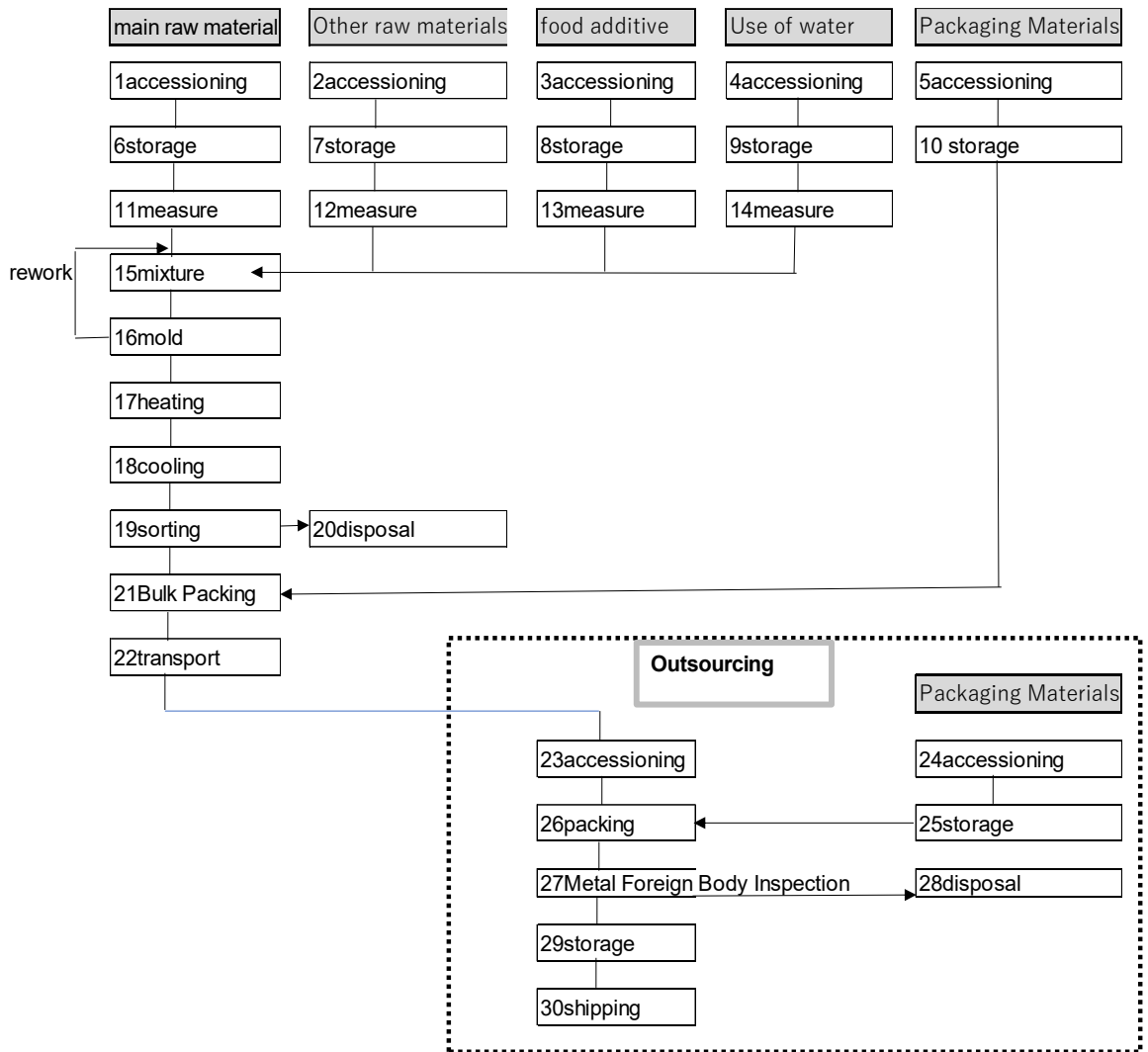
● Concepts, specific examples

1. A flow diagram should be prepared for a series of manufacturing or processing processes from the receipt of raw materials to the shipment of the final product, showing the operations of each process along the flow. The same flow diagram may be used for a group of products manufactured using similar processing steps.
2. The flow diagram is used as the basis for conducting a hazard analysis to evaluate the likelihood that a hazardous factor will occur, increase, decrease, or be introduced.
3. The flow diagram should be accurate and detailed enough to perform a Hazard Analysis.

【Construction of Flow Diagram】

4. A flow diagram shall be prepared according to the following procedures
 - 1) Briefly enumerate all processes and operations from receipt of raw materials to shipment of final products.
 - 2) Enclose the enumerated raw materials and processes in a frame, connect the frames with arrows, and number them in process order.
For raw materials, also include food additives, packaging containers, water used, gases (if used), etc. These should be listed in the same column with a framework and an arrow connecting them to the process in which they are used.
 - 3) In the processing of raw materials, clearly indicate any wastes generated or raw materials used in the processing that will be separately used in the product.
 - 4) In the process, if there is a pass/fail judgment, reprocessing, reuse, or redo process, clearly state it so that it can be controlled.
 - 5) Outsourcing processes are also to be specified.
5. Drawings of the facility showing the outline of each process and the planar and three-dimensional layout of the facility will help identify process points and possible cross-contamination areas and assist in the analysis of hazard factors.

Flow Diagram Example



HACCP Step 5 On-site Confirmation of Flow Diagram

●Requirements

The flow diagram shall be verified whether it correctly reflects the existing process steps of the operation.

●Concepts, specific examples

1. A person with sufficient knowledge of the process should check on site as follows to ensure that the process is clearly defined in the flow diagram so that the hazard analysis in HACCP procedure 6 can be sufficiently performed. It is recommended to check the flow diagram on site against the layout diagram of the site.

- 1) On site, check in order from the upstream process to confirm that the appropriate process is shown, including temporary storage and management of semi-finished products.
- 2) If there is any inconsistency between the flow diagram and the processes or activities on site, confirm with the person in charge the correct management method and revise the document.
- 3) Confirmation is made by observing the work at various times during the work period and checking if the flow diagram and the work are consistent.

HACCP Step 6,7 (Principle 1 and 2) Establishment of methods for analyzing hazards and controlling critical hazards

●Requirements

In the process from the purchase of raw materials to shipment, the company must analyze itself or identify, by appropriate means, important hazard factors that may cause health hazards and determine how to control them (where and what to implement). Microorganisms, chemicals (including allergens), and hard foreign matter must be considered as hazard factors.

●Concepts, specific examples

1. Biological, chemical and physical factors in food that may cause adverse health effects are referred to as "hazardous factors."

2. Organizations need to identify what kind of hazard factors specific to raw materials, manufacturing processes, and products exist in their factories.

This requirement provides two methods for identifying these hazards: (1) analyze the significant hazard factors by oneself, and (2) utilize information such as "industry-specific guides prepared by food business associations" that have been publicly announced.

Method 1) is based on the premise that the organization identifies and analyzes potential hazard factors in raw materials and each manufacturing process on its own, and then identifies critical hazard factors from the perspective of frequency and severity of occurrence of possible hazard factors. This method may require the organization to inspect and take data in-house.

Method (2) does not assume that the organization itself analyzes the hazard factors. The organization identifies hazard factors in an appropriate manner by utilizing publicly available information on hazard factors.

Publicly available information on hazard factors includes the following.

◆ Industry-specific guides prepared by food and other business associations (Japan, Ministry of Health, Labour and Welfare)

URL: <http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000179028.html>)

◆ HACCP Related Information Database (Japan, Food Industry Center)

Use "Food and Hazard Analysis" and "Hazard Control Technology Data" in the HACCP-related Information Search.

In "Food and Hazard Analysis", it is possible to search by food type.

(URL: <http://www.haccp.shokusan.or.jp/information/search/>)

- ◆ Food Safety Commission, Cabinet Office, Government of Japan Home Page (Japan)
Hazard information, fact sheets, and risk profiles from the Food Safety Commission, Japan's risk assessment agency, are available for viewing. (URL: <https://www.fsc.or.jp/>)

- ◆ "Fish and Fishery Products Hazards and Controls Guidance" (U.S. Food and Drug Administration: USFDA)
This is a very useful guidance for those who handle food products using fish and fishery products. It provides concise information on how to control hazards for each type of product. It can be downloaded free of charge from the following URL. However, the entire document is in English. Translated versions can be purchased from the website of the Japan Fisheries Association. "Fish and Fishery Products Hazards and Controls Guidance"(U.S. Food and Drug Administration:USFDA)

This guidance is very helpful when dealing with food products that use fish and shellfish. It provides a concise organization of how to control hazards for each type of product. It can be downloaded free of charge from the following URL. However, the entire document is in English.

A translated version can be purchased from the website of the Japan Fisheries Association.

(URL:

<https://www.fda.gov/downloads/food/guidanceregulation/ucm251970.pdf>)

- ◆ New Zealand Ministry of Primary Industries (MPI) Hazard Database
Hazards and their control methods are summarized in an easy-to-understand format.
(URL: <https://www.foodsafety.govt.nz/registers-lists/hazards/>)

- ◆ "Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems" (European Food Safety Authority: EFSA)
This is a guideline for hazard analysis provided by EFSA for small and medium-sized businesses. It can be downloaded free of charge from the following URL. However, the entire document is in English. (URL: <https://www.efsa.europa.eu/en/efsajournal/pub/4697>)

3. When referring to published hazard factor information (manuals, etc.), check whether the raw materials, manufacturing processes, etc. indicated therein are applicable to the company's target products. If there is nothing that can be applied as it is, refer to data from similar cases as much as possible, and if necessary, modify the data to suit your company's raw materials, processes, etc., and use it.
4. Based on the flow diagram (process diagram) at each plant, consider where and how to control the identified hazardous factors.
In general, there are three methods of control: (1) do not allow them to be introduced, (2) do not increase them, and (3) sterilize (eliminate) them. While (1) is handled by general hygiene control, part of (2) and (3) may be subject to critical control points (CCPs) in the process. Appropriate control methods, such as temperature control and handling methods, should be determined. In determining control methods, the "industry-specific guidelines prepared by food business associations" can be used as a reference.
5. Depending on the product, industry, business type, and process, there may be cases where critical hazard factors are not identified and hazard factors can be controlled only by general hygiene management. Even if general hygiene management (GMP) is implemented without fail, important hazard factors that may occur are controlled as critical control points.
6. The method of control should be documented as a "sanitation management plan. A model of a sanitation management plan is provided in the "Industry-Specific Guideline Prepared by Food Business Associations" for reference.

Critical Control Point (CCP): In a HACCP system, a process to which one or more control measures are applied that are essential to control a critical hazard factor (from Codex General Principles of Food Hygiene 2020: Japan Food Sanitation Association, first edition 2021).

●Items to be referenced in legal provisions related to food safety

Analyze hazards and determine critical control points

Appended Table 18 (Re: Article 66-2, paragraph (2)) of the Ordinance for Enforcement of the Food Sanitation Act

(i) Analysis of Hazard Factors

A list of factors that may cause food sanitation hazards (hereinafter referred to as "risk factors" in this table) shall be prepared for each process of manufacturing, processing, cooking, transporting, storing, or selling food or additives. (hereinafter in this table referred to as "control measures") for each process of manufacturing, processing, cooking, transporting, storing, or selling food or additives, and to establish measures to control these hazard factors (hereinafter in this table referred to as "control measures"). (2) The supplier shall establish the measures to control these hazard factors (hereinafter referred to as "control measures" in this table).

Appended Table 18 (Re: Article 66-2, paragraph (2)) of the Ordinance for Enforcement of the Food Sanitation Act

(ii) Determination of critical control points

Processes for which it is indispensable to take control measures to prevent, eliminate, or reduce to an acceptable level the occurrence of the hazard factors identified in the preceding item (hereinafter referred to as "critical control points" in this table).

(i) Processes for which it is essential to take control measures to prevent, eliminate, or reduce to an acceptable level (hereinafter referred to as "critical control points" in this table), with respect to the hazardous factors identified in the preceding item.

HACCP Step 8, 9 (Principle 3, 4) Establishment of control criteria and monitoring methods

●Requirements

Validated criteria (referred to as control criteria or tolerance limits) to determine whether critical hazard factors are being controlled must be established and implemented. The company shall establish and implement a method for monitoring whether the control is being carried out in accordance with these criteria.

●Concepts, specific examples

1. ①Determine criteria for checking whether critical hazard factors are controlled within acceptable limits at critical control points, and ②Determine a method for monitoring whether control is being achieved based on these criteria.
2. The criteria used to confirm that critical hazard factors are controlled within acceptable limits are generally referred to as "critical limits" (CL). The Codex HACCP implementation guidelines also require that this criterion be established. Tolerance limits are sometimes referred to as control criteria (CL), which means the same thing.
3. Monitoring is conducted continuously or at a considerable frequency, visually or by using measuring instruments, to see if control is achieved based on control standards or permissible limits (CL). Examples of monitoring methods can be found in the "Industry-Specific Guides Prepared by Food Industry Associations" for reference. The control criterion or tolerance limit (CL) is the most appropriate parameter to ensure that significant hazards are prevented, eliminated, controlled, or reduced to an acceptable level, and is a value that has been substantiated (validated) with scientific evidence.

4. Monitoring should be conducted continuously or at a reasonable frequency, but records may be kept in a logbook when abnormalities occur, rather than on a case-by-case basis. In either case, the records should be available for later review.

Control Criteria or Acceptable Limits (CL) :

Observable or measurable criteria that relate to control measures for Critical Control Points (CCPs) and that separate acceptable from unacceptable food (from Codex General Principles of Food Hygiene 2020: Japan Food Sanitation Association, first edition 2021).

●Items to be referenced in legal provisions related to food safety

Establishment of management standards

Appended Table 18 (Re: Article 66-2, paragraph (2)) of the Ordinance for Enforcement of the Food Sanitation Act

(iii) Establishment of control standards

For each critical control point, standards for preventing, eliminating, or reducing the occurrence of hazardous factors to an acceptable level (hereinafter referred to as "control standards" in this table) shall be established.

Establishment of Monitoring Methods

Appended Table 18 (Re: Article 66-2, paragraph (2)) of the Ordinance for Enforcement of the Food Sanitation Act

(iv) Establishment of monitoring methods

Methods shall be established for monitoring the status of implementation of control of critical control points on a continuous basis or at a reasonable frequency (hereinafter referred to as "monitoring" in this table). (iii) Methods for monitoring the status of implementation (hereinafter referred to as "monitoring" in this table) of the management of critical control points shall be established.

HACCP Step 10 (Principle 5) Establishment of corrective actions (improvement measures)

●Requirements

When there is a deviation from the control criteria (or tolerance limits), what action is to be taken (corrective action (correction, pursuit of the cause of the occurrence, and removal of the cause, also known as remedial action)) must be determined. (Corrective action (correction, investigation of the cause of the occurrence, and removal of the cause, also called improvement measures)) must be determined.

●Concepts, specific examples

1. In the event of a deviation from the control criteria or permissible limits (CL), the procedures for restoring the control status of the process, restarting the production line that was stopped when the deviation occurred, and isolating the product affected by the deviation and determining and implementing a disposal method are to be specified. Furthermore, it is necessary to investigate the cause of the deviation and take measures to prevent its recurrence. These are called "corrective actions" (improvement measures).
2. In the Codex HACCP implementation guidelines, the term "corrective action" or "remedial action" is used. Corrective action and corrective action have the same meaning.

●Items to be referenced in legal provisions related to food safety

Establishment of remedial measures

Appended Table 18 (Re: Article 66-2, paragraph (2)) of the Ordinance for Enforcement of the Food Sanitation Act

(v) Establishment of improvement measures

Improvement measures shall be established for each critical control point in the event that a violation of control standards is found as a result of monitoring.

HACCP Step11 (Principle 6) Setup of verification procedures

●Requirements

In addition to the "monitoring methods" specified in steps 8 and 9, a procedure must be established and implemented to verify that critical risk factors are being controlled. Whenever there is a change in the manufacturing process, raw materials, raw material ratio, or personnel, it must be verified that the method of controlling critical risk factors is properly set up, and if necessary, the method of control must be modified.4

●Concepts, specific examples

1. Verification procedures need to be determined to ensure that critical hazard factors are properly controlled based on predetermined methods.
2. Verification methods include monitoring by a person responsible for verification other than the person who recorded the data, checking improvement measures and verification records (see HACCP Procedure 12), observation of monitoring implementation, calibration of measuring equipment (instruments) used for monitoring, and inspection of intermediate and final products.
The verification methods include: monitoring by a person responsible for verification other than the recorder, confirmation of improvement measures and verification records (see HACCP Procedure 12), observation of monitoring implementation, calibration of measuring devices (instruments) used for monitoring, and inspection of intermediate and final products.
3. Once a control method has been established, it is necessary to confirm that the method for controlling critical risk factors has been properly established when there is a change in the manufacturing process, raw materials, manufacturing equipment, or employees at the manufacturing process site. This should be done when any of the following events occur
 - (1) Change in raw materials
 - (2) Changes in manufacturing processes or systems (including computers and their software)
 - (3) Changes in packaging and materials
 - (4) Changes in the delivery system of the final product
 - (5) Changes in the intended specifications of the final product or the intended consumers
 - (6) When verification results indicate a deficiency or potential deficiency in the HACCP plan
 - (7) A new hazard factor is identified in the same food or in the same food group
 - (8) New information regarding product safety is obtained.
4. Also, if any checks or corrections are made, record them (see HACCP Procedure 12).

●Items to be referred to in legal provisions related to food safety

Setting up a verification method

Appended Table 18 (Re: Article 66-2, paragraph (2)) of the Ordinance for Enforcement of the Food Sanitation Act

(vi) Establishment of verification methods

Procedures shall be established to periodically verify the effectiveness of the contents of the measures prescribed in the preceding items.

HACCP Step 12 (Principle 7) Record keeping

●Requirements

Records (including a logbook) of the implementation of control of critical hazards, implementation of corrective actions (remedial actions), and implementation and correction of verifications must be taken and retained for a certain period of time.

● Concepts, specific examples

1. Required documents and records

1) Documents and records required by the 12 procedures of HACCP

HACCP team member list and role assignment, product description, flow diagram, hazard factor analysis, Information that scientifically supports the determination of control measures (critical control points: CCPs), control criteria (CLs), and control standards (CLs) for the critical hazards to be controlled; validation of control measures, HACCP plan revision records, etc.

2) Records of activities in accordance with the HACCP plan

Monitoring records, corrective action records, verification records, personnel training records, etc.

3) Records of HACCP plan implementation

2. Three types of records need to be kept: "Implementation of Control of Hazard Factors," "Implementation of Corrective Actions (Improvement Measures)," and "Implementation and Correction of Verification. This is to ensure that what was implemented and when, the date and time the deviation occurred, and the nature of the event can be identified later. 3.

3. It is sufficient to record "implementation of corrective actions (improvement measures)" and "implementation and correction of verification" in a daily logbook. When describing them in a logbook, at least make sure to record what, when, and how they were implemented.

For "implementation of control of risk factors," the "industry-specific guidelines prepared by food business associations" for each industry and business category provide a record format, which can be used as a reference.

●Items to be referred to in legal provisions related to food safety

Creation of records

Appended Table 18 (Re: Article 66-2, paragraph (2)) of the Ordinance for Enforcement of the Food Sanitation Act

(vii) Preparation of records

Depending on the size and type of business, a document concerning the details of the measures stipulated in the preceding items and a record of the implementation of such measures shall be prepared.

III Good Manufacturing Practice (GMP)

GMP 2 Site Management

●Requirements

The organization shall establish and maintain in accordance with appropriate standards for business premises.

●Concepts, specific examples

1. Concept of GMP2

- 1) In GMP2, it is important to take measures to prevent "influences from the vicinity and premises of the business site from affecting the food safety risk to the products" and to maintain them.

For this purpose, the following measures are required.

- (1) Identify what exists in the vicinity and on the premises of the business site.
- (2) Confirm whether or not they pose a food safety risk to the company's products
- (3) Examine the measures to be taken and maintained so that the system can be finally established to "prevent food safety risks to products.
- (4) Periodically check for changes in the environment while implementing maintenance measures.

2. Confirmation of site boundaries

- 1) Ensure that the boundaries of the site are clear and in a condition that can be reliably accounted for.
- 2) Even if the site is located in an industrial park or other such area, make sure that the site of your organization is clear.
- 3) It is recommended that as much as possible, drawings or other means be used to show the confirmed settings in order to maintain clarity.

3. Confirmation of the surrounding environment

- 1) Check the area surrounding the facility for any concerns that may affect food safety. The following may be considered as examples.

(1) Insect and bird damage

Rivers, drainage ditches, etc.

Mountains, forests, parks, agricultural land, livestock farms, etc.

Garbage dumps, waste disposal sites, etc.

(2) Foreign matter

Garbage dumps, waste disposal sites, etc.

(3) Others (impact on buildings, odor, chemicals, etc.)

Regional effects such as salt damage, strong winds, freezing, etc.

Agricultural lands where pesticides are sprayed ·Livestock industry (feedlots, etc.)

Exhaust and smoke emissions from other factories, etc.

4. Check the business premises

- 1) Check for food safety concerns within the facility as well.

The following may be considered as examples.

(1) Insect and bird damage

·Green space, etc.

·Puddling areas

·Drainage, septic tanks, rainwater tanks, etc.

·Unnecessary objects and waste storage areas, etc.

(2) Foreign matter

- Waste dumps, treatment areas, etc.

5. Response to each impact

1) For each of the items identified as having an impact, measures to reduce the impact to a manageable level should be considered, verified, and periodically addressed.

Possible measures include the following

(1) Insect and bird damage

- Insect and bird damage - Removal or modification of the target, isolation, etc.
- Periodic checks of plantings and water ponding areas, and measures to deal with them. (If the site is subject to the Green Space Law, compliance is necessary, but appropriate consideration should be given to placement and management.)
- Building treatments (e.g., positive/negative pressure, entrances/exits, broken parts or gaps that may be points of entry, light sources, odor leaks, etc.).
- Periodic monitoring by the insect control contractor or your own organization (perimeter, building interior, etc.)

(2) Foreign material related

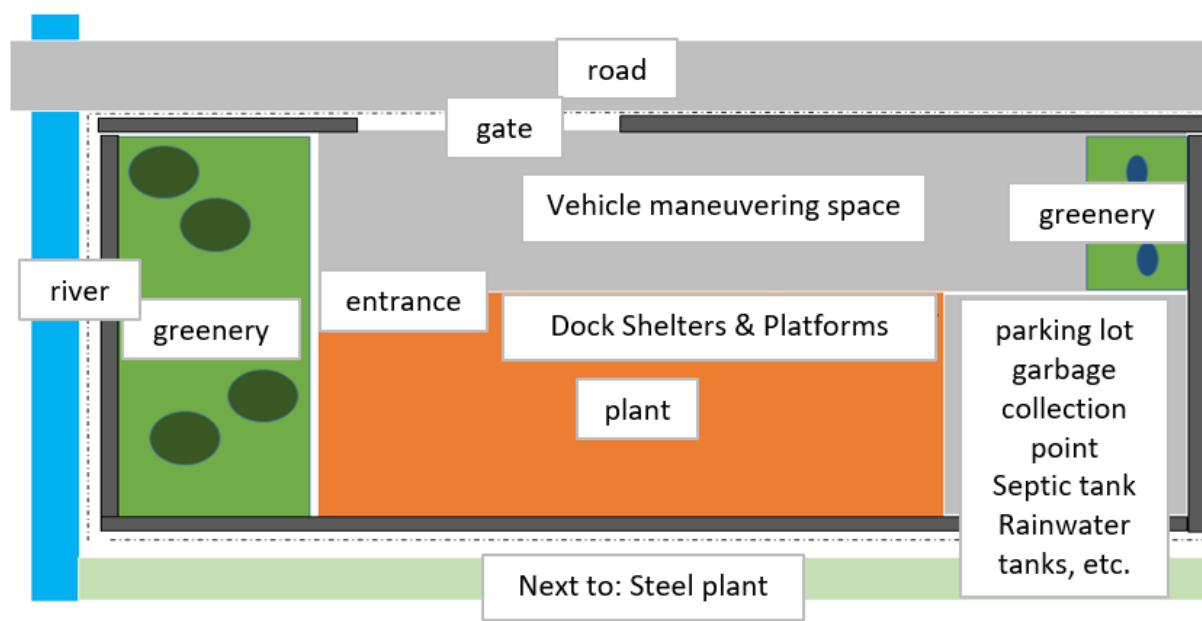
- Removal or modification of objects, isolation, etc.
- Countermeasures against foreign objects flying into the building or adhering to workers

(3) Others

- Arrangements with related parties in the surrounding environment.
- Periodic maintenance of buildings and facilities to prevent deterioration
- Periodic verification of manufacturing areas and products

[Example] Building Surroundings

(facilities on the site as well as outside facilities and environment (outside the dotted line)).



●Requirements

The organization shall design, construct and maintain the factory buildings and facilities (storage area, raw material and product handling area, preparation area, packaging and storage area, etc.) of the business site both outside and inside the plant to minimize food safety risks. In addition, the equipment layout and the flow lines of people, goods, and work shall be designed to meet the intended purpose and minimize food safety risks.

●Concepts, specific examples

【Regarding the location, design, and layout of the facility】

1. When designing a manufacturing or processing facility, the most important thing is to fully understand the impact on manufacturing and processing. In ascertaining the impact, reference should be made to the following
 - 1) Layout drawings of the manufacturing/processing area
 - 2) Flow diagrams showing the manufacturing/processing process
 - 3) Equipment, personnel, raw material and product transport methods, process capacity, etc.
 - 4) Work classification appropriate to the manufacturing/processing process

【Lines of movement of "goods," "people," etc.】

1. It is effective to describe manufacturing flow lines, personnel flow lines, etc. on the layout diagram of the manufacturing/processing area, and consider the impact on food safety from this flow of movement (flow lines).
2. Lines of flow include the following, of which "goods" and "people" are the most important. As much as possible, "objects" and "people" should be managed to avoid cross-contamination.
 - 1) Objects: Routes from receipt of raw materials to shipment of final products
 - 2) Personnel: Routes for personnel entering and leaving the workplace, routes for movement between workplaces, and routes for outside workers entering and leaving the workplace.
 - 3) Waste: Routes for transporting leftover and unwanted materials from the workplace to the outdoors
 - 4) Drainage: routes for drainage of work area
 - 5) Utilities: Routes for utilities such as steam, compressed air, carbon dioxide, nitrogen and other gases, air conditioning and ventilation, lighting, and water used directly or indirectly in manufacturing and processing

【Lighting】

1. The specifications shall be such that maintenance and cleaning are easy and that deterioration is minimized.
2. When installing ducts for electrical wiring, etc., they should be constructed so that dust and dead insects do not accumulate on the top, and they should be installed in locations where they can be easily cleaned.
3. If fluorescent lamps or light bulbs are damaged, protective covers (dust-proof type) should be installed or shatterproof tubes should be used to prevent shards and other physical hazards from affecting products and production/processing lines.
4. For windows used for daylighting, select plastic windows made of materials that are resistant to deterioration and shattering, and glass windows made of glass that are resistant to condensation, and apply shatterproof plastic film.
5. Illumination and color tones should be such that they do not cause misidentification of the workplace.
 - 1) Brightness that allows food handlers to work safely and hygienically must be provided.

- 2) If the illuminance of the area where work such as appearance inspection is performed is insufficient, it is necessary to take measures such as installing supplementary lighting such as electric stands.
- 3) When conducting color tone inspections, etc., the color tone of lamps should be considered in addition to illuminance.

【Illuminance of the work environment】

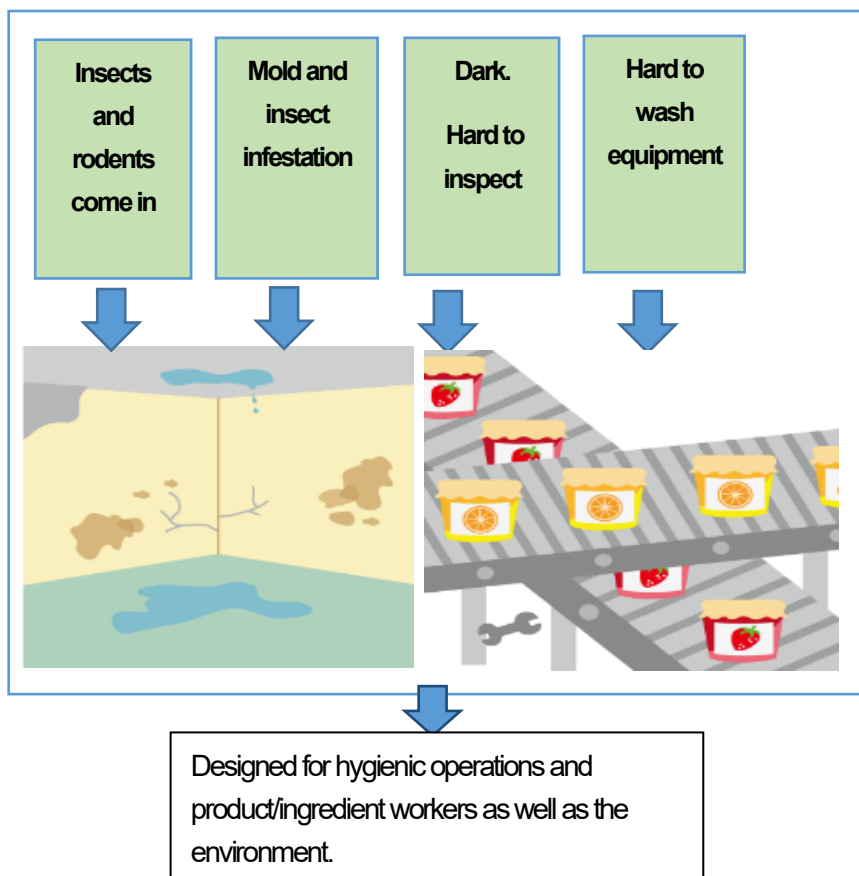
1. The illuminance of the work environment is specified in Article 604 of the Industrial Safety and Health Regulations and JIS. The work classification and standards in Article 604 are as follows: precision work: 300 lux or more, ordinary work: 150 lux or more, and rough work: 70 lux or more; the JIS illuminance standard is 500 lux for ordinary visual work in general manufacturing plants, etc.

【Drainage system】

1. Drainage routes should be designed and managed to minimize the possibility of contamination of products, etc.
2. Floors and drainage basins should be sloped to prevent puddles and be easy to clean.

【Specifications and general information in the production area】

1. The specifications of the facility should be designed to ensure that there is no cross-contamination or adverse effects on food products.
2. The specifications shall be easy to maintain, clean, and wash, and shall be resistant to deterioration.
3. Consider durability, such as the ability to handle heavy objects used in the work, wear, etc.
4. The material shall be capable of withstanding cleaning, washing, sterilization, and disinfection.
5. Design wastewater and wastewater systems so that they do not interfere with food safety.



●Items to be referenced in legal provisions related to food safety

Facility specifications: General

Illuminance of the work environment

The illuminance of the work environment is specified in the Industrial Safety and Health Regulations No. 604 and JIS.

Illuminance of the work environment

Illuminance in the work environment is specified in Article 604 of the Industrial Safety and Health Regulations and in JIS.

Occupational Safety and Health Regulations

Precision work	300 lux min.
Normal work	150 lux min.
Rough work	70 lux min.

Facility Management: Sanitation

Appended Table 17 (Re: Article 66-2, paragraph (1)) (Ordinance of the Ministry of Health, Labour and Welfare No. 68; addition)

(ii) Sanitation management of facilities

- (a) The facility and its surroundings shall be cleaned regularly and kept clean to prevent the occurrence of food sanitation hazards while the facility is in operation.
- (b) Do not place unnecessary articles, etc. in places where food or additives are produced, processed, prepared, stored, or sold.
- (c) Maintain the interior walls, ceilings, and floors of the facility in a clean condition.
- (d) Lighting, lighting, and ventilation inside the facility shall be adequate, and the temperature and humidity shall be controlled appropriately as needed.
- (f) Drainage ditches shall be cleaned to prevent the inflow of solids and ensure proper drainage, and shall be repaired promptly in the event that they are damaged.

GMP 4 Control of critical hazards that cannot be controlled by the control measures in HACCP procedures 6 and 7 (prevention of cross-contamination)

●Requirements

Based on the results of the Hazard Analysis in HACCP Procedures 6 and 7 (Principles 1 and 2), the organization shall determine which of the identified hazards are not controlled by the control measures in HACCP Procedures 6 and 7 and which are not effectively controlled outside of this item (GMP 4). The organization shall, based on the results of the HACCP Procedure 6 and 7 (Principles 1 and 2) Hazard Analysis, control significant hazards identified that are not controlled by the control measures in HACCP Procedures 6 and 7 and are difficult to effectively control outside of this item (GMP 4). Procedures must be established to prevent contamination and cross-contamination of raw materials (including containers and packaging materials), semi-finished products, work in process, rework, and finished products. The organization must periodically review these procedures and maintain them in effect.

●Concepts, specific examples

1. Control by GMP 4

GMP 4 includes the management of hazard factors controlled by the GHP (GMP) that require more attention of Codex HACCP, as well as the management of significant hazard factors that cannot be controlled by the HACCP plan.

1) Management of Hazard Factors Controlled by GHP (GMP), which requires more attention in Codex GPFH2020 and GMP4

Hazard factors identified by the Hazard Factor Analysis in HACCP Procedures 6 and 7 (Principles 1 and 2), which, if managed incorrectly by GMP, could cause significant food safety hazards, are listed as "Hazard Factors Requiring Greater Attention" in the GHP (GMP) Controls and GMP4. Hazard factors identified by the Hazard Factor Analysis in HACCP Procedure 6 and 7 (Principles 1 and 2) that could cause significant food safety hazards if there is an error in GMP controls are considered to be controlled under "GHP (GMP) requiring more attention" and are controlled under GMP4.

2) Significant Hazardous Factors Hazardous factors controlled by GMP4

(1) Critical Hazard Factors are "Hazard Factors identified by the Hazard Factor Analysis in HACCP Procedure 6 that, in the absence of controls, are reasonably likely to occur to an unacceptable level and whose control is essential for the intended use of the food" (Codex General Principles of Food Hygiene 2020: from the first edition of 2021 by the Japan Food Sanitation Association).

(2) For critical hazard factors, control measures for critical control points (CCPs) are established and controlled by the HACCP plan.

However, there are hazardous factors that are judged to be important hazardous factors but cannot be controlled by CCP control measures because continuous monitoring cannot be implemented or quantified CLs cannot be set. Control of these hazardous factors by GMP control measures corresponds to GMP4. Control procedures (monitoring methods, remedial measures, verification, etc.) are required.

(3) The critical hazard factors controlled by GMP4 are almost the same concept as the OPRP in ISO 22000; 2018.

2. Points to note for control by GMP4

1) Hazard factors controlled by GMP4 differ depending on the type of product, manufacturing process, hazard factor analysis, frequency and severity, etc. These should be considered and identified. The matrix of HACCP procedure 6, etc. can be used as a reference.

2) The procedures for control by GMP4 may involve not only the requirements of GMP, but also the control by the requirements of FSM. Examples of relevant requirements, which are not uniform depending on the industry and products of the organization, are shown below.

FSM 13 Purchasing Management

GMP 3 Design, construction, and layout of facilities and equipment, and work and product flow lines

GMP 6 Hygiene, work clothes and health management of employees, etc.

GMP 8 Tidiness, cleanliness, hygiene, sterilization and disinfection

GMP 11 Air and water management

GMP 13 Pest control

GMP 18 Equipment and instruments

GMP 19 Maintenance

3. Examples of Hazard Factors Controlled by GMP4

1) Allergen control

Line cleaning after manufacturing products containing allergens can be a control measure that should be controlled under GMP 4. If allergens cannot be removed by washing, the next product that does not contain allergens may contain allergens.

2) Control of *Listeria monocytogenes* ..

If RTE foods (ready-to-eat foods that do not require heating before consumption) after heat sterilization are contaminated with *Listeria monocytogenes* from the line, utensils, or

environment, they can multiply even at temperatures below 10°C, and food poisoning can occur if stored for a long time. Therefore, lines and utensils that come into direct contact with RTE foods should be monitored carefully. In addition, it is necessary to set up lines so that RTE foods and contact lines are kept at lower temperatures (preferably 4°C or lower).

4. Measures to prevent cross-contamination

- 1) Cross-check the detailed process flow diagram prepared by the HACCP team with the manufacturing site to enumerate the points where the work flow lines of on-site employees intersect with the flow lines of raw materials (including containers and packaging materials), semi-finished products, work-in-process products, recycled products, reworked products, and finished products.
- 2) For each of the listed locations, hazard factors are extracted, the frequency of occurrence and severity of results are evaluated (comprehensive evaluation), and control measures, including appropriate isolation, are established for each.
The Hazard Factor Analysis Sheet used in HACCP Procedure 6 and 7 (Principle 1 and 2) can be utilized for setting up the measures, and the following list of identified hazard factors can also be used effectively. The evaluation of the frequency of occurrence and severity of consequences can refer to HACCP Procedure 6 and 7 (Principle 1 and 2).
- 3) Control procedures should be validated, implemented, monitored, verified, and periodically reviewed as necessary. When evaluating control measures, it is necessary to consider what is already in place in operating procedures, GMP work rules, etc. and what new measures are needed.

Items to be referenced in legal provisions related to food safety

Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))

(ii) Facility sanitation

(a) Regularly clean the facility and its surroundings, and maintain cleanliness to prevent the occurrence of food sanitation hazards while the facility is in operation.

(b) Do not place unnecessary articles, etc. in places where food or additives are produced, processed, prepared, stored, or sold.

(iii) Hygiene control of equipment, etc.

(a) Machinery and equipment shall be used appropriately for their intended purposes in order to maintain hygiene.

(b) Machinery, equipment, and parts thereof shall be cleaned and sanitized and stored hygienically in designated locations to prevent metal fragments, foreign substances, or chemical substances, etc. from mixing with food or additives. In the event of malfunction or damage, they shall be repaired promptly and maintained for proper use.

(c) When detergent is used for cleaning machinery, equipment, and their parts, the detergent shall be used in an appropriate manner.

(e) Equipment, cleaning materials, and protective gear that may come in contact with food or additives shall be disinfected with hot water, steam, or disinfectants each time they are contaminated or work is completed, and then dried.

(f) Detergents, disinfectants, and other chemical substances must be handled with care and, if necessary, the names of the contents must be indicated on the containers and packaging to prevent contamination of food or additives.

●Requirements

Organizations must ensure that facilities for employees are designed and operated to minimize food safety risks, including allergens.

●Concepts, specific examples

【Facilities for Employees】

1. Facilities for employees include shoe boxes and shoe lockers for changing from commuting shoes to on-premises footwear, changing rooms, toilets, hand washing facilities, cafeterias, rest rooms, and smoking areas. These must be kept clean at all times to prevent the introduction of contaminants or foreign substances into the manufacturing or processing site.

【Changing rooms】

1. A sufficient number of lockers, etc. should be provided. Lockers and changing rooms should be located so that clean work clothes worn in the production area are not cross-contaminated with personal clothing or used work clothes.
2. Changing rooms should be located in areas where work clothes are not contaminated before food handlers move to the work area.

【Hand washing facilities】

1. Facilities for washing and drying hands in a hygienic manner are required.
 - 1) It is important that there be a sufficient number of such facilities in appropriate locations for food handlers, and that there be facilities for washing, drying, and sanitizing, and hot water facilities, if necessary.
 - 2) Maintain an adequate supply of water (or hot water if necessary for proper hand washing), and provide liquid soap, nail brushes, paper towels, disinfectants, etc. appropriate for hand washing, which are clean and always available for use.
 - 3) To prevent re-contamination of washed hands after hand washing, faucets should be designed so that they can be opened and closed without touching them with the hands.
 - 4) Hand washing and disinfection procedures should be posted in an easily understood manner.
 - 5) Hand washing facilities should not be used for washing food or mechanical equipment.

【Toilets】

1. It is important that toilets be of hygienic construction.
 - 1) There should be a sufficient number of toilets for the number of employees.
 - 2) They should be sufficiently separated from areas where food is handled.
2. Hand washing and disinfection facilities and means to dry hands should be provided.
3. Always keep the area clean and perform periodic cleaning and disinfection.

【Cafeteria, Break Rooms, and Smoking Areas】

1. Places where food and beverages are stored and consumed, such as company cafeterias and break rooms, should be set up to minimize the possibility of cross-contamination with the production area. 2.
2. Cafeterias should be kept clean and controlled so that waste materials are not left unattended to prevent them from becoming a source of pests.
3. Smoking areas should be located and controlled to minimize the potential for cross-contamination with work clothes and manufacturing areas.

●Items to be referenced in legal provisions related to food safety

Facilities for food handlers, hand washing and lavatories

Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))

(ii) Sanitation of facilities

(g) Latrines shall be kept clean at all times, and shall be cleaned and disinfected regularly.

(iii) Hygiene control of facilities, etc.

(h) Hand washing facilities shall be equipped with soap, paper towels, etc., and disinfectants, and shall be maintained in a state whereby hands can be washed and dried appropriately.

(iii) Hand washing facilities shall be equipped with soap, paper towels, etc. and disinfectants, and shall be maintained in a condition that enables hand washing and drying to be performed properly. (2) Hand washing and drying facilities shall be maintained in such a way that they can be used appropriately and that a sufficient supply of water can be provided. In addition, hand washing facilities shall be equipped with appropriate soap, etc. for hand washing, and shall be clean and ready for use at all times.

GMP 6 Sanitation, work clothes and health management of employees, etc.

●Requirements

The organization must document and enforce appropriate hygiene standards for employees in accordance with the laws and regulations of the country in which the employees are working. This must include hand washing methods and frequency, health check methods, work clothing and footwear rules, entry and exit from the manufacturing facility, food handling methods, and foreign material contamination control.

These requirements must be made known to employees and applied without exception to contractors and visitors.

●Concepts, specific examples

1. Concepts in GMP6

1) In GMP6, the organization needs to take appropriate sanitation standards to prevent contamination factors.

(1) Provide appropriate guidance and control to prevent contamination from occurring due to employee behavior.

(2) Establish a manufacturing environment that prevents contamination and foreign matter from entering the product.

(3) External visitors are also to be handled in such a way that they do not affect food safety.

2) The important point in this section is to "ensure that workers are properly trained and instructed so that there are no problems with on-site operations.

To this end, "documentation" is required to ensure that the information is accurately communicated to each worker.

2. Management of employees' health conditions

1) Managers shall explain the health conditions and food safety risks to employees when they join the company, etc., and seek their understanding of their pre-existing medical conditions to the extent necessary, what to do in case of illness, and what to do in case of food poisoning, etc., so that they can maintain appropriate knowledge and awareness of food safety.

2) Managers are to ascertain employees' pre-existing medical conditions as necessary for food safety.

3) The health condition of employees shall be checked before work. If any physical abnormality is observed, the employee must report it to the person in charge of the work site, etc. If an

employee reports an abnormality in his/her physical condition, he/she should not be allowed to work handling products unless it is clear that the abnormality does not affect food safety (e.g., minor tooth decay, etc.).

- 4) In the event of a suspected infectious disease or food poisoning, report it to management, the food safety manager, etc. If necessary, disinfect the facility, equipment, etc., check with the parties (including outside visitors) who came in contact with the product, and take action on products manufactured or shipped prior to the suspected infection or food poisoning.
 - 5) Conduct periodic stool samples to confirm that there are no abnormalities.
 - 6) For external visitors, especially those entering manufacturing areas (equipment, inspectors, consultants, etc.), confirm their length of stay, health status, and contact information so that confirmation can be obtained in the event of an abnormality. Visitors (including maintenance workers), especially those visiting food production, processing or handling areas, should be instructed and supervised, where appropriate, and, like employees, should wear protective clothing that will not contaminate food and comply with other employee hygiene requirements. Instruct visitors to report any type of illness/injury that could cause cross-contamination problems through the business's sanitation policy prior to the visit.
3. Management of personal hygiene of employees
- 1) Establish and document basic hygienic behaviors in the series of work from start to finish, and provide explanations at the time of employment, etc., to properly align and maintain employees' personal hygiene levels. Examples of employee hygiene behaviors include the following. It is necessary to set them appropriately by selecting and choosing the appropriate ones and considering unique items according to the organization's situation.
 - (1) Hand washing and disinfection at specified times
 - (2) No unhygienic behavior with items (hands, gloves, utensils, etc.) that may come in contact with products
 - (3) Refrain from sneezing or coughing at the work site, and make efforts to avoid splashing, especially in areas related to the product.
 - (4) Wear masks properly as specified, covering the nose and mouth.
 - (5) To prevent the introduction of foreign substances into the manufacturing area, wear the designated work clothes properly to prevent hair and body hair from mixing in. In addition, air showers, adhesive rollers, and other measures should be taken at designated times.
 - (6) When wearing work clothes or work shoes, do not carelessly go outside the production area or take any actions that may result in contamination.
 - (7) Do not wear ornaments or other items to prevent foreign matter from falling out.
 - (8) Keep fingernails appropriately short and clean. Do not wear nail polish.
 - (9) Do not wear makeup that could fall off and affect the product (e.g., face powder, etc.).
 - (10) No use of perfume
 - (11) No food or drink is allowed to be stored or consumed in the work area. Observe operation in designated areas.
 - (12) When work clothes are stored in common in lockers where personal clothes and belongings are owned, handle them in such a way that they will not be contaminated.
 - (13) Do not bring unnecessary items to the work site. If there is a need for regular medication, etc., consult with the manager and take measures to ensure that contamination of products is prevented.
 - (14) Wash hair and bathe regularly to maintain proper hygiene.
 - 2) Appropriate consideration shall be given to the shape of work clothes and shoes to prevent hair and body hair from falling out and mixing with products.
 - 3) Rules for washing and replacing work clothes and footwear are to be established and implemented so that employees can wear clean work clothes and footwear in good condition according to their work needs, to prevent contamination and foreign matter from entering the products.
 - 4) When gloves are used, the material is selected according to the purpose, the usage and storage methods are specified, and the gloves are handled in a clean and good condition. If disposable gloves are used, check the material and strength of the gloves according to the work to be

performed, determine the appropriate replacement frequency, and strive to prevent damage. Control external visitors as necessary in relation to the above. 4.

4. Maintenance of hygienic environment

- 1) Appropriate consideration shall be given to the shape of work clothes and shoes to prevent hair and body hair from falling out and mixing with products.
- 2) Rules for washing and changing work clothes and footwear are to be established so that employees can wear clean and good condition work clothes and footwear according to the necessity of the work, and they are to be operated reliably to prevent contamination and contamination by foreign substances.
- 3) When gloves are used, the material is selected according to the purpose, the usage and storage methods are specified, and the gloves are handled in a clean and good condition.
- 4) When disposable gloves are used, check the material and strength according to the work, determine the appropriate replacement frequency, and strive to prevent damage. Rules for washing hands before wearing gloves should be established and implemented.
- 5) In relation to the above, control external visitors as necessary.

●Items to be referenced in legal provisions related to food safety

Food handlers and health conditions

Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))

(vii) Hygiene Control for Persons Handling Food or Additives

(a) Health examinations of persons who handle food or additives (hereinafter referred to as "food handlers") (a) Medical examinations of persons who handle food or additives (hereinafter referred to as "food handlers") shall be conducted for the purpose of ascertaining the health conditions necessary to prevent food sanitation hazards from occurring.

(b) When a prefectural governor, etc. has given instructions that a person handling food, etc. should undergo a stool examination, the person handling food, etc. shall be instructed to undergo a stool examination.

(c) When a food handler is showing any of the following symptoms, efforts should be made to grasp the details of the symptoms and to determine whether the symptoms require medical examination by a physician and suspension of work to handle food or additives

(1) Jaundice

(2) Diarrhea

(3) Abdominal pain

(4) Fever

(5) Pyogenic skin disease, etc.

(6) Secretions from the ears, eyes, or nose (limited to those that may infect infectious diseases, etc.)

(7) Nausea and vomiting

(d) When a person who has a skin injury is engaged, the area shall be covered with a water-resistant covering. Foods or additives that may be contaminated by vomit should be discarded. In the event of vomiting in the facility, the area should be disinfected immediately with a disinfectant.

(e) When food handlers are engaged in work to handle food or additives, they should wear work clothes specially designed for the purpose, and hats and masks as necessary. In addition, they shall use special footwear in the work area and shall not leave the designated area while wearing the footwear used in the work area.

(f) Personnel handling food shall not bring into the facility where food is handled any ornaments or other items that may interfere with hand washing or cause foreign matter to be mixed in.

(g) When using gloves, food handlers shall, in principle, use gloves made of water-resistant materials for the parts that come into direct contact with raw materials.

(h) Personnel who handle food, etc. must cut fingernails short, wash hands, and keep fingers clean so as not to cause food sanitation hazards.

- (h) Food handlers shall wash and sanitize their fingers thoroughly when they finish urinating or handling fresh raw materials or raw materials before heating. In cases where disposable gloves are used to handle fresh raw materials or raw materials before heating, the gloves shall be changed after the work.
- (3) In handling food or additives, food handlers shall not do the following while handling food or additives from the viewpoint of preventing the occurrence of food sanitation hazards
 - (1) Unnecessarily contaminate fingers, utensils or containers/packaging
 - (2) Spitting phlegm, dandruff or spit
 - (3) Mixing or causing the possibility of mixing comb or cough droplets with food or additives.
- (vi) Persons handling food, etc. shall not change clothes, smoke, or eat or drink outside of the designated areas.
- (w) When persons other than food handlers enter the facility, have them change into clean, exclusive work clothes and follow the hygiene control regulations for food handlers as indicated in this section.

GMP 7 Training

●Requirements

The organization must ensure that all employees receive adequate education and training in food safety principles (including HACCP) and practices appropriate to their jobs. In addition, a system must be established to ensure that employees receive appropriate guidance and supervision. This education and training should enable employees to recognize their role in food safety and the significance of their efforts.

●Concepts, specific examples

1. Food safety managers
 - 1) The person in charge of food safety shall enhance his/her own knowledge, techniques and skills, and shall set up education programs (content, timing, method, frequency (including refresher courses), etc.) for food handlers, and conduct education and training accordingly, and record the results.
2. Food Hygiene Manager

Refer to the explanation in FSM2.
3. Education and training
 - 1) Education and training are to be conducted and recorded for all employees, including new employees, according to their roles in handling food products, in order to provide them with the knowledge and skills necessary for food safety.
 - 2) Ensure that current rules and procedures can be reviewed at any time, incorporating the opinions of on-site food handlers.
 - 3) Records created from education and training can be used for individual evaluation.
 - 4) Re-training (hygiene training) is conducted for employees as necessary, and records are kept.
 - 5) Conduct HACCP training.

●Items to be referenced in legal provisions related to food safety

Education and Training
 Article 66-5 Standards specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 50-3, paragraph (1), item (i) of the Act concerning matters listed in the same paragraph shall be as follows

(v) Education and training shall be provided for those who manage the manufacture of utensils or containers and packaging and for workers, and information and efforts necessary for preventing food sanitation hazards shall be shared among persons concerned.

Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))

(i) Appointment of a person responsible for food sanitation, etc.

(a) Appointment of a person who conducts business prescribed in Article 50-2, paragraph (1) of the Act (including the cases where it is applied mutatis mutandis pursuant to Article 62, paragraph (3) of the Act) Hereinafter referred to as a "business person" in this table) shall appoint a person responsible for food sanitation. Article 63 A person engaged in a business prescribed in Article 56-2, paragraph (1) of the Food Sanitation Act (including cases where it is applied mutatis mutandis under Article 62, paragraph (3) of the Act) shall designate a person responsible for food sanitation. However, this shall not apply to business operators prescribed in each item of Article 66-2, paragraph (4). In addition, a food sanitation supervisor prescribed in Article 48 of the Act may also serve as a person responsible for food sanitation.

(b) A person responsible for food sanitation shall be a person who falls under any of the following
(1) A person who satisfies the qualification requirements for a food sanitation inspector prescribed in Article 30 of the Act or a food sanitation supervisor prescribed in Article 48 of the Act

(2) Cooks, confectionery sanitarians, nutritionists, ship's cooks, sanitation supervisors prescribed in Article 7 of the Slaughterhouse Act (Act No. 114 of 1953), occupational health supervisors prescribed in Article 10 of the same Act, or poultry slaughtering sanitation supervisors prescribed in Article 12 of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Act No. 70 of 1990)

(iii) A person who has attended a training session conducted by a prefectural governor, etc. or a training session deemed appropriate by a prefectural governor, etc.

(c) Food sanitation supervisors shall comply with the following matters

(1) Attend seminars held by prefectural governors, etc. or seminars that are recognized by prefectural governors, etc. on a regular basis and endeavor to acquire new knowledge concerning food sanitation (limited to those concerning business under Article 51 of the Act (including cases where it is applied mutatis mutandis under Article 62, paragraph (3) of the Act)). (limited to businesses under Article 51 of the Act (including cases where it is applied mutatis mutandis under Article 62, paragraph (3) of the Act)) (2) To follow the instructions of the business person.

(d) A business person shall follow the instructions of a person responsible for food sanitation.

(d) A business person shall respect the opinions of the person responsible for food sanitation.

(e) A person responsible for food sanitation shall take necessary precautions to ensure compliance with the measures prescribed in Article 66-2, paragraph (3), and shall endeavor to state necessary opinions to the business person.

(xiii) Education and training

(a) Provide education necessary for sanitation management to persons who handle food, etc.

(b) Education and training shall be provided for those who handle chemical substances so that they can safely handle the chemical substances used.

(c) Periodically verify the effectiveness of education and training in (a) and (b) above, and review the content of education and training as necessary.

GMP 8 Housekeeping, cleaning, sterilization and disinfection

●Requirements

The organization must maintain an appropriate level of hygiene at all times by conducting tidying and cleaning operations throughout all processes and phases, and disinfecting where necessary.

And cleaning tools, cleaning agents and disinfectants must be used for their intended purpose and properly stored.

● Concepts, specific examples

【Method Plan】

1. Cleaning removes food residues and contaminants that may be sources of contamination, including allergens. Cleaning methods and materials required depend on the nature of the food operation, the type of food, and the surfaces to be cleaned. Disinfection may be necessary after cleaning, especially for surfaces that come in contact with food.
2. Attention should be paid to sanitation during cleaning and maintenance operations so that food safety and appropriateness are not compromised. Food preparation and storage areas should use cleaning agent materials appropriate for food contact surfaces.
3. Chemicals used for cleaning and disinfection should be handled with care and used according to the manufacturer's instructions. For example, they should be used at the appropriate dilution and contact time and, if necessary, stored away from food in clearly identified containers to avoid food contamination.
4. Organizing, cleaning, and sanitation procedures are to be effective and documented procedures.
5. Train food handlers in standardized methods. It is also effective to show actual cleaning procedures and to post pictures or illustrations of the procedures. Trained personnel should perform cleaning, washing, and sanitizing.
6. Monitor whether the cleaning and disinfection program is being implemented according to the rules and regulations by visual inspection and other means, and verify whether it is effective by using sanitary inspections such as product inspection and wipe-down inspections. Monitoring methods will depend on the nature of the procedure, but may include pH, water temperature, conductivity, detergent concentration, disinfectant concentration, and other parameters important to ensure that the cleaning and disinfection program is being implemented as planned and to verify its effectiveness.
7. Training is provided based on the results of basic training and sanitation inspections.
8. Care should be taken to ensure that cleaning procedures do not lead to food contamination. For example, sprays from high-pressure washing can spread contamination from dirty areas such as floors and drains to large areas, and can contaminate food contact surfaces or bare food.
9. In some operations and/or food processing areas where water increases the potential for microbial contamination, such as when the food handled is low moisture and the product is manufactured under dry conditions, controlling the amount of water used in cleaning (e.g., removing and collecting residues and dry cleaning) can reduce the risk of microbiological contamination.
10. The following items are to be implemented for the handling of detergents and chemicals used for cleaning, sterilization, and disinfection.
 - 1) Appoint a person responsible for the management
 - 2) Inventory control of chemicals and other materials (incoming and outgoing shipments, amount used, number of items in stock, user and first-in first-out)
 - 3) Locking and key management of drug storage
 - 4) Training of food handlers on the handling of chemicals, etc. (including proper dilution, contact time, etc.)
 - 5) Prevention of mixing of detergents and chemicals with food (e.g., labeling of containers with names of contents, etc.)
11. To ensure that cleaning and washing of the facility is carried out systematically, plans and procedures are to be prepared as follows
 - 1) Plan for cleaning and washing facilities
The frequency of the work, the date of implementation, the person who performs the work, and the method of recording the work should be described.

2) Written procedures for cleaning and washing facilities

Ensure to describe the person responsible for the work, subject, method, frequency, monitoring and verification procedures, designation of work tools, post-work inspection procedures, and inspection procedures prior to the start of production, etc.

【Cleaning Tools, Cleaning Equipment, etc.】

1. If foreign matter or microorganisms adhere to equipment, facilities, or utensils used for cleaning, washing, sterilization, or disinfection, it may lead to contamination of products with foreign matter or microorganisms. Use separate cleaning machinery, equipment, and utensils designed for different sanitation zones (areas), such as for food-contact surfaces and non-contact surfaces, to suit the purpose.

Contaminated cleaning equipment and utensils can also spread contamination.

2. Inspection and maintenance

- 1) Check operation and deterioration before and after use, and immediately repair or replace any defective items.
- 2) Since dirt remains on the back and bottom of equipment, facilities, and utensils, disassemble them to check for contamination. Cleaning equipment should be kept clean, maintained, and replaced regularly to avoid contact surfaces and sources of cross-contamination of food.

3. storage location

- 1) Cleaning equipment should be stored in an appropriate location to prevent contamination.
- 2) Cleaning utensils should be hung and stored to dry so that they do not stick to the floor or other surfaces.
- 3) Storage areas should be designated and kept clean so that food handlers can use them immediately. Posting a notice to this effect is another way to keep the area clean.

4. Identification

- 1) It is necessary to devise ways to ensure that cleaning and washing utensils used in contaminated areas are not misused in clean areas. It is important to color-code them according to their use, such as "red" for floors and "blue" for cooking utensils, and to separate their storage locations.

●Items to be referenced in legal provisions related to food safety

Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))

(iii) Sanitation of equipment, etc.

(c) When detergents are used to clean machinery, equipment, and their parts, they must be used in an appropriate manner.

(f) Detergents, disinfectants, and other chemical substances shall be handled with due care, and if necessary, the names of the contents shall be indicated on the containers and packaging to prevent contamination of food or additives.

(g) Equipment and materials for cleaning facilities and equipment are to be used appropriately for their intended purpose, cleaned and dried each time they are used, and stored in a designated place.

GMP 11 Air and water management

●Requirements

The organization shall define the required quality criteria according to the application, and regularly monitor and record the air, high-pressure gas, and water (including ice and steam) used in food production in order to minimize the effect on food safety.

Water not intended for use in food production, and water that has been used but is acceptable for contact with food, must be controlled so that it is not mixed with water used exclusively for production.

●Concepts, specific examples

1. When manufacturing food products, it is possible to use different types of water for different purposes, and in such cases, standards should be established according to the intended use.
2. Water quality is to be checked by water quality tests, etc., and if necessary, filtered, sterilized, etc., to ensure water quality before use
3. If necessary, comply with microbiological and water quality standards for drinking water recognized by local, national, or international authorities.
4. In Japan, in principle, water used for food production or water suitable for drinking should be used, and water for food production means water that complies with applicable laws and regulations.
5. In Japan, should be referred to in the legal and regulatory requirements.
 - 1) Water quality standards based on the Water Supply Law (51 items): Ministerial Ordinance on Water Quality Standards (Ordinance of the Ministry of Health, Labour and Welfare No. 101, May 30, 2003)
 - 2) Water for food production: Standards for foods, additives, etc. (26 items) (Ministry of Health and Welfare Notification No. 370, 1959)
 - 3) Water suitable for drinking: Regulated by the Food Sanitation Law Enforcement Regulations following the revision of the Food Sanitation Law (enacted on June 1, 2020). (Reference: Appended Table 17 of the Food Sanitation Law Enforcement Regulations, July 14, 2020)
6. In order to reduce the cost of water, there are cases where water other than water for food production is used in the manufacturing process (e.g., for primary washing of food, heating and cooling), and these waters must be controlled to prevent contamination of water for food production. Specific examples include the following.
 - 1) Well water that is only pumped up
 - 2) Water that has not been disinfected with hypochlorous acid or chlorine
7. In the food industry, water that has been used but is acceptable for contact with food may be reused in food production for the effective use of water resources. Specific examples include the following.
 - 1) Water used for heating and sterilizing equipment
 - 2) Water used for heating and cooling prepackaged foods
 - 3) Secondary washing water for cut vegetables (water used in the final stage of the washing process)
 - 4) Reused steam drain water
8. In addition to water, ice and steam used in food production must also be addressed to minimize their impact on food safety, including the following
 - 1) Ice and steam should be made and handled in a manner that prevents contamination. In particular, ice machine cleaning agents and can-cleaning agents (chemical agents) used in boilers that generate steam should be approved for food use and should not be mixed with ice and steam.
 - 2) A filtration device (filter) should be installed near the end of the ice maker's water supply and steam piping.
 - 3) Make sure that ice/steam in direct contact with food products does not have any adverse effects (odor, coloration, etc.) on food products.
 - 4) Description of air and gas
9. Compressed air, carbon dioxide, nitrogen, and other gases
 - 1) Equipment for gases used in manufacturing and filling should be of specifications that do not present a risk of food contamination, and should be properly maintained.

- 2) Gases that come in contact with foodstuffs shall be those approved for general use in food additives.
 - 3) Ensure that air and gases that come into contact with food are free of dust, oil, and water.
 - 4) Gases should be filtered as close to the point of use as possible.
10. air conditioning and ventilation
- 1) To prevent dust, debris, insects, etc. from entering and contaminating the air, the following points should be taken into consideration when devising air conditioning and ventilation systems.
 - (1) The air conditioning and ventilation system should be designed to be easy to clean, wash, and replace filters.
 - (2) Consideration should be given to the air balance between intake and exhaust air in the facility.
 - (3) Avoid inflow of outside air through windows, doors, and crevices.
 - (4) Soot and vapor should be easily excluded (to prevent condensation and mold formation, etc.).
 - (5) If necessary, maintain differential pressure to prevent air from flowing into the clean area.
 - 2) Periodically check the outside air intakes for damage, clogging of filters due to suction of dust, insects, etc., and deterioration due to rust and corrosion.
 - 3) It is convenient to have inspection ports for both intake and exhaust for inspection, cleaning and washing, and filter replacement.
 - 4) When aiming to step up to the JFS-C standard, it is desirable to monitor and control the cleanliness of the air in areas where products that are prone to the development and survival of microorganisms are manufactured, in accordance with procedures.

●Items to be referenced in legal provisions related to food safety

- Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))
- (iv) Control of water used, etc.
- (a) Water used in the manufacture, processing, or cooking of food or additives shall be water supplied by waterworks provided under Article 3, paragraph (2) of the Waterworks Act (Act No. 177 of 1957), dedicated waterworks provided under paragraph (6) of the said Article, or simplified exclusive waterworks provided under paragraph (7) of the said Article, or other water suitable for drinking (hereinafter referred to as "water suitable for drinking"). (hereinafter referred to as "water fit for drinking"). (2) The water shall be water that is suitable for drinking (hereinafter referred to as "water suitable for drinking"). However, this shall not apply to use in cooling or other processes that do not affect the safety of food or additives.
- (b) In the case of using water fit for drinking, water quality tests shall be conducted at least once a year, and a written report shall be kept for one year (or for the period of one year or more if the food or additive to be handled is to be used or consumed for one year or more). However, if there is a possibility that the water source, etc. has been contaminated due to an unforeseen disaster, a water quality test shall be conducted each time.
- (c) If, as a result of the inspection in (b), it becomes clear that the conditions in (a) are not met, immediately discontinue use.
- (d) When water storage tanks are used, the water storage tanks must be cleaned regularly and kept clean.
- (e) When water suitable for drinking is used and a sterilization or water purification device is installed, periodically check that the device is working properly and record the results.
- (f) Ice that comes in direct contact with food shall be made from water that meets the conditions in (a) above, which is supplied by a properly controlled water supply system. Ice should be handled and stored in a hygienic manner.
- (g) When used water is to be reused, necessary treatment is to be performed so as not to affect the safety of the food or additives.

●Requirements

The organization shall establish adequate systems for segregation, collection and disposal of waste. Waste placement and containers must be controlled to prevent the attraction of pests and the development of harmful organisms and microorganisms.

Waste flow lines must be set up so as not to cause cross-contamination of food.

●Concepts, specific examples

1. Waste and other materials generated as a result of food production and processing (including by-products not suitable for food use) can become a breeding ground for microorganisms, pests, insects, and other harmful organisms and lead to contamination of the production and processing environment if not properly managed.
2. Contact between wastes and raw materials, materials, and manufacturing/processing equipment should be avoided.
3. A person in charge of consistent management (identification, accumulation, segregation, storage, removal, and disposal) of wastes, etc., should be designated, and a written procedure for such management work should be prepared. It is important to periodically check the status of waste management, such as whether the work has been carried out according to the procedure manual.
4. Confirm that wastes are promptly disposed of according to the following procedures.
Waste, etc. generated in manufacturing/processing lines → Containers of waste, etc. → Temporary storage location → Indoor/outdoor storage location of waste, etc. → Pickup by designated contractor → Issuance and storage of manifest slip (in accordance with laws and regulations)
5. Control and store wastes in such a way that they do not affect products, raw materials, and materials and equipment that come in contact with products.
6. In order to prevent cross-contamination of wastes with products, in principle, wastes should not be stored in areas where food is handled or stored (except for temporary storage during manufacturing - even then, be aware of cross-contamination with products). Containers for wastes should be stored in a manner that prevents cross-contamination.
7. Ensure that waste containers are clearly distinguishable from other containers.

●Items to be referenced in legal provisions related to food safety

general

Regulations for Enforcement of the Food Sanitation Act

Article 66-5 The standards specified by an Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 50-3, paragraph (1), item (i) of the Act with regard to the matters listed in the same paragraph shall be as follows

(iv) Proper implementation of cleaning and maintenance inspections of facilities and disposal of waste in order to maintain a clean working environment.

Appended Table 17 (Re: Article 66-2, paragraph (1)) of the Ordinance for Enforcement of the Food Sanitation Act

(vi) Handling of waste and wastewater

(a) Procedures shall be established for the storage of waste and its disposal.

- (b) Containers for waste shall be clearly distinguishable from other containers, and shall be kept clean to prevent leakage of contaminated liquids or odors.
- (c) Waste shall not be stored in areas where food or additives are handled or stored (including adjacent areas), unless it is deemed possible to prevent the occurrence of food sanitation hazards.
- (d) Waste shall not be stored in areas where food or additives are handled or stored (including adjacent areas) unless it is deemed possible to prevent food sanitation hazards.
- (d) Waste should be stored in a location that can be properly controlled so as not to adversely affect the surrounding environment.
- (e) Waste and wastewater shall be treated appropriately.

GMP 13 Pest control

●Requirements

The organization must implement controls (surveys and countermeasures) to minimize the risk of insects, rodents, birds, and other pests occurring or entering the premises and facilities. If chemicals are used, handling procedures must be established to ensure that they do not affect food products.

●Concepts, specific examples

【Pest control measures】

1. Pest control measures shall be taken as follows
 - 1) Analysis and inspection plan for pests such as rodents and insects
Target pests are identified based on past occurrences in the facility, biological evidence, and characteristics of products handled, and inspection plans are formulated.
 - 2) Pest control and invasion prevention measures
Remove internal sources of pests and implement measures to prevent external invasions and incursions.
 - 3) Monitoring and extermination of pests such as rodents and insects
Monitoring will periodically confirm that sanitation and pest control measures within the facility are secured and that there is no evidence of pest infestation. If extermination is necessary based on the results of monitoring, countermeasures that do not affect food or interfere with facility operations should be formulated and implemented by competent personnel. Identify the cause of the infestation, take corrective action to prevent the problem from reoccurring, and document monitoring and eradication.
2. When pest control is outsourced to a specialized contractor, the above information should also be confirmed with the specialized contractor and measures should be promoted. Even when monitoring and eradication are outsourced, the organization reviews monitoring reports and, if necessary, ensures that its designated pest control operators take remedial action (e.g., eradication of small pests, elimination of hiding places or entry routes).
3. Plantings that produce flowers or fruits that attract pests such as rodents and insects should be avoided, and the smell of wastes and sewage should be prevented from spreading. Mowing and pruning of plants should be done regularly to avoid sources of pests.
4. Areas prone to puddling can be a source of chironomids and other pests. For example, in unpaved parking lots, it is possible to prevent outbreaks by frequently adding gravel to the parking lot.

5. Yellow or green fluorescent lights or plastic curtains, which are considered to be less visible to insects, should be installed in outdoor lighting, entrances, corridors, etc.
6. The eaves of the facility and areas around the air supply facilities should be designed to prevent birds and other insects from nesting in them. Mesh and filters should be inspected regularly. 7.
7. Drainage ditches around the plant should be designed to prevent rodents and insects from entering through the openings of the facility. Measures such as netting or water sealing at the ends of drains are effective. 8.
8. Windows that are not opened and closed should have their gaps filled and be removed as necessary. Ensure that entrances and exits for employees and goods are closed except when necessary. 8. wire mesh screens should be installed on windows, doors, etc. that open and close to reduce the risk of entry of small pests.
9. Use screens on swinging door windows to prevent dust and insects from entering the building due to wind pressure when opening and closing the doors.
10. Make sure that lighting around window and shutter openings does not leak to the outside. Attaching light-blocking film or insect repellent sheets to windows is also an effective method. Roll-up doors should be closed tightly against the floor.
11. Insect traps at work area entrances should be located inside the building where light cannot be seen from the outside.

【Measures for facilities that are easy to clean】

1. Insufficient cleaning leads to the internal generation of pests. The gap between walls and floors should have an easy-to-clean structure, such as an arched joint.
2. Openings and pits caused by damage to floors and walls are likely to become entryways for pests and internal emergence sites, so damaged areas should be repaired as soon as possible.
3. Equipment and objects should be kept away from the walls of the facility and arranged for easy inspection and cleaning.

【Drug Control】

1. It is important to have established procedures for chemical administration, spraying, and initiation of production and processing after spraying
2. Ensure that the use of chemicals is restricted to well-trained personnel.
3. The amount of chemicals entering and leaving the warehouse should be controlled and stored in a locked area isolated from the manufacturing/processing area.
4. It is necessary to record the type of chemical used, the amount used, the concentration used (dilution factor), the date and time of application, and the location of application.
5. It is acceptable to outsource the entire pest control to a specialized contractor because more efficient measures can be expected and chemical management can be omitted.
6. It is important to inspect regularly for pest infestation and internal development of pests, such as once a week or once a month, depending on the season and other factors.
7. To prevent pests from mixing with products, poisonous bait should not be used in the production area.

- Items to be referenced in legal provisions related to food safety

Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))
(ii) Sanitary management of facilities

- (e) As a rule, windows and entrances shall not be left open. When they are left open, measures shall be taken to prevent the entry of dust, rats, insects, etc.
- (v) Measures against rats and insects
 - (a) The facility and its surroundings shall be maintained in a condition that allows for proper maintenance and management, and breeding grounds for rats and insects shall be eliminated.
 - (b) Extermination of rats and insects shall be carried out at least twice a year, and the records of the extermination shall be kept for one year. However, if the objective can be achieved by conducting periodic, uniform surveys of the locations of rats and insects, their habitats and routes of entry, and the state of damage, and taking necessary measures based on the results of said surveys, then the method and frequency may be implemented in accordance with the conditions of the facility in question.
 - (c) When using pesticides or insecticides, care must be taken in handling them so as not to contaminate food or additives.
 - (d) To prevent contamination by rats and insects, raw materials, products and packaging materials shall be stored in containers and kept away from floors and walls. Once opened, the product shall be stored in a container with a lid or other measures to prevent contamination.

GMP 15 Transport

●Requirements

The organization shall establish a system to ensure that containers and vehicles used to transport raw materials (including packaging materials), semi-finished products, work-in-process, recycled products, reworked products, and finished products (including perishable products in their final packaging and packaging), including outsourced vehicles, are fit for their intended use and are maintained, kept clean and protected from contamination, and transported within their intended temperature range.

●Concepts, specific examples

1. Concepts in GMP15
 - 1) In GMP15, organizations need to ensure that raw and packaging materials are free of defects prior to use to prevent food safety risks to the product.
It is also required to ensure that the product (including intermediate stages) can proceed to the customer or the next process without any abnormality.
2. When receiving raw and packaging materials
 - 1) With respect to materials used in the manufacture of products, they must be in a condition free of abnormalities prior to use.
When purchasing or using items that are already packaged as ready-to-use products, the specifications of each raw or packaging material should be checked, and only if no problems arise when delivered under general transportation conditions, such as "refrigerated", "frozen", or "room temperature" temperature control, rather than in a specialized vehicle, should it be allowed.
 - 2) If abnormal temperature, damage, contamination, etc. are found upon receipt, the product should not be used, but should be checked and returned as necessary.
 - 3) When semi-finished products or work-in-progress are received from related parties and used as raw materials, if the counterparty uses a special vehicle, confirm the transportation conditions, establish items to be checked upon receipt, and take action such as returning the product if any abnormality is found.
Examples of items to be checked: appearance (presence of damage, sealed condition, etc.), temperature zone during transportation, pallets used, etc.

3. When transporting semi-finished products, work-in-process, reworked products, reworked products and finished products
 - 1) When delivering products to the destination, check the product specifications and consider the necessary conditions that allow delivery without abnormalities.
(e.g., temperature and humidity settings, stacking and loading methods, pallet-related items used, delivery containers, and other special conditions)
 - 2) Confirm that the delivery vehicle can handle the set conditions without any problems and that the environment is such that the product can be delivered without damage or contamination.
 - (1) Can the temperature and humidity be set to the required temperature and humidity? Can the temperature and humidity be maintained at the maximum loading capacity? If not, can the maximum loading capacity be changed?
 - (2) Is the temperature and humidity recorded at the required frequency? (2) Is the temperature and humidity recorded as often as necessary, and is it possible to confirm that there are no abnormalities in the 55hermos-hygrometer as needed?
 - (3) If containers and pallets are not manufactured by the company, check the frequency of cleaning, disinfecting, and replacement.
 - (4) Is the interior of the vehicle kept in an appropriate state of cleanliness?
 - (5) Confirm whether mixed loads with non-products are allowed, and if so, the loading capacity and the items that can be loaded.
 - (6) Confirm that no outsiders other than the person in charge of delivery are involved.
4. If necessary, the organization will also conduct checks to maintain the delivery environment. If any abnormality is found, it is necessary to seek appropriate improvement.

● Items to be referenced in legal provisions related to food safety

- transport
Regulations for Enforcement of the Food Sanitation Act Appended Table 17 (Re: Article 66-2, paragraph (1))
- (xi) Transportation
- (a) Vehicles, containers, etc. used for transporting food or additives shall be cleaned and disinfected as necessary to prevent contamination of the food, additives, or their containers and packaging.
- (b) Vehicles, containers, etc. shall be maintained in a clean condition, and shall be kept in an appropriate condition by repairing, etc.
- € When food or additives and cargo other than food or additives are mixed, food or additives shall be placed in appropriate containers or otherwise classified, as necessary, to prevent contamination from cargo other than food or additives.
- (d) Foods or additives in transit shall be managed so as not to be contaminated by dust and exhaust gases, etc.
- € When vehicles, containers, etc. used for transporting food or additives of different items and cargo other than food or additives are used, they are to be cleaned by effective methods and disinfected as necessary.
- (f) In the case of food or additives in bulk, vehicles, containers, etc. exclusively for food or additives shall be used as necessary, and it shall be clearly indicated that they are exclusively for food or additives.
- (g) Care shall be taken to control temperature and humidity during transportation.
- (h) Delivery times shall be set based on the temperature and humidity during transportation, and shall be properly controlled so as not to exceed the prescribed delivery time.
- (h) In the case of delivering and serving cooked food, the time until it is served for eating and drinking shall be taken into account and properly controlled.

GMP 17 Stock Management

●Requirements

The organization shall establish a system to use raw materials and ingredients (including packaging materials), partially processed products, work in progress, reworks, and finished products in a designated order and within the defined expiry period, and shall store these materials under the proper conditions to avoid contamination and deterioration.

●Concepts, specific examples

【Storage period】

1. Raw materials (including containers and packaging materials), semi-finished products, work-in-process, recycled products, reworked products, and finished products should be stored for an appropriate period of time and used within the specified period, utilizing first-in, first-out, etc.
2. During storage, the traceability of raw materials (including containers and packaging materials), semi-finished products, work-in-process, recycled products, reworked products, and finished products (see FSM 14) should be managed so that they can be linked to the records.

【Storage location】

1. Raw materials (including containers and packaging materials), semi-finished products, work-in-process products, recycled products, reworked products, and finished products shall be stored in storage facilities that are not contaminated and do not deteriorate due to temperature, humidity, or other factors.

GMP 18 Devices and Tools

●Requirements

The organization shall design and select equipment and instruments to be suitable for their intended use, and shall use, maintain, and store them in a manner that minimizes food safety risks.

●Concepts, specific examples

1. Concept in GMP18
 - 1) GMP18 requires organizations to prevent food safety risks derived from equipment and instruments.
Examples of risks include the following
 - (1) Biological: Contamination due to residual food residues, etc.
 - (2) Chemical: Mold and allergen residues due to inadequate cleaning and drying, chemical damage due to detergent residues, etc.
 - (3) Physical: Foreign matter contamination due to breakage, deterioration, or loss.It is necessary to consider how to sufficiently prevent these risks before enabling production activities.
2. When selecting equipment and instruments
 - 1) Cleaning and drying
 - (1) As much as possible, it is desirable to be able to "wash the entire unit in a washing room, etc." and "reliably dry the unit in a drying room, etc.". For equipment that needs to be fixed to the floor, consider specifications that can be accommodated without difficulty, such as disassembly of cleaning parts.
 - (2) Assuming actual operation, the necessary capacity and quantity should be provided to allow sufficient time for cleaning and drying.

(3) Confirm that periodic cleaning and confirmation of water and residue in pipes, ducts, etc. are possible.

2) Specifications

(1) Check that areas that come in contact with foodstuffs are food-compliant, and take action to ensure that this can be verified.

(2) For parts that come in contact with food, confirm that they can be easily cleaned, inspected, and replaced, and consider the degree of deterioration that should be addressed and the frequency of such action to be realistically feasible.

(3) Avoid items (screws, labels, etc.) that may fall off the top of the food as much as possible, and monitor as necessary.

(4) Check carefully before initial use to ensure that there are no paint chips, facets, or other contaminants.

(5) If the product is made of metal, it should be made of a material that is resistant to rust and corrosion.

3. After installation of equipment

1) Establish procedures for cleaning, drying, and, if necessary, disinfection.

(1) Cleaning method: cleaning tools to be used, water temperature during cleaning, whether or not detergent is used, etc.

(2) Drying method: temperature setting of drying room, temperature setting for drying with warm air, time required for drying, etc.

(3) Others: Whether alcohol spray is used or not, etc.

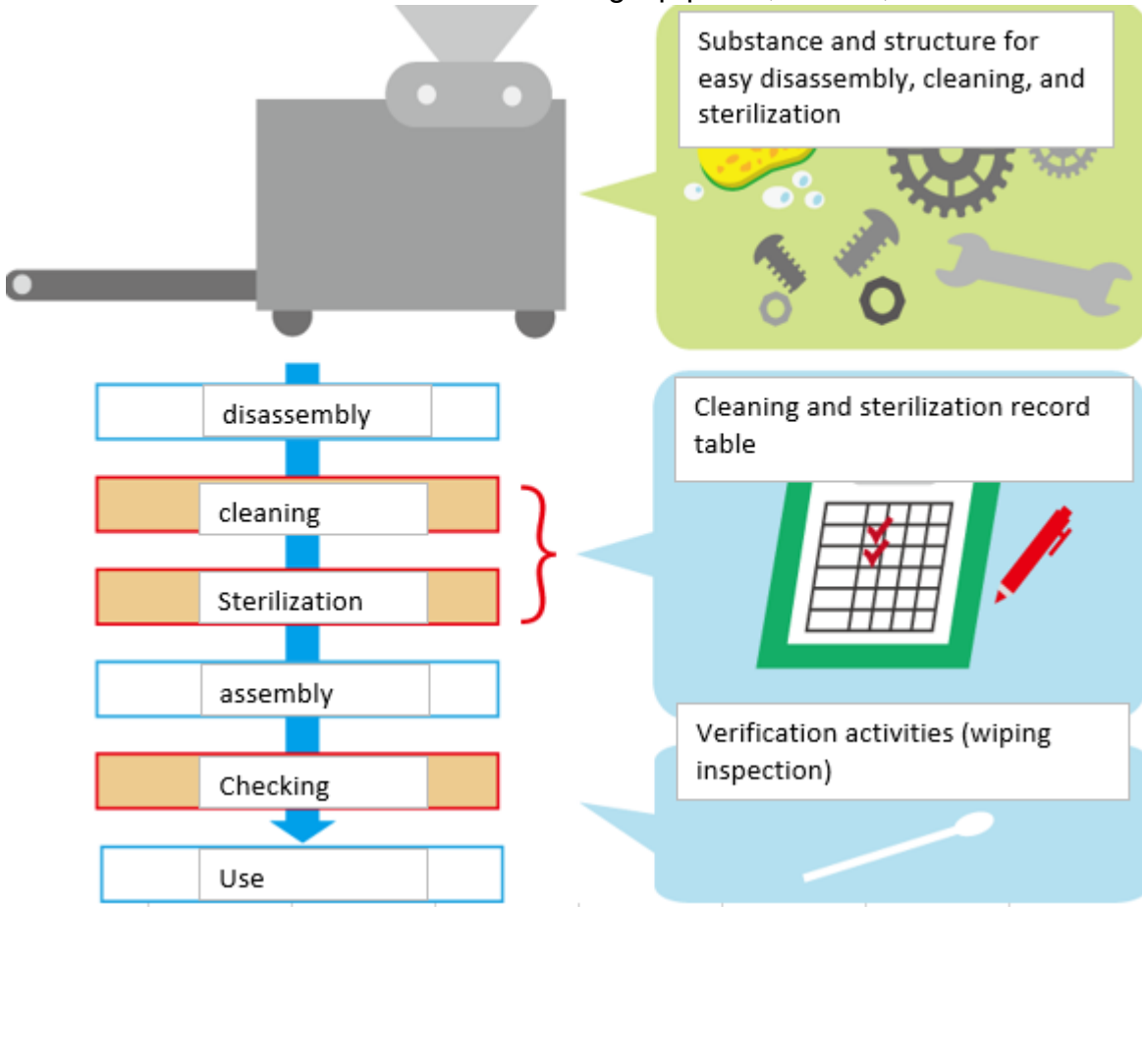
2) It is desirable to verify whether any of the intended hazardous factors will remain if the procedures are implemented as discussed. As an example, after actual washing and drying according to the procedures, the residual allergens may be confirmed by means of a bacterial test or ELISA test of wiped specimens.

3) If workers need to be informed and educated about the established procedures, it is desirable to have a procedure manual or visual explanation materials. In addition, it is recommended that records be kept to ensure that the procedures are followed, such as records of checks on areas prone to insufficient cleaning and records of the completion of drying, if necessary.

4) Monitoring should be conducted at an appropriate frequency for damage, deterioration, and other areas where food safety risks may be a concern. When monitoring is conducted, it is desirable to keep records.

5) Inform workers to report any abnormalities such as breakage, parts falling off, or abnormal noise.

■Activities to maintain sanitation of food handling equipment, facilities, and utensils



●Items to be referenced in legal provisions related to food safety

Sanitation of equipment and instruments

Regulations for Enforcement of the Food Sanitation Act

Article 66-5 The standards specified by Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 50-3, paragraph (1), item (i) of the Act concerning matters listed in the same paragraph shall be as follows

- (i) Allocation of necessary personnel, establishment of work contents, and maintenance of facilities and equipment, etc., so that the containers and packaging are manufactured appropriately
- (ii) Maintaining the cleanliness and health of personnel engaged in the manufacture of containers and packaging (hereinafter referred to as "workers" in this Article and the following Article).
- (iii) The facility or work area shall be designed to maintain the cleanliness and health of the equipment, containers, and packaging (hereinafter referred to as "equipment, containers, and packaging"), and to ensure that the workers understand the work procedures and matters necessary for hygiene management, and that they perform their work in accordance with those procedures and matters.
- (iii) The facility or work area shall be designed to prevent contamination by dust, dirt, or other contaminants as necessary, based on the usage of the equipment or containers and packaging, and shall be maintained in a clean condition.

Sanitation of equipment and instruments

Appended Table 17 (Re: Article 66-2, paragraph (1))

(iii) Hygiene control of facilities, etc.

(a) To maintain hygiene, machinery and equipment shall be used appropriately for their intended purposes.

(b) Machinery, equipment, and parts thereof shall be cleaned and sanitized to prevent metal fragments, foreign substances, or chemical substances from mixing with food or additives, and shall be stored hygienically in designated locations. In the event of malfunction or damage, it shall be repaired promptly and maintained for proper use. e. Equipment, cleaning equipment, and parts shall be stored in a hygienic location.

(e) Items that may come in contact with food or additives, such as utensils, cleaning equipment, and protective gear, shall be disinfected with hot water, steam, or disinfectants and dried each time they are contaminated or work is completed.

(li) Cleaning facilities are to be kept clean.

GMP 19 Maintenance

●Requirements

The organization must establish a system for the planned maintenance of all equipment and instruments critical to the safety of the product.

Maintenance activities must be performed in such a way that they do not pose a food safety risk.

●Concepts, specific examples

1. maintenance and management of equipment and instruments

1) Procedures shall be developed and implemented for the maintenance of all equipment and instruments that are important for product safety. The procedures shall include the following concepts

(1) After-the-fact maintenance: A management method in which maintenance is performed after a failure has occurred and the equipment has stopped or its functions have deteriorated.

(2) Preventive maintenance: Management methods that focus on prevention, such as equipment inspection and periodic parts replacement.

(3) Improved maintenance: Management method that focuses on improvement and reinforcement to prevent recurrence of breakdowns.

2) Procedures for maintenance and management of equipment and instruments include the following items

(1) Planning of maintenance and inspection

(2) Persons in charge of maintenance and inspection

(3) Identification of equipment and instruments requiring maintenance and inspection

(4) Frequency of maintenance and inspection

(5) Procedures for performing maintenance and inspections (including chemicals to be used)

(6) Methods for checking and recording the status of maintenance and inspections

(7) Procedures for returning to a state in which food production can be performed after maintenance (including cleaning, etc.)

●Items to be referenced in legal provisions related to food safety

Maintenance of equipment and instruments

Article 66-5 The standards specified by an Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 50-3, paragraph (1), item (i) of the Act with regard to the matters listed in the same paragraph shall be as follows

(iv) Proper implementation of cleaning and maintenance inspections of facilities and disposal of waste materials in order to maintain a clean working environment.

The end

Disclaimer: This translated document is machine translated by JFSM and is provided for information purposes only.
In the event of a difference of interpretation or a dispute, the original Japanese version of this document is binding.

JFS-A Standard Document (Sector: CI, CII, CIII, CIV/K) Version 3.0 [Guidelines] Edition 1.0
July 25, 2022 Issued
Editing and publishing Japan Food Safety Management Association

The copyright of this guideline belongs to the Food Safety Management Association of Japan or legitimate third parties. If you wish to use any of the contents of these guidelines, please contact us in advance at

SHINTOMICYO BLDG.,

3-10-9 Irifune, Chuo-ku, Tokyo 104-0042

Japan Food Safety Management Association(JFSM)