JFS-B Plus Standard Document

(Sector: CⅠ, CⅡ, CⅢ, CⅣ /K)

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

Version 1.0

〔Guideline〕

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Introduction

This guideline provides ideas and specific examples of what organizations should implement with regard to the JFS-B Plus 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.

These guidelines are for B Plus standards for the food manufacturing sector (CI - C IV) and the "Chemical Products (including biochemical products) Manufacturing Sector (K)". (Table 1)

Table 1 List of Sectors by GFSI (Sectors presented by GFSI that are covered by this standard document are framed.)

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	Perishable animal and plant products (mixed products)		
CIV	Processing of ambient stable products	K	Manufacture of chemical products (including biochemical products) (Production of chemical products (including biochemical products) and cultures used as food ingredients or processing aids in food production)
D	Production of feed		
E	catering		

Reference: The GFSI Benchmarking Requirements version 2020.1 PART I

【Food manufacturing sector (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

Manufacturing sector of chemical products (including biochemical products) (K)

K ：Manufacture of chemical products (including biochemical products)

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

In addition, chemical products here means a chemical product (including a biochemical product) related to food.

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 1).

And JFS-B Plus is a standard that adds to the JFS-B standard the requirements for organizations in capacity building programs developed by international industry associations for food-related businesses. By operating this standard, the organizations can comply with internationally researched food safety management system activities.

Overall view of JFS Standard Document and Certification Program is shown in Figure 2.

Figure 1: Basic structure of the JFS standard

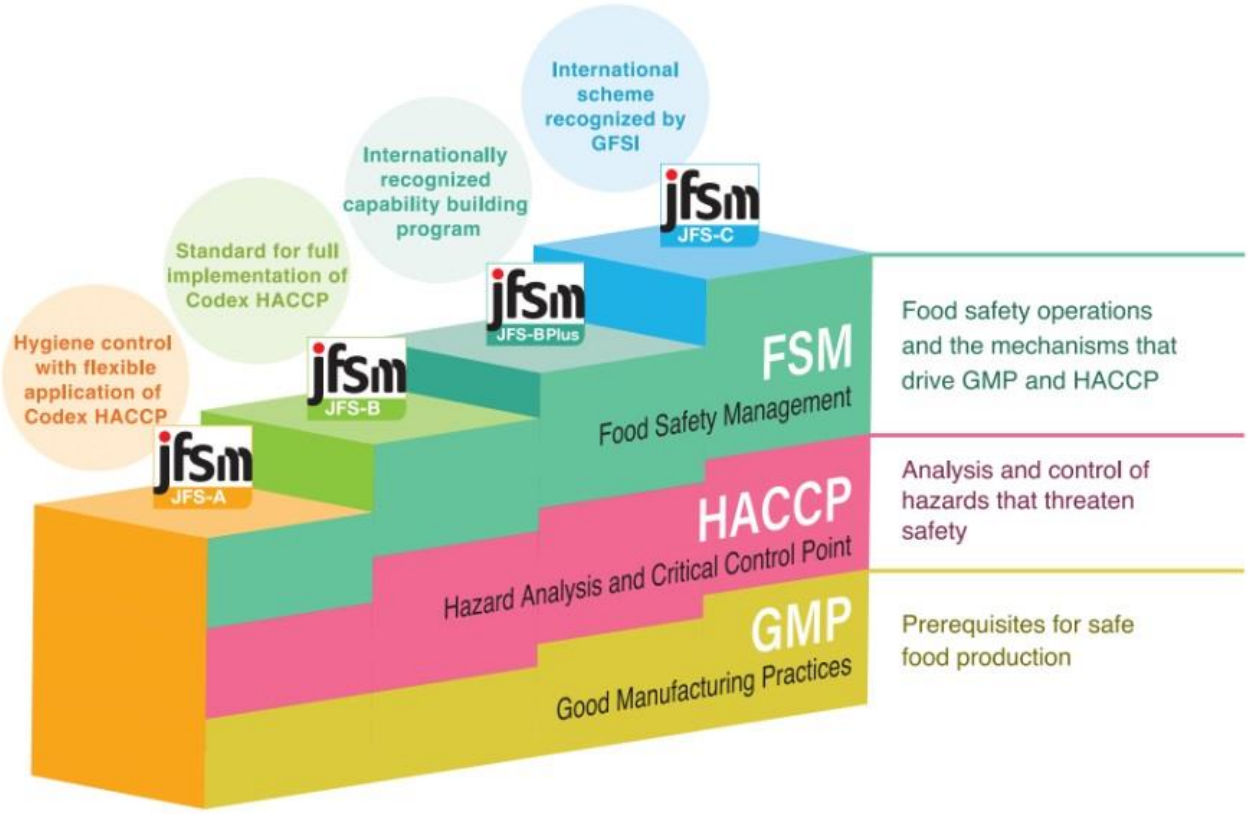


Figure 2. Overall view of JFS Standard Document and Certification Program

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 Plus 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 Plus Guideline>

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

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

JFS-B Plus 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. There shall also be evidence that employees are made aware of them. Management or senior management must determine who is responsible for food safety management.

●Concepts, specific examples

1. Role of management or senior management
   1)Periodically verify and review the effectiveness of the company's own efforts to ensure food safety and quality and to secure consumer confidence.
   2)Clearly define an organizational chart that includes a communication system for instructions, reporting, and consultation, and share it with employees.
2. Communication system for instructions, reporting, and consultation
   1) In order to clarify the communication system for instructions, reporting, and consultation, it is easier to manage by using meeting bodies and morning meetings to determine the activities necessary for food safety. Instructions, reporting, and consultation are as follows.
   (1) Instructions: The clarification of tasks and roles by a supervisor, manager, or other person.
   (2) Reporting: The person who performed the work communicates the facts to a supervisor, manager, or another 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 23.2 (Product Release).

3. Informing employees.
   Examples of evidence that employees are informed about the organizational structure include, but are not limited to, meeting minutes, morning meeting records and communication notes. This can also be confirmed in communications during internal and external audits, etc.
4. Food safety officer
   1) Determine a food safety officer as the person responsible for food safety management.
   2) The food safety manager's knowledge of food safety policies, food safety knowledge, and field knowledge and experience in the organization will enable him or her to create an effective system.
   3) If there is a separate food safety manager or food safety officer, it is important to share information and collaborate. They may also serve concurrently.

● Items to be referred to in Japanese 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 center
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 and food safety culture

● **Requirements**

Management or senior management shall show evidence of its commitment to building, implementing, maintaining and continually improving its food safety management systems.
This commitment shall include elements of a food safety culture, and this means, at a minimum, communicating with employees, responding to Kaizen suggestions, training to improve food safety, and assessing the performance of food safety activities. In addition, these efforts shall be incorporated and implemented in the food safety management systems of the entire organization.

● 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. Communicate to employees in a timely manner the importance of compliance with laws, standards, social norms, and rules set by the organization.
3) Ensure that employees are aware of factors that can influence food defense and food fraud risks. To this end, establish and maintain a system that allows the organization to constantly obtain the following information.
   - ●All related laws
   - ●Scientific and technological developments
   - ●Industry code of practice
   - ●Other information on food safety and product quality issues, etc.
4) Set 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 Step 11(Principle 6) and FSM 14.1 and 22.2.
8) Other matters necessary for the establishment, implementation and maintenance of food safety management systems.

2. The following is a reference example of food safety culture elements for Management or senior management to include in their commitments to promote improvement through the food safety management system. (5 Dimensions)

1) Clarify the vision and mission.
   Is food safety integrated into your business strategy? (including providing resources and other support).
   Does the company provide direction and objective goals to employees and clearly state what is expected of them?
   Does it provide messaging with leadership to employees?

2) Conduct outreach to the people.

Have the necessary stakeholders been clarified and the governance structure clarified?
Do you communicate with employees on site? (e.g., by holding meetings)
Is there an organization in place for learning and training?
Does the company have an evaluation system (incentives, rewards, recognition, etc.) for actions taken by employees?

3) Consistency.
Is the Management or senior management taking the responsibility seriously as the person who is ultimately responsible for the company?
Are employees' performances properly evaluated?
Are all processes kept in writing?

4) Adaptability.
Do they demonstrate food safety expectations while understanding the personal cultural differences of each employee?
Does the company provide prompt feedback on employee offers?
Is the business model appropriately changed to manage risks and solve problems?

5) Recognize hazards and risks.
Does the company provide risk prevention education, such as by providing basic hazard information?
Are employees involved in activities to prevent near misses?
Are hazards verified when they occur and are risks communicated?

3. Fundamental to a well-functioning food safety management system is the establishment and maintenance of a positive food safety culture that recognizes the importance of the actions of all employees involved in providing safe and appropriate food. Therefore, it is advisable that not only Management or senior management but also all employees make a commitment. Reference examples are as follows.
(Reference case)
In order to prevent contamination by foreign matter, we will conduct thorough visual checks of the manufacturing process after washing/cleaning and before the start of manufacturing. etc.

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.
In addition, records of implementation shall also be maintained.

● Concepts, specific examples

1. The organization shall clarify the food safety laws and regulatory Requirements for its own organization and define the methods of control. The organization shall comply not only with the laws and regulations of the country of manufacture, but also with the laws and regulations pertaining to food safety in the country of sale. When relevant laws and regulations are revised or new laws and regulations are enacted, it is necessary to grasp them in a timely manner, communicate them to the organization, and change management methods as necessary. The laws and regulatory Requirements of the country of sale must also be understood. Evidence of the results of the implementation of the control procedures must be retained. An example of a record of the implementation of the procedures is a list of relevant laws, regulations, and Requirements, and records of their confirmation and updating.
2. Laws, regulations, and regulatory Requirements pertaining to food safety to which reference should be made (this item is applicable to the scope in Japan)
   Business operators engaged in manufacturing or processing shall assign a food hygiene supervisor or food hygiene manager who meets the necessary Requirements.
   1) Food Hygiene Supervisors: These are appointed 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 Hygiene Manager: A Food Hygiene Manager is appointed for each facility that is to obtain a business license and each facility that is to submit a business notification, except in cases where a Food Hygiene

Manager is appointed in accordance with the provisions of the Enforcement Regulations of the Food Sanitation Law.
(See FSM 1, ● Items to be referred to in Japanese legal provisions related to food safety.)

FSM 6 Food Safety Policy and Goals

●Requirements

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

●Concepts, specific examples

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

FSM 7 Food Defense

● **Requirements**

The organization shall identify the risk of intentional food contamination by persons within or outside the organization, assess the magnitude of the risk, and prioritize and implement response measures to reduce or eliminate the risk.
The organization shall also establish access controls for areas where food defense vulnerabilities have been identified.
The organization shall establish and implement procedures for responding to possible intentional contamination of product.

● Concepts, specific examples

1. Food defense means the means of preventing, avoiding, or responding to intentional food contamination by biological, chemical, or physical hazards by persons within or outside the organization.
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 priority of solutions 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.
   1) 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 22.2)
7) Provide necessary education and training to personnel according to the organization's food protection plan8)
8) The organization shall establish access controls for areas where food defense vulnerabilities have been identified.
9) Establish and implement procedures for responding to the possibility that uncontrolled access has occurred and products have been intentionally contaminated.

7. Access controls implemented for areas where food defense vulnerabilities are identified are also included in the food defense plan. Access controls can include guards, ID cards, or systems that limit or record access to authorized personnel.

【Reference】

1. In addition to monitoring cameras and lock controls, communication among employees is a deterrent to food protection.
2. Excessive reliance on hard measures of food defense may instead damage the good relationship between employees and managers. Thus, for example, an organization could explain to employees that the monitoring cameras are not installed based on suspicion of employees, but so that the company can prove the actions of employees 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 for examining trends in social cases, cases of other companies in the same industry, prevention cases, and predictive signs is required.
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 of Japan in March 2008 is a useful reference. (This is applicable in Japan)
(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 8 Food Fraud Prevention

● **Requirements**

The organization shall document, implement and maintain assessment procedures to identify potential and overt food fraud vulnerabilities such as tampering with records and labeling of products and intentional dilution, and prioritize food fraud mitigation measures.
The organization shall develop a documented plan that specifies the measures the organization implements to mitigate the identified threats of food fraud. This plan shall cover the GMP and shall be incorporated into the food safety management system.

● Concepts, specific examples

1. "Food fraud" refers to intentional acts committed primarily for economic reasons, such as tampering for the purpose of cost reduction or misrepresentation of good quality. Examples include dilution, substitution, concealment, fraudulent labeling, function enhancement by unauthorized means, counterfeiting, etc. Among these, this requirement covers food fraud as it relates to food safety.
   Examples of food fraud related to food safety include the following:
   1) Melamine contamination of powdered milk made in China in 2008
   2) Horse meat contamination of beef-based food products sold in Ireland in 2013 (contamination of veterinary drugs)
2. Methods to "identify potential and actual falsification of records and labeling and intentional dilution of products" include the following:
   1)Refer to past or currently developing cases of food fraud in the supply chain. The organization will have a process in place for accessing cases of fraud. Such information can be obtained, for example, from

- ●Industry Associations
- ●Government Sources
- ●Private information centers
- ●Information systems established by the organization in the FSM2

2) Identify in what situations food fraud can occur.
It is also effective to assume food fraud in each production flow as follows:
(1) Fraud in raw materials used
(2) Fraud during manufacture
(3) Fraud in products after shipment (including resale of discarded defective products as food)

3) Evaluate the ease of occurrence (vulnerability).

3. Supply chains are becoming more complex, extending overseas, and the risk of food fraud is increasing. "Assessing vulnerability" means analyzing what types of food fraud are likely to occur and how likely they are to occur due to external and internal factors in the context of such changes in the environment surrounding the organization. Vulnerability assessors need to understand the potential food fraud risks, which includes knowledge of the raw materials used in the field and the concept of vulnerability assessment described above. Vulnerability assessment is conducted from two perspectives: product/supplier.
Examples of vulnerability assessment steps include:
1) Clarify the raw materials and their specifications related to the food products handled.
2) Estimate what are the events that could cause fraud (what kind of fraud could occur).
3) Estimate the magnitude of risk for any possible fraud that may occur.
4) Estimate the magnitude of the impact of fraud on food safety.
5) Prioritize vulnerabilities by risk and magnitude of impact.
4. Based on the results of the vulnerability assessment, a management plan to reduce food fraud shall be developed after conducting an evaluation of current control measures related to food fraud. The plan shall clearly identify priorities. The following methods can be used as means to reduce food fraud:
1) Conduct appropriate monitoring in response to vulnerabilities
2) Verification of origin and labeling
3) Specification Management

4) Conduct supplier audits
5) Analytical testing
6) Use of anti-counterfeiting technology
7) Collect whistleblower testimonials from within the organization.

5. Examples of methods include the following:
   1) Add fraud to the scope when conducting second-party audits.
   2) Request that suppliers monitor their supply chains.
   3) Change the origin/supplier of raw materials to one where there is no precedent for fraud.
   4) Strengthen controls in situations where fraud practices are likely to occur (extremely low prices from suppliers used below market prices, soaring raw material prices, tight supply, frequent advance shipment times, sudden increases in order volumes, and understaffed production systems).
   5) Add fraud vulnerability to the frequency of analysis/testing.
   6) Review the supplier's financial situation.
6. Organizations are required to clarify the scope of the above food fraud prevention plan and incorporate and operate it into their food safety management system.
7. The food fraud vulnerability assessment shall be reviewed at least annually and/or whenever significant changes occur. The food fraud reduction plan will be revised/updated as needed.
8. Please refer to the following for concepts on fraud prevention. (1) is the scope of application in Japan.)
   1) The "FCP's Focus on Collaboration," which was created by the Food Communication Project (FCP) launched by the Ministry of Agriculture, Forestry and Fisheries (MAFF) in the wake of the food fraud, is a good reference. This was created as an effort to curb the occurrence of food fraud.
   https://www.maff.go.jp/j/shokusan/fcp/whats_fcp/kyoudou.html
   2) U.S. Pharmacopeia (USP) "Food Fraud Mitigation Guidance"
   https://www.usp.org/sites/default/files/usp/document/our-work/Foods/food-fraud -mitigation-guidance.pdf

FSM 9 Document and record management

● **Requirements**

The organization shall establish documented procedures to create, maintain, and record for control processes to ensure food safety and evidence effective operations.
In addition, the organization shall keep records necessary to prove the implementation of food safety management, determine an appropriate storage period, and store them.

● Concepts, specific examples

1. Concepts in the FSM9
   1) 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.
   (1) Necessary documents have been selected.
   (2) Selected documents are stored and used in the latest version.
2. What is "documentation"?
   1) " Documentation" includes not only documents and document data, but also images, photographs, diagrams, audio, and video, and fulfills the following purposes
   (1) 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.
   (1) 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

1) 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 in the requirements】

No.	item	Content of documentation or records	check
FSM4	Compliance with food safety laws	records of the implementation of compliance procedures	
FSM6	Food Safety Policy and Goals	Clear, concise, documented food safety policies	
FSM8	Food Fraud Prevention	Plan that specifies the measures the organization implements to mitigate the identified threats of food fraud.	
FSM9	Document and record management	Documents and records management procedures	
FSM13.2	Supplier Performance	Procedures for the evaluation, approval, and continual monitoring of suppliers. Documentation of results of surveys, evaluations, approvals, and follow-up with suppliers.	

FSM14.1	Traceability	·Record of all externally procured raw materials (including containers and packaging materials), products, or services ·Records to identify batches, semi-finished products, work-in-progress, recycled products, reworked products, finished products and packaging throughout the manufacturing process ·Record of purchasers and delivery destinations for all products supplied ·If the procedure has been updated, record it	
FSM14.2	Traceability verification	Record results of traceability verification	
FSM16	Allergen Management	Allergen management plan	
FSM17	Control of Measuring and Monitoring Devices	Record of actions taken when equipment and devices are found to be inaccurate	
FSM21	Complaint Handling	A system of management to respond to complaints and utilize complaint data Record of complaints, investigation results, and corrective actions.	
FSM22.1	Serious Incident Management	Food incident management procedures	
FSM22.2	Verification of food incident management manual	Records of annual testing to verify the effectiveness of the food incident management procedures	

FSM23.2	Product Release	Appropriate procedures for product release (shipping)	
FSM24	Control of non-conforming products	Rules to avoid using and shipping items that may cause safety issues.	
FSM25	Corrective Action	Corrective action documentation	
HACCP Step 12 (Principle 7)	Documents and Record	Make the necessary documents (in HACCP) and keep records.	
GMP4.1	Cross-contamination (including allergen cross-contact) and isolation	Procedures for necessary control measures against cross-contamination (including allergen cross-contact)	
GMP4.2	Control of hazards that require enhancement	Procedures for control measures for hazards that require particularly enhanced controls, other than CCPs.	
GMP6	Hygiene, workwear and Health management of personnel, etc.	Document appropriate sanitation standards for employees.	
GMP7	Training	Education and training implementation records	
GMP8	Housekeeping, cleaning, sterilization and disinfection	Management procedure of maintain an appropriate level of hygiene at all times by conducting tidying and cleaning operations throughout all processes and phases, and disinfecting where necessary.	

GMP11	Air and water management	Records of periodic monitoring of air, high-pressure gas, water, etc. used in food production.	
GMP19	Maintenance	System for systematic maintenance of all equipment critical to product safety.	

● Items to be referred to in Japanese 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.
(b) When water suitable for drinking is used, the water quality shall be tested at least once a year, and the report shall be kept for one year (or longer if the food or additive being handled has been used or consumed for more than one

year). However, if there is a possibility that the water source may be contaminated due to an unforeseen disaster, the water quality shall be tested each time.
(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. However, if the objective can be achieved by such means as conducting periodic, uniform surveys of the locations, habitats, and infestation routes of rats and insects and the status of damage, and taking necessary measures based on the results of said surveys, the survey may be conducted in a manner and frequency appropriate to the conditions of the facility concerned.

(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 referred to in Japanese 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

【Purchasing】

1. This standard requirement requires that each organization establish and implement procedures to verify what it purchases from outside sources according to the magnitude of the risk it poses to food safety.
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)

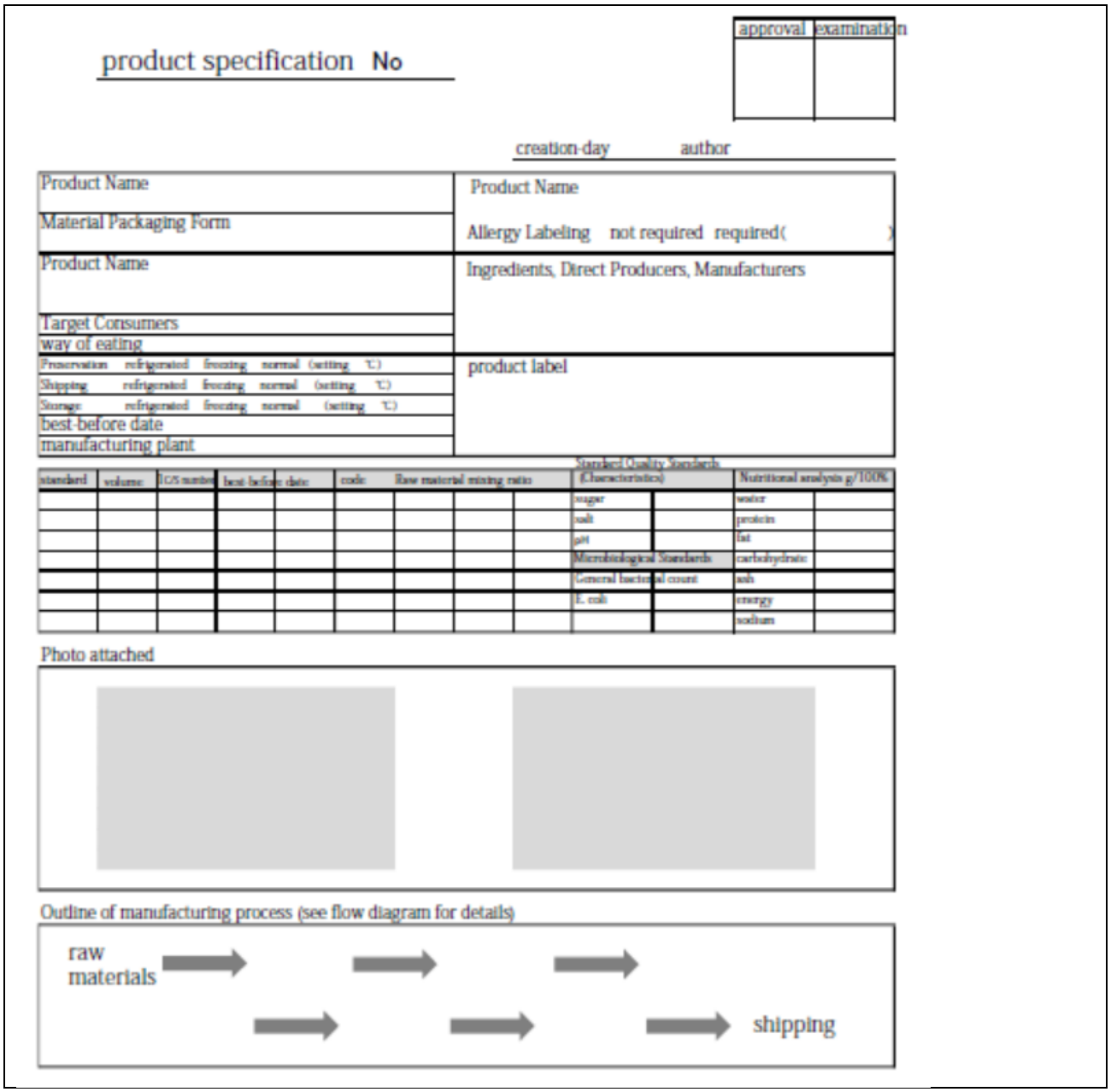
【Subcontractor management】

1. Subcontracting is the process of outsourcing an organization's own processes to another organization. The organization periodically monitors and verifies the subcontracted process to ensure that the results of the subcontracted process do not pose a food safety hazard to the organization's products.
2. This Subcontracting includes not only product manufacturing by contractors and services provided by personnel dispatch, but also the provision of services. This subcontracting 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 subcontracting rests with the purchasing organization.
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. Subcontracted 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 Step 6(Principle 1). 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 subcontracting.
   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 subcontracting 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)



product specification No

approval	examination

creation-day author

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

standard	volume	TOS number	best-before date	code	Raw material mixing ratio				Standard Quality Standards (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 document, 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.

Results of survey, evaluations, approvals, and follow-ups with suppliers shall be maintained.

●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 documented procedures for the evaluation, approval and monitoring of suppliers, which are described in detail below.
   1) 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 a level at which suppliers have established their own scope of applicability and have initiated efforts related to food protection.
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

FSM 14.1 Traceability

●Requirements

The organization shall establish, implement, and maintain appropriate tracing procedures covering all processes from supplier (at least one step before) to recipient (at least one step after) to ensure product identification. These procedures must include procedures (e.g., labeling) to continuously identify the product throughout the manufacturing process and throughout distribution.

To ensure traceability, at least the following shall be recorded:

●Record of all externally procured raw materials (including containers and packaging materials), products, or services

●Records to identify batches, semi-finished products, work-in-progress, recycled products, reworked products, finished products and packaging throughout the manufacturing process

●Record of purchasers and delivery destinations for all products supplied

●If the procedure has been updated, record it

●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). In addition, each organization is required to identify (e.g., by labeling) its products throughout the manufacturing process and on an ongoing basis throughout delivery. 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, batches, semi-finished products, recycled products, reworked products, finished products and packaging throughout the manufacturing process.
      (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 14.2 Traceability verification

● **Requirements**

The organization shall verify the documented procedures for implementing and maintaining traceability through traceability test at least once a year to ensure that they are functioning effectively. The results of verification shall also be recorded.

●Concepts, specific examples

1. The organization shall document the procedures for implementing and maintaining tracing, verify them at least once a year to ensure that the procedures are working effectively, and update them as necessary.
2. The results of the verification shall be recorded. (See FSM 9.2)

FSM 16 Allergen Management

●Requirements

The organization shall document and implement allergen management plans. The allergen management plans shall include:

●Control procedures to properly assess the risk of allergen cross-contact and, based on that assessment, reduce, or eliminate the risk of cross-contact.

●Procedures for handling raw materials (including containers and packaging materials), semi-finished products, work in progress, reworked products, and final products to prevent cross-contact with allergens during all processes from manufacturing to shipping.

●Cleaning procedures and verification procedures for areas that come into contact with food

●Procedures for identifying and displaying allergens that shall be controlled in all processes from manufacturing to shipping

All final products containing or potentially containing allergens should be identified in accordance with the laws and regulations of the country to which they are expected to be shipped, and appropriate customer Requirements.

●Concepts, specific examples

1. Allergens to be controlled
   The substances that cause allergies are called allergens. Worldwide, there are eight main allergens: cereals including gluten, crustaceans, eggs, fish, milk, peanuts, soybeans, and tree nuts. Organizations need to consider accidents caused by allergens in consumers.

   *Reference cases in Japan (Source: Consumer Affairs Agency Website)

   https://www.caa.go.jp/policies/policy/food_labeling/food_sanitation/allergy/

   (For the latest version, please check the relevant website.)
2. Organizations need to manage allergens from the following three

perspectives:

1) Preventing or minimizing the possibility of allergen cross-contact.
2) Information identifying allergens in food products shall be clear and accurate. In particular, for purchased raw materials, suppliers are required to demonstrate appropriate allergen controls and their Requirements.
3) Ensure that allergens contained in food are communicated to each stage of the logistics process after shipment.

3. Allergens to be controlled in all processes from manufacturing to shipping shall be identified, and a written allergen control plan shall be established, implemented, and properly maintained:
   1) Identify allergens that may be contained based on the specifications of the raw materials used.
   2) Differentiate the receiving and storage areas for each different allergen.
   3) Identify allergens to be controlled according to the production plan, so that they can be checked on each production line.
   4) Distinguish between machinery and equipment used in the weighing room.
   5) Identify areas in the manufacturing facility where allergen powder is dispersed and implement measures to prevent dispersal.
   6) To handle line changeovers (powders, oil and fat products (chocolate, spreads, etc.)) where water cannot be used for cleaning.
   7) Control the labeling and use of allergens in recycled and work-in-process products.
   8) Implement measures to prevent incorrect labeling.
   9) In controlling allergens, the laws and regulations of the country of sale (allergen labeling regulations) shall be observed.
4. Develop control procedures to reduce or eliminate the risk of cross-contact. Examples of control procedures include the following:
   1) Containers and utensils used in production (plastic bags, scoops, etc.) shall be identified for each allergen to be controlled and avoid use in mixed.
   2) Develop procedures for handling raw materials (including containers and packaging materials), semi-finished products, work-in-process, reworked products, and finished products to prevent allergen cross-contact at all stages of production and shipment.
   3) Determine procedures and verification methods for cleaning and washing

methods for manufacturing processes to prevent cross-contact.

4) When producing different products on the same production line, plan production in order of the number of allergens present, from lowest to highest, if possible.

5. During the development of products containing allergens, check the validity of controls by line testing, etc.
6. When preparing product labeling, allergens shall be indicated in accordance with the laws and regulations (allergen labeling regulations) of the country in which the product is supposed to be sold.
7. If verification (e.g., analysis) is required, establish and implement procedures, and record and store the verification results.
8. Related items include FSM 4 (Compliance with food safety laws), 13.1 (Purchasing), 13.2 (Supplier Performance), FSM 18 (Product labeling), GMP 3, 4.1, 4.2, 6, 7, 8, 9, 11, 13.2, 14.1, 17 (Requirements related to contamination in manufacturing processes, etc.) see also.
9. For more information on examples of "Allergen Management", see CODEX Alimentarius, Code of practice on food allergen management for food business operators (CXC 80-2020).

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.
The organization shall take appropriate action when equipment and devices are found to be inaccurate, and these actions shall be recorded.

● 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 referred to in Japanese 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 expiration date labeling

● Make sure that the date is correct.

Multiple workers will be involved in the confirmation process. The date will be confirmed by work orders, calendars, etc. The printed wrappers are affixed to the confirmation sheet or other documents and recorded.

Points to check Are the dates you have set correct? Is the print location correct? Is the printing blurred, chipped, blurred, or missing? Be careful when the year or month switches!
Presentation of printed content alerts on the packaging line

(Partially quoted from "The Next Section of the Explanation of the Advanced 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 referred to in Japanese legal provisions related to food safety

Labeling

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.
In addition, the organization shall establish and implement analysis and testing procedures (methods, standards, etc.) to confirm that the product meets product specifications within its shelf life.

●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. It also requires that analysis and testing procedures (methods, criteria, etc.) be established and implemented to verify that products meet specifications during the shelf life of the products.
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

FSM 21 Complaint Handling

● **Requirements**

The organization shall document a system of management to respond to complaints and utilize complaint data to identify, correct, and manage omissions and deficiencies in food safety efforts.
Additionally, organization must record and maintain complaints, investigation results, and corrective actions.

● 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. 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.
6) For complaints from suppliers and consumers, the responsible person shall confirm the completion of the response.
7) The organization record and maintain the record of complaints, investigation results, and corrective actions.

4. When nonconformity is found based on a suggestion from a supplier or consumer, corrective action shall be taken.
5. 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 22.1 Serious Incident Management

● **Requirements**

The organization shall document serious food incident management procedure, implement it in the event of an incident, and maintain it in effect at all times to ensure that they can respond in the event of a serious incident.
This procedure shall also describe the methods for product withdrawal and product recall.
It shall also include systems and procedures for providing necessary information to customers, consumers, and relevant authorities.
Incidents that occur shall be recorded and evaluated.

● Concepts, specific examples

1. A critical incident is a food incident that has the potential to affect food safety, but does not include incidents that do not affect food safety but may affect quality.
2. Since it is often not known at first whether an incident is serious or not, it is advisable to work on the assumption of a worst-case scenario when an incident occurs.
3. Documented food incident management procedure for incident reporting, product withdrawal and product recall shall be prepared as follows
   1) In the event of a major incident, 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.

4. To establish the severity of the incident and whether or not there is a risk to customers, the incident t should be documented and evaluated. Incident 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 referred to in Japanese 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 22.2 Verification of food incident management manual

● **Requirements**

The organization shall verify the effectiveness of its food incident management procedure by conducting tests at least annually on products supplied by the organization to ensure that product recalls are implemented, and maintain records of the verifications.

● Concepts, specific examples

1. Conduct mock recall tests to verify and record the effectiveness of the recall program at least once a year. Based on the results of the verification, review the recall program as necessary, and also verify and revise as necessary the food incident management procedure that contains it.
   1) In this test, it is required to be carried out under the assumption that the product is available on the market. However, for organizations that manufacture products on a contract basis (OEM manufacturing) or that conduct business-to-business (B to B) transactions, there are situations in which it is difficult to imagine that the organization will be the subject of a market recall. The recall test in this situation indicates that the recall test should be performed assuming that the products containing the organization's products have been distributed to consumers. In other words, the organization shall imagine a situation

in which a consumer had purchased these products and conduct tests to verify whether information about the traceability of the target products can be identified from this situation, from the supplier one step before to the shipping destination one step after.

2) In this test, it is easy to imagine if you assume that allergens are mixed in.

FSM 23.1 product specifications

● **Requirements**

The organization shall document and maintain specifications for raw materials (including packaging materials), semi-finished products, work in progress, remanufactured products, reworked products, and finished products.
The organization shall have a system for communicating changes to product specifications both internally and externally.
The organization shall designate a person responsible for managing product specifications.

● Concepts, specific examples

1. Maintain documentation of specifications for goods and services that the organization procures from external sources. Specifications requested by the organization for purchased goods, etc., or obtained from suppliers, etc., are evaluated that they are appropriate within the organization and ensure that intended to.
2. It is important to maintain and control the specifications stored as documents so that they can be used as needed for checking at the time of acceptance.
3. The organization shall evaluate the inherent risks of the items it purchases or receives supplies from and establish checks upon acceptance (e.g., inspection certificates, condition, temperature, labeling, etc.), as well as establish procedures for these checks.
4. Inherent risks include, for example, the following hazards:
   1) In ground beef requiring adequate heat: enterohemorrhagic E. coli O-157
   2) In redfish where temperature control is not properly implemented: histamine accumulation

   This requirement calls for attention to hazard factors in purchased products based on the product characteristics handled by the organization.

5. If externally procured goods or services do not conform to specifications, procedures shall also be established to ensure that they are not misused. Procedures should be documented as necessary.
6. When providing specifications to business partners in business transactions, it is necessary to have a system in place that allows the provision of the latest information at all times.
7. In addition to specific Requirements for goods and services, specifications may include:
   1) Statement of compliance with laws and regulations
   2) Handling of specification changes
   3) Review of specifications (e.g., frequency, timing, etc.)
   4) Whether or not to re-consign and its conditions, etc.
   5) Providing inspection items that conform to specifications and a certificate of inspection (also called Certificate of Quality or Certificate Of Analysis)
8. The organization shall determine and implement a review process for this information, including the frequency of periodic reviews. In addition, the organization shall have a system for communicating changes to product specifications both within the organization and to external parties that require those specifications. The organization shall designate a person responsible for managing product specifications. (The person responsible for managing specifications may be a person who not only manages the specifications themselves, but also evaluates and approves them; the scope of the person responsible is determined in accordance with the organization's management system.)
9. HACCP Steps 2 and 3 require information on the food safety of products. It is recommended that the specifications to be maintained and controlled by this requirement be organized in relation to such information.

FSM 23.2 Product Release

● **Requirements**

The organization shall document and implement appropriate procedures for product release (shipping).
Product release procedures shall include steps to ensure that the final product meets specifications

● Concepts, specific examples

Product Release (shipping) Procedures

1. The procedures for releasing (shipping) a product includes the following. These procedures shall be documented.
   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 (shipping).
   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 shall document and enforce rules for not using or shipping raw materials (including containers and packaging materials), semi-finished products, work-in-process products, recycled products, reworked products, and finished products that may pose a safety hazard.
The organization shall also determine who will be responsible for managing nonconforming products.

● 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 of control of non-conforming products 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 referred to in Japanese 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 documented corrective actions in the event of nonconformities affecting food safety. (Corrective action is the process of correcting a nonconformity to a condition that is not a nonconformity, determining the cause of the nonconformity and eliminating the cause of the nonconformity.)

● 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 and control measures for food safety, and takes those control measures rather than relying on testing and inspection of the final product.
Successful 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.
HACCP plan is a document or set of documents prepared in accordance with HACCP principles (from International Food Standards Committee (CODEX) General Principles of Food Hygiene 2020: (Reference) Japan Food Sanitation Association 2021 Translation First Edition) to ensure control of critical hazards in food operations.
HACCP system means the development of a HACCP plan and the implementation of procedures according to that plan (from International Food Standards Committee (CODEX) General Principles of Food Hygiene : Good Hygiene Practices （GHP''s） and the Hazard Analysis and Critical Point (HCCP) System ,2020 (English edition).

HACC Step1 HACCP team assembly and identification of the scope of application

● Requirements

HACCP team shall be assembled with competent staff, and the scope of application of the HACCP system and applicable GMPs shall be identified. The scope shall be documented what products and processes are covered by which HACCP plan.

● Concepts, specific examples

1. By forming the HACCP team with people with as many specialized skills as possible from the manufacturing/processing department, quality assurance/quality control department, and the maintenance department responsible for the maintenance and preservation of facilities and machinery used in manufacturing, it is possible to eliminate blind spots in hazard analysis and facilitate communication. The HACCP team leader (food safety officer) should be a food hygiene officer or food hygiene manager who has knowledge of the product and specialized skills, and knowledge of the product's characteristics and processes, furthermore, has

strong communication skills and is able to summarize opinions within the organization.

When the Food Safety Officer and the HACCP team leader are different personnel, it is necessary to ensure that they communicate with each other.

2. Depending on the size of the business, there are many cases in which various tasks are performed holding multiple positions, and for this reason, the top management 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 organization to the extent possible.
3. If the number of employees is small, the team does not necessarily need to be composed of several people. It is also possible to use outside resources.
4. If the organization lacks in-house knowledge or expertise, it can be also effective to receive external training or to obtain the participation and advice of external food hygiene experts. A guide for industry associations by the Ministry of Health, Labor and Welfare can be used as a reference.
5. The HACCP team shall identify the scope of the HACCP system and appropriate GMPs (PRPs in ISO 22000). Examples of documentation of products and processes covered by the HACCP plan include inclusion in product manuals.
6. The main roles of the HACCP team, other than the above No.5, are as follows:
    1) Preparation of HACCP Plan
    2) Establishment of GMP
    3) Preparation of sanitation standard operating procedures
    4) Education and training for personnel in charge of HACCP plan implementation
    5) Implementation of HACCP system and GMP verification
    6) Review, amendment or change of the HACCP plan based on verification results
    7) Identification of changes in raw materials, product composition, manufacturing processes, etc. and review of HACCP plans accordingly
    8) Review, improve, or modify HACCP plans as needed based on new food hygiene information
    9) Response to external inspections

7. The HACCP team is responsible for managing food safety efforts within the organization.

HACCP Step2 Product 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.
This system should be systematic and comprehensive and take into account legal and regulatory Requirements related to food safety.

● Concepts, specific examples

1. In order to clarify the characteristics of the product, describe the specifications and characteristics of the final product, divided into necessary items, as follows:
   1) Specifically, for the final product, describe the name and type of product, the intended use/purpose of the 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, distribution method, internal targets for controlling hazards in the product (Ingredient standards for bacteria specified in the Food Sanitation Law, etc.), including the standard criteria specified by the recipient.
   2) In facilities that manufacture multiple products, it can be effective to group foods together for purposes of developing HACCP plans, depending on similar characteristics and processing steps.
   3) If allergens are included, or if there may be cross-contact of allergens in the same facility, this shall also be noted.

HACCP Step3　Identification of Intended Use

● Requirements

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

● Concepts, specific examples

1. The intended use (method of use) and intended users (consumers) of the product shall be described in the document as follows:
   1) Clarify the methods of consumption and use of the food and the target consumers. Particular attention shall be paid to the content, especially in the case of vulnerable health consumers, young children, and the elderly.
   2) If the intended use includes cases where the product requires cooking with heat or where precautions after opening the package, the necessary information shall be stated.
   3) It shall clearly state what the risks are if the intended use is not followed and misused.
2. For foods intended for susceptible populations, a high level of assurance that the food is safe can require enhanced process controls, more frequent monitoring, product testing to verify the effectiveness of controls, or other activities.

HACCP Step 4 Construction of Flow Diagram

● Requirements

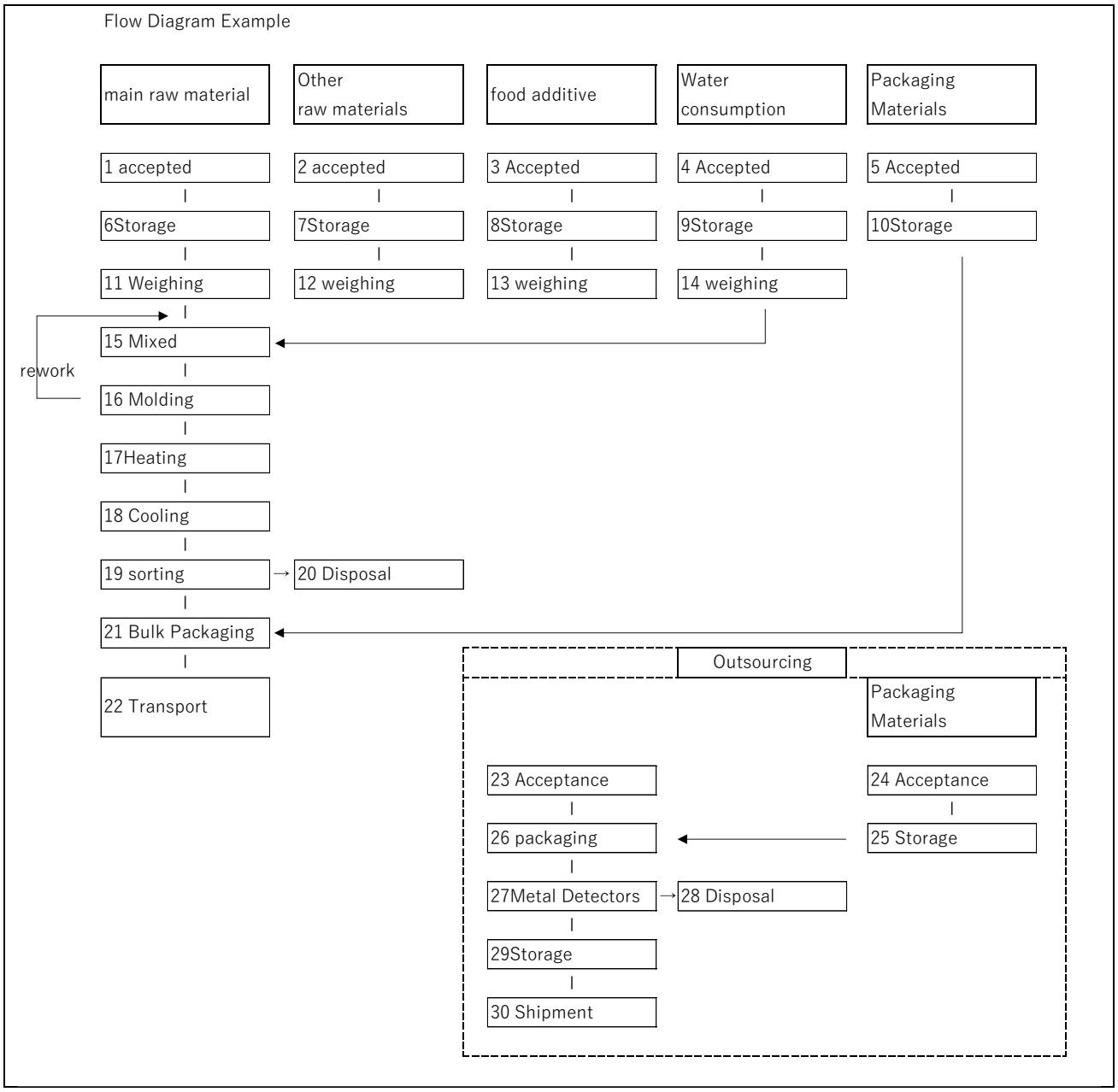
The flow diagram that covers all steps in the operation shall be constructed.

● Concepts, specific examples

1. For a series of manufacturing or processing processes from receipt of raw materials to shipment of the final product, a flow diagram shall be prepared to show the operations of each process along the flow. This shall include any applicable rework. The same flow diagram can be used for a group of products manufactured using similar processing steps.
2. The flow diagram is used as the basis for evaluating the likelihood of occurrence, increase, decrease, survival, or contamination of a hazard factor when conducting a hazard factor analysis.
3. The flow diagram shall be accurate and detailed enough to perform a hazard analysis.
4. The flow diagram shall be created according to the following procedure:
   1) Briefly list all processes and operations from receipt of raw materials to shipment of final products and applicable rework.

2) The listed raw materials and processes shall be enclosed in a frame, the frames are connected with arrows, and the process is numbered in order. For raw materials, food additives, water and packaging materials used, gas (only if used), and other materials that come into contact with the product shall be also written down, and these shall be written in a box in the same row, and arrows shall be connected to the process in which they are used.
3) In the course of raw material processing, if waste is generated or it becomes a processed raw material to be used in other products, it shall be clearly stated.
4) In the process, if there are processes with pass/fail judgment, reprocessing, reusing or reworking, etc., it shall be clearly stated so that it can be controlled.
5) The process being outsourced shall also be clearly stated.

5. By drawings of the facility showing the outline of each process and the planar and three-dimensional layout of the facility, it is possible to identify process key points and areas where cross-contamination is possible, which can aid in hazard analysis.



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 shall verify on-site that the process is clearly defined in the flow diagram so that the hazard analysis in HACCP Step 6 (Principle 1) can be sufficiently performed. At that time, the on-site verification shall be performed as follows, while checking against the site layout diagram:
   1) At the site, verification shall be carried out step by step from the upstream process, to check that appropriate processes are shown, including temporary storage of products and management of semi-finished products.
   2) If a process or activity is inconsistent with the flow diagram at the site, check with the responsible person for the correct control method and correct the documentation.
   3) Verification shall be observing the work during various work periods to ensure that the flow diagram matches the work.

HACCP Step 6 (Principle 1) Hazard Analysis

●Requirements

The HACCP team shall list all the hazards that are reasonably likely to occur in each process steps.
Potential hazards in each process shall be identified, the critical hazards shall be identified, and all measures to control them must be considered.
Hazards shall include allergens, if necessary.

●Concepts, specific examples

1. Hazard analysis is to identify potential hazards to be controlled by the HACCP plan, determining critical hazards, and clarifying control measures for each critical hazard. For this purpose, information is first collected on potential hazards and the conditions under which they can occur throughout the entire process from raw materials, manufacturing and processing, storage and distribution to consumption, and the likelihood of occurrence of the hazards and the severity of the hazards when they do occur are identified.
   1) Hazards shall be specific and shall explain the cause or reason for their presence. The potential misuse of the product by potential consumers

that would make the food unsafe, as well as any unintended uses that could be known from known cases, shall also be considered.

2) Hazards should also be identified and considered whenever possible. Examples are provided below:

(In the case of metallic foreign bodies, which are physical hazards)

●A certain part A in the manufacturing process is subject to routine maintenance, but it has been missing in the past, and since there is a possibility that it may get mixed into the product in the future and cause injury to consumers who eat it, it is identified as a major hazard and management measures are required.

●On the other hand, a certain part B in the manufacturing process is managed through daily maintenance, and there have been no cases in the past of it being missing and contaminating the product, so, it is considered to be controlled through general hygiene management and is not identified as a significant hazard.

2. By conducting a Hazard Analysis, an appropriate management system can be created for the facility according to the frequency of possible hazards and the severity of the consequences.
3. The actual process of hazard analysis is to first list, by raw material and process, the hazards in the final product that can lead to health hazards when eaten.
4. Following the flow diagram from raw materials to final products, identify raw materials and processes that can lead to the occurrence of hazards, narrow down important hazards in terms of the frequency of occurrence of hazards in each process and the severity of the results, prepare the Hazard Analysis Sheet that lists the causes of occurrence (contamination, proliferation, survival, contamination, etc.) and the control measures to control them.
5. When preparing the Hazard Analysis Sheet, it is necessary for all members of the HACCP team to share their expertise and knowledge, and to discuss and summarize these findings.

《Steps to prepare the Hazard Analysis Sheet》

6. The steps for creating the Hazard Analysis Sheet are explained using the "Example Hazard Analysis Worksheet" given in the International Commission on Food Standards (CODEX) Committee's General Principles of Food Safety

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 Analysis Worksheet")

List raw materials and manufacturing and processing processes according to the flow diagram.

Write the same numbers along the flow diagram for materials that come in contact with the product, such as main raw materials, secondary raw materials, water used, and packaging materials, as well as for the manufacturing and processing processes.

Perform the hazard analysis of all raw materials used in the food product. This can be done in two ways:

1) Methods to analyze hazards related to raw materials in the process of receiving raw materials
2) Methods to conduct hazard analysis separately for raw materials and processes

This guideline describes the method in 1).

[Step 2] (Column (2) of "Example of Hazard Analysis Worksheet")

List potential hazards originating from raw materials and manufacturing and processing processes.

Hazards shall be described specifically. For example, instead of "food poisoning bacteria," list "Salmonella," "pathogenic E. coli O-157" and so on are enumerated. Also, instead of just "metal fragments," describe the source of contamination and the reason for their presence, such as "contamination from metal foreign bodies derived from broken blades from crushing," "pieces of kitchen knives," etc.

[Step 3] (Column (3) of "Example of Hazard Analysis Worksheet")

Based on the frequency of occurrence (likelihood of occurrence) and the severity of the consequences (the extent of damage if they occur) of the listed hazards, evaluate whether or not they are significant hazards that shall be reduced/eliminated from the food to guarantee the safety of the final product.

When conducting a Hazard Analysis to determine critical hazards, consider the following whenever possible:

1) Hazards related to the type of food to be produced and processed, including ingredients and processes (e.g., results of hazard surveys or sampling and testing in the food chain, recall cases, information from scientific literature or epidemiological data)
2) Likelihood of a hazard occurring in the absence of additional controls, taking into account GMP (PRP in ISO22000)
3) Frequency of occurrence and severity of consequences of adverse health effects due to hazards in food in the absence of controls
4) Identified acceptable levels of hazards in the food (e.g., based on regulations, intended uses, and scientific information)
5) Nature of the facility and machinery and equipment in which the food is produced
6) Survival or growth of pathogenic microorganisms
7) Generation or persistence of toxins (e.g., mold toxins), chemicals (e.g., pesticides, veterinary drugs, allergens) or physical hazards (e.g., glass, metals) in food
8) Potential for food to become unsafe as a result of its intended use, and/or mishandling of the product by the consumer
9) Conditions leading to the above

For the evaluation of hazards in Step 3, recommend using a matrix table of "frequency of occurrence" and "severity of results" as shown below, and entering the numbers into the hazard analysis sheet. There are various examples of matrix tables created, and it is advisable to adopt one in consideration of the target product, manufacturing process, etc.

However, this does not apply to cases that can be clearly evaluated with "yes/no".

An example of the concept of thelikelihood of an enumerated cause of harm and the magnitude of damage if it
(Based on "Risk Assessment Handbook", METI 2011.6)

			Severity of Results				
			0	I	Ⅱ	Ⅲ	Ⅳ
			not (verb-negating suffix; may indicate question or invitation with rising intonation)	complaint	recall	serious illness	lethal
frequency of occurrence	4	Often Occurs	**risk**	**risk**	**Serious risk**	**Serious risk**	**Serious risk**
	3	Occasionally Occurs	OK to manage	**risk**	**risk**	**Serious risk**	**Serious risk**
	2	Occurred at other companies Has occurred at other companies	OK to manage	OK to manage	**risk**	**risk**	**Serious risk**
	1	No information on other companies There is no	OK to manage	OK to manage	OK to manage	**risk**	**risk**
	0	unthinkable	OK to manage	OK to manage	OK to manage	OK to manage	OK to manage

How to read the matrix

major risk	It is an extremely high risk, suggesting the potential to become a significant source of harm, which would likely be controlled by control measures that would be CCPs under HACCP Procedure 7, Principle 2.
risk	The current control measures are likely to be inadequate, indicating the need to add some means to strengthen and enforce the current GMP (General Sanitation Management Program).
OK to manage	The current means of management is adequate to manage the situation.

[Step 4] (Column (4) of "Example of Hazard Analysis Worksheet")

In this step, for significant hazards marked with ○ or Yes in [Step 3] ((3) in the "Example of Hazard Analysis Worksheet"), identify the factors causing the hazard and describe the basis for the decision in column (4). For those hazards marked with X or No in column (3), describe the basis for judgment.

[Step 5] (Column (5) of "Example of Hazard Analysis Worksheet")

For each hazard rated as critical, identify control measures to ensure the safety of the final product. The following is an example of a hazard evaluation (Step 3) and a hazard analysis sheet.

Consider which control measures to apply to each critical hazard, as multiple control measures may be needed to control one hazard. For example, to control Listeria monocytogenes, heat treatment may be required to kill viable organisms in the food, and environmental cleaning and disinfection can be

required to prevent contamination from the processing environment after heating.

It can be possible to control multiple hazards through specific control measures. For example, if Salmonella spp. and E. coli O-157 are present in a food, heat treatment can control both hazards.

*Reference examples of the Hazard Analysis Sheet are as follows.

Source: Ministry of Health, Labour and Welfare of Japan website (http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000098735.html)

Example of Hazard 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 pathogenic Harmful Microorganisms			
	Salmonella spp.	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.	
	Pathogenic Escherichia coli			
	Staphylococcus aureus			
	Heat-resistant spore bacteria			
	Clostridium botulinum	NO	Contamination is possible due to unsanitary handling during manufacturing and processing, but the bacteria are anaerobic and cannot grow during storage.	
	Welch bacillus			
	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)

Product name: Boiled soba noodles

(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	Organisms: Presence of pathogenic Harmful Microorganisms			
	Salmonella spp.	6	May be more contaminated than soil	Can be controlled in the sterilization
	Pathogenic Escherichia coli	6	May be more contaminated than soil	Can be controlled by Sterilization
	Heat-resistant spore bacteria			
	Bacillus cereus	7	May be more contaminated than soil	Can be controlled by cooling (NO.33)
	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 foreign matter			
	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 referred to in Japanese 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

● Requirements

Critical Control Points (CCPs) shall be determined.

● Concepts, specific examples

1. What are Critical Control Points (CCPs)?
   1) Critical control points (hereafter referred to as CCPs) are steps at which control is essential for the manufacture of a product in order to reduce or eliminate significant hazards from the food to acceptable levels, they are set in processes where deviations could lead to food that can be unsafe, and they are stages with procedures or operations that require especially strict control.
   2) For each hazard that is identified as a significant hazard as a result of the hazard analysis, it is always necessary to establish one or more control measures that can control that hazard.
   3) Among the control measures for the critical hazards listed in HACCP Step 6 (Principle 1), consider control measures that could serve as CCPs.
   4) At CCPs, it is necessary to set permissible limits as described below, conduct monitoring, and take measures such as not allowing products manufactured during the period when the limit was exceeded to be shipped if there is a deviation.
   5) CCPs can be needed at multiple stages to control a single hazard.
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).

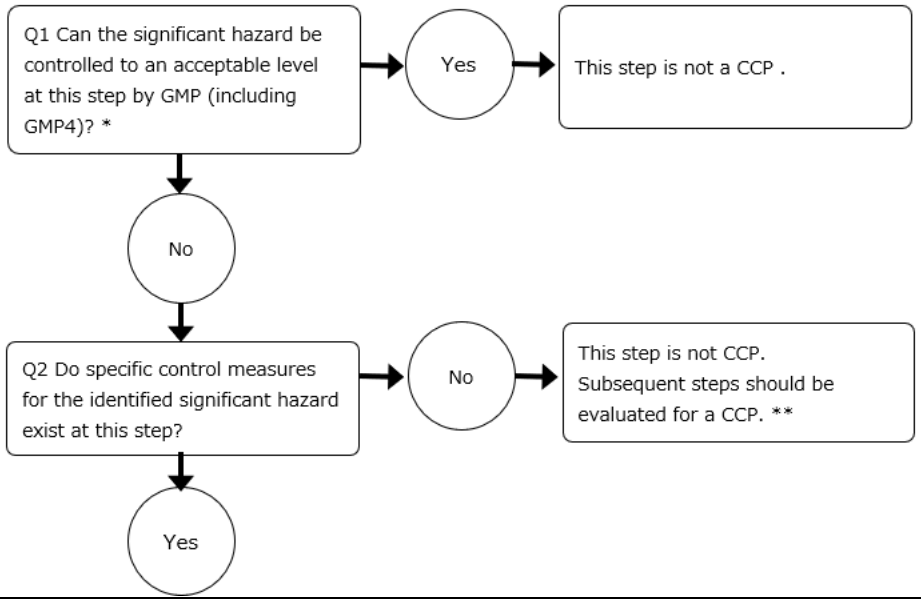
3. How to determine CCPs - Example of Decision Tree application. (This is an example of a CCP decision tool, and CCP decision methods are not limited to Decision Tree.)

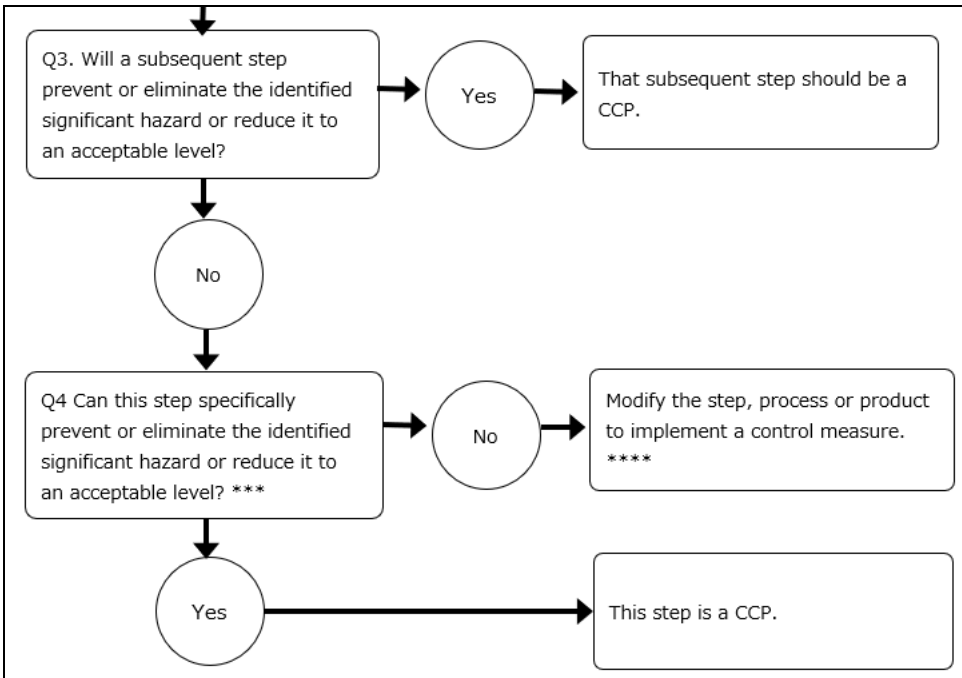
See the figure below for the procedure / The main points are as follows:

1) The Requirements for CCPs are that it can be monitored continuously or with a reasonable frequency using a pre-defined monitoring method, and if the parameter deviates critical limit (CL), production can be stopped immediately and process control can be restored to the

original state in a short period of time, and food produced during the period of deviation can be identified and isolated.

2) Only those processes for which significant hazards are identified in the hazard analysis are subject to Decision Tree application.
3) Consider the significance of the hazard (i.e., the likelihood of its occurrence and the severity of the effect of the hazard in the absence of controls) and whether it can be adequately controlled by the GMP. A GMP can be a normal GMP, or it can be a GMP that requires greater attention (e.g., monitoring and recording) to control the hazard (so-called GMP 4.2). (See *)
4) If CCPs were not identified in Q2-Q4, review the process and control measures again and re-conduct the hazard analysis. (See **)
5) Determine whether a control measure at a process where a significant hazard has been identified is used in combination with a control measure at another process to control the same hazard, in which case both processes should be considered CCPs (See ***).
6) If there are no specific and special control measures, the process and control measures should be reviewed again and the hazard analysis shall be re-performed. (See ****)





(Above figure taken from CXC 1-1969, Rev. 2022, General Principles of Food Hygiene of the International Commission on Food Standards (CODEX).)

4. Specific examples of CCPs

1) Examples of CCPs that prevent the occurrence of hazards are as follows:

(1) Acceptance of raw materials: Prevention of antimicrobial residues by checking raw material inspection reports submitted by suppliers

(2) Cooling: Prevention of pathogen growth through appropriate temperature control

(3) Refrigerated storage: Prevention of pathogen growth through appropriate temperature control

(4) Weighing of food additives: Prevention of over-additives

2) Examples of CCPs that eliminate hazards include the following:

(1) Heating process or sterilization process with chemicals: Sterilization of pathogenic bacteria

(2) Metal detection: Detection by detector and elimination of metal fragments

3) Examples of multiple CCPs that control a single hazard are as follows:

(1) Control 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 vegetative cells of spore-forming pathogens, and the cooling process can also be a CCP to prevent spore germination and growth.

If control measures for identified significant hazards do not exist at any stage, the product or manufacturing process should be modified.

● Items to be referred to in Japanese 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) Critical Limits

● Requirements

Validated critical limit(s) shall be stipulated for each CCP.

● Concepts, specific examples

1. What is the Critical Limit (CL)?
   1) CL is a monitoring criterion that distinguishes between acceptable and unacceptable conditions of a control measure of hazards and is an observable or measurable criterion that distinguishes between acceptable and unacceptable conditions of food in relation to the control measures applied as a critical hazard (CCP). A CL can have one or more parameters.
   2) Since incorrectly set, CL can lead to the occurrence of hazards, they shall be validated based on scientific data and set appropriately.
   3) Deviations from the CL require corrective action.
   4) The CL shall meet the following conditions:
      (1) The most appropriate parameters for ensuring that hazards are prevented, eliminated, controlled or reduced to acceptable levels, and whose value is scientifically proven
      (2) Criteria using parameters that can be determined in real time whenever possible.
      If it is found that the control condition is not appropriate, corrective measures shall be taken immediately, so it is desirable for this to be indicated by parameters that can be judged in real time.
   5) CL is usually the minimum or maximum value of a critically important parameter related to the control measure and can be used, such as temperature, moisture, time, pH, water activity (Aw), available

chlorine, contact time, conveyor belt speed, viscosity, conductivity, flow rate, etc., or sensory indicators (color, gloss, odor, taste, viscosity, physical properties, foam, sound, etc.) or observed pump settings, etc.

As an alternative to the parameters indicating CL, another indicator can be established, but this indicator shall also be based on scientific data.

Example: If the CL for the boiling process of a certain product is "product center temperature 63°C, heating time 30 minutes," it is not practical to measure the center temperature of all products; therefore, apart from this indicator, "water temperature of boiling tank, amount of product put in, and heating time" are measured as non-destructive and efficient CLs.

2. How to set CL

1) CL should be scientifically validated by evidence that, when properly implemented, they can control hazards to an acceptable level.
2) If indicated by laws, regulations, etc., values that allow the target hazard to be controlled reliably are adopted. In other cases, values are set based on literature data, experimental data, etc.
3) Even if the values indicated in manufacturing standards, etc. are adopted as CL, collecting evidence (evidence) on whether they are applicable to the organization (products, manufacturing facilities, manufacturing processes, etc.) is also a validity check.
4) In normal manufacturing process control, it is rare to use CL alone for control, and it is common to set a standard (Operational Limit: OL) that provides more leeway than the CL and allows control before CL deviations occur.

● Items to be referred to in Japanese 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) To ensure that CCP is properly controlled and to keep accurate records for later verification, monitoring is the comparison with CL, and, to do the observation, measurement, or test inspection based on a schedule established in the HACCP plan.
   2) In the management of CCP, the act of watching to ensure that there are no deviations from CL is called monitoring.
   3) Any deviation from the CL requires corrective action.
   4) Monitoring records are also used when verifying the HACCP plan.
2. How to monitor
   1) The monitoring method shall meet the following conditions:
      (1) To be carried out continuously or with reasonable frequency.
      (2) The method shall provide rapid results (physical and chemical measurements are usually chosen over microbiological tests).
   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 deviation in the CCP.
   4) The [5W1H] that defines the monitoring method means the following:
      (1) Rationale (Why): Is there scientific validity for monitoring the control status of CCP?

(2) What (What): Is the CCP within the acceptable range of the CL (does not deviate from the CL)?
(3) In which process (Where): Clarify the applicable process (CCP process)
(4) How (How): Is it a rapid and accurate physical, chemical, or sensory observation, measurement, or inspection method
(5) Frequency (When): Is it continuous? Or, if not, is there a frequency of not missing deviations?
(6) Who (Who): Personnel trained in monitoring methods

5) Continuous recording of measured values is not enough to control hazardous factors. They shall be checked by someone other than the person in charge of monitoring at an appropriate and sufficient frequency.
6) When the HACCP plan is developed, a monitoring person shall be identified. This person should be able to implement by oneself or implement by instructed on the appropriate procedures that need to be implemented when monitoring indicates the need to take corrective action. To take corrective action, data obtained from monitoring should be evaluated by a designated person with the knowledge and authority.
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 of the monitoring should be recorded.

● Items to be referred to in Japanese 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 the immediate action taken when monitoring parameters deviate from the CL.
   2) In CCP, which is a process that should be especially strictly controlled to prevent the occurrence of hazards, it is important to determine the methods and procedures for corrective action in advance because any deviation of the monitoring parameters from the CL may result in the occurrence and escalation of food safety risks. (See FSM 24, 25)
   3) In the HACCP plan, the actions to restore process control and procedures for restarting the line, as well as the actions to isolate affected product and determine and implement its disposition, shall be defined.
   4) To minimize the likelihood that the deviation will recur, the cause analysis shall be performed to identify and correct the cause of the deviation, if possible. The cause analysis shall 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
   Items to be included in the HACCP plan as corrective action are as follows:
   1) Action to restore the control status of the process
      ● Repair, adjust, or replace machinery, etc., to return the process to a normal state of control.
   2) Treatment for products manufactured during the deviation
      ● Identify and withhold products that deviate from the CL and evaluate them.
      ● Decide on treatment methods, such as reprocessing or disposal.
3. Person in charge of implementing corrective actions
   Shall be done by an authorized person in charge who has sufficient knowledge of CCP management, understands the process well, and can make quick decisions.
4. Corrective Action Implementation Records

The corrective action implementation record shall include the following items:

1) Details of the deviation, the manufacturing process or location where it occurred, and the date and time of occurrence
2) Name, lot number, quantity, etc. of the product that was the subject of the action
3) Results of investigation into the cause of deviation
4) Details of actions taken to restore the process to its original state
5) Details of treatment to be done to the product manufactured during the deviation
6) Signature of the person in charge who carried out and recorded the above items
7) Signature of the person who inspected the corrective action and the date of inspection

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

● Requirements

HACCP plan shall 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

The following is a procedure showing the Requirements of this item in chronological order of actual activities.

1. validation
   1) Validation is the assurance that the HACCP plan is capable of controlling the critical hazards and shall be performed before the HACCP plan is implemented. Items for which validation should be performed include the following:
      ⇒ Identification of hazards, and CCP, CL, control measures, frequency and type of CCP monitoring, corrective actions (improvement

measures), frequency, and type of verification and type of information to be recorded, etc.

2) Validation of control measures and CL of CCP shall be conducted during the development of the HACCP plan.

3) Validation involves reviewing the scientific literature, using predictive models, conducting validation studies, and using guidelines developed by authoritative sources (e.g., Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 - 2008)).

4) Evidence should be obtained that demonstrates that control has been consistently achieved, during production under the first implementation period and production conditions of the HACCP plan.

2. Implementation of HACCP Plan

Implement activities in accordance with the established HACCP plan.

3. Verification

1) After implementation of the HACCP plan, evaluate its effectiveness and verify that the HACCP system is functioning properly. Verification is basically conducted once a year, or as needed.

2) By recognizing weaknesses in their own HACCP system from the results of periodic verifications, modify their HACCP plan to make it better.

3) Verification shall be conducted respectively, for HACCP plans. and for the entire HACCP system.

(1) HACCP plans

i. Verify the HACCP plan for each CCP. The cases to be covered are as follows:

① Calibration of measuring devices (instruments) used for monitoring

② Testing and inspection of raw materials (including containers and packaging materials), semi-finished products, work-in-process products, reworked products, and finished products

③ Measurement of manufacturing and processing conditions

④ Review CCP monitoring records, corrective action records, and verification records

⑤ Confirmation that operators are working in accordance with the HACCP plan

⑥ Observation that control measures are operated according to the HACCP plan

ii. Verification of monitoring also includes verifying that the monitoring is correct by using a different measuring instrument or method. For example, for temperature, cross-checking with another thermometer or measuring the center temperature if the steam temperature of the heater is monitored instead of the center temperature, and for verification of the heating process, conducting a microbiological test on the sample after the heating process to confirm that no microorganisms remain in the sample.

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

iii. The items to be stipulated in the verification plan are as follows:

① Contents

② frequency

③ Action based on verification results

④ Method of recording the results of the verification

iv. Verification should be performed by someone other than the person performing monitoring and corrective action.

(2) Entire HACCP system

i. Verification of the entire HACCP system shall be conducted on a regular basis using the following procedures as needed:

① Analysis of consumer complaints or cause for recall

② On-site confirmation that monitoring work is being performed according to established procedures

③ Testing and inspections to verify product safety

ii. The results of the verification are recorded, inspected, and the HACCP system is reviewed as necessary.

4. Re-validation of the HACCP system

In addition to the validation at the time of HACCP plan development, re-validation shall be performed when any of the following occur:

1) Change in raw materials
2) Changes in manufacturing processes or systems (including computers and their software)
3) Change of packaging
4) Change in final product delivery system
5) Changes in the intended specifications or the intended consumer, of the final product

6) When verification results indicate deficiencies or potential deficiencies in the HACCP plan
7) When a new hazard is identified in the same food or in the same food group
8) When new information regarding product safety becomes available

※. Requirements for testing and inspection methods used for verification are as follows:
① This includes evaluating and verifying whether CCPs and CLs are properly established and controlled to ensure product safety.
② The test and inspection methods for verification shall be validated. For details, see FSM19.1 (Note that the test and inspection methods for verification shall include visual inspection and confirmation by sensory indicators).

HACCP Step 12 (Principle 7) Documents and Record

● Requirements

Necessary documents shall be prepared and maintained.
These documents shall contain documents related to the standard operating procedures (SOP) and the work instructions (WI) necessary and applicable to the scope of conformity assessment of the organization.

● Concepts, specific examples

What documents and records are required?
1. Documents and records required by the 12 steps of HACCP include the following:
   1) HACCP Team Member List and Role Assignment
   2) Product Description
   3) Flow diagram
   4) Hazard Analysis
   5) HACCP Plan
   6) Determination of CCP
   7) Determination of CL and information providing scientific support for the CL
   8) Validation of control measures
   9) HACCP plan revision records, etc.
2. Records of activities according to the HACCP plan include the following:

1) Monitoring records
2) Corrective action records
3) Verification records
4) Training records of the person in charge, etc.

3. Records of HACCP plan implementation
   This is important to provide evidence to prove control (scientific literature used during validation, minutes of HACCP team meetings, etc.) as well as to address deviations when they occur. Records can be maintained electronically, if necessary.
4. The organization shall document standard operating procedures and work instructions covering the scope of certification.
5. "Standard Operating procedures (SOPs)" are documented procedures for performing standard tasks.
6. "Work Instructions (WI)" means documents that instruct employees what work is to be performed.

● Items to be referred to in Japanese 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. These standards shall include the management of waste and unnecessary materials on the premises.

● Concepts, specific examples

1. Concept in GMP2
   1) In GMP2, it is important to take measures to ensure that "influences from around and on the premises do not affect the food safety risk to the product" and to maintain them. To this end, the following actions are required.
      (1) Identify what exists in the vicinity and premises of the business site.
      (2) Check whether they pose food safety risks to own products.
      (3) Consideration of measures to be taken and maintained so that the system can ultimately be capable of "preventing food safety risks to products.
      (4) Regularly check for changes in the environment, in parallel with carrying out 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 location, the organization's own site shall be clearly identified.
   3) It is recommended that as much as possible, drawings or other means be used in order to clearly maintain the confirmed settings.
3. Confirmation of the surrounding environment
   1) Identify any food safety concerns regarding the area surrounding the facility. One example can include the following:
      (1) Insect and bird damage related
      ・ Rivers, drainage ditches, etc.
      ・ Mountains, forests, parks, agricultural land, livestock, etc.
      ・ Garbage dumps, waste disposal sites, etc.
      (2) Foreign body related

- Garbage dumps, waste disposal sites, etc.

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

- Regional effects of salt damage, strong winds, freezing, etc.
- Agricultural lands where pesticide spraying is conducted - Livestock industry (feedlots, etc.)
- Exhaust and smoke emissions from other factories, etc.

4. Confirmation of business premises

1) Identify any food safety concerns that can also be present in the facility. One example can include the following:

(1) Insect and bird damage related

- Green space, etc.
- Areas where puddles can form
- Drainage, septic tanks, rainwater tanks, etc.
- Unnecessary items, waste storage, etc.

(2) Foreign body related

- Waste storage, 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 shall be considered, verified, and periodically addressed. Possible measures include the following:

(1) Insect and bird damage related

- Removal or modification of the subject, isolation, etc.
- Periodic check, maintenance and repair of plantings and water ponding areas

(If the site is subject to the Green Space Act, compliance is required but proper consideration shall be given to placement and management)

- Maintenance of the building, including repairs (positive and negative pressure, entrances and exits, damaged areas and gaps that serve as entry points, light sources, odor leaks, etc.)
- Periodic monitoring by insect control contractors or own organization (perimeter, building interior, etc.)

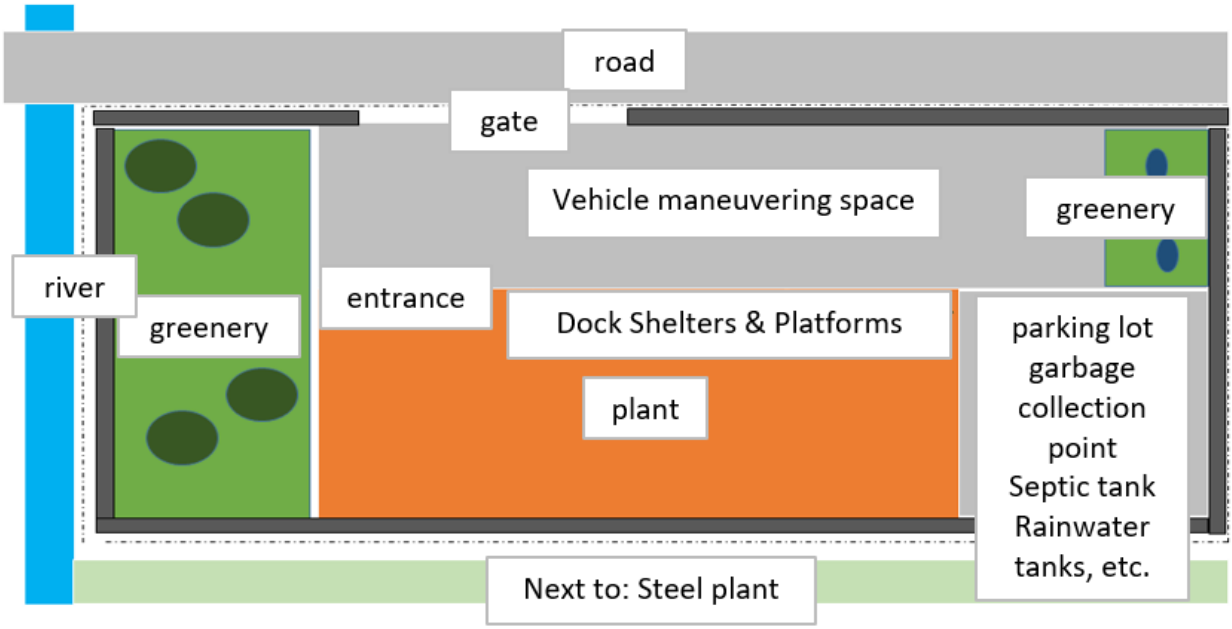
(2) Foreign body related

- Removal or modification of the subject, isolation, etc.
- Countermeasures against contamination by foreign matter flying into buildings or adhering to workers

(3) Others

- Arrangements with stakeholders in the surrounding environment
- Deterioration countermeasures through periodic maintenance of buildings and facilities
- Periodic verification of production 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 (including drainage system and lighting) and the flow lines of people, goods, and work shall be designed to meet the intended purpose and minimize food safety risks.
The organization shall set the lighting necessary for food safety to an appropriate level of illuminance.

Additionally, the organization shall ensure that facilities and equipment that come into contact with food are constructed and made of materials that allow for appropriate maintenance, cleaning, and disinfection.

●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】(This item is applicable to the scope in Japan)

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.

【Temperature control】

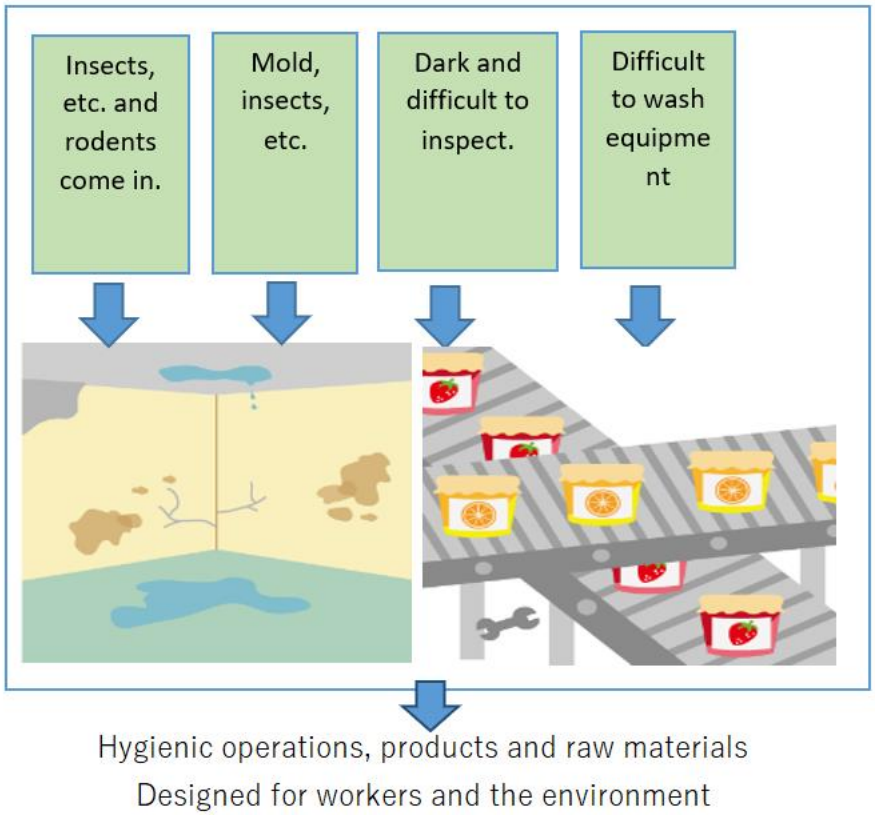
1. Depending on the characteristics of the food, appropriate facilities for temperature control of the ambient environment in which the food is handled shall be available when necessary.

【Air (air conditioning and ventilation) in the manufacturing environment】

1. Provide appropriate means of natural or mechanical ventilation, especially for:
    1) Minimize airborne contamination of food by aerosols and condensation droplets, etc.
    2) Assistance in controlling ambient temperature
    3) Control of odors that can affect food conformity
    4) Control humidity to ensure food safety and suitability. (e.g., to prevent moisture gain in dried foods that can allow microbial growth and the formation of toxic metabolites)
2. Ventilation systems shall be designed and constructed so that air does not flow from contaminated areas to clean areas. Systems shall be easy to maintain and 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 referred to in Japanese 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 of Japan, No. 604 and JIS.

task organization	Illuminance (lux)
Precision work	More than 300 lux
normal operation	More than 150 lux
rough work	More than 70 lux

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 4.1 Cross-contamination (including allergen cross-contact) and isolation

● Requirements

The organization shall prevent physical, chemical (including allergens), biological contamination, and cross-contamination (including allergen cross-contact) of raw materials (including containers and packaging materials), semi-finished products, work in progress, reworked products, and finished products.
The necessary control measures, including isolation, shall be established to cover all aspects of food safety, and these procedures shall be documented and maintained effectively through periodic review.

● Concepts, specific examples

1. This standard requirement is related to HACCP Steps 4 and 5 in the actual work performed.
2. As sources of contamination, all aspects of food safety are covered, including foreign substances, microorganisms, chemicals, and allergens.
3. An effective way to prevent cross-contamination (including allergen cross-contact) is to isolate raw materials (including containers and packaging materials), semi-finished products, work-in-process, reworked products, and finished products from the sources of contamination or objects that can contain such sources of contamination as described in Section 2 during the manufacturing process. Normally, the degree of product contamination

decreases as processing proceeds, but in the case of pathogenic microorganisms, they have a tendency to spread from highly contaminated to less contaminated locations and objects. Isolation is effective in preventing this contamination. When storing the above-mentioned objects to be isolated, it is recommended that each object be placed in a specific location, such as a storage room or refrigerator, and that dedicated containers be used to protect the objects from cross-contamination (including allergen cross-contact).

4. For contamination associated with the movement of people and objects, as well as cross-contamination (including allergen cross-contact), it is also effective to identify the areas where it occurs and establish preventive measures.

[Improve zoning and flow lines to prevent cross-contamination (including allergen cross-contact).]

1. When evaluating and formulating, it can be easier to understand the control points of pollution sources if a manufacturing and processing process diagram, air supply and exhaust plan, and product and raw material entry and exit plan are prepared.
2. The flow of zoning and flow line improvements to prevent cross-contamination (including allergen cross-contact) is as follows:
   1) Clarify the movement of people and goods, and create a flow line diagram.
   2) Evaluate the possibility for cross-contamination (including allergen cross-contact) due to the movement of people and goods, taking into account the characteristics of the product and the potential for contamination.
   3) As a result of the evaluation, control measures for cross-contamination prevention (including allergen cross-contact prevention) are developed.

● Items to be referred to in Japanese 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 4.2 Control of hazards that require enhancement

● Requirements

The organization must establish control measures for hazards that require particularly enhanced controls, other than CCPs, document those procedures as necessary, and maintain them effectively through periodic review.

● Concepts, specific examples

1. Controls according to GMP 4.2
   1) The Requirements of this standard require that for potential hazards identified in HACCP Step 6 (Principle 1) hazard analysis, for which
      ① Of the hazards that did not result in the establishment of a critical control point (CCP),
      ② And for those hazards that require particularly strong control,

Necessary control measures be established, those procedures documented as necessary, and those procedures be maintained effectively through regular review.

2) 1) is synonymous with "GHPs requiring more attention" in CXC 1-1969, Rev. 2022, General Principles of Food Hygiene of the International Commission on Food Standards (CODEX).

* Hazards identified by the HACCP Step 6 Hazard Analysis that are considered to have the potential to cause significant food safety hazards if mistakes are made that do not meet the Requirements for control by GMP, are considered to be "GHPs that require more attention " and consequently are considered to be controlled by GMP 4.2.

2. Points to note for controls according to GMP 4.2

1) Depending on the type of product, manufacturing process, hazard analysis, frequency and severity, etc., the hazards controlled in GMP 4.2 will vary. These should be considered and identified. The matrix in HACCP Step 6 (Principle 1) and other information can be used as a reference.

2) Control procedures according to GMP 4.2 can involve not only GMP Requirements, but also controls according to FSM Requirements. Although they vary depending on the industry and products of an organization, examples of relevant Requirements are provided below:

FSM 13.1, 13.2, Purchasing and Supplier Management
FSM 16 Allergen Management
FSM 19.2 Environmental Monitoring
GMP 3 Design, construction, layout of business site and work and product flow lines
GMP 6 Hygiene, workwear and Health management of personnel, etc.
GMP 8 Housekeeping, cleaning, sterilization, and disinfection
GMP 11 Air and water Management
GMP 13 Pest control
GMP 18 Equipment and Tools
GMP 19 Maintenance

3) When implementing the above, monitoring, corrective action, and verification records should be established at a frequency appropriate to the characteristics of the product and the size of the organization. Monitoring can include the following:

●Definition of monitoring methods (including who is responsible, frequency, and, if applicable, sampling regime)

●Monitoring of records to be kept

3. Examples of Hazards Controlled by GMP 4.2

1) Allergen management:

Cleaning the line after manufacturing products containing allergens can be a control measure to be managed under GMP 4.2. If the allergens cannot be removed by cleaning, there is a risk of the next product containing no allergens containing allergens being included. In addition, if there are multiple production lines in the same production area, the simultaneous production of products containing allergens can cause cross-contact of allergens with products from different lines.

2) Management 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 lines, utensils, or the environment, they can multiply even at temperatures below 10°C, and food poisoning can occur if stored for long periods. Therefore, lines and utensils that come into direct contact with RTE food products shall 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. Required control measures

1) See HACCP Steps 5, 6, and 11.

2) However, in-depth analysis/consideration shall be conducted by paying attention to "Controls according to GMP 4.2" listed in "1".

3) Records of the results of the implementation of the procedures shall be kept as necessary.

GMP 5 Personnel Facilities

●Requirements

The organization shall provide changing rooms and hand washing facilities. Facilities for employees, including these, must be properly managed to minimize food safety risks, including allergens.

The organization shall separate toilets and areas where food and drinks are stored and consumed such as cafeterias, and break rooms, from areas where food is manufactured, packaged, and stored.

●Concepts, specific examples

【Facilities for Employees】

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

【Changing rooms】

1. Provide a sufficient number of lockers, etc. In lockers and changing rooms, clean work clothes worn in the production area shall be kept from cross-contamination with personal clothing or used work clothes.
2. Changing rooms shall be located so that food handlers' clothing does not become contaminated before moving to the work area.
3. Changing rooms, if necessary, shall be suitable facilities for employees to change clothes for the work they perform.

【Hand washing facilities】

1. The facility shall be capable of washing and drying hands in a sanitary manner.
2. It is important to have a sufficient number of facilities in appropriate locations based on the number of food handlers, and to have washing, drying, sterilization, disinfection facilities, and hot water facilities, as needed.
3. Maintain an adequate supply of water (or hot water if necessary for proper hand washing), and provide soap, paper towels, disinfectants, etc. suitable for hand washing shall be provided, clean, and ready to use at all times. Hand disinfectants shall not be used as a substitute for hand washing, but shall only be used after hand washing.
4. To prevent re-contamination of washed hands after hand washing, the faucet should be designed so that it can be opened and closed without touching it by hand.
5. Post easy-to-understand hand washing and disinfection procedures.
6. Hand washing facilities shall not be used for washing food or mechanical equipment.

【Toilet】

1. The toilet shall be of hygienic construction.
2. Install a sufficient number of them for the number of employees.
3. The area shall be sufficiently separated from the area where food is manufactured, packaged, and stored. However, if sufficient isolation can be achieved, zoning (such as using separate rooms) is not required.
4. Establish hand washing and disinfection facilities and means to dry hands.
5. Always keep the area clean, and clean and disinfect it regularly.

【Dining room, rest room, smoking room】

1. Dining rooms, rest rooms, etc., and places where food and drink are stored and consumed shall be sufficiently isolated from areas where food is manufactured, packaged, and stored to minimize the possibility of cross-contamination. (Pay particular attention to the bringing in of hard foreign objects and allergens.) However, if sufficient isolation is possible, zoning, such as separate rooms, is not required.
2. Dining rooms, rest rooms, etc., and other areas where food and drink are stored and consumed shall be kept clean, and food, drink, and waste must be controlled to be not left lying around to prevent them from becoming a source of harmful organisms.
3. Smoking areas shall be located and controlled so that

●Items to be referred to in Japanese 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.
The criteria shall include provisions of hand washing and toilet facilities, ways and frequency of hand washing, medical screening procedure to identify conditions impacting food safety, proper protective clothing, rules on the clothing and shoes, rules on accessing production area, ways of food handling, and control measures for foreign materials, and management procedures and reporting system in the event of an infected person that poses food safety risks.
These Requirements must be made known to employees and applied without exception to contractors and visitors.
The organization shall also determine who will be responsible for managing personnel with health conditions.

● Concepts, specific examples

1. Concepts in GMP6
   1) In GMP6, the organization needs to take appropriate sanitation standards to prevent contamination factors.
      (1) Provide appropriate guidance and control to prevent contamination from occurring due to employee behavior.
      (2) Establish a manufacturing environment that prevents contamination and foreign matter from entering the product.
      (3) External visitors are also to be handled in such a way that they do not affect food safety.
   2) The important point in this section is to "ensure that workers are properly trained and instructed so that there are no problems with on-site operations.

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

2. Health management of personnel
    1) In advance, determine a manager who shall be responsible for the management of employees with health conditions in case they arise.
    2) The manager shall explain the health conditions and food safety risks to employees when they join the company, etc., and seek their understanding of identifying illnesses to the extent necessary, what to do in case of illness, what to do in case of food poisoning, etc., and take actions to ensure that they maintain appropriate knowledge and awareness of food safety.
    3) The manager shall ascertain the employee's illnesses as needed for food safety.
    4) Have them undergo periodic medical examinations.
    5) Conduct periodic stool analysis to confirm that there are no abnormalities.
    6) Check the health condition before work and record the results. Employees are to be trained and informed that they shall report any abnormalities in their physical condition 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.). The following are examples of illness symptoms that shall be reported to the person in charge of the site, etc.:
        - Jaundice / diarrhea / vomiting / fever / sore throat with fever / visible infected skin lesions (furuncles, cuts, etc.) / discharge from ears, eyes, or nose.
    7) If there is a suspicion of infection or food poisoning accompanied by fever, diarrhea, vomiting, etc., or if there is a suspicion of infection among skin injuries (burns, cuts, etc.), etc., report the problem to management, food safety manager, etc. If necessary, disinfect the facility, equipment, etc., check on the persons (including external visitors) who came in contact with the product, and take action regarding products manufactured or shipped prior to that time.
    8) A response procedure should be developed in case an employee becomes ill while working and there is a risk of infection or food poisoning. Procedures should include cleaning the facility as needed

and contacting other employees, contractors, visitors, etc. with whom they came in contact.

9) There are some illnesses for which it is appropriate to prohibit entry to the processing area even after symptoms have resolved. In such cases, seek the results of a physician's diagnosis, if necessary.

10) Persons with cuts or wounds shall be assigned to work in areas where they cannot be in direct contact with food, if necessary. If the employee is allowed to continue working, the cut or wound shall be covered with an appropriate waterproof bandage and gloves shall be worn when appropriate. Take appropriate measures to ensure that the bandage does not become a source of contamination. (e.g., color-coded, detectable by metal detectors)

11) For contracted businesses and visitors, contact information shall be obtained in advance in preparation for the above-mentioned emergencies.

12) Do not ship food that can have been touched by workers with health conditions until you have confirmed that there are no safety issues. See FSM 24. If the food has already been shipped before confirming that it is not unsafe, follow the procedures in FSM 22.1.

13) 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 referred to in Japanese legal provisions related to food safety

Food handlers and health conditions
Regulations for Enforcement of the Food Sanitation Act Appended Table 17
(Re: Article 66-2, paragraph (1))
(vii) Hygiene Control for Persons Handling Food or Additives
(a) Health examinations of persons who handle food or additives (hereinafter referred to as "food handlers") (a) Medical examinations of persons who handle food or additives (hereinafter referred to as "food handlers") shall be conducted

for the purpose of ascertaining the health conditions necessary to prevent food sanitation hazards from occurring.
(b) When a prefectural governor, etc. has given instructions that a person handling food, etc. should undergo a stool examination, the person handling food, etc. shall be instructed to undergo a stool examination.
(c) When a food handler is showing any of the following symptoms, efforts should be made to grasp the details of the symptoms and to determine whether the symptoms require medical examination by a physician and suspension of work to handle food or additives
(1) Jaundice
(2) Diarrhea
(3) Abdominal pain
(4) Fever
(5) Pyogenic skin disease, etc.
(6) Secretions from the ears, eyes, or nose (limited to those that may infect infectious diseases, etc.)
(7) Nausea and vomiting
(d) When a person who has a skin injury is engaged, the area shall be covered with a water-resistant covering. Foods or additives that may be contaminated by vomit should be discarded. In the event of vomiting in the facility, the area should be disinfected immediately with a disinfectant.
(e) When food handlers are engaged in work to handle food or additives, they should wear work clothes specially designed for the purpose, and hats and masks as necessary. In addition, they shall use special footwear in the work area and shall not leave the designated area while wearing the footwear used in the work area.
(f) Personnel handling food shall not bring into the facility where food is handled any ornaments or other items that may interfere with hand washing or cause foreign matter to be mixed in.
(g) When using gloves, food handlers shall, in principle, use gloves made of water-resistant materials for the parts that come into direct contact with raw materials.
(h) Personnel who handle food, etc. must cut fingernails short, wash hands, and keep fingers clean so as not to cause food sanitation hazards.
(h) Food handlers shall wash and sanitize their fingers thoroughly when they finish urinating or handling fresh raw materials or raw materials before heating.

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

GMP 7 Training

● Requirements

The organization must ensure that all employees, including new employees, receive adequate education and training in food safety principles (including HACCP) and practices appropriate to their jobs.
In addition, a system must be established to ensure that employees receive appropriate guidance and supervision.
The organization shall keep records of the implementation of education and training. Additionally, the system for retraining as necessary shall be documented and implemented.
This education and training shall enable employees to recognize their role in food safety and the significance of their efforts.
This education and training should enable employees to recognize their role in food safety and the significance of their efforts.

● Concepts, specific examples

1. Food safety managers
   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. It is important to periodically review the training programs and update them as necessary so that food handlers, maintenance staff, and other personnel involved in food operations continue to be aware of all procedures necessary to maintain food safety and suitability (see FSM 2).

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. This retraining system shall be established and implemented in writing.
   5) Conduct HACCP training.
   6) In addition to the above, the educational program shall include, at a minimum, the following items:
      - ●Product reliability, including food fraud
      - ●Product Characteristics
      - ●Food Defense
      - ●Food-related legal Requirements
      - ●Product/process changes
      - ●Feedback from previously documented training/instructional programs

●Items to be referred to in Japanese 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 shall document and implement a management procedure of maintain an appropriate level of hygiene at all times by conducting tidying and cleaning operations throughout all processes and phases, and disinfecting where necessary.
This procedure should include procedures for verifying that sanitary conditions are ensured.
Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended purpose, clearly identified and stored in areas separated from food production areas.

● 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.

【Management of cleaning tools, washing 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 supplies, cleaning agents, and sanitizers should be clearly identified and stored in areas separated from areas where food is produced, packaged, and stored. If they can be stored away from each other, this is not a problem.
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.

GMP 11 Air and water management

● Requirements

The organization shall establish application-specific standards and regular monitoring procedures for air, high-pressure gas, and water (including ice and steam) used in food production to minimize impacts on food safety, and the records shall be kept.
If water not intended for use in food production and water that has been used and is still acceptable in contact with food is applied to food production, it shall be controlled to prevent it from being contaminated with water for food production.

● Concepts, specific examples

1. Air, high-pressure gases, and water (including ice and steam) used in food production can cause physical/chemical/biological contamination of food depending on their use. To minimize the impact on food safety, it is essential to establish standards required for each application, establish procedures for regular monitoring, and keep records of such monitoring.
2. When manufacturing food products, it is possible to use different types of water for different purposes, in which case standards shall be established for each application.
3. The quality of water to be used shall be checked by water quality tests, etc., and if necessary, filtered, sterilized, or otherwise treated to ensure water quality before use.
4. Where appropriate, municipality, national or internationally recognized microbiological and water quality standards for drinking water shall be followed.
5. In Japan, water that comes in contact with food is, in principle, water for food production or water suitable for drinking, and water for food production means water that complies with applicable laws and regulations.
6. In Japan, it should be referred to in legal and regulatory Requirements:
   1) Water quality standards based on the Water Supply Law (51 items): Ministerial Ordinance on Water Quality Standards (May 30, 2003, Ministry of Health, Labor and Welfare Ordinance No. 101)
   2) Water for food production: Specifications and Standards for Foods, Additives, etc. (26 items) (Ministry of Health and Welfare Notification No. 370, 1959)
   3) Water fit 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)
7. 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 with water for food production. Specific examples include the following:
   1) Well water that has simply been pumped

2) Water that has not been sterilized with hypochlorous acid or chlorine, etc.

8. In addition, in some food industries, water that has been used but is acceptable for contact with food can be reused for food production in order to make effective use of water resources, as in 6. above, these waters shall also be controlled to prevent contamination to water used for food production. Specific examples include the following:
   1) Water used to heat and sterilize facilities
   2) Water used to heat and cool prepackaged foods
   3) Secondary washing water for cut vegetables (water used in the final stage of the washing process)
   4) Steam condensate reuse water
9. 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
10. 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.
11. 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 referred to in Japanese 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.
Containers for storing waste materials (including by-products not suitable for food use) shall be clearly distinguished from other containers.
Waste flow lines must be set up so as not to cause cross-contamination of food.

● Concepts, specific examples

1. Waste, etc. (including by-products not suitable for food use) generated as a result of food production and processing shall be properly managed because they can become a breeding ground for microorganisms, rodents, insects, and other harmful organisms, which may lead to contamination of the production and processing environment. For example, the purpose is to prevent contamination of the surrounding environment and attraction of pests due to overflowing waste (including by-products not suitable for food use) in waste containers in factories and outdoor waste storage areas, as

well as outbreaks of sanitary pests and microorganisms due to long-term storage, etc.

2. Avoid contact between waste and raw materials, ingredients, food, or manufacturing/processing facilities. Keep disposal facilities away from food production facilities.
3. Designate a person in charge of consistent management (identification, accumulation, segregation, storage, removal, and disposal) of waste, etc., prepare a written procedure for such management work, and provide training. The status of waste management shall be periodically checked to ensure that the procedures are being followed, etc. Records of disposal shall be maintained.
4. For example, check that the following flow is being processed promptly: Waste, etc. generated in manufacturing/processing lines → Containers of waste, etc. → Temporary storage area → Indoor/outdoor waste storage area → Pickup by designated contractors → issue and storage of manifest slips (according to laws and regulations)
5. Waste, etc. shall be managed and stored so as not to affect products, raw materials, and materials and equipment that come in contact with the products.
6. In order to prevent cross-contamination between wastes, etc. and products, in principle, wastes, etc. should not be stored in areas where food is handled or stored. (Excluding temporary storage during production, and similar activities. However, even in this case, care shall be taken to prevent cross-contamination with products.)
7. Containers (trash cans, containers, etc.) for storing waste shall be clearly distinguishable from other containers and made of a material suitable for the waste application. They should be impermeable if necessary. Containers used to hold hazardous substances prior to disposal shall be stored in specific containers and locked as necessary to prevent intentional or accidental contamination of food. In addition, tools used to store and handle allergen-containing wastes shall be garbage cans, transport tools, or containers, with a lid that are handled in a manner that prevents or minimizes the potential for allergen cross-contact.

● Items to be referred to in Japanese 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 shall monitor pests and implement controls (surveys and countermeasures) to minimize the risk of insects, rodents, birds, and other pests occurring or entering the premises and facilities.
If chemicals are used, handling procedures shall be established to ensure that food is not affected.
Pest control shall be carried out by persons with the necessary competence.

● Concepts, specific examples

【Pest control measures】
1. Pest control measures shall be taken as follows
   1) Analysis and inspection plan for pests such as rodents and insects

Target pests are identified based on past occurrences in the facility, biological evidence, and characteristics of products handled, and inspection plans are formulated.

2) It is important that pest control, including surveys and monitoring plans, is carried out frequently enough and appropriately by competent personnel with the necessary skills. It is also effective to obtain the cooperation of external pest control contractors with expertise in the field.

3) Pest control and invasion prevention measures
Remove internal sources of pests and implement measures to prevent external invasions and incursions.

4) Monitoring and extermination of pests such as rodents and insects
Monitoring will periodically confirm that sanitation and pest control measures within the facility are secured and that there is no evidence of pest infestation. If extermination is necessary based on the results of monitoring, countermeasures that do not affect food or interfere with facility operations should be formulated and implemented by competent personnel. Identify the cause of the infestation, take corrective action to prevent the problem from reoccurring, and document monitoring and eradication.

2. When pest control is outsourced to a specialized contractor, the above information should also be confirmed with the specialized contractor and measures should be promoted. Even when monitoring and eradication are outsourced, the organization reviews monitoring reports and, if necessary, ensures that its designated pest control operators take remedial action (e.g., eradication of small pests, elimination of hiding places or entry routes).
3. Plantings that produce flowers or fruits that attract pests such as rodents and insects should be avoided, and the smell of wastes and sewage should be prevented from spreading. Mowing and pruning of plants should be done regularly to avoid sources of pests.
4. Areas prone to puddling can be a source of chironomids and other pests. For example, in unpaved parking lots, it is possible to prevent outbreaks by frequently adding gravel to the parking lot.
5. Yellow or green fluorescent lights or plastic curtains, which are considered to be less visible to insects, should be installed in outdoor lighting, entrances, corridors, etc.

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

【Measures for facilities that are easy to clean】

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

【Drug Control】

1. it is important to have established procedures for chemical administration, spraying, and initiation of production and processing after spraying
2. Ensure that the use of chemicals is restricted to well-trained personnel.

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

● Items to be referred to in Japanese 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 transportation vehicles, including contracted vehicles, used for the transportation of raw materials and ingredients (including packaging materials), partially processed products, works in progress, recycled products, reworks, and finished products (including packed fresh products in final packaging) are suitable for the intended use, maintained in good repair and clean, protected from contamination, and transported within its intended temperature range.

● 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, recycled products, reworked products, and finished products
   1) When delivering to the destination, check the product specifications and consider the necessary conditions for a trouble-free delivery.
   Examples: 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 problems and that the environment is such that the product can be delivered without damage or contamination.
   (1) Can the required temperature and humidity be set? Also, can the required temperature and humidity range be maintained even when the vehicle is fully loaded? If not, can the maximum load be changed?
   (2) Is the temperature and humidity recorded at the required frequency? Also, is it possible to check that there are no abnormalities with the thermometer and hygrometer as appropriate?
   (3) If containers and pallets are not the company's own, check the frequency of cleaning, disinfecting, and replacement.
   (4) Is the interior of the vehicle kept in proper clean condition?
   (5) Confirmation of whether mixed loading with non-products is allowed, and if so, the loading capacity, items that can be loaded, etc.
   (6) Confirmation that no outsiders other than the person in charge of delivery are involved.
4. On the organization, too, if necessary, check and make efforts to maintain the delivery environment. If any abnormalities are found, it shall be necessary to request appropriate improvements.

● Items to be referred to in Japanese 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, recycled products, reworks, and finished products in a designated order and within the defined expiry period, and shall store these materials under the proper conditions to avoid contamination and deterioration.
Storage facilities and equipment shall be designed to allow food to be stored under appropriate storage conditions.

●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 shall be used within a specified period by establishing an appropriate shelf life and utilizing first-in, first-out, etc.
2. During storage, the traceability (see FSM 14.1) of raw materials (including containers and packaging materials), semi-finished products, work-in-process, recycled products, reworked products, and finished products shall be managed so that they can be linked to the records.

【Storage location】

1. Facilities and equipment for storing food shall be designed to store the food under appropriate conditions according to the specifications of the food.
   1) Raw materials (including container and packaging materials), semi-finished products, work in progress, reworked products, and finished products shall be stored in storage facilities, that are not contaminated, and do not deteriorate due to temperature, humidity, etc. This is related to GMP 4.1 and 4.2.
   2) Storage conditions that do not degrade means storing the product under appropriate conditions that ensure the required specifications.

GMP 18 Devices and Tools

●Requirements

The organization shall suitably design and select equipment and tools for the intended uses and shall use, maintain, and store so as to minimize food safety hazards.

●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.

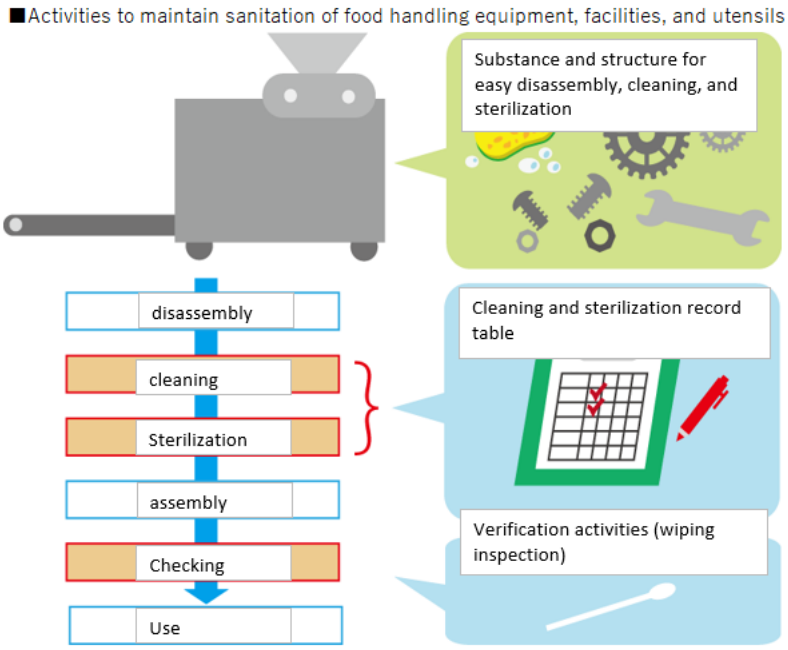
(3) Others: Whether alcohol spray is used or not, etc.

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.



● Items to be referred to in Japanese 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 shall document and implement a system for systematic maintenance of all equipment critical to product safety. Maintenance activities shall be performed in such a way that they do not pose a food safety risk.
This system shall include procedures (such as cleaning, washing, and sterilization procedures) for returning the food production facility to a state capable of producing food after maintenance activities.
Maintenance activities shall not represent food safety hazards.
All materials used for maintenance shall be suitable for the intended purpose.

● Concepts, specific examples

1. Maintenance of facilities and equipment
   1) Maintenance activities need to be carried out in a way that does not pose a risk to food safety. Therefore, the organization develops and implements documented procedures for the maintenance of all facilities and equipment that are important to product safety. The procedures include the following concepts:
   (1) Ex-post maintenance: Maintenance method in which maintenance is performed after a breakdown has caused a shutdown or a decline in functionality
   (2) Preventive maintenance: Management methods that focus on prevention, such as equipment inspections and periodic parts replacement
   (3) Improvement maintenance: Management methods that focus on improvement and reinforcement to prevent recurrence of breakdowns
   2) Procedures for the maintenance of facilities and equipment shall include the following items:
   (1) Developing a maintenance and inspection plan
   (2) Person in charge of maintenance and inspection
   (3) Identification of facilities and equipment 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 inspection

(7) Procedures for restoring food production to a condition ready for use after maintenance (including cleaning, etc.) Procedures for restoring food production to a condition where it can be performed after maintenance (including cleaning, washing, sterilization, etc.)

2. Maintenance Notes
   1) Repair so as not to contaminate food, etc.
   2) All materials used for maintenance shall be suitable for their intended use so that they do not pose a food safety risk.
   3) Check that equipment (facilities) and tools are not damaged or have any missing screws or other parts.
   4) Preventive maintenance shall be carried out in a planned manner, in addition to ex-post maintenance.
   5) Ensure that preventive maintenance plans include equipment that monitors and controls food safety. (e.g., sieves, air conditioning filters, magnetic traps, metal detectors, etc.)
   6) In the event of malfunction or damage, promptly repair the equipment and return it to normal condition.
   7) When performing maintenance, do not contaminate surrounding manufacturing or processing lines or equipment.
   8) Lubricants and heat transfer media that can come into direct or indirect contact with food shall be selected so that they do not impair safety even if they come into contact with food.

● Items to be referred to in Japanese 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

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