JFS-B Standard Document

(Sector：ＣⅠ,CⅡ,CⅢ,CⅣ/K)

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

Version 3.0

〔Guidelines〕

Edition 1.0

Japan Food Safety Management Association

May 5, 2022

Table of Contents

Introduction

This guideline provides ideas and specific examples of what organizations should implement with regard to the JFS-B standard issued by Japan Food Safety Management Association (JFSM).

The food safety management system established by each food business organization differs depending on many factors such as industry, business category, business scale, and social background. This report is intended to be used as a reference for each organization to build a food safety management system suited to their own needs.

The overall JFS standard is shown in Table 1 and Figure 1. (Sector:CI~CIV/K) These guidelines are for Sector B standards for the food manufacturing sector (CI - C IV) and the "Chemical Products (including biochemical products) Manufacturing Sector (K)". (Table 1)

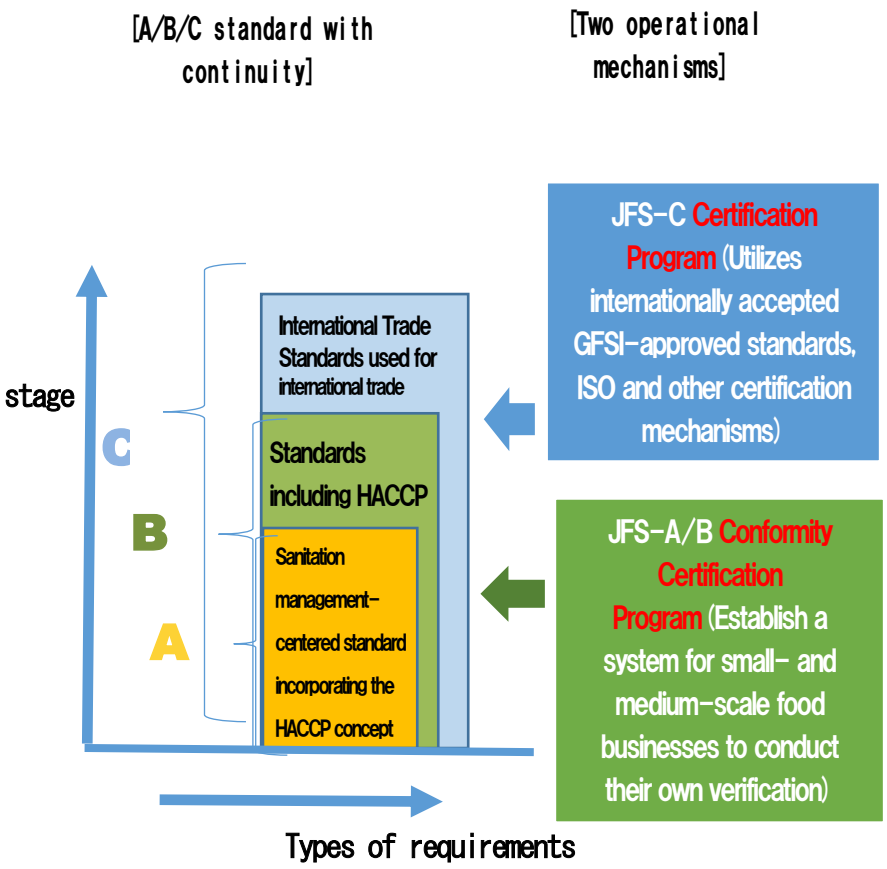

Figure 1: Overall view of the JFS Standards and Certification/Certification of Conformity Program

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
AII	Farming of Fish and Seafood	FII	Food Broker / Agent

BI	Farming of Plants (other than grains and pulses)	H	Provision of Food Safety Services
BII	Farming of Grains and Pulses	G	Provision of Storage and Distribution Services
BIII	Pre-process handling of plant products	I	Production of Food Packaging
C0	Animal primary conversion	JI	Hygienic Design of Food Buildings and Processing Equipment (for building constructors and equipment manufacturers)
CI	Processing of perishable animal products		
CII	Processing of perishable plant products	JII	Hygienic Design of Food Buildings and Processing Equipment (for building and equipment users)
CIII	Processing of perishable animal and plant products (mixed products)		
CIV	Processing of ambient stable products	K	Manufacture of chemical products (including biochemical products) (Manufacture of additives, vitamins, minerals, cultures, flavors, enzymes, processing aids, etc.)
D	Production of feed		
E	Catering		

Reference: The GFSI Benchmarking Requirements version 2020 PART I

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

The JFS-B 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（CI~CIV）

CI : Processing of perishable animal products
CII : Processing of perishable plant products
CIII : Processing of perishable animal and plant products (mixed products)
CIV : Processing of ambient stable products

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

K : Manufacture of chemicals (including biochemical products)
(Production of chemical products (including biochemical products) and cultures used as food ingredients

or processing aids in food production)
Chemical products herein refer to chemical products (including biochemical products) related to food products.

In addition, the JFS-B standard refers to the requirements of the Global Markets Program (a program to improve food safety initiatives for small and medium-sized businesses, hereinafter referred to as GMaP) proposed by the Global Food Safety Initiative (GFSI) in order to be consistent with international recognition of food safety, and includes intermediate items. This enables compliance with internationally researched food safety management system activities and clarifies the next food safety steps to be taken when an organization wants to improve its initiatives, such as when it expands its size or sales channels.

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）.

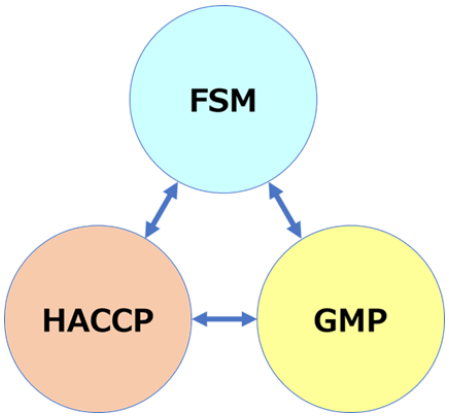

Figure 2: Basic structure of the JFS standard

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-B 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 the JFS standards.

<Structure of the JFS-B Guideline>

- 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.

Table 2 Comparison of JFS-A/B/C standard requirements

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 personne

JFS-Astandard Ver.3.0

No.	item（GMP１４item）
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

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GMP 17	Stock Management
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GMP 19	Maintenance

JFS-Cstandard Version 3.0 supplementary requirements

No.	item（GMP２２item）
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
GMP 15	Transport
GMP 16	Storage
GMP 17	Stock Management
GMP 18	Devices and Tools
GMP 19	Maintenance

JFS-Astandard Ver.3.0

No.	item（HACCP１０item）
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-Bstandard Ver.3.0

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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 （principle１）	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-Cstandard Version 3.0 supplementary requirements

No.	item（HACCP１２item）
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-B Standard (Sector：C Ⅰ～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

Ⅰ. Role of management or senior management

Ⅰ) 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

Ⅰ) 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.

(Ⅰ) 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

Ⅰ) 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 sanitation manager" and "food sanitation supervisor"

	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 4　Compliance with food safety laws

●Requirements

When developing a food safety management system, the organization shall develop, implement and maintain detailed procedures to ensure that all processes and operations that have an effect

on food safety are in compliance with the laws of both the country of manufacture and the intended country of sale.

●Concepts, specific examples

1. The organization shall identify the food safety laws and regulatory requirements for its own organization and establish methods of control. Not only the laws and regulations of the country of manufacture, but also the laws and regulations pertaining to food safety in the country of sale must be observed. Whenever there is a revision of relevant laws and regulations or the enactment of new laws and regulations, it is necessary to grasp them in a timely manner and communicate them within the organization to change the system. The legal and regulatory requirements of the country of sale must also be understood.
2. Those to be referred to in the legal and regulatory requirements pertaining to food safety (this item is applicable to the extent in Japan)
   A food sanitation manager or food sanitation supervisor who meets the necessary requirements shall be assigned.

1) Food Hygiene Manager: This is placed in accordance with Article 48 of the Food Sanitation Law. Target foods are whole milk powder, sweetened milk powder, adjusted milk powder, meat products, fish meat ham, fish meat sausage, irradiated food, edible oils and fats, margarine, shortening, and additives.
2) Food Sanitation Manager: A food sanitation manager is appointed for each facility that is to be licensed to operate, except in cases where a food sanitation manager is appointed in accordance with the Food Sanitation Law Enforcement Regulations.

(See FSM 1, ● Items to be referred to in the legal provisions related to food safety.)

FSM 6 Food Safety Policy and Goals

●Requirements

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

●Concepts, specific examples

Ⅰ. 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.

Ⅰ) 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;

Ⅰ) 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 7 Food Defense

●Requirements

The organization must identify the risk of intentional food contamination by persons within or outside the organization, assess the magnitude of the risk, and prioritize and implement response measures to reduce or eliminate the risk.

●Concepts, specific examples

Ⅰ. Food defense means the means of preventing, avoiding, or responding to intentional food contamination by biological, chemical, or physical hazards.

2. Identifying the risk of intentional food contamination by persons within or outside the organization and assessing the magnitude of that risk is called a food defense vulnerability assessment, and the response plan is called a food defense plan.

3. In the vulnerability assessment of food protection (analyzing threats and identifying weak points), it is necessary to envision situations in which intentional food contamination or tampering with food products is possible, discover areas with a high probability of occurrence, and then determine priorities such as access control.

4. Develop and implement procedures to conduct a vulnerability assessment of the facility (analyze threats and identify weaknesses).

5. Based on the results of the vulnerability assessment, develop and implement a food defense plan that includes methods, responsibilities, and decision criteria to prevent intentional food contamination and tampering.

6. The product defense plan will include the following elements.

Ⅰ) A responsible person with responsibility for food protection must be designated.

2) Have policies and procedures in place to record and control the entry and exit of employees, contractors, and visitors to and from the facility area.

3) Procedures must be in place to ensure safety during storage and delivery of raw materials, utensils, containers and packaging materials, drugs, and food products.

4) The site must be physically secured (security)

5) Have procedures in place for how to respond when food, packaging, or equipment is found to be intentionally contaminated or defective

6) Have an effective recall program (see FSM 22)

7) Provide necessary education and training to personnel according to the organization's food protection plan

【Reference】

Ⅰ. In addition to monitoring cameras and locking controls, communication among employees is a deterrent to food protection.

2. Excessive reliance on hard measures of food defense may in fact damage the good relationship between employees and management. Thus, for example, an organization may explain to employees that monitoring cameras are not installed based on suspicion of employees, but rather to provide proof of employee behavior in the event of a food accident.

3. Food defense is not limited to physical measures of the facility; internal attacks from interested parties must also be anticipated. Ensuring that there are no short-term workers or disgruntled or disgruntled workers is particularly useful.

4 A mechanism is needed to examine trends in social examples, examples of other companies in the same industry, prevention examples, and predictive signs.

5. The "Guidance for Formulating a Voluntary Action Plan for Enhancing Confidence in the Food Industry" - Five Basic Principles - published by the Ministry of Agriculture, Forestry and Fisheries in March 2008 is a useful reference.

(Basic Principle 1) Clarify the consumer's point of view

(Basic Principle 2) Establish compliance awareness
(Principle 3) Basis of proper hygiene and quality control
(Basic Principle 4) Establish systems for appropriate hygiene and quality control
(Basic Principle 5) Efforts to collect, communicate, and disclose information

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.
Records shall be taken and properly maintained as determined necessary to demonstrate the implementation of food safety controls.

●Concepts, specific examples

Ⅰ. Concepts in the FSM9

Ⅰ) It is important to maintain the FSM9 to" ensure that the necessary settings are retained" and "can be explained to third parties, and that records are kept without shortages and can be reviewed at a later date".

The following actions are required.

(Ⅰ) Necessary documents have been selected.

(2) Selected documents are stored and used in the latest version.

2. What is "documentation"?

Ⅰ)" Documentation" includes not only documents and document data, but also images, photographs, diagrams, audio, and video, and fulfills the following purposes

(Ⅰ) Ensure that everyone but the creator knows exactly what is going on in your company, your setup, and your procedures

(2) Standardize work and prevent variation in perception and understanding among individuals

(3) Records are kept to enable tracing and investigation of causes (see "Records" below)

(4) Facilitates correct explanations to third parties and clarifies the legitimacy of your organization

2) Documented documents should be managed so that the latest version can always be referenced and operated. For this reason, it is desirable to establish appropriate rules for modifying and storing documents, and to consider a system that can be managed as easily as possible. An example is as follows.

(Ⅰ) Specify where documents are to be stored

(2) Create a list of documents

(3) Attach a setup number, obsolete number, etc. to the document to make it clear that it is the latest version

(4) Discard old versions or store them in a designated place to prevent misuse

3. This standard and documentation

Ⅰ) The following table lists the items that are clearly "required to be documented" in this standard.

Even if the requirements do not directly require "documentation and records," there are cases where it is optimal to present them in writing. On the other hand, the existence of a large number of documents leads to complicated management.
If it can be judged that "it can be handled by methods other than documents," reducing the number of documents appropriately may be effective for both the on-site work of workers and the operation of managers.

It is desirable to consider the appropriate measures and take actions suitable for one's own organization.

4. 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) Stablish "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.

【Documents and records required by the requirements】

No.	item	Content of documentation or records	check	remarks
FSM6	Food Safety Policy	Clear, concise, documented food safety policies		
FSM13.2	Supplier Management	Documentation of results of surveys, evaluations, approvals, and follow-up with suppliers		
FSM14	Traceability	Record results of traceability verification		
FSM22	Serious Incident Management	Records of annual testing to verify the effectiveness of the accident response manual		
FSM25	Corrective Action	Corrective Action Documentation		
HACCP Step12	Documentation and record keeping	Create the necessary documentation (in HACCP) and keep records		All documents and records required by HACCP are required to be documented and recorded in this procedure 12.
GMP6	Sanitation, work clothes and health	Document appropriate sanitation standards for employees		

	management of employees, etc.			
GMP11	Air and water management	Records of periodic monitoring of air, high-pressure gas, water, etc. used in food production		

●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 11 Procedures and Instructions

●Requirements

Organizations must consider relevant safety requirements when designing products and manufacturing processes. The organization shall establish, implement and maintain effective

procedures and instructions in all processes and activities that affect food safety. These work procedures and instructions must be visible to employees.

●Concepts, specific examples

1. For all processes and operations that affect food safety, roles are to be determined and procedures are to be shared.
2. Procedures should be disseminated in a manner that is easily understood by those involved, using documents and other means as necessary.
3. The key points of the procedures and documentation are as follows.
   1) Procedures should be determined for all processes that affect food safety.
   2) It should be easy to understand and can be used when new employees join the company and for re-training.
   3) It will be easier to create the document if "when, where, who, what, and how it should be done" is clarified.
4. Depending on the situation where employees are becoming multilingual, it is desirable to address the issue in the language used by the employees, in writing or otherwise, whenever possible.

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

Management and Operation Procedure

Article 66-2, paragraph (3) of the Ordinance for Enforcement of the Food Sanitation Act
(ii) A procedure manual (hereinafter referred to as a "procedure manual") for appropriately implementing measures necessary for public health in these processes, 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, and (iii) Prepare a sanitation management plan and procedure manual as necessary.
(iv) Verify the effectiveness of the sanitation management plan and procedure manuals, and review their contents as necessary.

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 13.1 Purchasing

●Requirements

The organization must develop and implement purchasing procedures to ensure that all externally procured raw materials, materials, and services that affect food safety comply with the organization's requirements.
When processes affecting food safety are subcontracted, control of these processes must be ensured by presenting the control methods to the subcontractor, for example, by describing the control methods in specifications and contracts.

●Concepts, specific examples

【Procurement】

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.
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
   3) Compliance with specifications in Certificate of Quality and Certificate of Analysis
3. The ultimate responsibility for food safety when making purchases rests with the purchasing organization.
4. FSM 13.1 requires management of what the organization purchases from outside (raw materials, containers and packaging materials, and services), whereas FSM 13.2 requires management of their suppliers (suppliers and providers).
5. In some cases, purchasing procedures are exempted from application when purchasing from (or accepting) an intra-group company. However, this requirement requires that the same purchasing procedures be applied when purchasing from an intra-group company as when purchasing from an external source.
6. Laws, regulations and regulatory requirements pertaining to food safety to which reference should be made

1) Requirements for raw materials
   (1) Packaging materials are capable of adequately protecting products from contamination and damage and are properly labeled.
   (2) Raw materials that are properly controlled are to be procured.
   (3) Management of agricultural, forestry, livestock, and fishery products (primary products) used as raw materials includes the following
   ①Prevention of contamination by dust, soil, or sewage is implemented at the production stage.

② Appropriate management of wastes, toxic substances, etc. at the production stage.
③Prevention of contamination by pesticides, veterinary drugs, feed, rodents/insects, foreign substances, microorganisms, feces, etc. is implemented at the production stage.
④Facilities at the production stage are maintained clean and properly managed through cleaning and appropriate repairs.
⑤Prevention of contamination by rodents, insects, chemical substances, foreign substances, microorganisms, etc. is implemented at the stage of collection, storage, and transportation.
⑥Clearly inedible materials are separated.
⑦Temperature and humidity control and other necessary measures are taken to prevent spoilage and deterioration of food products.
⑧ Hygiene control is conducted for those who handle the food.

(4) When it is obvious that raw materials contain parasites, pathogenic microorganisms, pesticides, etc., or foreign substances, and these cannot be killed or removed to an acceptable level by normal manufacturing and processing, such raw materials will not be accepted.

2) Requirements for packaging materials used for food products (the scope of this item applies in Japan)

(1) Use appropriately controlled products that are manufactured and processed in accordance with laws and regulations such as the Standards for Foods and Additives (1959, Ministry of Health and Welfare Notification No. 370) and whose safety is assured.
(2) When selecting packaging materials, select materials with appropriate gas barrier performance, tensile and puncture strength, etc., depending on product characteristics (strong odor, distribution temperature range, etc.), expiration date, size, capacity, etc.
(3) Select materials with materials and surface treatments that will not peel off labeling or erase printing due to friction or adhesion of condensation drops during distribution and storage.
(4) When reusing packaging materials, prepare a procedure for reuse in advance and manage it so as not to contaminate the product. In case of damage or significant contamination, discontinue use and dispose of the product.
(5) Packaging containers and packaging gases should be non-toxic and should not impair the safety and suitability of the product for storage and use.
(6) Reusable packaging materials and containers/packaging should be durable, easy to clean and wash, and disinfectable.
(7) Raw materials that do not conform to the acceptance criteria should be handled according to documented procedures to avoid accidental use.
(8) In order to further enhance the safety of synthetic resin food utensils, containers, and packaging, the Law for Partial Revision of the Food Sanitation Law, etc., promulgated on June 13, 2008, introduced the positive list system, which allows the use of only substances that have been evaluated for safety with respect to food utensils and containers and packaging. (Ministry of Health, Labour and Welfare, June 2040). (Enacted on June 1, 2020 by the Ministry of Health, Labor and Welfare)

【Subcontractor management】

1. Outsourcing is the process of outsourcing an organization's own processes to another organization. The organization periodically monitors and verifies the outsourced process to ensure that the results of the outsourced process do not pose a food safety hazard to the organization's products.
2. This outsourcing includes not only product manufacturing by contractors and services provided by personnel dispatch, but also the provision of services. This outsourcing includes not only product manufacturing by contractors and services provided by personnel dispatch, but also the provision of services. The services provided by the provider include transportation and storage, inventory control (see GMP 15 and 17), insect, rodent, and sanitation consultants, sanitation of workplaces and facilities, maintenance of equipment and facilities, cleaning of work clothes, provision of meals for employees, etc.

3. The ultimate responsibility for the food safety management system in the case of outsourcing rests with the contractor.
4. Any changes to the contractual arrangements must be approved by both parties and communicated to the relevant personnel.
5. Covered subcontractors include contract manufacturers and service providers.
   1) Contract manufacturers agree to and contract with all terms and conditions related to food safety, customer requirements, commercialization, shipping, etc.
   The contract manufacturer shall develop and implement an organization to ensure compliance with the terms of the contract.
   2) Contracted service providers document and contract specifications for services affecting food safety.
   3) The contract shall include training of personnel involved in providing the services as well as clarification of the services.
6. Outsourced supplier management is described in the flow diagram required by HACCP Procedure 4, if necessary, and control methods are determined through the hazard factor analysis required by HACCP Procedure 6. In addition, an evaluation of suppliers is performed in accordance with FSM 13.2.
7. The following contents shall be performed as necessary to ensure the appropriateness of outsourcing.
   1) Confirmation of food safety management system
   2) Confirmation of the product process control system
   3) Verification of accuracy and results of in-process inspections
   4) Periodic verification of final products
   5) Ensure food safety from physical and chemical aspects
   6) Verification of personnel competence and education/training system
8. With regard to the operation of HACCP, when outsourcing CCP processes, etc., the management system, process control, and conformance of the final product must be equivalent to the food safety management system established by the own organization.

Example of Supplier Data Entry Form (Product Specification)

approval	examination

product specification No

creation-day author

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

Standard Quality Standards

standard	volume	TGS number	best-before date	code	Raw material mixing ratio				(Characteristics)		Nutritional analysis g/100%	
									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)

raw materials → → → → → → shipping

FSM 13.2 Supplier Performance

●Requirements

The organization shall establish, implement and maintain procedures for the evaluation, approval and continual monitoring of suppliers, which have an effect on food safety.
When accepting raw materials, packaging materials, and services from unapproved suppliers in an emergency (such a natural disaster), the organization shall confirm that the products meet the required specifications by an evaluation, inspection, visit, etc. before use.
The results of investigations, evaluations, approvals, and follow-up with suppliers must be documented.

●Concepts, specific examples

1. This requirement requires that the organization establish and implement procedures to control suppliers (suppliers/providers) of raw materials, containers/packaging materials, and services that affect food safety based on risk assessment.
2. In the event of an emergency, when supplies are received from unapproved suppliers, this is only an acceptable emergency measure and assumes that raw materials, containers and packaging materials, and services are purchased from approved suppliers.
3. The controls required of the organization are to establish and implement procedures for the evaluation, approval and monitoring of suppliers, which are described in detail below.

Ⅰ) Evaluation

After determining the person responsible for the evaluation, the necessary related information shall be collected and evaluated with reference to the following methods and contents.

(1) Evaluation Method

① Verbal interview
② Document and record checks
③ Visit and on-site confirmation or audit

(2) Assessment Contents

① Information on supplier organization: organizational reliability, product supply capacity, manufacturing site operational status, quality assurance system, supplier evaluation results (records related to bilateral audits, third-party certification, etc.), compliance, traceability
② Information on delivery method: delivery date, delivery location, delivery conditions (temperature, humidity and special environment), etc.
③ Whether or not there are any cases of food product mislabeling at the raw material origin/supplier
④ Whether there are any circumstances that are likely to cause falsification (i.e., prices of suppliers used are extremely lower than market prices, market prices of raw materials soar, supply is tight, shipping times are frequently moved forward, rapid increase in order volume, understaffed production system).

(3) Qualifications and competence of evaluators

Personnel in charge of conducting supplier evaluations shall be knowledgeable of the items listed in the specifications and applicable laws and regulations, and shall be audit-trained.

2) Approval

The organization defines who approves suppliers based on the evaluation results. Then, the rules/processes for the approver to approve and the method of information sharing with the HACCP team shall be defined as a procedure.

3) Monitoring

Rules (method, frequency, timing, etc.) for periodic re-evaluation of suppliers are defined as a procedure. Monitoring also includes activities related to follow-up, such as suspending transactions with suppliers or providing guidance to suppliers in case of problems, depending on the results of a series of evaluations of suppliers.

4. This requirement refers to the supplier's food protection, but it does not require a level of compliance with FSM 7 (food protection) to this standard, but rather allows the supplier to define its own scope of applicability and initiate its own initiatives for food protection. This is an acceptable level. 5.
5. In emergency situations (e.g., natural disasters), it is anticipated that an immediate decision may be required when evaluating unauthorized suppliers. This standard requirement does not permit omitting the point at which suppliers are evaluated under normal circumstances, but it is permissible to shorten the time period for checking, provided that equivalence is recognized in the method.
6. In addition, this includes maintaining objective evidence of equivalence between products using raw materials, packaging materials, and services purchased from unauthorized suppliers and normal products at the time of product shipment (release).

Example of New Purchaser Data

Key Data on New Purchasers

Category	
Buy first name	
Representative	
Person in charge	
Location	

Purchaser Judgment

(5 points each, 30 points total, 20 points or more as acceptable)

Price		Strength	
Insured		Technology	
Delivery date		Actuarial	
Total			

Size and condition of business

Delivered product	Specifications	Quality	Price	Evaluation
squid somen				
Matsumae pickles				
salted fish (entrails)				
Crab				
A number of flavors				
ikameshi				

Assessment Results

Contract history or references

remarks

approval	examination	author	
			Date
			Company Name

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

Appended Table 17 (Re: Food Sanitation Enforcement Regulations, Article 66-2, paragraph 1)
14 Other
(a) To the extent necessary for preventing the occurrence of food sanitation hazards, efforts shall be made to prepare and preserve records concerning the source of purchase, the state of manufacture or processing, the destination of shipment or sale, 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 14 Traceability

●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.
The organization must verify such procedures at least annually through trace testing to ensure that they are functioning effectively. And the verification results shall also be recorded.

●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】

5. 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	—

FSM 16 Allergen Management

●Requirements

The organization must develop and implement an allergen control plan. The plans shall include a risk assessment of allergen cross-contamination and control measures to be implemented to reduce or eliminate the risk of cross-contamination.
All finished products containing or potentially contaminated with allergens must be identified in accordance with the laws and regulations of the country to which they are expected to be shipped.

●Concepts, specific examples

1. Allergens to be controlled

Substances that cause allergies are called allergens. In Japan, the following allergens are required or recommended for labeling. In this standard, accid ents due to food allergens in consumers should be considered.

Items subject to mandatory labeling (7 items)

egg	milk	wheat	peanut	shrimp	soba	crab

Target items for which labeling is recommended (21 items)

salted salmon roe	banana	Sesame	Chicken	orange	kiwi fruit	Japanese yam
mackerel	apple	beef	Pecan	cashew	Salmon	matsutake
Gelatin	soybeans	Peach	Squid	abalone	pork	almond

*From Food Labeling Standards (as of September 19, 2019)

2. Allergens to be controlled within all manufacturing facilities must be identified, a plan developed, implemented, and properly maintained.

1) Identify allergens that may be present based on the specifications of the raw materials used.

2）Differentiation of receiving and storage locations for each different allergen

3）In accordance with the production plan, allergens to be controlled are to be identified so that they can be checked on each production line.

4) Distinguish between machinery and equipment used in the weighing room.

5) Identify locations in the manufacturing facility where allergen powder is dispersed and implement measures to prevent dispersal.

6) Switch lines that cannot be cleaned with water (powder, oil and fat products (chocolate, spreads, etc.))

7) Label and control the use of allergens on recycled products and work-in-process products

8）Measures to prevent labeling errors

9）In controlling allergens, the laws and regulations of the country of sale (allergen labeling regulations) must be observed.

3. Develop control procedures to reduce or eliminate the risk of cross-contact. Examples of control procedures include the following. Examples of control procedures include the following

1）Containers and utensils (plastic bags, shovels, etc.) used in production should be identified for each allergen to be controlled and avoid mixed use.

2) Procedures for handling raw materials (including containers and packaging materials), semi-finished products, work-in-process products, reworked products, and finished products should be developed to prevent allergen cross-contact in all processes from manufacturing to shipping.

3) Determine methods for cleaning, washing, and verifying manufacturing processes to prevent cross-contact.

4) When different products are manufactured on the same production line, plan to produce them in the order of least allergenic to most allergenic, if possible.

4. When developing products containing allergens, confirm the validity of control by line testing, etc.

5. When preparing product labeling, allergens are labeled in accordance with the laws and regulations (allergen labeling regulations) of the assumed marketing countries.

6. If verification (analysis, etc.) is required, establish and implement the procedure, and record and store the verification results.

7. To establish and implement procedures to ensure that items required in relation to contamination in FSM 13-1 (Purchasing), 13-2 (Supplier Management), FSM 18 (Product Labeling), GMP 3, 4, 5, 17 (Manufacturing Processes), etc., are in compliance. (Requirements related to contamination in manufacturing processes, etc.).

FSM 17　Control of Measuring and Monitoring Devices

●Requirements

The organization shall identify measuring and monitoring devices that are parameters critical to ensure food safety.
In addition, the specified equipment and devices shall be calibrated regularly. Calibration of these instruments and devices must be performed to equivalent standards, including national and international standards, or to reasonably accepted traceable methods.

●Concepts, specific examples

1. It is necessary to clarify the measuring instruments for parameters that are important to ensure food safety, and to identify those instruments that are necessary for monitoring. Measuring instruments that are not relevant to ensuring food safety are not included in the scope.
2. "Calibration" here is one of the means to confirm the validity of the measurement of numerical parameters and is a verification. It includes international standards, national standards, domestic calibration/manufacturer's assurance and in-house verification, etc. From among these, it is necessary to determine the appropriate method in the target equipment or device and inspection.
3. Calibration is required for instruments, devices, and methods used in measurement and monitoring activities.
4. Calibrated instruments and devices for measurement/monitoring, testing, and inspection are to be controlled to prevent damage or misadjustment.
5. Calibration is to be performed in accordance with legal requirements, the schedule recommended by the equipment manufacturer, and the schedule determined by the organization
6. Record when measuring, monitoring, test, and inspection instruments and devices are found to be inaccurate, and establish procedures to evaluate and take appropriate action on potentially affected products

●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 18　Product labeling

●Requirements

Organizations must label or attach information to their products that will enable a trading partner or consumer to safely handle, display, store, store, prepare, or use the product.
It must also establish and implement procedures for labeling or attaching the correct information.

●Concepts, specific examples

1. Information required by laws and regulations (allergens, food additives, etc.) should be provided in accordance with the methods and procedures specified in the laws and regulations.
2. The following items should be considered from a food safety standpoint when labeling products.
   1) Clarify the intended users and target consumers, such as the point of sale.
   2) Clarify the product's specific eating conditions, such as for raw consumption or for cooking.
   3) Clarify the intended use of raw materials and seasonings.
   4) Basis for setting expiration dates and best-before dates should be clarified.
   5) Handling temperatures and methods should be clarified.
3. Information required for products should be printed or attached to packaging materials based on product specifications.
4. Procedures are to be established to confirm that the contents of the labeling are correct. 5.
5. Procedures are established to ensure that products and labeled packaging materials are not mistakenly mixed up.

Product Labeling Considerations (Example)

■Check the expiration date labeling.

●Confirm that the date is correct.

・Check the date of expiry by multiple workers.

・Check the date on the work instructions, calendar, etc.

・The date should be confirmed on a work instruction sheet, calendar, etc. - Record the date by attaching the printed packaging to a confirmation sheet, etc.

●Points to check

・Check that the date is correct.

・Are there any errors in the printing location?

・Are there any blurs, chips, blots, or omissions in the printing?

Be careful when the year or month changes!

●Present a reminder of the printed contents on the packaging line.

(Partially quoted from "Explanation of the Matters for Upgrading Infrastructure Development" (Food Industry Center, Japan))

■Example of information management of raw materials containing allergenic food [1].

●Data of allergenic substances contained in raw materials ●Allergenic substances contained in final products can be grasped

Ingredients	Manufacturer	specification	allergen				
			wheat	egg	milk	・・・	gelatine
A			○	△	×		×
Ingredients	Manufacturer	specification	allergen				
			wheat	egg	milk	・・・	gelatine
B			○	△	×		×
Ingredients	Manufacturer	specification	allergen				
			wheat	egg	milk	・・・	gelatine
E			○	△	×		×

⇒

Product name	Classification	raw materials	allergen				
		materials used	wheat	egg	milk	・・・	gelatine
Udon noodles with curry topping	curry	A	○	△	×		×
		B	○	△	×		×
		C	○	△	×		×
	udon noodles	D	○	△	×		×
		E	○	△	×		×
Allergens in final product			○	○	×		×

(Partially quoted from "Explanation of the Matters Related to the Development of Advanced Infrastructure" (Food Industry Center, Japan).

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

Display

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

(ix) Provision of information

(a) Business operators shall endeavor to provide consumers with information necessary for them to safely consume food or additives (hereinafter referred to as "products" in this table) that they collect, manufacture, import, process, prepare, store, transport, or sell. (a) A business person shall endeavor to provide consumers with the information necessary for consumers to safely consume and eat the food or additives (hereinafter referred to as "products" in this table).

(b) A business person shall endeavor to provide consumers with information necessary for the safe consumption of food or additives (hereafter referred to as "products" in this table), including information on health hazards (limited to those symptoms diagnosed by a physician as being caused by or suspected to be caused by said food or additives. 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 caused or 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.

FSM 19 Analysis and Inspection

●**Requirements**

The organization shall conduct appropriate inspections where and as they affect food safety. Such inspections must be performed by a competent laboratory or analytical laboratory.

●Concepts, specific examples

1. To ensure food safety, inspection plans should be developed to ensure that inspection of products, semi-finished products, raw materials and environmental wipe test specimens are conducted systematically for items that affect food safety and legal requirements, as well as product requirements from customers.
2. The laboratory or analytical laboratory with testing competence should be using procedures, validated methods, etc. that conform to ISO 17025 to ensure that this testing method is a valid result. The results of such inspections should be verified on a regular basis.
3. Documentation is required that defines procedures (methods, standards, etc.) for incoming raw material inspections, as well as inspections of manufacturing processes and products.

Inspection details and records specified in the inspection control rules (example)

Inspection Name	Subject of Inspection	Inspection Contents																	Records
		supplier	name	Lot No.	volume	standard	Color, odor	appearance	Tasks	Temp.	time	Metals, foreign matter	Size, shape	Damage, dirt	foreign substance	Shipment Date	Shipping to	Packing condition	microbe	
Purchasing Acceptance Inspection	Materials	○	○	○	○	○		○						○						Receiving Control Chart
	Raw materials	○	○	○	○	○	○	○						○						
In-house Acceptance Inspection	Raw materials	○	○	○	○	○	○	○						○						
In-process inspection	Semi-finished products		○	○					○	○	○									In-process inspection list
Final Inspection	Finished product		○	○	○	○		○				○	○	○	○					Final Inspection Chart
Outgoing Inspection	Finished Products		○	○	○	○										○	○	○	○	Shipping Instructions and Shipping Inspection Chart

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

Appended Table 17 (Re: Article 66-2, paragraph (1)) of the Ordinance for Enforcement of the Food Sanitation Act
14 Other
(a) To the extent necessary for preventing the occurrence of food sanitation hazards, efforts shall 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 pertaining to 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 21 Complaint Handling

●Requirements

The organization must establish, implement, and maintain a management system that utilizes complaints from suppliers and consumers and their data to identify, correct, and manage omissions and deficiencies in food safety initiatives.

●Concepts, specific examples

1. A distinction should be made between food safety-related events and other events, for example, those related to quality. What is required in this item are events related to food safety.

2. For complaints from suppliers and consumers, the key to promptly resolving complaints is to establish a system to properly identify and promptly respond to complaints.
3. Procedures for responding to complaints should include the following.
The following are possible procedures for establishing a system to respond to complaints.
1) A manual on how to respond to complaints from suppliers and consumers should be prepared.
2) Employees should be aware of their responsibility for handling and investigating complaints from clients/consumers.
3) The company shall try to understand as accurately as possible what the complainant wants in response to a complaint from a supplier or consumer. If the complainant wants answers to his/her questions regarding the investigation of the cause of the complaint (including presumption), responses to the product complained of, and measures to prevent recurrence, etc., the employee shall inform the complainant that the information will be provided appropriately. At that time, if necessary, a deadline for a response will be given. (When it is found during the investigation process that the cause of the complaint is not with the organization, the complainant will be informed of this as soon as possible. (If the complaint is a false accusation or a monetary claim, the company will consider a different method of handling the complaint.)
4) Reply to the complainant with the details of the investigation and response to the complaint from the client/consumer as described in 3) above, and record the details.
5) Examine the cause of the complaint and its relation to GMP and HACCP systems, find any omissions or deficiencies in the food sanitation system, correct them if necessary, and record the results.
6) For complaints from suppliers and consumers, the responsible person shall confirm the completion of the response.
2. When nonconformity is found based on a suggestion from a supplier or consumer, corrective action shall be taken.
3. establish, implement, and maintain a system to continuously improve and control the food sanitation system by utilizing complaints from suppliers and consumers and their data.

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.
Based on the incident response manual, products supplied by the organization must be tested at least once a year to verify the effectiveness of the procedures and records of the verification must be maintained.

※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

Ⅰ. 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. (Refer to the A/B program document.) 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.

FSM 24 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.

FSM 25 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.

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.

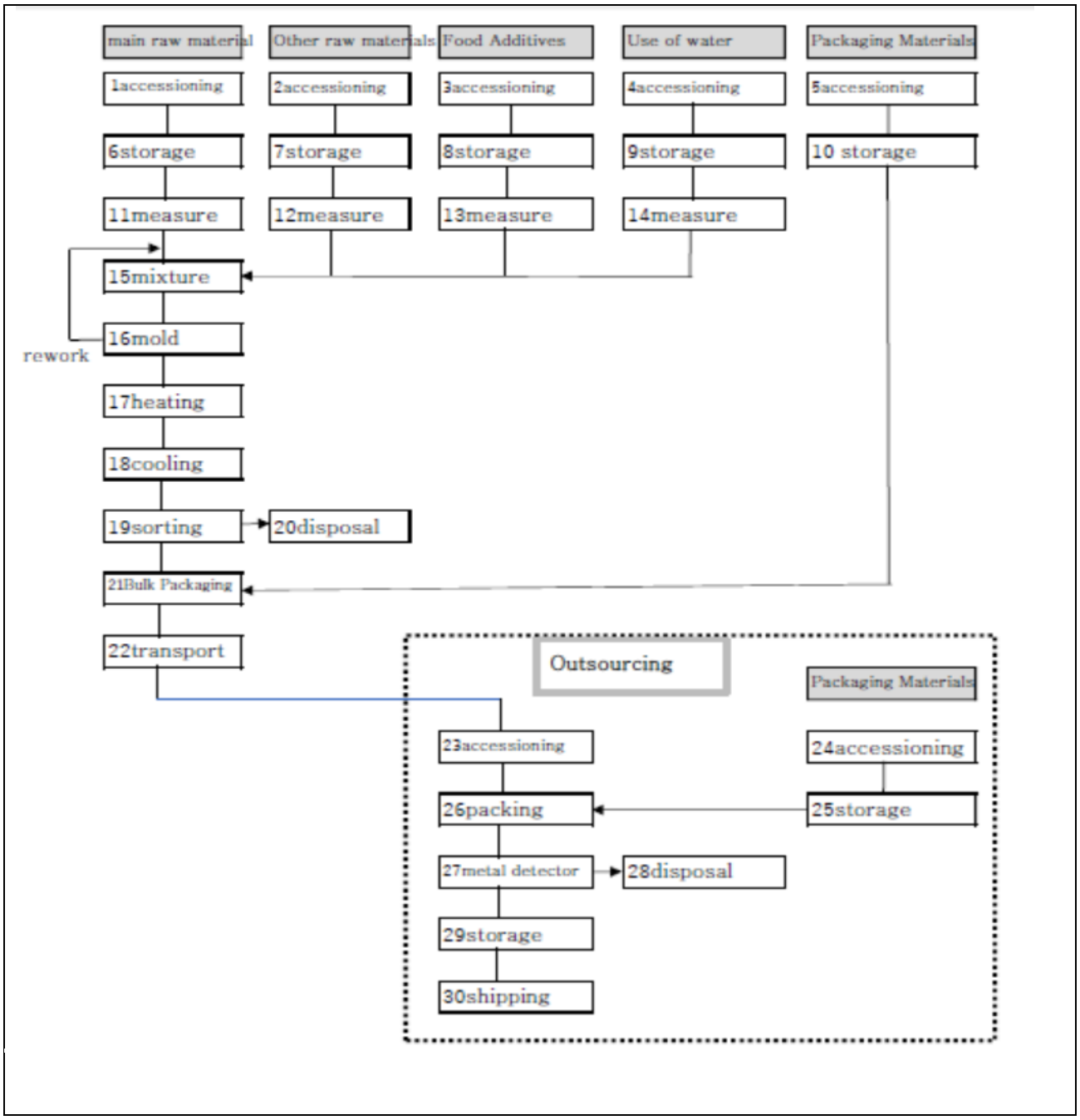
2. The flow diagram is used as the basis for conducting a hazard analysis to evaluate the likelihood that a hazardous factor will occur, increase, decrease, or be introduced.
3. The flow diagram should be accurate and detailed enough to perform a Hazard Analysis.

【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 （Principle 1） Hazard Analysis

●Requirements

Potential hazards in each process must be enumerated, the critical hazards must be identified, and all possible means to control them must be considered.
Hazards shall include allergens where required.

●Concepts, specific examples

1.Hazard Factor Analysis is to determine the critical hazard factors to be controlled by the HACCP plan and to identify the control methods for each critical hazard factor. For this purpose, information is first collected on hazardous factors that may occur in the entire process from raw materials through manufacturing, processing, storage, and distribution to consumption, as well as the conditions under which they may occur, to determine the likelihood of occurrence of hazardous factors and the severity of the hazard if they do occur.
2. By conducting a risk factor analysis, it is possible to create an appropriate management system for the facility according to the frequency and severity of possible hazardous factors.
3. The actual process of hazard factor analysis is to list the hazard factors in the final product by raw material and process, which may lead to health hazards when consumed.
4. Following the flow diagram from raw materials to the final product, identify raw materials and processes that may lead to the occurrence of hazardous factors, narrow down the important hazardous factors in terms of frequency and severity of occurrence of hazardous factors in each process, and identify the factors (contamination, proliferation, survival, adulteration, etc.) and control factors for those hazardous factors. The hazard factor analysis sheet should be prepared to list the causes of occurrence (contamination, proliferation, survival, contamination, etc.) and the control measures to control them.
5. In preparing this sheet, all members of the HACCP team should share their expertise and knowledge, and discuss and summarize them.

《Steps to Create a Hazard Analysis Sheet》

6. The steps for preparing the Hazard Factor Analysis Sheet follow the "Example Hazard Analysis Worksheet" shown in Codex GPFH2020.

Example of Hazard Factor Analysis Worksheet (Prepared from Codex General Principles of Food Hygiene 2020: Japan Food Sanitation Association 2021 First Edition Figure 2)

(1) column	(2) column	(3) column	(4) column	(5) column
Raw Materials / Operation works (stage)	Identify hazards that are expected to occur or are likely to increase in this process. B: Biological C: Chemical P: Physical	Do these potential hazards need to be addressed in the HACCP plan? (Yes or No)	Justify your judgment in column (3). (If rated "0": Indicate the basis for the judgment and the cause of the hazardous factor. ×(If rated "x": Indicate the reason(s) for the rating.)	What measures can be applied to prevent, eliminate or reduce to an acceptable level the hazards? (Specify the means to control the hazards rated as critical in column (3)).
	B:			
	C:			
	P:			
	B:			
	C:			
	P:			
	B:			
	C:			
	P:			

【Step 1】(Column (1) of "Example of Hazard Factor Analysis Worksheet")

List raw materials and manufacturing and processing processes according to the flow diagram. List the main raw materials, secondary raw materials, water used, packaging materials, etc., and the manufacturing and processing processes along the flow diagram, with the same numbers.
Perform a hazard analysis of all raw materials used in the food. This can be done in two ways.

①Perform hazard analysis on raw materials in the process of receiving raw materials.

②Perform hazard factor analysis separately for raw materials and processes.

This guideline describes the method in ①.

【Step 2】 (Column (2) of "Example of Hazard Factor Analysis Worksheet")

List potential hazardous factors originating from raw materials and manufacturing and processing processes.
Hazard factors should be described in detail. For example, instead of "food poisoning bacteria," list "Salmonella," "pathogenic E. coli O-157," etc. Also, describe the source of contamination and the reason for its presence, such as "contamination from a metal foreign body derived from a blade broken during grinding" or "pieces of a kitchen knife," rather than simply "pieces of metal.

【Step 3】(Column (3) of "Example of Hazard Factor Analysis Worksheet")

Based on the likelihood of the listed hazards and the magnitude of damage if they occur, evaluate whether or not they are critical hazards that must be reduced or eliminated from the food product to ensure the safety of the final product.
When conducting a Hazard Analysis to determine critical hazards, consider the following to the extent possible

1) Hazard factors associated with the type of food to be produced and processed, including raw materials and processes (e.g., from hazard factor surveys or sampling and inspection, recalls, scientific literature information, or epidemiological data in the food chain)
2) Likelihood of occurrence of the hazard factor in the absence of additional controls, taking into account GMP (PRP)
3) Frequency and severity of adverse health effects due to the hazard in the food in the absence of controls
4) Identified allowable levels of the hazardous factor in the food (e.g., based on regulations, intended use, and scientific information)
5) Nature of the facility and machinery and equipment used to produce the food
6) Survival or growth of pathogens

7) Generation or persistence of toxins (e.g., mold toxins), chemicals (e.g., pesticides, veterinary drugs, allergens) or physical hazards (e.g., glass, metal) in the food
8) Potential for food to become unsafe due to its intended use and/or mishandling of the product by the consumer
9) Conditions leading to the above

For the evaluation of hazard factors in Step 3, it is recommended to utilize a matrix table of "Severity of Occurrence" and "Frequency of Occurrence" as shown below and enter them numerically on the hazard factor analysis sheet. There are various examples of creating a matrix table, and it is recommended to adopt it in consideration of the target product, manufacturing process, etc. However, this does not apply to cases where the product can be clearly evaluated on a "yes/no" basis.

An example of the concept of the likelihood of the listed hazard factors and the magnitude of damage if they occur.
(Based on the "Risk Assessment Handbook" published by the Ministry of Economy, Trade and Industry in June 2011)

		Severity of Results				
		None	complaint	Recalls	serious	fatal
frequency of occurrence	Occurs often	**15**	19	22	24	25
	Occurs occasionally	10	**14**	18	21	23
	Has occurred at other companies	6	9	**13**	17	20
	No information available from other companies	3	5	8	**12**	16
	Unthinkable	1	2	4	7	11

How to Read Matrix

20～25	It is an extremely high risk, suggesting that it may be a significant source of harm, and is likely to be controlled by control measures that are CCPs under Principle 2 of HACCP Procedure 7.
12～19	It indicates that the current control measures may become inadequate, and that some additional measures are needed to strengthen and enforce the current GMP (General Sanitation Management Program).
1～11	Can be managed with current management tools.

【Step 4】（Column (4) of "Example of Hazard Factor Analysis Worksheet"）

In this step, for significant hazard factors marked with ○ (or Yes) in【Step 3】((3) in the "Example of Hazard Factor Analysis Worksheet"), identify the causes of the occurrence and describe the basis for the judgment in column (4). For those hazard factors marked with X or No in column (3), the basis for judgment should be described.

【Step 5】（Column (5) of "Example of Hazard Factor Analysis Worksheet"）

For each hazard factor rated as critical, identify control measures to ensure the safety of the final product. The following is an example of a Hazard Factor Assessment (Step 3) and Hazard Factor Analysis Sheet.
Consider which control measures to apply to each critical hazard factor; sometimes more than one control measure is needed to control one critical hazard factor. For example, to control Listeria monocytogenes, heat treatment may be required to kill viable organisms in the food, and then cleaning and sanitizing the environment may be required to prevent contamination from the processing environment after heating.
It is possible that specific control measures can control multiple sources of harm. For example, if Salmonella spp. and E. coli O-157 are present in the food, heat treatment may be used to control both hazards.
For other hazard analysis sheets for other items, please refer to the examples provided on the MHLW website. (http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000098735.html)

Example of Hazard Factor Analysis Sheet

Product name: Catering Bento

(1)	(2)	(3)	(4)	(5)
Ingredients/Process	Hazards expected to occur in (1)	Is it an important hazard that needs to be reduced or eliminated from the food supply?	Basis for decision in column (3)	Control measures for hazards identified as important in column (3)
Refrigerated (Vegetables)	Organisms: Presence of Harmful Microorganisms Salmonella spp. Pathogenic Escherichia coli Staphylococcus aureus	NO	Contamination is possible due to unsanitary handling during manufacturing and processing, but can be controlled by adhering to hygienic handling of food and other products.	
	Heat-resistant spore Clostridium botulinum Welch bacillus	NO	Contamination is possible due to unsanitary handling during manufacturing and processing, but the bacteria are anaerobic	
	Bacillus cereus	NO	Possible contamination due to unhygienic handling during manufacturing and processing, but can be controlled by adhering to hygienic handling of food and other products.	
	Chemical: None			
	Physical: Presence of metallic foreign bodies	YES	Possible presence of metallic foreign matter due to improper handling during manufacturing and processing	Controlled by metal detection (NO.9)

(1)	(2)	(3)	(4)	(5)
Ingredients/Process	Hazards expected to occur in (1)	Is it an important hazard that needs to be reduced or eliminated from the food supply?	Basis for decision in column (3)	Control measures for hazards identified as important in column (3)
Buckwheat flour/accepted	Organisms: Presence of pathogenic microorganisms Harmful Microorganisms			
	Salmonella spp.	6	May be more contaminated than soil	Can be controlled in the sterilization process (NO.32)
	Pathogenic Escherichia coli	6	May be more contaminated than soil	Can be controlled by Sterilization Process (NO.32)
	Heat-resistant spore Bacillus cereus	7	May be more contaminated than soil	Can be controlled by cooling
	Welch bacillus	19	Not likely to proliferate since not placed under anaerobic conditions thereafter	
	Clostridium botulinum	15	No possibility of proliferation, as the material will not be placed under anaerobic conditions thereafter.	
	Chemical: Residual pesticides	17	Inspection certificate is issued once a year to confirm that the product has passed the inspection.	
	Physical: Presence of Hard foreign body	13	Can be eliminated by visual check at weighing (NO.14)	
	Metallic foreign body	18	Can be eliminated by visual check at weighing (NO.14)	

●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")

HACCP Step 7 (Principle 2) Critical Control Points (CCPs)

●Requirements

Critical Control Points (CCPs) shall be determined.

●Concepts, specific examples

1. What is a Critical Control Point (CCP)
 1) Critical Control Point (CCP) (hereinafter referred to as "CCP") is a step in the production of a product for which control is essential to reduce or eliminate significant risk factors from the food to an acceptable level, and which is established in a process whose deviation leads to a potentially unsafe food. A step in a procedure or operation that is essential to control in order to reduce or eliminate the allowable level of a hazard factor, and in which deviations lead to potentially unsafe food products.
 2) For each critical risk factor identified as a result of the risk factor analysis, one or more control measures must be established to control that risk factor.
 3) Among the control measures for the critical risk factors listed in Principle 1, consider control measures that can be used as CCPs.
 4) The CCP requires measures such as setting tolerance limits as described later, monitoring, and not allowing products manufactured during deviations to be shipped when deviations occur.
 5) CCPs may be required for multiple phases to control one hazard factor.

2. how to determine CCP
 1) The basic principle is to establish procedures for all processes and implement GMP control. Among them, CCPs are those steps that have a direct adverse effect on food products, such as those related to "do not bring in," "do not let in," "do not let out," and "do not increase" food poisoning bacteria, which are hazard factors, and the "last resort" step in the process.
 2) If the control of a hazardous factor can be controlled by GMP, the control measures are not defined as CCPs, but if the hazardous factor cannot be fully controlled by GMP alone, the process in which the control measures are taken is defined as a CCP. However, if the hazardous factor cannot be controlled by GMP alone, the process in which the control measures are taken shall be designated as CCP. If the hazardous factors can be controlled only by GMP throughout the entire process, there are no significant hazardous factors, and therefore, a CCP may not be set.
 3) A process being analyzed should not be considered as a CCP if control measures can be used in the process being analyzed but are also applicable at later stages of the process, or if other control measures for the relevant hazard factor exist in other processes.
 4) Determine if control measures in one process are used in combination with control measures in another process to control the same hazard factor. If so, both processes should be considered as CCPs.
 5) Clearly define the method to determine the CCP.
 6) If the steps that should be CCPs are controlled by GMP, there is a risk that the hazardous factors may not be fully controlled; if processes that can be adequately controlled by GMP are made CCPs, this may result in wasted effort and a relative lack of control over other processes.
 7) The requirements for CCP are that it must be possible to monitor continuously or at a reasonable frequency using a predetermined monitoring method, and that if the parameter

deviates from the Critical Limit (CL), production must be stopped immediately, process control must be restored in a short time, and the food produced during the deviation must be identified and isolated. The CCP requirement is to be able to identify and isolate the food products that were produced during the deviation.

8) The value of the monitoring parameter (limit value) at the boundary of whether or not the safety of the product can be ensured is called the permissible limit (CL).

3. Examples of CCPs

1) Examples of CCPs to prevent occurrence of hazardous factors are as follows.
   (1) Receiving raw materials: Prevention of residual antimicrobial substances by checking test reports submitted by suppliers
   (2) Cooling：Prevention of pathogen proliferation through appropriate temperature control
   (3) Refrigerated storage : Prevention of pathogen proliferation through appropriate temperature control
   (4) Weighing of food additives : Prevention of excessive addition
2) Examples of CCPs that eliminate risk factors are as follows
   (1) Heating or chemical sterilization process: Sterilization of pathogenic bacteria
   (2) Metal detection: Detection by detectors and elimination of metal fragments
3) Examples of multiple CCPs that control a single hazardous factor are as follows
   (1) Control of patty thickness and heating time/temperature to kill non-spore-forming pathogenic microorganisms in hamburgers.
   (2) The heating process can be a CCP to kill trophozoites of spore-forming pathogens, and the cooling process can also be a CCP to prevent spore germination and growth.

If control measures for the identified critical hazards are not present at any stage, the product or manufacturing process should be modified.

●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
(ii) Determination of critical control points
Processes for which it is essential to take control measures to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified hazardous factors (hereinafter referred to as "Critical Control Points" in this table).

HACCP Step 8 （Principle 3） Establishment of Critical Limits

●Requirements

Critical limit(s) shall be stipulated for each CCP.

●Concepts, specific examples

1. What is the Critical Limit (hereinafter referred to as CL)?
   1) CL is a criterion that distinguishes whether a CCP is acceptable or unacceptable for controlling a hazard factor.
   2) CL should be measurable or observable.
   3) CL may have more than one parameter.
   4） CL must be set correctly based on scientific data because incorrectly set CLs can lead to the occurrence of hazardous factors.
   5） Corrective action is required in case of deviation from the CL.

6) CLs must meet the following conditions
(1) Parameters that are optimal in ensuring that hazards are prevented, eliminated, controlled, or reduced to acceptable levels, and values that are substantiated by scientific evidence.
(2) Criteria using parameters that can be determined in real time whenever possible.
If the control condition is found to be inappropriate, remedial measures must be taken promptly, so it is desirable that the CL be presented in terms of parameters that can be determined in real time.

7) CL is usually a minimum or maximum value of a very important parameter related to the control measure (temperature, moisture content, time, pH, water activity (Aw), effective chlorine, contact time, conveyor belt speed (velocity), viscosity, conductivity, flow rate, or other measured values or sensory indicators (color, gloss, odor, taste, viscosity, physical properties, foam, sound, etc.) or observation of pump settings.

2. How to establish CL
1) CLs should be scientifically validated by evidence that, when properly implemented, they can control the hazard factor to an acceptable level.
2) If indicated by laws, regulations, or norms, the CL should adopt a numerical value by which the target harm factor can be controlled. In other cases, they should be set based on literature data, experimental data for validation, etc.
3) Even if the numerical value indicated in the manufacturing standard, etc. is adopted as the CL, collecting evidence (evidence) on whether it can be applied in the organization (products, manufacturing facilities, manufacturing processes, etc.) is also a validity check.
4) In ordinary manufacturing process control, it is not common to control only by CLs, but to set an operational limit (OL), which is a standard that can be controlled before deviation from the CLs, with more leeway than the CLs.

●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.

HACCP Step 9 （Principle 4） Monitoring System

●Requirements

Monitoring procedures shall be established for each CCP.

●Concepts, specific examples

1. What is monitoring?
1) Monitoring is the observation, measurement or test inspection based on a schedule determined in the HACCP plan, compared to the CL, to ensure that the CCP is properly controlled and to keep accurate records that can be used during later verification. The HACCP plan is to be followed by observations, measurements or test inspections based on a schedule determined in the HACCP plan, compared to the CL, in order to keep accurate records that can be used for subsequent verification.
2) In the control in CCP, monitoring is to ensure that no deviation from the CL has occurred.
3) In case of deviation from the CL, corrective action is required.
4) Monitoring records are also used to verify the HACCP plan.

2. How monitoring is to be conducted

1) The monitoring method must meet the following conditions
   (1) The monitoring must be continuous or at a reasonable frequency.
   (2) The method should provide results promptly. (Physical and chemical measurements are usually chosen over microbiological testing)
2) It is important to monitor the conformity of control measures for risk factors for all products. Monitoring should be continuous if possible (e.g., temperature and time of heating) so that every product, from the first one to the last one, or every batch, can be monitored to ensure that all products meet the CL. However, there are some measurements that cannot be monitored continuously (e.g., water activity, preservative concentration). In such cases, the frequency of monitoring should be sufficient to ensure compliance with the CL as much as possible and to minimize the amount of product affected by deviations. and in a manner that allows easy corrective action to be taken.
3) If possible, process adjustments should be made when monitoring results indicate a trend toward deviations in the CCP.
4) The [5W1H] that defines the monitoring method means the following.
   (1) Rationale (Why): Is there scientific validity in monitoring the management status of the CCP?
   (2) What (What): Is the CCP within the acceptable range of CL (not deviating from CL)?
   (3) Where (Where): Clarify the relevant (CCP process) process
   (4) How (How): Is it a rapid and accurate physical, chemical or sensory observation, measurement or inspection method?
   (5) Frequency (When): Is there a frequency with which deviations are not missed, either continuously or not continuously?
   (6) Who (Who): Personnel trained in monitoring methods
5) Continuous recording of measured values alone is not enough to control hazard factors. It is necessary for someone other than the person in charge of monitoring to check them at an appropriate and sufficient frequency.
6) When the HACCP plan is prepared, a person in charge of monitoring should be designated. This person should be able to perform or be instructed on the appropriate steps to take when monitoring indicates that corrective action needs to be taken. Data obtained from monitoring should be evaluated by a designated person with the knowledge and authority to take corrective action.
7) All records and documents related to CCP monitoring should be signed or initialed by the person conducting the monitoring, and the results and the time the monitoring was conducted should be recorded.

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

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） Corrective Actions

●**Requirements**

A procedure of corrective actions (correction, and investigation and removal of root cause) shall be established for deviations from a critical limit.

●Concepts, specific examples

1. What is corrective action?
   1) Corrective action is an immediate action taken when monitoring parameters deviate from the CL.
   2) In CCP, which is a process that should be strictly controlled to prevent the occurrence of hazards, it is important to establish corrective action methods and procedures in advance, because if monitoring parameters deviate from the CL, food safety risks may occur and increase. The HACCP plan should be based on a HACCP plan.
   3) During the HACCP plan, the procedures for restoring the control status of the process and restarting the line, as well as for isolating the affected product and determining and implementing a disposal method for the affected product, should be specified.
   4) To minimize the possibility of recurrence of deviations, a cause analysis should be performed to identify and correct the cause of the deviation, if possible. The cause analysis should identify the reason for the deviation or limit the amount of product affected by the deviation.
2. Items to be included in the HACCP plan as corrective actions
   1) Items to be described in the HACCP plan as corrective actions are as follows.
   (1) Actions to restore the process to its original state of control
   Restore the process to its normal state of control by repairing, adjusting, replacing, etc., the machinery.
   (2) Actions for products manufactured during deviations
   Products that do not conform to the CL are identified, withheld, and evaluated.
   Decide how to dispose of them, e.g., reprocessing or disposal.
3. Persons in charge of implementing corrective actions
   1) The person in charge of implementing corrective actions is the person in charge who has sufficient knowledge of CCP management, understands the process well, and has the authority to make a prompt decision.
4. Corrective Action Implementation Record
   1) Corrective action implementation records should include the following items
   (1) Details of the deviation, the manufacturing process or location where the deviation occurred, and the date and time of occurrence
   (2) Name, lot number, quantity, etc. of the product subject to corrective action
   (3) Results of investigation into the cause of the deviation
   (4) Details of actions taken to restore the process to its original state
   (5) Details of measures to be taken for products manufactured during the deviation
   (6) Signature of the person in charge of implementation and recording of the above items
   (7) Signature of the person in charge of inspecting the contents of corrective actions and the date of inspection

●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 Step 11 （Principle 6） Establish HACCP plan validation and verification procedures

●Requirements

A HACCP plan must be validated prior to implementation. Verification procedures shall be established to confirm whether the defined handling (HACCP Plans) is carried out as specified and to judge whether it is necessary to modify the defined handling.
Verification shall be carried out considering the design of equipment, change in processing method and technology development in the manufacturing process.

●Concepts, specific examples

1. Necessity of validation
   1) It is to ensure that the HACCP plan is capable of controlling the critical hazard factors. Items to be validated: Identification of critical risk factors, CCP, CL, control measures, frequency and type of CCP monitoring, corrective actions (remedial actions), frequency and type of verification, and type of information to be recorded, etc.
   2) Validation of control measures and CCP CLs shall be conducted during the preparation of the HACCP plan.
   3) Validation includes review of scientific literature, use of predictive models, conducting validation studies, use of guidelines developed by authoritative sources, etc.
   4) Evidence should be obtained to demonstrate that controls were achieved consistently during the initial implementation of the HACCP plan and under production conditions during manufacturing.
2. Necessity of verification
   1） To evaluate the effectiveness of the HACCP plan and ensure that the HACCP system is functioning properly.
   2） To modify the HACCP plan and make it better by recognizing weaknesses in one's own HACCP system based on the results of periodic verifications.
3.Verification of each HACCP plan
   1) Verification of the HACCP plan for each CCP shall include the following items
   ① Calibration of measuring devices (instruments) used for monitoring
   ② Testing and inspection of raw materials, intermediate products or final products
   ③Measurement of manufacturing and processing conditions
   ④ Confirmation of CCP monitoring records, corrective action records, and verification records
   ⑤ Confirmation that workers are working in accordance with the HACCP plan
   ⑥ Observation that control measures are operated in accordance with the HACCP plan.
   2) Verification of monitoring includes verifying whether the monitoring is correct or not by using different measuring instruments or methods. For example, for temperature, cross-checking with a different thermometer, or for verification of the heating process, conducting a microbiological test on a sample after the heating process to confirm that no microorganisms remain in the sample.

《Items that should be specified in the HACCP plan as internal verification work》

3）The items to be stipulated in the verification plan are as follows

① Contents
② Frequency
③ Actions to be taken based on verification results
④ Method of recording verification results

4. testing and inspection methods
1) To assure product safety, this includes evaluating and verifying that CCPs and CLs are properly established and controlled. Testing and inspection methods for verification are to be conducted in a reasonable manner. Visual inspection and sensory evaluation can also be used as a means of verification, but in this case, documented procedures and objective criteria based on photographs and samples should be established.
5. Verification of the overall HACCP system
1) Verification of the HACCP system shall be conducted on a regular basis using the following procedures as necessary
(1) Analysis of the cause of consumer complaints or recalls
(2) On-site confirmation that monitoring operations are being carried out in accordance with established procedures
(3) Testing and inspection of final products
2) Results of the verification are recorded and reviewed.
6. Re-validation of the HACCP system
1) Revalidation shall be conducted once a year as a rule, and also 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
(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.

●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） Documents and Record

●Requirements

Necessary documents shall be prepared and maintained.

● 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, CCP determination, CL determination and information to scientifically support CL, 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

In addition to serving as evidence to prove control, they are also important for dealing with deviations when they occur.

●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.

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

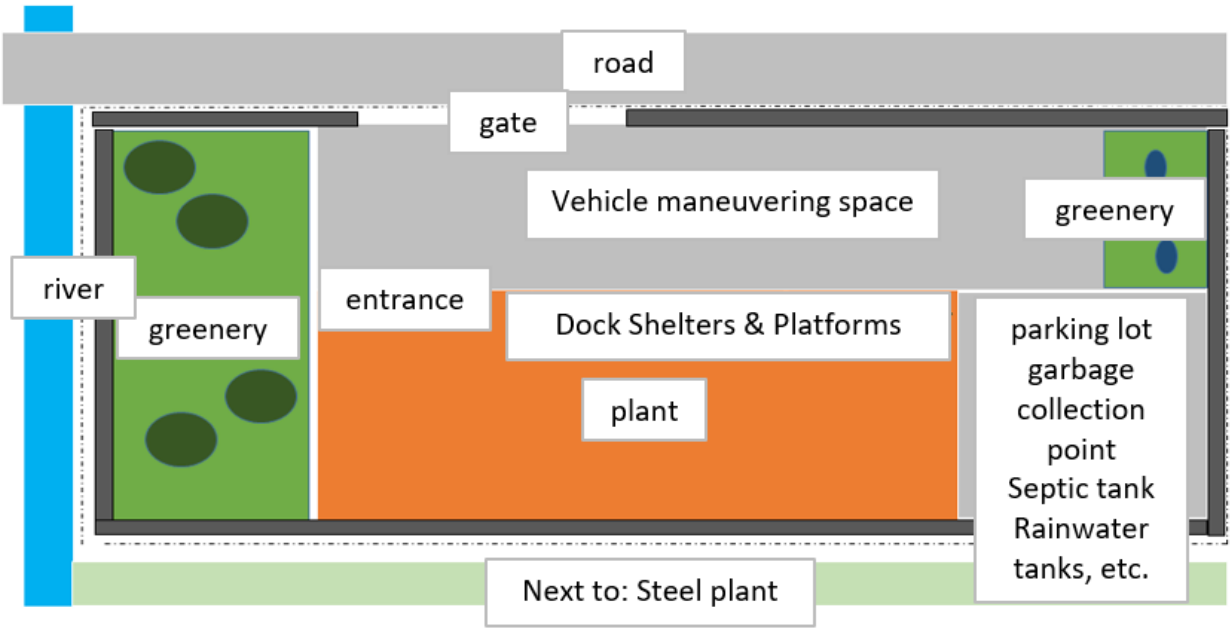
・Arrangements with related parties in the surrounding environment.

・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)).



GMP 3　Design, construction, layout of business site and work and product flow lines

●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】

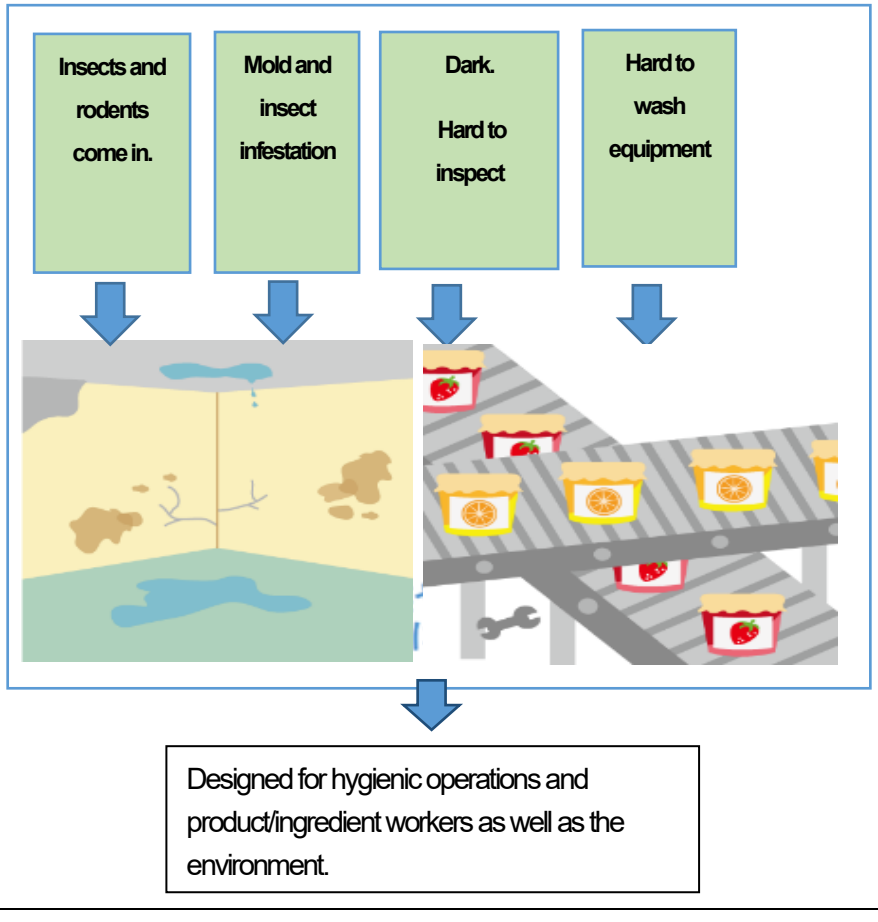
1. The illuminance of the work environment is specified in Article 604 of the Industrial Safety and Health Regulations and JIS. The work classification and standards in Article 604 are as follows: precision work: 300 lux or more, ordinary work: 150 lux or more, and rough work: 70 lux or more; the JIS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

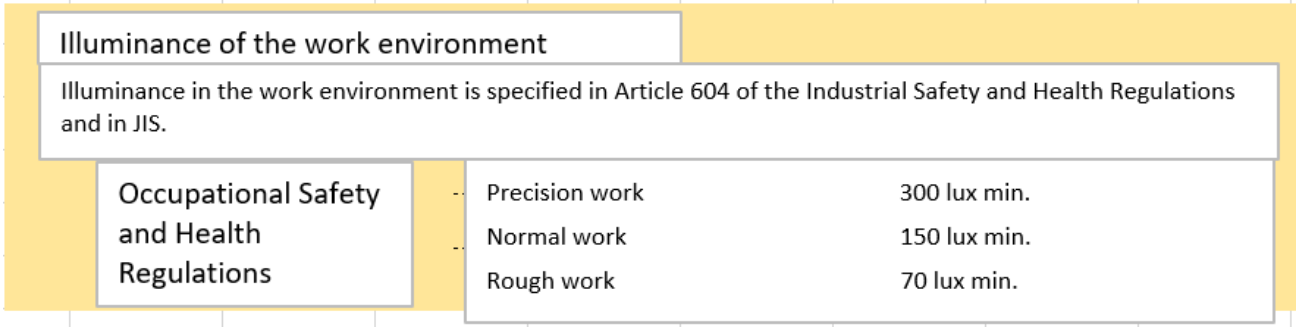
【Specifications and general information in the production area】

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.



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 Critical Control Points (CCPs) (prevention of cross-contamination)

●Requirements

Based on the results of the HACCP Procedure 6 (Principle 1) Hazard Analysis, the organization shall establish procedures to prevent contamination and cross-contamination of raw materials (including containers and packaging materials), semi-finished products, work in process, reworked products, and finished products by controlling critical hazard factors identified that are not controlled by control measures at the critical control points (CCP) and that are difficult to effectively control outside this item (GMP 4). The organization shall regularly review these procedures and keep 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) Control of Hazard Factors Controlled by GHP (GMP) that Require More Attention in Codex GPFH2020 and GMP4 Hazardous factors identified by the hazard analysis in HACCP Procedure 6 that could cause significant food safety hazards if there is an error in GMP controls are considered to be controlled under "GHPs (GMPs) requiring more attention" and are controlled under GMP4. controlled by GMP 4.

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 13.1, 13.2, Purchasing, supplier management
FSM 16 Control of allergens
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 (Principle 1) 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 (Principle 1).
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.
4) Overall control over allergens is implemented in FSM 16.

●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.

GMP 5　Personnel Facilities

●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】

Ⅰ. 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】

Ⅰ. 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】

Ⅰ. Facilities for washing and drying hands in a hygienic manner are required.

Ⅰ) 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　Hygiene, workwear and Health management of personnel, 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

Ⅰ. 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., lame 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 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

Ⅰ. 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.

GMP 12 Waste Management

●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】

Ⅰ. Pest control measures shall be taken as follows

Ⅰ) 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】

Ⅰ. 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 thermo-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.
(c) 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.
(e) 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.

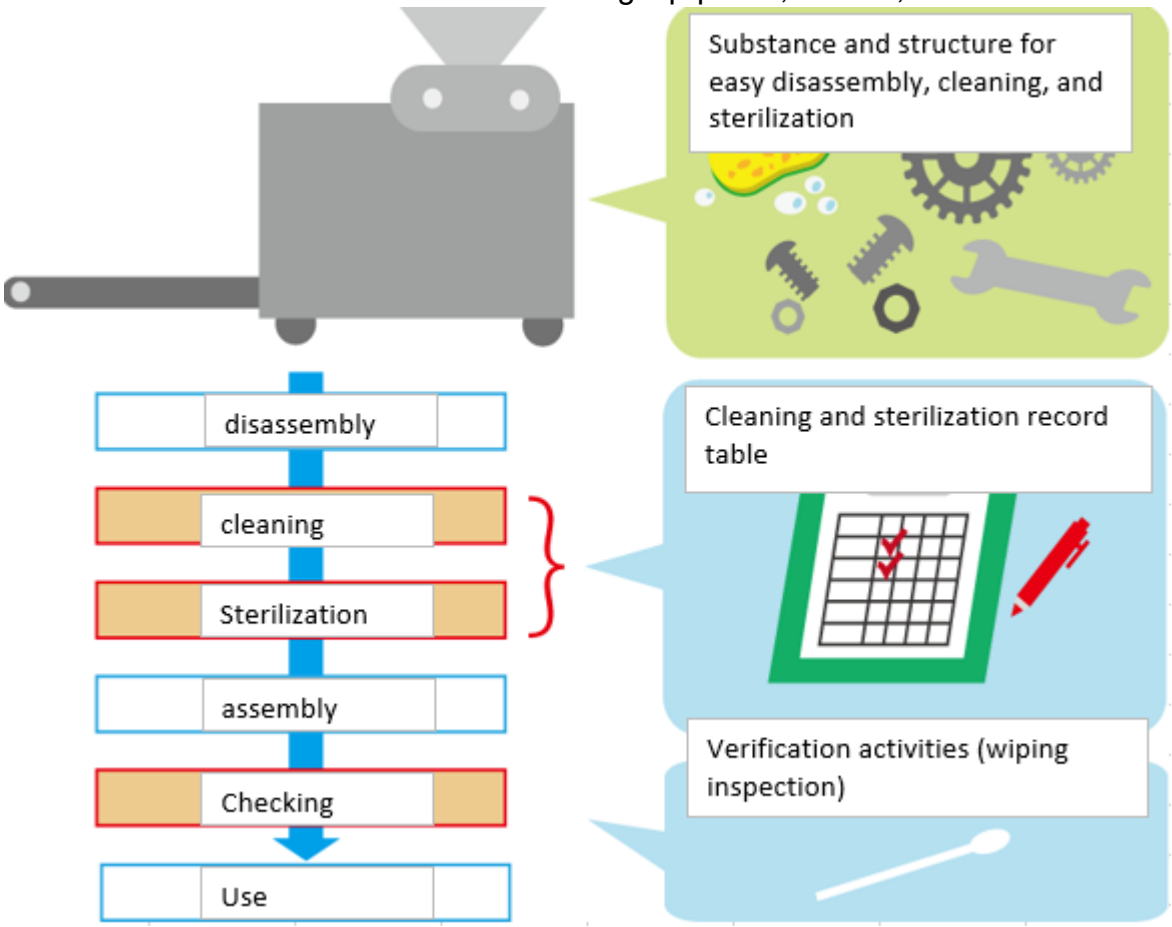
(3) Avoid items (screws, labels, etc.) that may fall off the top of the food as much as possible, and monitor as necessary.

(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.)

2. maintenance precautions

1) Repair the equipment so as not to contaminate food, etc.
2) Make sure that equipment (facilities) and instruments are not damaged or missing screws, etc.
3) Implement preventive maintenance as well as after-the-fact maintenance in a systematic manner.
4) Preventive maintenance plans should include equipment that monitors or controls food safety.(e.g., sieves, air conditioning filters, magnetic traps, metal detectors, etc.)
5) In the event of malfunction or damage, promptly repair the equipment and return it to normal condition.
6) When performing maintenance, avoid contaminating surrounding manufacturing/processing lines and equipment.
7) Lubricants and heat media that may come in direct or indirect contact with food should be selected that will not impair safety even if they come in contact with food.

●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

JFS-B Standard Document (Sector：CI,CII,CIII,CIV/K) Version 3.0〔Guidelines〕 Edition 1.0
May 25, 2022 Issued
Editing and publishing Japan Food Safety Management Association

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