JFS-B standard

(Sector : ＣⅠ,ＣⅡ,ＣⅢ,ＣⅣ/K)

＜Manufacture of food products and

Manufacture of chemicals

(including biochemical products)＞

Ver.3.1

[Guideline]

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preface

This guideline provides ideas and specific examples of what organizations should implement with regard to the JFS-B standard issued by Japan Food Safety Management Association (JFSM).
The food safety management system established by each food business organization differs depending on many factors such as industry, business category, business scale, and social background. This report is intended to be used as a reference for each organization to build a food safety management system suited to their own needs.

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	Processing of 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 2024 PART I

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

Chemical products herein refer to chemical products (including biochemical products) related to food products, and include the production of additives, vitamins, minerals, cultures, flavorings, enzymes and processing aids.（Table 1: List of Sectors by GFSI）

Pet food is included in the following food manufacturing sector

Food Manufacturing Sectors（CI～CIV）

CI : Processing of perishable animal products

CII : Processing of perishable plant products

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

CIV : Processing of ambient stable products

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

K : Manufacture of chemicals (including biochemical products)

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

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

■ Elements and structure of the JFS standard (Sectors: CI~CIV/K)

consists of FSM, which is the requirements for the management of organizational activities ; HACCP, which is the method for controlling hazards ; and GMP , which is the requirements for good manufacturing practices regarding general hygiene management (Figure 1).



Figure 1

■ Features of this Standard Document

The JFS Standards allow flexible conformity assessment based on scientific evidence and do not uniformly require extensive capital investment. This approach helps reduce the financial burden on small and medium-sized enterprises while supporting the effective implementation and maintenance of food safety management systems.

(Feature 1)Alignment with International Practices

This Standard has been developed with reference to relevant international documents. It incorporates the elements necessary for an effective food safety management system while minimizing the operational and administrative burden on organizations, thereby allowing them to focus on establishing and effectively operating their management systems.

In operating the food safety management system, this Standard does not establish food safety culture or food fraud as separate, explicit requirements. Instead, it encourages organizations to incorporate appropriate measures relating to these matters as means of effectively meeting the relevant requirements. If food safety culture and food fraud were established as separate requirements during the initial development of the management system, organizations might regard the implementation of specific measures as an end in itself. This could detract from the fundamental objective of ensuring the effective operation of the food safety management system, increase the workload, and result in formalistic implementation.

Accordingly, this Standard is designed to facilitate the assessment of whether the food safety management system is being implemented effectively. It makes clear that the objective is the effective fulfillment of all applicable requirements and that measures relating to food safety culture and food fraud may support that objective. The Guidelines explain the underlying concepts and provide practical examples, enabling organizations to select approaches appropriate to their circumstances.

This guideline provides specific ideas and examples, and the following text colors are used to allow organizations to consider appropriate responses.

- Content related to food safety culture: Green
- Content related to measures against food fraud: Purple

Furthermore, organizations that have successfully established and effectively operated their food safety management systems and wish to progress to the higher-level JFS-B Plus or JFS-C Standards may refer to the "Implementation Support Handbook" available on the JFSM website.

(Feature 2) Food safety levels can be improved through step-up progression

Food businesses (organizations) can engage in food safety management in accordance with international food safety management systems. Furthermore, organizations seeking to further

enhance their food safety management systems may progress to higher-level Standards such as JFS-B Plus and JFS-C.

(Feature 3) Supports compliance with Japan's Revised Food Sanitation Act

Under the Act Partially Amending the Food Sanitation Act and Related Acts (Act No. 46 of 2018), food business operators are required to implement hygiene management tailored to the characteristics of the food they handle (so-called "hygiene management incorporating the HACCP concept") in order to prevent food safety hazards (Article 50-2, Paragraph 2 of the Food Sanitation Act).

This Standard incorporates the HACCP concepts and approaches contained in GPFH 2022 (*3). As a result, this Standard not only supports compliance with Japan's Revised Food Sanitation Act but also enables organizations to establish HACCP systems consistent with internationally recognized approaches.

■ How to use the JFS- B standard Ver . 3.1 Guideline

This guideline aims to help you understand the meaning and purpose of the requirements of the JFS-B standard and what specific actions should be taken.

This provides guidelines regarding points.

The order of the standards does not indicate the order in which the implementation system should be established. In reality, it is possible to start with GMP or with FSM, so it is desirable for each organization to take the appropriate approach .

The ideal food safety management methods vary depending on the food business operator (organization). This guideline is based on the JFS-B standard.

To support all food businesses that intend to implement a food safety management system (FSMS) that meets the standard requirements, the JFS-B standard includes fundamental concepts and various examples related to the requirements. Furthermore, the JFS-B standard requires food businesses (organizations) to address food safety management through on-site ingenuity. It does not require capital investment to comply with the JFS-B standard.

To make the most of these guidelines, and incorporating information from government agencies and industry associations, we will create a plan for each food business (organization).

We would like you to implement food safety management measures in accordance with the JFS- B standard .

These guidelines are structured as follows:

・Requirements

- Concepts and specific examples

• Annex: A list of documented information explicitly required by the standard, and legal provisions related to food safety that should be referenced.

Note: The legal provisions listed are examples of mandatory provisions from Japanese domestic laws and regulations, based on the corresponding laws and regulations at the time of the guidelines' issuance.
Since laws and regulations may be amended, please check for the latest information regarding laws and regulations.

■Points to note in this guideline

The specific examples in these guidelines are not requirements, but rather illustrate concepts and concrete examples. If it is possible to technically and scientifically explain that the requirements of the JFS standard are met, other approaches and methods can be chosen. By using these guidelines in conjunction with research data and food safety theories published to date by research institutions and industry associations, it is possible to leverage the technical information and know-how possessed by individual industries.

While the legal provisions in these guidelines are based on Japanese laws and regulations, the laws and regulatory requirements related to food safety management systems vary depending on the industry, business type, and region. JFS standards and these guidelines assume compliance with these laws and regulatory requirements, but they are not entirely covered by these guidelines; therefore, each organization must individually confirm these requirements.

These guidelines will be helpful in understanding the JFS standards .

JFS-B Standard (Sector: C 1 ~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 shall share and operate an organizational structure that, at a minimum, clarifies the duties and responsibilities of those whose duties affect food safety. Management or senior management shall determine who is responsible for food safety management.

●Thinking, specific examples

1. Organizational structure and determination of the person responsible for food safety management.

1) Regularly review and revise the effectiveness of initiatives related to ensuring food safety and quality, and maintaining consumer trust.

2) A food safety officer shall be appointed as the person responsible for food safety management. When appointing the food safety officer, it is important that they have knowledge of the organization's food safety policies, food safety, and on-site knowledge and experience, as this will enable the creation of an effective system.

3) Clearly define the organizational chart, including the communication system for instructions, reports, and consultations, and share it with employees.

4) It is desirable to designate a person who can temporarily act as a substitute in the event that the person in charge is absent or otherwise unavailable.

5) Appropriately considering organizational restructuring and personnel changes is considered important for sustainability and to prevent over-reliance on individuals. It can also help reduce the risk of food fraud.

2. Sharing and implementation of organizational structure

1) To clarify the communication system for instructions, reports, and consultations, it is helpful to use meetings, morning assemblies, etc., to decide on the activities necessary for food safety, which will make management easier.

Instructions, reports, and consultations are as follows:

(1) Instructions: The work and roles are clearly defined by a supervisor or manager.

(2) Reporting: The person who performed the work must inform their supervisor or manager of the facts.

(3) Consultation: When it is difficult to determine whether the work is being done appropriately, or when undertaking new activities, etc., seek confirmation of appropriateness.

2) Establish a communication system that ensures safe food products can be shipped even in the event of significant changes in the manufacturing environment, such as a sudden increase in order volume, earlier shipping times, or personnel shortages.
(The decision to ship is also related to the FSM23 (Product Release) procedure.)

FSM 2 Commitment of management or senior management

● Requirements

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

●Thinking, specific examples

1. Clarification of organizational structure and job descriptions in the establishment, implementation, maintenance, and continuous improvement of the food safety management system.

1) Develop a food safety policy.
2) Clearly define all organizations involved in food safety and their respective roles, and provide opportunities for communication (see example below) to inform all employees.
3) Timely communicate to employees the importance of complying with laws and regulations, social norms, and organizational rules.
4) Set business objectives that support food safety.
5) Review the food safety management system in a timely manner.
6) Provide necessary resources in a timely manner.
7) Continuously improve procedures through verification of HACCP Step 11, FSM 14, 22, etc.
8) To address other matters necessary for the establishment, implementation, and maintenance of the food safety management system.
9) In addition to instructions from management (top-down), we will consider developing systems and a workplace environment that encourage autonomous actions and suggestions from employees (bottom-up).

(1) Continue providing education, training, and information sharing to enable employees to take appropriate actions autonomously.
(2) Understand the behavior of employees in their daily work and make improvements as necessary.
(3) Clearly demonstrate to all employees that the organization prioritizes food safety.

10) The management, as the ultimate person responsible, must respond sincerely and demonstrate consistency.

11) Management will engage in activities, actions, and information sharing to create a comfortable working environment for employees. This is expected to have the following effects, improving the safety of manufactured products and, as a result, increasing customer trust in our company.
(1) Individual employee satisfaction gradually improves, and the company's management objectives become assimilated with individual employees' work objectives.
(2) A common purpose is fostered among employees, strengthening their sense of camaraderie and leading to contributions to the organization.
(3) An atmosphere is created in which employees can proactively implement and operate in accordance with company rules and work procedures, as well as in managing hazards and maintaining necessary records.

2. Examples of "evidence that employees have been informed"

1) Examples of evidence that employees have been informed include the following. In addition, in cases (3) to (5), it is possible to consider the effectiveness and improvement of the commitment along with the dissemination of information, so it is desirable to consider methods that are appropriate to the organization's direction and strategy and that are sustainable.
(1) Opportunities for employee communication related to food safety
(2) Posting on the wall
(3) Records of information disseminated through training to improve food safety
(4) Collecting improvement suggestions from employees and responding to those suggestions.
(5) Development and performance evaluation of food safety activities

etc.

3. Reference materials

1) When considering further promoting proactive employee behavior, the following materials may also be helpful.

• JFSM "Handbook for Supporting the Introduction of a Food Safety Culture"
https://www.jfsm.or.jp/scheme/documents/index.php
– Ministry of Agriculture, Forestry and Fisheries, "FCP Food Safety Culture Tool"
https://www.maff.go.jp/j/shokusan/fcp/other_tools/250331.html

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.

●Thinking, specific examples

1. Clarify the necessary food safety laws and regulations for your organization and establish management methods.

1) Not only must the laws of the country of manufacture be complied with, but also the food safety laws of the country of sale. When there are amendments to relevant laws or the enactment of new laws, it is necessary to grasp them in a timely manner, communicate them within the organization, and change the system accordingly. The laws and regulatory requirements of the country of sale must also be understood.

2. Food safety laws and regulations that should be referenced (this section applies to the scope within Japan)

1) Appoint a food hygiene manager or food hygiene supervisor who meets the necessary requirements.

(1) Food hygiene manager: Appointed in accordance with Article 48 of the Food Sanitation Act. For the foods covered, refer to Article 13 (Designation of Foods, etc.) of the Enforcement Order of the Food Sanitation Act.

(2) Food hygiene manager: In accordance with the provisions of the Enforcement Regulations of the Food Sanitation Act, a food hygiene manager shall be appointed for each facility that is to obtain a business license.

FSM 6 Food Safety Policy and Goals

● **Requirements**

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

●Thinking, specific examples

1. Development of a food safety policy

1) The manager or management team shall create a food safety policy that meets safe and appropriate quality standards, and shall create the policy with the following points in mind so that all employees understand and recognize it:

(1) The organization will provide consumers with safe and reliable food products, starting from the consumer.

(2) Respond appropriately to changes in the social environment and comply with laws, regulations, fair rules, and social norms.

(3) Regularly review whether the food safety policy is appropriate.

(4) Provide necessary resources, including human resources, in a timely manner.

(5) The management, as the ultimate person in charge, must respond sincerely and demonstrate consistency.

2. Examples of how to ensure all employees understand and are aware of the food safety policy.

1) We always teach this during employee training.

2) Post it in a place where employees will see it regularly.

3) We communicate this during morning meetings and other gatherings attended by all employees.

etc.

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.

●Thinking, specific examples

1. What is food defense?

1) This refers to measures to prevent, avoid, and respond to intentional food contamination by biological, chemical, and physical hazards.

2) Identifying the risk of intentional food contamination by individuals inside or outside the organization and evaluating the magnitude of that risk is called a food defense vulnerability assessment, and the countermeasures taken are called a food defense plan.

3) In assessing the vulnerability of food defenses (analyzing threats and identifying weaknesses), it is necessary to consider situations where intentional food contamination or tampering may occur, identify areas with a high probability of such occurrences, and then determine priorities such as access control.

2. Consideration of countermeasures

1) Create and implement procedures for conducting a vulnerability assessment of the facility (analyzing threats and identifying weaknesses).

2) Based on the results of the vulnerability assessment, develop and implement a food defense plan that includes methods, responsibilities, and criteria for preventing intentional food contamination and tampering. The food defense plan should include the following elements:

(1) A person responsible for food defense must be designated.

(2) There must be policies and procedures in place to record and manage the entry and exit of employees, contractors, and visitors into the facility area.

(3) There must be procedures in place to ensure the safety of raw materials, equipment, containers and packaging materials, pharmaceuticals and food products during storage and delivery.

(4) The site must be physically safe (security must be provided).

(5) There must be procedures in place for how to respond when intentionally contaminated or spoiled food, packaging, or equipment is discovered.

(6) There is an effective recall program (see FSM22).

(7) The organization provides necessary education and training to its personnel in accordance with its established food defense plan.

3. Reference case

1) In addition to monitoring cameras and lock management, communication among employees serves as a deterrent for food safety.

2) Over-reliance on hard measures for food safety can actually damage the good relationship between employees and managers. For example, an organization can explain to employees that "monitoring cameras are not installed based on suspicion of employees, but rather to prove employee actions in the event of a food safety incident."

3) Food defense must not only involve physical measures within the facility, but also anticipate internal attacks from stakeholders. Ensuring the absence of short-term workers or employees with complaints or dissatisfaction is particularly effective.

4) A mechanism is needed to examine social examples, examples from competitors, preventative measures, and trends such as warning signs.

5) The "Guidelines for Formulating Voluntary Action Plans to Improve the Reliability of the Food Industry" – Five Basic Principles – published by the Ministry of Agriculture, Forestry and Fisheries in March 2008, can be used as a reference.

The five basic principles are as follows:

(Basic Principle 1) Clarification of the consumer's perspective

(Basic Principle 2) Establishing a compliance awareness

(Basic Principle 3) Basics of appropriate hygiene and quality control

(Basic Principle 4) Establishment of a system for appropriate hygiene and quality control

(Basic Principle 5) Efforts to collect, transmit, and disclose information

4. Reference materials

The following resources may also be helpful in effectively implementing, maintaining, and improving food defenses.

• JFSM "Food Defense Implementation Support Handbook"
https://www.jfsm.or.jp/scheme/documents/index.php

FSM 9 Document and record management

● Requirements

The organization shall establish and implement procedures to control documents and records to ensure food safety and to create, maintain, and preserve documents and records to evidence effective operations. Records shall be taken and properly maintained as determined necessary to demonstrate the implementation of food safety controls.

●Thinking, specific examples

1. The approach in FSM9

1) In FSM9, the following measures are required to ensure that "necessary settings are reliably maintained and can be explained to third parties" and that "records are kept completely and can be reviewed later."
   (1) The necessary documents have been selected.
   (2) The selected documents are stored and used in their latest versions.

2. What is "documentation"?

1) "Documentation" can be defined as including not only documents and document data, but also images, photographs, diagrams, audio, and video, and fulfilling the following purposes:
   (1) To enable others, not just the creator, to correctly understand the company's situation, settings, and procedures.
   (2) Standardize the work process to prevent variations in perception and understanding among individuals.
   (3) Keeping records makes it possible to trace the events and investigate the causes (see "Records" below).
   (4) It becomes easier to provide accurate explanations to third parties, and the legitimacy of the organization becomes clearer.
2) Documents must be managed so that the latest version is always available for reference and use. Therefore, it is desirable to establish appropriate rules for modifying and storing documents and to consider a system that makes management as easy as possible. An example would be as follows.

(1) Specify the location where the document will be stored.
(2) Create a list of documents.
(3) Add a setting number, deprecation number, etc., to the document to clearly indicate that it is the latest version.
(4) Dispose of old versions or store them in a designated location to prevent misuse.

3) Items explicitly required to be documented in this standard are shown in a separate table. Even if the requirements do not directly call for documentation or records, it may be best to provide documentation in writing, but the existence of numerous documents can lead to management complications.

If it can be determined that the issue can be addressed through means other than documentation, appropriately reducing documentation can be effective in improving the work of employees and the operations of managers. It is desirable to carefully consider this and take appropriate measures that are suitable for one's own organization.

4) Whether storing paper documents or digital data, organize them by date, type, etc., and create an environment where they can be quickly referenced when needed.

3. Purpose of Recording

1) Keeping records makes the following actions possible:
(1) The company can clearly demonstrate to third parties that it has an appropriate food safety management system .
(2) It is possible to analyze trends in activities over a certain period of time.
(3) Information can be shared within the organization.

2) The necessary records will vary depending on the organization's industry, business type, size, and the complexity of its operations.

3) Some documents, mainly records, require long-term storage. Therefore, an "appropriate storage period" will be determined considering the product's shelf life, etc., and management will be carried out to prevent accidental disposal during that period.

4) Establish "rules for correcting records" to prevent corrections of errors from being suspected of "falsification." For example, it is desirable to use a method that is clearly understandable to third parties, such as "drawing a double line through the incorrect entry and writing the date of the correction and the name of the person who made the correction at the corrected location."

4. Reference materials

When considering how to incorporate the concept of deterrence, detection, and trust-building into records and data, rather than treating them merely as evidence, the following materials may be helpful in preventing record tampering.

• JFSM "Handbook for Supporting the Introduction of Food Fraud"
https://www.jfsm.or.jp/scheme/documents/index.php

FSM 11 Procedures and Instructions

● **Requirements**

The organization shall 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 shall be visible to employees.

●Thinking, specific examples

1. Work procedures and instructions

1) Define roles and procedures for all processes and operations that affect food safety.

2) Procedures should be communicated using documents or other means as needed, employing methods that are easy for those involved to understand. Examples of situations where documentation would be effective include the following:

(1) This may be assigned to a new worker.

(2) There is a high turnover rate among workers.

(3) There are points to be aware of.

(4) The response and judgment will differ depending on the situation.

(5) It is thought that it would be easier to understand if it were shown visually, such as with actual images.

(6) We want to prevent individual variations in procedures and unintentional changes by relying on oral communications and tacit knowledge.

3) The procedures and documentation points are as follows:

(1) Establish procedures for all processes that affect food safety.

(2) It needs to be easy to understand so that it can be used when new employees join the company or for retraining.

(3) It becomes easier to create the plan if you clarify "when, where, who, what, and how it should be done."

4) Given the increasing number of multilingual employees, it is desirable to provide support in the language used by employees, such as through documents, whenever possible.

FSM 12 Resource Management

● **Requirements**

Management or senior management shall 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).

●Thinking, specific examples

1. Utilization of management resources (people, goods, and money) by managers or management team.

1) Since management resources are limited, we will determine priorities, devise ways to maximize effectiveness, and consider how to rationally ensure food safety.

2) Managers or management should ensure that their goals and plans are not out of line with reality in order to respond to changes in the manufacturing environment.

We constantly check to ensure that on-site employees are adequately educated and trained.

3) Continuing operations with insufficient resources can lead to problems and potentially affect the sustainability of the organization. To ensure appropriate resource allocation, without relying on the efforts or awareness of workers, the following resources may be helpful.

• JFSM "Handbook for Supporting the Introduction of a Food Safety Culture"
https://www.jfsm.or.jp/scheme/documents/index.php

2. Examples of specific management resources

1) People: Employees (number, skills, etc.)

2) Things: Buildings, interiors, machinery, equipment, facilities, etc.

3) Money: Funds used for food safety activities, etc.

3. Examples of rational implementation

1) Training: Sending many employees to external training programs can be costly and difficult to conduct regularly. However, if one person receives training and then conducts internal training to disseminate it horizontally, it becomes possible to share the latest information throughout the entire organization.

2) Interior: If the interior has deteriorated due to long-term use, it is effective to prioritize repairs over several years, starting with those that directly affect food safety, rather than repairing everything at once.

FSM 13.1 Purchasing

● Requirements

The organization shall 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 shall be ensured by presenting the control methods to the subcontractor, for example, by describing the control methods in specifications and contracts.

1. The concept behind FSM13.1 and 13.2

1) FSM 13.1 requires organizations to control what they purchase from external sources (raw materials, packaging materials, and services), while FSM 13.2 requires them to control their suppliers (providers).
2) The ultimate responsibility for food safety when purchasing rests with the purchasing organization.
3) Purchasing procedures may be exempted in cases where purchases are made (or accepted) from companies within the group. However, this requirement stipulates that the same purchasing procedures as those used when purchasing from external sources must be applied even when purchasing from companies within the group.

2. Procedures for Acceptance

1) Confirm that the raw material specifications and contract details are accurate.
2) Regularly verify that the raw materials purchased meet the company's standards and that verification procedures are followed.
3) If necessary, an audit of the food safety management system of the manufacturer of the purchased goods , or a review of the audit results by a third party, will also serve as a confirmation example.

3. Specific examples of verification methods

1) Inspection of a sample representative of the lot of the purchased item.
2) Acceptance inspection of purchased items (acceptance temperature, expiration date/best before date, appearance, etc.)
3) Conformity with specifications in quality certificates and analysis certificates

4. Laws and regulations concerning food safety that should be referenced.

1) Requirements for raw materials
   (1) Packaging materials must adequately protect the product from contamination and damage and allow for appropriate labeling.
   (2) Procure raw materials that are properly managed.
   (3) Management of agricultural, forestry, livestock, and fishery products (primary products) that are used as raw materials includes the following:
   ① Measures are taken to prevent contamination by dust, soil, or wastewater during the production process.
   ② Waste, toxic substances, etc. are properly managed during the production process.
   ③ During the production stage, measures are taken to prevent contamination from pesticides, veterinary drugs, feed, rodents, insects, foreign objects, microorganisms, feces, etc.

④ Production facilities are kept clean and properly maintained through cleaning and appropriate repairs.

⑤ During the collection, storage, and transportation stages, measures are taken to prevent contamination by rodents, insects, chemical substances, foreign matter, microorganisms, etc.

⑥ Items that are clearly unsuitable for consumption are separated.

⑦ Food spoilage and deterioration are prevented through temperature and humidity control and other necessary measures.

⑧ We maintain hygiene standards for those handling the equipment.

(4) If it is clear that the raw materials contain parasites, pathogenic microorganisms, pesticides, or other foreign substances, and these cannot be killed or removed to an acceptable level through normal manufacturing and processing, the raw materials will not be accepted.

2) Requirements for packaging materials used in food products (This item applies to the extent that it is applicable within Japan)

(1) Use products that are manufactured and processed in accordance with legal regulations such as the Standards and Specifications for Foods and Food Additives (Ministry of Health and Welfare Notification No. 370 of 1959), and that are properly managed and whose safety is guaranteed.

(2) When selecting packaging materials, choose materials that are suitable in terms of gas barrier performance, tensile strength, puncture strength, etc., based on the characteristics of the product (strong odor, distribution temperature range, etc.), shelf life, size, capacity, etc.

(3) Select materials or surfaces that will not peel off or fade due to condensation or friction during distribution and storage.

(4) When reusing packaging materials, a reuse procedure manual will be created in advance and managed to prevent contamination of the product. If there is damage or significant soiling, use will be discontinued and the materials will be discarded.

5. Management of subcontractors

1) Outsourcing means entrusting one's own processes to another organization. The organization must regularly monitor and verify the outsourced processes to ensure that the results of the outsourced processes do not affect the food safety of the organization's products.

2) This outsourcing includes not only the provision of services by the contractor through product manufacturing and personnel dispatch, but also the provision of other services. These services may include transportation and storage, inventory management (see GMP15, 17), pest control, rodent control and hygiene consulting, sanitation of workplaces and facilities, maintenance of equipment and machinery, cleaning of work clothes, and provision of meals for employees.

3) When outsourcing, the ultimate responsibility for the food safety management system rests with the outsourcing company.

4) Any changes to the terms of the contract must be approved by both parties and communicated to the relevant personnel.

5) The external contractors covered include contract manufacturers and service providers.

6) The contract manufacturer shall agree to and contract all terms relating to food safety, customer requirements, commercialization, and shipment. The contract manufacturer shall establish and implement an organization to ensure compliance with the terms of the contract.

7) Contracted service providers shall document and contract the specifications of services that may affect food safety.

8) The contract shall include a clear definition of the services provided, as well as training for the personnel involved in providing those services.

9) External vendor management shall be described in the flow diagram required in HACCP Step 4 as necessary, and the management method shall be determined through hazard analysis required in HACCP Step 6. Furthermore, supplier evaluation shall be conducted in accordance with FSM 13.2.

10) To ensure the appropriateness of outsourcing, the following will be taken as necessary:

(1) Confirmation of the food safety management system

(2) Confirmation of the product process control system

(3) Verification of the accuracy and results of in-process inspections

(4) Periodic verification of the final product

(5) Ensuring food safety from a physicochemical perspective

(6) Confirmation of personnel competence and training system

11) When outsourcing CCP processes, etc., in relation to the operation of HACCP, the organization must have a management system, process control, and final product conformity equivalent to the food safety management system established within the organization.

6. Relationship with food fraud

1) "Food fraud" refers to intentional acts carried out primarily for economic reasons, such as falsification aimed at cost reduction or misleading consumers. Examples of such fraudulent practices in purchasing include false labeling and falsification of origin or specifications. Whether or not these issues should be considered in purchasing decisions is as follows:

(1) Confirm past or current cases of fraud in the supply chain by referring to information from industry associations, government sources, private information centers, etc.

(2) If a potential case of mislabeling is considered to have a high impact on food safety, measures will be taken in accordance with FSM 13.2 to reduce the risk, and efforts will be made to detect the mislabeling at an early stage. The following are some examples of possible methods.

① Implementation of appropriate monitoring (origin information, labels, etc.) to address vulnerabilities.

② Specification management

③ Change the origin of raw materials to a place where there is no precedent for misrepresentation.

④ Strengthening control over situations where deception is likely to occur.

Example: The price offered by the supplier being used is significantly lower than the market price.

Raw material prices are soaring, and supply is becoming tight.

Shipping times are often moved up.

A sudden surge in order volume occurs.

There are concerns about the production system when there is a shortage of personnel.

⑤ Consider the frequency of analysis/testing in relation to disguised vulnerabilities (see FSM19).

2) When considering incorporating the concept of preventing food fraud, the following materials may be helpful.

• JFSM "Handbook for Supporting the Implementation of Food Fraud Prevention"
https://www.jfsm.or.jp/scheme/documents/index.php

FSM 13.2 Supplier Performance

● Requirements

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

●Thinking, specific examples

1. The concept behind FSM13.2

1) This requirement mandates that organizations establish and implement procedures for managing suppliers of raw materials, packaging materials, and services that may affect food safety, based on risk assessments.

2) In the event of receiving supplies from an unapproved supplier in an emergency, this is merely an emergency measure and is based on the premise that raw materials, packaging materials, and services will be purchased from approved suppliers.

3) The management required of an organization is to establish and implement procedures for evaluating, approving, and monitoring suppliers.

2. Evaluation of Suppliers

After appointing an evaluation officer, collect the necessary information and conduct the evaluation, referring to the following methods and content.

1) Evaluation Method

(1) Oral interview

(2) Verification of documents and records

(3) Visit and conduct on-site verification or audit

2) Evaluation content

(1) Information on supplier organizations: organizational reliability, product supply capacity, manufacturing site operation status, quality assurance system, supplier evaluation results (records related to second-party audits, third-party certifications, etc.), compliance, traceability

(2) Information regarding delivery methods: delivery date, delivery location, delivery conditions (temperature, humidity, special environment), etc.

(3) Whether or not there have been cases of food fraud at the source/supplier of raw materials.

(4) Presence or absence of conditions that make fraud likely (the price of the supplier being used becomes extremely low compared to the market price, raw material prices soar, supply becomes tight, there are frequent instances of earlier shipping times, a sudden increase in order volume, production system with insufficient personnel)

3) Qualifications and abilities of the evaluator

(1) The person responsible for evaluating suppliers must have knowledge of the matters described in the specifications and applicable laws and regulations, and must be an audit trainee.

3. Approval from suppliers

1) The organization shall designate a person to approve suppliers based on the evaluation results. Furthermore, it shall define the rules and processes for approval by the approver, as well as the procedures for sharing information with the HACCP team.

2) Establish rules (methods, frequency, timing, etc.) for the periodic re-evaluation of suppliers as a procedure. Monitoring will also include follow-up activities, such as suspending business with a supplier or providing guidance to the supplier if problems are found based on the results of a series of evaluations of the supplier.

3) Although this requirement refers to the supplier's food defense, it does not require the supplier to comply with FSM 7 (Food Defense) to the same level as this standard. Rather, it allows the supplier to define the scope of applicability and to commence food defense efforts to the extent that they have done so.

4) In response to emergencies (such as natural disasters), it is expected that quick decisions will be necessary when evaluating unapproved suppliers. While this standard does not allow the

omission of points that are normally used to evaluate suppliers, it is permissible to shorten the verification period if an equivalent method is recognized.

5) In addition, this includes maintaining objective evidence that products using raw materials, packaging materials, and services purchased from unauthorized suppliers are equivalent to regular products when the products are shipped (released).

4. Relationship with food fraud

1) "Food fraud" refers to intentional acts carried out primarily for economic reasons, such as falsification aimed at cost reduction or misleading consumers into believing the product is of high quality. Examples of such acts against suppliers include concealment, false labeling, use of unauthorized means, and falsification of the origin or specifications of purchased goods. Regarding whether these considerations are necessary for our suppliers, we believe the following:

(1) Confirm past or current cases of fraud in the supply chain by referring to information from industry associations, government sources, private information centers, etc.

(2) If a potential misrepresentation is considered to have a high impact on food safety, measures will be taken to reduce the risk or to enable early detection of the misrepresentation. The following are some examples of possible methods.

① When conducting a second-party audit, falsification should also be included in the scope of the audit.

② Request suppliers to monitor the supply chain.

③ Change suppliers to those with no prior history of falsification.

④ Consider whether the supplier is capable of handling situations where fraud is likely to occur.

Example: The price of the supplier being used becomes extremely low compared to the market price.

Raw material prices are soaring, and supply is becoming tight.

Frequent earlier shipping times

A sudden surge in order volume occurs.

There are concerns about the production system when there is a shortage of personnel.

⑤ Take the possibility of fabricated vulnerabilities into account when determining the frequency of analysis/testing.

⑥ Check the financial status of the supplier.

2) When considering incorporating the concept of preventing food fraud, the following materials may be helpful.

• JFSM "Handbook for Supporting the Implementation of Food Fraud Prevention"
https://www.jfsm.or.jp/scheme/documents/index.php

FSM 14 Traceability

● Requirements

The organization shall establish procedures for implementing and maintaining traceability, covering all processes from the supplier (at least one step before) to the recipient (at least one step after) to ensure product identification.
The organization shall verify such procedures at least annually through trace testing to ensure that they are functioning effectively. The verification results shall also be recorded.

●Thinking, specific examples

1. The concept of traceability

1) Traceability records are important for verifying the manufacturing process of the product in question and ensuring the safety of the food product in the event of a serious product accident.
2) In these requirements, "recipient" 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 products.
3) Shipped products are not always delivered to the purchaser; they may be delivered to a warehouse or other location designated by the purchaser. Therefore, this requirement dictates that the owner of the product and the "recipient" where the product is actually located be identified in order to enable a speedy response in the event of a problem. Raw materials, packaging materials, services, and outsourced processes (hereinafter referred to as "raw materials, etc.") purchased from external sources should also be traceable up to one step prior.
4) Each organization is required to reliably identify the recipient (at least one step prior) from the supplier (at least one step later). Connecting these organizations will enable traceability of the entire supply chain.

2. Development of record information necessary for traceability

1) Establish traceability procedures depending on the product (including labeling that identifies raw materials and products, and external procurement).
2) Identify the condition of raw materials, etc., at the main product stage (including primary processed products).
3) Determine the lot size for products and raw materials as necessary.
4) Establish and implement procedures for creating and preserving records of incoming and outgoing goods.
5) Confirm that traceability is functioning, including for work-in-progress, refurbished goods, and reworked goods.
6) Store product samples for each lot as needed.

3. Provision of traceability records

1) Establish and implement procedures for creating and preserving records.
2) If requested by the government, we will submit records related to traceability.

4. Verification by trace testing

1) The organization shall verify the procedure at least once a year through trace testing and make corrections if any concerns about its functionality are found. The following considerations are useful for conducting effective testing:
   (1) The products to be tested for trace testing should be intentionally selected from products that have previously shown problems, new products, or other items where concerns are anticipated.
   (2) Do not select the same product(s) every time without reason, and change the test subjects as appropriate.
   (3) Trace tests should not be conducted by the person in charge alone, but by multiple people, and the results should be discussed.
   (4) Determine the scheduled time from the start to the completion of the trace test, and determine whether it is being carried out appropriately.
2) If the trace test cannot be completed, identify the cause and revise the procedure. Even if the trace test is completed successfully, the following considerations are useful to determine whether it is functioning effectively.
   (1) Were there any records or other information that were not known to anyone other than the specific individual?
   (2) Is it taking too long from start to finish?
   (3) Were there any records or documents located in a place different from what was expected?
   (4) If the records are password protected or otherwise only accessible to a specific individual, how will this be handled if that individual is absent?

FSM 16 Allergen Management

● Requirements

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

●Thinking, specific examples

1. Allergens that need to be managed

1) Substances that cause allergies are called allergens. Globally, the eight main types of allergens are grains containing gluten, shellfish, eggs, fish, milk, peanuts, soybeans, and tree nuts. Organizations need to consider consumer allergen-related incidents.

*Reference case in Japan

Source: Consumer Affairs Agency website

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

(Please check the website for the latest version.)

This standard requires consideration of consumer incidents caused by food allergens. Allergens that need to be controlled within all manufacturing facilities must be identified, a plan must be developed, implemented, and properly maintained.

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

(2) Separate the receiving and storage locations for different allergens.

(3) Identify the allergens to be managed in accordance with the production plan and make them verifiable for each production line.

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

(5) Identify areas within the manufacturing facility where allergen powders may be dispersed and implement measures to prevent dispersion.

(6) Consider switching lines that cannot be cleaned using water.

Examples: Powders, oils and fats products (chocolate, spreads, etc.)

(7) Manage the labeling and use of allergens in recycled products and work-in-progress products.

(8) Consider measures to prevent mislabeling.

(9) Take measures to ensure compliance with the laws and regulations (allergen labeling regulations) of the country of sale.

2. Control procedures to reduce or eliminate the risk of cross-contact

1) Specific examples of management procedures include the following:

(1) Containers and utensils used in production (plastic bags, scoops, etc.) should be identified for each allergen being managed, and mixed use should be avoided.

(2) Establish handling procedures for raw materials (including containers and packaging materials), semi-finished products, work in progress, reworked products, and finished products to prevent cross-contact of allergens at all stages from manufacturing to shipment.

(3) Determine the cleaning, washing, and verification methods for the manufacturing process to prevent cross-contact.

(4) When manufacturing different products on the same production line, plan production to start with products containing fewer allergens and then increase in the number of allergens, if possible.

2) When developing products containing allergens, the appropriateness of control measures should be confirmed through line testing, etc.

3) When creating product labels, allergens must be displayed in accordance with the laws and regulations (allergen labeling regulations) of the country where the product is expected to be sold.

4) If verification (analysis, etc.) is required, establish and implement the procedures, record the verification results, and store them.

5) See also FSM 13.1 (Purchasing), 13.2 (Supplier Control), FSM 18 (Product Labeling), and GMP 3, 4, 5, 17 (Requirements related to contamination in manufacturing processes, etc.).

6) Depending on the magnitude of the risk, consider management under GMP4.

FSM 17 Control of Measuring and Monitoring Devices

● Requirements

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

●Thinking, specific examples

1. Selection of target equipment, accuracy verification and calibration, and recording.

1) Select equipment and devices to be used for measurement and monitoring activities to ensure food safety.

The list also includes scales for weighing food additives (such as potassium sorbate and nitrites) for which usage standards are set under the Food Sanitation Act.

(For details on usage standards, please refer to "Standards and Specifications for Foods, Food Additives, etc. (Ministry of Health and Welfare Notification No. 370, December 28, 1959)," etc.)

2) Periodic accuracy checks and calibrations are necessary to ensure that measurements are performed appropriately using the equipment and instruments.
Therefore, an acceptable error range (for example, ±2°C, ±5 seconds, etc.) is set for each device.
Furthermore, the calibration frequency should be determined by considering a period that does not exceed the acceptable range, taking into account the schedule recommended by the equipment manufacturer.
To ensure thorough implementation, consider a schedule that allows for easy repetition on specific dates, such as once a week, month, or year, while maintaining the minimum necessary frequency. If setting a frequency of once every few months or once every few years, it is advisable to incorporate it into your annual schedule or take other measures to avoid missing the scheduled event.

3) Create a list of all devices and equipment used for measurement and monitoring. The list should clearly indicate the acceptable error range, accuracy control, calibration, and maintenance frequency for each device.

4) Conduct accuracy checks thoroughly and record them. A logbook may be used for recording.

5) Measurement and monitoring equipment, testing equipment, and inspection equipment that have undergone accuracy checks and calibration must be managed to prevent damage or adjustment errors.

6) If it becomes clear that measuring/monitoring equipment, testing equipment, or inspection equipment is not appropriate (has errors exceeding the permissible range), a record (including a logbook) shall be kept, posted at the site, and marked on the equipment itself .
The procedure for evaluating potentially affected products and taking appropriate action will be defined.

2. Methods for periodic accuracy checks and calibration

1) Establish a method to check the accuracy at a set frequency and confirm that it is within the acceptable error range. One example is as follows:
(1) Check if the timer matches the time signal using a telephone or other means.
(2) For thermometers, it is recommended to refer to the " Guidelines for Hygiene Management Incorporating the Concept of HACCP (For Small-Scale General Restaurant Businesses), Revised January 2024" (published on the Ministry of Health, Labour and Welfare website), etc.

3) Calibration should be performed using methods recommended by the equipment manufacturer, including national and international standards, or other equivalent standards, or by reasonably accepted traceable methods.

3 . Reference materials

If you are considering incorporating methods to enhance authenticity through analysis, such as preventing tampering with verification records, the following materials may be helpful.

• JFSM "Handbook for Supporting the Implementation of Food Fraud Prevention"
https://www.jfsm.or.jp/scheme/documents/index.php

FSM 18 Product labeling

● Requirements

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

●Thinking, specific examples

1. Confirmation of information and setting of information provision methods.

1) Information required by law (allergens, food additives, etc.) shall be provided in accordance with the methods and procedures of the law. The following are some points to be considered regarding food safety when labeling products:
   (1) Clearly define the users and target consumers, such as the sales destinations.
   (2) Clearly define the specific eating conditions for products such as those intended for raw consumption or cooking.
   (3) The intended use of raw materials, seasonings, etc. shall be clearly stated.
   (4) Clearly define the basis for setting the expiration date and best-before date.
   (5) Clearly define the handling temperature and method.
2) Information necessary for the product shall be printed or attached to the packaging material in accordance with the product specifications.
3) Establish procedures to verify that the displayed information is correct.
4) Establish procedures to prevent mistaking the product for the packaging materials, etc.

2. Reference materials

The following resources may be helpful when considering incorporating measures to prevent food fraud, such as preventing tampering with labeling.

• JFSM "Handbook for Supporting the Implementation of Food Fraud Prevention"
https://www.jfsm.or.jp/scheme/documents/index.php

FSM 19 Analysis and Inspection

● Requirements

The organization shall conduct appropriate analyses and inspections where necessary to ensure food safety.
Such analyses and inspections shall be performed by a competent laboratory or by personnel with the necessary competence.

●Thinking, specific examples

1. Setting up the test

1) In order to ensure food safety, it is necessary to plan inspections so that products, semi-finished products, raw materials, and environmental swab samples are systematically tested for factors that affect food safety, legal requirements, and customer product requirements.

2) It is desirable that a competent testing department or analytical laboratory conducts testing using procedures and validated methods that conform to ISO 17025 to ensure that the results of this testing method are valid. The test results should be reviewed periodically.

3) Documents outlining procedures (methods, standards, etc.) for raw material acceptance inspections and inspections of manufacturing processes and products are required.

2. Relationship with food fraud

1) "Food fraud" refers to intentional acts carried out primarily for economic reasons, such as falsification aimed at cost reduction or misleading consumers into believing a product is of high quality. Examples include dilution, substitution, concealment, false labeling, enhancement of function through unauthorized means, and forgery.

It would also be beneficial to consider a system that can detect these occurrences through testing. Whether or not such a system is necessary will be examined as follows.

(1) Confirm past or current cases of fraud in the supply chain by referring to information from industry associations, government sources, private information centers, etc.

(2) In cases where potential misrepresentation is considered to have a high impact on food safety, we will consider opportunities for detection through inspections, establish a system for communication and investigation in the event of deviations from inspection results, and make the importance of this clear to all relevant parties.

(3) If it is difficult to make a judgment with the current inspections, we will consider additional inspections that can confirm the effects of the falsification, as needed.

2) Food fraud also includes "falsification of records and labeling of products." It is desirable to consider a system in place to ensure that inspection results are properly recorded and accessible, including measures related to FSM9 3.4) .

When considering incorporating measures to prevent food fraud, such as preventing the falsification of inspection results , the following materials may be helpful.

• JFSM "Handbook for Supporting the Implementation of Food Fraud Prevention"
https://www.jfsm.or.jp/scheme/documents/index.php

[Reference] Examples of inspection contents and records as defined in the inspection management regulations

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	O	O	O	O	O		O						O						Receiving Control Chart
	Raw materials	O	O	O	O	O	O	O						O						
In-house Acceptance Inspection	Raw materials	O	O	O	O	O	O	O						O						
In-process inspection	Semi-finished products		O	O					O	O	O									In-process inspection list
Final Inspection	Finished product		O	O	O	O		O				O	O	O	O					Final Inspection Chart
Outgoing Inspection	Finished Products		O	O	O	O										O	O	O	O	Shipping Instructions and Shipping Inspection Chart

FSM 21 Complaint Handling

● Requirements

The organization shall establish, implement, and maintain a system that utilizes complaints and related data received from business partners and consumers to identify and address deficiencies in food safety activities.

●Thinking, specific examples

1. Establishment of a system for managing complaints and their data.

1.) It is necessary to distinguish between events related to food safety and other events, such as those related to quality. This item requires that events be related to food safety.

2) Creating a system to properly understand and respond to complaints from business partners and consumers is key to resolving complaints quickly.

3) The following steps can be considered when creating a system for handling complaints:

(1) Develop a manual outlining how to handle complaints from business partners and consumers.

(2) Employees shall recognize their responsibility for handling and investigating complaints from business partners and consumers.

(3) When dealing with complaints from business partners or consumers, we will try to understand as accurately as possible what the complainant wants. If the complainant wants an investigation into the cause of the complaint (including estimations), a response regarding the product in question, and measures to prevent recurrence, we will inform them that we will provide the information appropriately. At that time, we will also provide an estimated date for the response, if necessary.

If the investigation reveals that the cause of the complaint lies not with the organization, the complainant will be notified of this as soon as possible. If the complaint appears to be unfounded or motivated by financial gain, a different course of action will be considered.

(4) Regarding complaints from business partners and consumers, the content of the investigation and response described in (3) will be provided to the complainant, and the details will be recorded.

(5) Investigate the cause of the complaint and its relationship to the GMP and HACCP systems, identify any gaps or omissions in the food hygiene system, correct them if necessary, and record the results.

(6) The person in charge will confirm that complaints from business partners and consumers have been resolved.

4) If non-conformities are discovered based on reports from business partners or consumers, corrective actions will be taken.

5) Establish, implement, and maintain a system for continuously improving and managing the food hygiene system by utilizing complaints and data from business partners and consumers.

2. Reference materials

Disseminating information and providing education regarding complaints and how to handle them is considered to contribute to fostering a food safety culture. Therefore, the following materials may be helpful when considering these matters.

• JFSM "Handbook for Supporting the Introduction of a Food Safety Culture"
https://www.jfsm.or.jp/scheme/documents/index.php

FSM 22 Serious Incident Management

● **Requirements**

The organization shall document a 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. 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.

●Thinking, specific examples

1. Subject to serious accidents

1) A serious incident refers to a food incident that may affect food safety, and examples include the following. Note that this does not include cases that do not affect food safety but may affect quality.

(1) Compulsory recall or voluntary recall due to food safety issues
(2) Administrative action such as administrative guidance or business suspension order on the grounds of food safety issues
(3) When food safety is affected by natural disasters or fires, etc.

2) The impact on food safety is often unknown at the time of the incident. When an accident occurs, it is desirable to act based on the worst-case scenario.

3) In the event of an incident that has a significant impact on food safety, a report will be submitted to the auditing company after the initial response has been completed.

In addition, in the case of a voluntary recall, the Ministry of Health, Labour and Welfare must be notified through the relevant public health center at the time the recall begins.

Verification of mandatory recall or voluntary recall procedures

1) The following procedures will be established for responding to food accidents, including accident reporting, product removal, and product recall.

2) In the event of a serious accident, the response will be based on the relevant management procedures, such as those for handling non-conformities and complaints.

3) Appoint a person in charge with the authority to manage serious accidents.

4) Establish and maintain an up-to-date emergency contact network for customers, consumers, and relevant government agencies.

5) Appoint a person responsible for providing information to customers, consumers, and relevant government agencies, and ensure effective communication.

6) Clearly define the internal communication mechanism, such as the notification system to employees.

7) To evaluate the ability to respond to serious accidents, simulated training and reviews will be conducted at least once a year based on the accident response manual.

8) Record and evaluate the accident in order to prove its seriousness and whether it poses a risk to customers.

The accident record must include the following:

(1) Related products and manufacturing locations
(2) Quantity of affected products
(3) Scope of affected products (lot, batch, etc.)
(4) Records of production
(5) Quantity and location of shipments

3. Response to natural disasters or fires, etc.

1) In the event of a natural disaster or fire, etc., there is a possibility that raw materials, work-in-progress, products, etc. present at the site may be affected in terms of food safety. After the initial response to the disaster, etc., if there is a possibility that raw materials, work-in-progress, products, etc. present in the affected area may be affected, isolation or identification will be carried out as necessary.

2) When the site is restored and production resumes, it is important to properly check whether there have been any impacts from the accident or the restoration work. Examples include the following:
(1) Deterioration of raw materials and work-in-progress due to accidents
(2) Contamination of raw materials and work-in-progress products due to accidents, and inclusion of foreign matter.
(3) Contamination and foreign matter contamination due to restored equipment
(4) Contamination and foreign matter from the surrounding environment (walls, ceilings, etc.)
3) It is desirable to keep records of the post-restoration verification process, if necessary.

FSM 23 Product Release

● **Requirements**

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

●Thinking, specific examples

1. Product Release Procedure
1) Verify that the products to be shipped conform to the product specifications.
2) Confirm that not only the product specifications but also the process control is properly implemented .

2. Examples of things to check before release
1) The release procedure is up-to-date and available to users.
2) The specifications for raw materials, ingredients, additives, packaging materials, recycled products, refurbished products, and the final product are clearly defined.
3) The person who makes the final decision on shipment is clearly defined.
4) Procedures are in place to confirm that the products to be shipped conform to the product specifications and that process control has been properly implemented.

FSM 24 Control of Non-conforming products

● Requirements

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

●Thinking, specific examples

1. Identifying non-conforming products and establishing management rules.

1) Raw materials (including containers and packaging materials), semi-finished products, work-in-progress products, recycled products, reworked products, and final products that have safety issues will be treated as non-conforming.

2) Appoint a person in charge, implement management procedures, and ensure that non-compliant items are not used unintentionally or shipped incorrectly.

3) In order to detect non-conformities at each stage of the process, it is effective to clearly define the manufacturing procedures and inspection procedures in advance.

4) Any non-conforming products found should be clearly identified and isolated to prevent them from being used by mistake.

Furthermore, when identifying the scope of non-conforming products, appropriate judgment will be made to ensure that non-conforming products are not mixed in with compliant products.

5) Non-conforming products shall be discarded or modified (reworked, reworked, etc.).

6) If recurrence prevention is necessary, corrective actions will be taken according to FSM25.

2. Approach to Appropriate Implementation

1) Non-conformities may be discovered not only through manufacturing and inspection procedures, but also through customer complaints, etc.

2) These requirements serve to act as checkpoints at each intermediate stage leading to the final product, stopping any non-conformities.

3) If the discovery of nonconformities is perceived as a bad thing, reports will be less likely to be submitted from the field. Therefore, it is important to recognize that process control is in place to detect nonconformities. The following materials may be helpful when considering these points.

• JFSM "Handbook for Supporting the Introduction of a Food Safety Culture"
https://www.jfsm.or.jp/scheme/documents/index.php

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.)

●Thinking, specific examples

1. Determination of corrective action procedures

1) Corrective actions shall be planned and implemented by a person with the competence to conduct root cause analysis and develop countermeasures, so as quickly and reliably as possible eliminate the causes of any non-conformities that affect food safety and to establish procedures to prevent recurrence.

2) It is desirable to record the series of actions taken in relation to corrective measures.

2. Flowchart for Corrective Actions

1) Understand the actual situation of non-conformities (including customer complaints).

2) Identify the cause of the nonconformity.

3) Take necessary measures to prevent the non-conformity from recurring.

4) Review the effectiveness of the corrective actions taken.

Ⅱ Hazard Analysis and Critical Control Point (HACCP)

Hazard control (control of harmful 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 (HACCP) System ,2020 (English edition).

HACCP Step 1 HACCP team assembly and identification of the scope of application

●Requirements

The organization shall assemble the HACCP team with competent staff, and the scope of application of the HACCP system shall be identified.

●Thinking, specific examples

1. Identifying the scope of application of the HACCP system

1) The organization identifies the scope of the HACCP system. Within that scope, it identifies which products and processes will be covered by the HACCP plan.
2) Identify the knowledge and expertise required for the HACCP system in question and reflect this in the formation of the HACCP team.

2. Formation of the HACCP team

1) By forming a team with individuals possessing a variety of specialized skills, to the extent possible, blind spots in hazard analysis can be eliminated, and communication can be facilitated.
(1) Manufacturing and processing department
(2) Quality Assurance and Quality Control Departments
(3) Personnel in the engineering department responsible for the maintenance of machinery and equipment used in facilities, construction, and manufacturing.
etc.

2) The HACCP team is responsible for managing food safety initiatives within the organization.
3) The HACCP team identifies the scope of the HACCP system and appropriate GMP. Within that scope, they identify which products and processes will be covered by the HACCP plan.

3. HACCP Team Leader (Food Safety Officer)

1) The ideal candidate is a food hygiene manager or food hygiene supervisor who possesses product knowledge and specialized skills, as well as knowledge of product characteristics and processes, and who has strong communication skills and can synthesize opinions within the company.
2) When the food safety officer and the HACCP team leader are different personnel, it is necessary to ensure that they coordinate effectively.
3) Depending on the size of the business, employees often handle multiple tasks, and therefore the manager may act as the team leader, or one person may be responsible for all aspects of food safety. However, it is important to strive to ensure cooperation from employees within the company to the extent possible.
4) If there is a lack of knowledge or expertise within the organization, it is effective to take external training courses or to obtain the participation and advice of external food hygiene experts. It is also possible to refer to the industry association guidelines issued by the Ministry of Health, Labour and Welfare.

HACCP Step 2 Product Information Description

●Requirements

The organization shall document product specifications. The document shall describe all product information necessary to conduct hazard analysis. It is desirable to formulate HACCP plans for each product or product group, and for each process line or process location.

●Thinking, specific examples

1. Confirm and clarify product information.

1) For the final product, describe the specifications and characteristics as follows, divided into necessary items.
   (1) Name and type of product
   (2) Product characteristics
   (3) Name of raw materials
   (4) Names and usage standards of additives
   (5) Packaging form
   (6) Units and Quantities

(7) Materials of containers and packaging
(8) Expiration date or best-before date and storage method
(9) Internal targets for hazard management in products (including standards specified by the customer, and component standards for bacteria as defined by the Food Sanitation Act)

2) In facilities that manufacture multiple products, it may be effective to treat foods that share similar characteristics and processing steps as a single HACCP plan for the purpose of creating a HACCP plan, where the hazards related to the target products (groups) are the same in the HACCP plan for controlling them based on the 12 steps and 7 principles of HACCP.
3) If the product contains allergens or if cross-exposure of allergens is possible within the facility, this should also be noted.
4) Identify the scope of application of the HACCP system and appropriate GMP (PRP in Codex).

HACCP Step 3 Identification of Intended Use

●Requirements

The organization shall clearly describe intended use of the product and target users (consumers) in a written document.

●Thinking, specific examples

1. Description of the product's intended use (method of use) and target consumers.

1) Clearly define the method of consumption or use, and the target users (consumers). Pay particular attention to the content when dealing with groups that are highly susceptible to food poisoning microorganisms (vulnerable individuals, infants, the elderly, etc.).
2) If the product requires heating or has any precautions to take after opening, describe the necessary information.
3) In the case of food products intended for highly susceptible populations, strengthening process control, increasing monitoring frequency, verifying the effectiveness of controls through product testing, or other activities may be necessary to ensure a high level of food safety.

HACCP Step 4 Construction of Flow Diagram

●Requirements

The organization shall construct the flow diagram that covers all steps in the operation.

●Thinking, specific examples

1. Overview of Flow Diagrams

1) Create a flow diagram that shows the work content of each step in the entire manufacturing and processing process, from receiving raw materials to shipping the final product, following the flow of the process.

2) The same flow diagram can be used for product groups manufactured using similar processing steps.

3) Flow diagrams are used as a basis for evaluating the likelihood of hazards occurring, increasing, decreasing, or being introduced when conducting hazard analysis.

4) Flow diagrams should be accurate and detailed enough to conduct a hazard analysis.

2. Steps for creating a flow diagram

1) Briefly list all processes and operations from the acceptance of raw materials to the shipment of the final product.

2) Enclose the listed raw materials and processes in boxes, connect the boxes with arrows, and number them in order of process.

Regarding raw materials, include food additives, packaging containers, water used, and gas (if used) , and list them in the same category within a frame, connecting them with arrows to the process in which they are used.

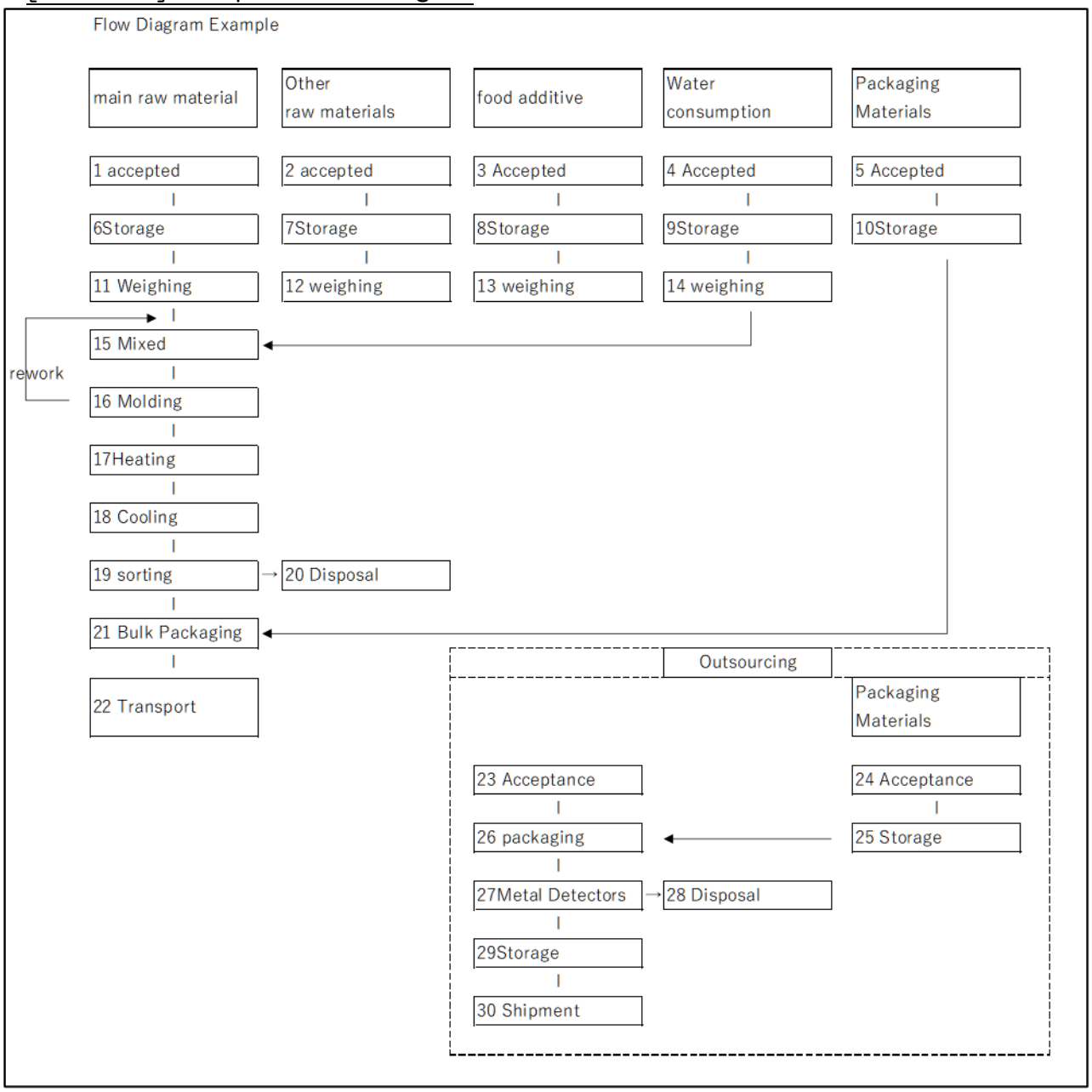
3) When raw material processing, any waste generated or used as processing material for other products must be clearly indicated.

4) Clearly specify how to manage any processes that involve pass/fail judgments, rework, reuse, or rework.

5) Clearly state any processes that are outsourced.

6) Creating facility drawings that show the outline of the process and the planar and three-dimensional layout within the facility will help identify key points in the process and areas where cross-contamination is possible, thus aiding in hazard analysis.

[Reference] Example of a flow diagram



HACCP Step 5 On-site Confirmation of Flow Diagram

●Requirements

The organization shall verify the flow diagram correctly reflects the existing process steps of the operation.

●Thinking, specific examples

1. Verification of the flow diagram against the actual site

1) Ensure that the process is clearly defined in a flow diagram so that hazard analysis can be performed according to HACCP Steps 6 and 7.
A person with sufficient knowledge of the process will conduct on-site verification as follows: At that time, it is a good idea to check on-site while comparing it with the site layout diagram.

2) On-site, the process should be checked sequentially from the upstream processes, and it should be confirmed that the appropriate processes are being demonstrated, including temporary storage and management of semi-finished products.

3) If the processes or activities at the site are inconsistent with the flow diagram, confirm the correct management method with the person in charge and revise the document.

4) The verification process involves observing the workflow during various work periods and confirming that the flow diagram matches the actual work.

HACCP Step 6 (Principle 1) Hazard Analysis

●Requirements

The organization shall identify and list potential hazards at each process step, determine which hazards are significant, and consider appropriate control measures for those hazards. Hazards shall include allergens where required.

●Thinking, specific examples

1. The Concept of Hazard Analysis

1) Hazard analysis involves determining the critical hazards that should be managed under the HACCP plan, and clarifying the methods for controlling each critical hazard. To this end, information is first collected on potential hazards and their conditions throughout the entire process, from raw materials to manufacturing, processing, storage, distribution, and consumption, in order to understand the likelihood of each hazard occurring and the severity if it does occur.

2) By conducting a hazard analysis, it is possible to create an appropriate management system for the facility that corresponds to the frequency and severity of potential hazards.

3) In creating the system, all members of the HACCP team must contribute their expertise and discuss and compile it together.

2. Methods for analyzing hazards

1) First, list the potential hazards in the final product that could lead to health problems when consumed, for each raw material and process.

2) Identify raw materials and processes that may lead to the occurrence of hazards by following the flow diagram from raw materials to the final product. Narrow down the important hazards in terms of the frequency and severity of occurrence of hazards in each process, and create a hazard analysis sheet that lists the causes of occurrence (contamination, growth, survival, mixing, etc.) and the control measures to control them.

The steps for creating a hazard analysis sheet are explained in accordance with the "Example of a Hazard Analysis Worksheet" shown in the General Principles for Food Hygiene CXC 1-1969, Rev. 2022 of the International Food Standards Committee (CODEX).

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 the "Example of Hazard Analysis Worksheet")

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

The main raw materials, auxiliary raw materials, water used, and packaging materials, along with the manufacturing and processing steps, should be numbered according to the flow diagram. Hazard analysis should be conducted for all raw materials used in food products. There are two methods for this:

① Method for conducting hazard analysis related to raw materials in the raw material receiving process.

② Method of conducting separate hazard analyses for raw materials and processes.

This guideline describes the process using method ①.

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

1) List the potential hazards arising from the raw materials and manufacturing processes.

2) Hazards should be described specifically. For example, instead of just "food poisoning bacteria," list "Salmonella," "pathogenic E. coli O-157," etc. Also, instead of just "metal fragments," describe the source of contamination and the reason for their presence, such as "contamination with metal foreign matter originating from a blade broken during crushing" or "fragments of a kitchen knife."

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

1) Based on the likelihood of each listed hazard occurring and the severity of the damage if it occurs, assess whether or not these hazards are significant hazards that must be reduced/eliminated from the food to guarantee the safety of the final product.

2) When conducting a hazard analysis to determine important hazards, consider the following as much as possible:

(1) Hazards related to the type of food being manufactured and processed, including raw materials and processes (e.g., from investigations or sampling and testing of hazards in the food chain, recalls, scientific literature information or epidemiological data)

(2) The likelihood of hazards occurring without additional controls, taking GMP (PRP) into consideration.

(3) Frequency and severity of adverse health effects caused by hazards in food in the absence of controls.

(4) The acceptable levels of identified hazards in food (e.g., based on regulations, intended use and scientific information)

(5) The nature of the facilities and machinery used to manufacture food products.

(6) Survival or proliferation of pathogens

(7) Generation or persistence of toxins (e.g., mycotoxins), chemicals (e.g., pesticides, veterinary drugs, allergens), or physical hazards (e.g., glass, metals) in food.

(8) The possibility that the food may become unsafe due to its intended use and/or mishandling by consumers.

(9) Conditions leading to the above

3) For the evaluation of hazards in Step 3, it is recommended to use a matrix table that combines "severity at the time of occurrence" and "frequency of occurrence," and to enter the numbers into the hazard analysis sheet. There are various examples of matrix tables, and it is best to adopt one that takes into account the target product, manufacturing process, etc. However, this does not apply if the evaluation can be clearly done with "YES/NO".

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

			Severity of Results				
			a	b	c	d	e
			Not	Complaint	Recall	Serious	Lethal
frequency of occurrence	E	Often Occurs	**15**	**19**	**22**	**24**	**25**
	D	Occasionally Occurs	10	**14**	**18**	**21**	**23**
	C	Has occurred at other companies	6	9	**13**	**17**	**20**
	B	No information in other companies	3	5	8	**12**	**16**
	A	Unthinkable	1	2	4	7	11

How to read the matrix

20~25	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.
12~19	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).It is highly likely that it will be managed under GMP4.
1~11	The current means of management is adequate to manage the situation.

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

1) In this step, for important hazards marked with ○ (or Yes) in Step 3 ((3) of the "Example of Hazard Analysis Worksheet"), identify the cause of its occurrence and write the reasoning behind it in column (4). Also, for hazards marked with × or No in column (3), write the reasoning behind it.

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

1) For hazards identified as important, identify control measures to ensure the safety of the final product. Below are examples of hazard assessment (Step 3) and hazard analysis sheets.

(1) Consider which control measures to apply to each critical hazard. Multiple control measures may be necessary to control one critical hazard. For example, to control Listeria monocytogenes, heat treatment to kill live bacteria in food may be necessary, and further cleaning and disinfection of the environment may be necessary to prevent contamination from the processing environment after heating.

(2) In some cases, multiple hazards can be controlled by specific control measures. For example, if Salmonella and E. coli O-157 are present in food, heat treatment can control both hazards.

2) For hazard analysis sheets for other items, please refer to the examples posted on the Ministry of Health, Labour and Welfare website.

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000098735.html

[Reference] Example of a 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.			
	Pathogenic Escherichia coli	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.	
	Staphylococcus aureus			
	Heat-resistant spore bacteria			
	Clostridium botulinum			
	Welch bacillus	NO	Contamination is possible due to unsanitary handling during manufacturing and processing, but the bacteria are anaerobic and cannot grow during storage.	
	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)	

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

●Requirements

The organization shall determine Critical Control Points (CCPs) .

●Thinking, specific examples

1. What is a Critical Control Point (CCP)?

1) A critical control point (CCP) (hereinafter referred to as CCP) is a stage in the production of a food product where control is essential to reduce or eliminate significant hazards from the food to an acceptable level, and where deviations could lead to potentially unsafe food products, and where there are procedures or operations that require particularly strict control.

2) For each hazard identified as a significant hazard as a result of the hazard analysis, at least one control measure must be established to control that hazard.

2. Examination of control measures

1) Consider control measures that could become Critical Control Points (CCPs) among the control measures for the significant hazards listed in Principle 1.

2) CCP requires setting acceptable limits as described later, conducting monitoring, and taking measures such as not shipping products manufactured during the period of deviation when deviations occur.

3) Controlling a single hazard may require multiple stages of CCP (Critical Control Points).

4) When determining a CCP, it is fundamental to establish procedures for each process and implement GMP management. Among these, the stage that directly has a negative impact on food, such as the stage related to "preventing introduction," "preventing contamination," "preventing multiplication," and "eliminating" food poisoning bacteria, which are hazards, becomes the "last line of defense" and is designated as the CCP.

5) Hazards that can be controlled by GMP are not designated as CCPs. However, if hazards cannot be fully controlled by GMP alone, the process in which those control measures are taken is designated as a CCP. If hazard control is possible throughout the entire process using GMP alone, there are no significant hazards, and therefore no CCP may be designated.

6) If control measures can be used in the process being analyzed, but can also be applied in later stages of the process, or if other control measures for the hazard exist in other processes, the process being analyzed should not be considered a CCP.

7) Determine whether the control measures for one process are used in combination with the control measures for another process to control the same hazard. In that case, both processes should be considered as CCPs (Critical Control Points).

8) If a stage that should be a CCP is managed by GMP, there is a risk that hazards will not be fully controlled. If a process that can be adequately controlled by GMP is made a CCP, it will result in wasted effort, and there is a risk that the control of other processes will be relatively weaker.

9) The requirements for a CCP are that it can be monitored continuously or at a reasonable frequency using a pre-defined monitoring method, that if the parameters deviate from the Critical Limit (CL), production can be stopped immediately, process control can be restored to its original state in a short time, and food products produced during the deviation can be identified and isolated.

8) The value of the monitoring parameter that marks the boundary between whether or not product safety can be ensured is called the tolerance limit (CL).

3. Method for determining CCPs – Application example of Decision Tree

(This is just one example of a CCP determination tool; the method for determining CCPs is not limited to the Decision Tree.)

1) The requirements for a CCP are that it can be monitored continuously or at a reasonable frequency using a pre-defined monitoring method, that if its parameters deviate from the Critical Limit (CL), production can be stopped immediately, process control can be restored to its original state in a short time, and food products produced during the deviation can be identified and isolated.

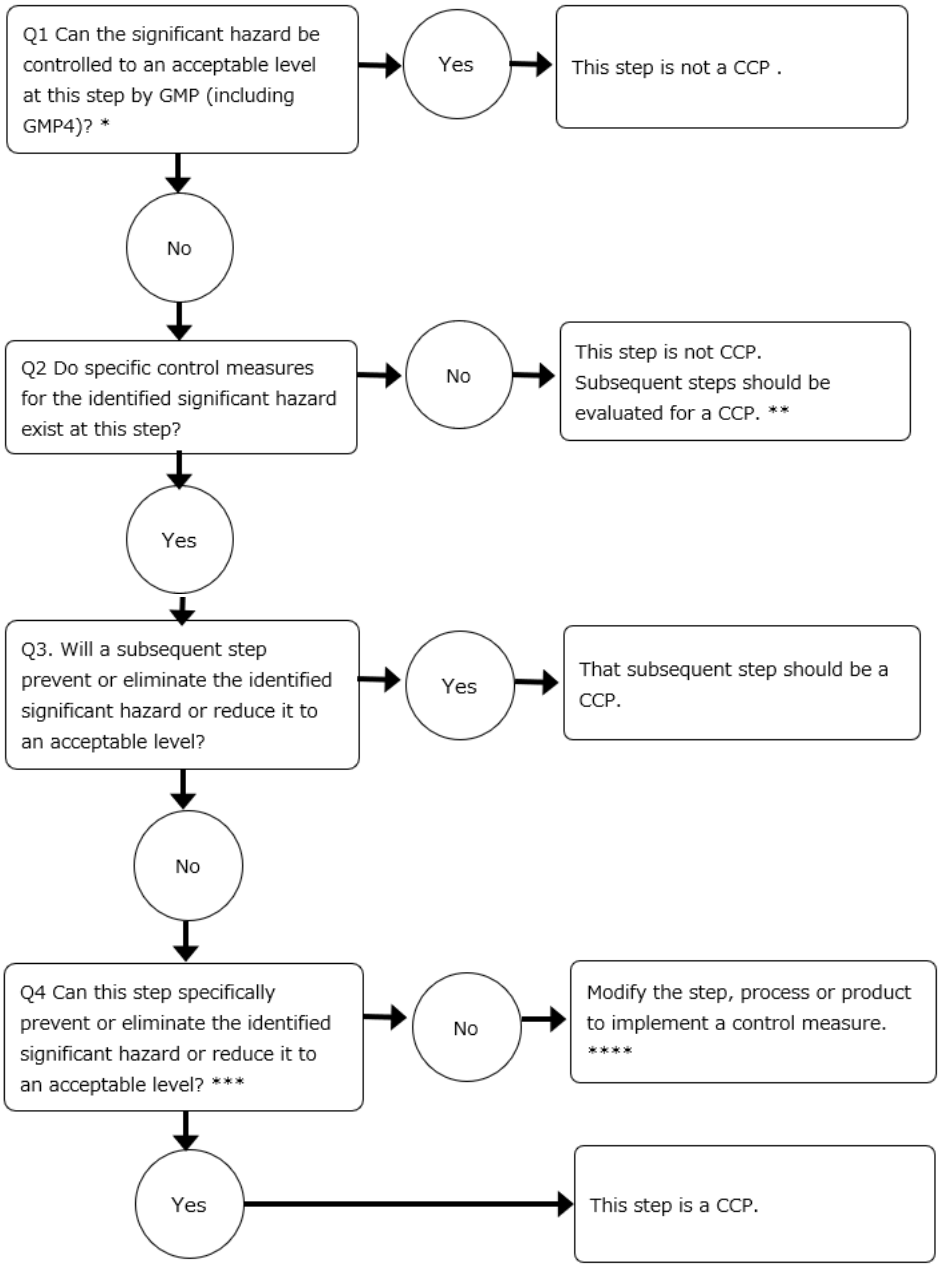
2) In the hazard analysis, only each process for which significant hazards have been identified is subject to the application of the Decision Tree.

3) Consider the importance of the hazard (i.e., the likelihood of its occurrence in the absence of control and the severity of the harm's impact), and whether it can be adequately controlled by GMP. GMP may be standard GMP or GMP requiring greater attention (monitoring, recording, etc.) to control the hazard (so-called GMP 4). (See diagram below, *)

4) If no CCPs are identified in Q2-4, review the processes and control measures again and conduct a hazard analysis again. (See diagram below, **)

5) Determine whether a process control measure for a critical hazard has been identified is used in combination with another process control measure to control the same hazard. In that case, both processes should be considered as CCPs. (See diagram below, ***)

6) If specific and special control measures are not in place, review the process and control methods again and conduct a hazard analysis. (See diagram below, ****)



(The above diagram is quoted from the General Principles of Food Hygiene CXC 1-1969, Rev. 2022 of the International Food Standards Committee (CODEX).)

4. Specific Examples of CCPs

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

(1) Raw material acceptance: Prevention of antimicrobial substance residue by checking test reports submitted by suppliers.

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

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

(4) Measurement of food additives: Prevention of excessive addition

2) Examples of CCPs that eliminate hazards are as follows:

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

(2) Metal detection: Detection using a detector and removal of metal fragments.

3) Examples of multiple CCPs that control a single hazard are as follows:
(1) To kill non-spore-forming pathogenic microorganisms in the hamburger, control the thickness of the patty and the heating time/temperature.
(2) The heating process can serve as a CCP to kill the vegetative cells of spore-forming pathogens, and the cooling process can also serve as a CCP to prevent spore germination and proliferation.
4) If no control measures exist at any stage for the identified significant hazards, the product or manufacturing process should be modified.

HACCP Step 8 (Principle 3) Establishment of Critical Limits

●Requirements

The organization shall establish Critical limit(s) for each CCP.

●Thinking, specific examples

1. The concept of the critical limit (hereinafter referred to as CL)

1) CL is a criterion that distinguishes whether a CCP is acceptable or not in terms of managing hazards.
2) CL should be measurable or observable.
3) CL may have one or more parameters.
4) If the CL is set incorrectly, it can lead to the occurrence of hazards, so it must be set correctly based on scientific data.
5) If the CL deviates, corrective action will be required.
6) CL must satisfy the following conditions:
(1) The parameter is the optimal value, supported by scientific evidence, for ensuring that the hazard is effectively prevented, eliminated, controlled, or reduced to an acceptable level.
(2) Criteria using parameters that can be judged in real time as much as possible. If it is found that the management status is not appropriate, corrective measures must be taken promptly, so it is desirable that the criteria be expressed using parameters that can be judged in real time.
7) CL is usually the minimum or maximum value of a very important parameter related to the control means, and may be measured values such as temperature, moisture content, time, pH, water activity (Aw), available chlorine, contact time, conveyor belt speed, viscosity, conductivity, flow rate, etc., or sensory indicators (color, gloss, smell, taste, viscosity, physical properties, bubbles, sound, etc.) or observations of pump settings.

2. CL settings

1) The scientific validity of CL should be confirmed by evidence that, when properly implemented, it can control hazards to an acceptable level.

2) If specified by laws or regulations, adopt a value that allows the target hazard to be controlled. In other cases, set the value based on literature data, experimental data for validation, etc.

3) Even when adopting numerical values indicated in manufacturing standards, etc., as CL, collecting evidence to confirm their applicability within the organization (product, manufacturing equipment, manufacturing process, etc.) also serves as a validity check.

4) In typical manufacturing process management, control is rarely based solely on CL (Customer Limit). It is more common to set an operational limit (OL) that allows for control before deviation from CL occurs, providing a margin of safety beyond the CL.

HACCP Step 9 (Principle 4) Monitoring System

●Requirements

The organization shall establish monitoring procedures for each CCP.

●Thinking, specific examples

1. Monitoring

1) Monitoring involves conducting observations, measurements, or tests based on the schedule set out in the HACCP plan, comparing them with CLs, to ensure that CCPs are properly controlled and to create accurate records that can be used during subsequent verification.

2) In the management of CCP, monitoring to ensure that no deviations from CL occur is called monitoring.

3) If the CL deviates, corrective action will be required.

4) Monitoring records will also be used when verifying the HACCP plan.

2. Monitoring Methods

1) The monitoring method must meet the following conditions:

(1) It must be continuous or occur at a considerable frequency.

(2) The method must provide results quickly (physical and chemical measurements are usually preferred over microbiological tests).

2) It is important to monitor that the control measures for hazards are applicable to all products. Monitoring should be continuous if possible, so that it is possible to monitor that the CL is met from the first to the last, or for the entire batch, and for all products (e.g., heating temperature and time).

However, some measurements cannot be monitored continuously (e.g., water activity, preservative concentration).

In such cases, the monitoring frequency must be sufficient to ensure compliance with the CL as much as possible and to minimize the amount of product affected by the deviation. When a deviation from the CL occurs, it is necessary to detect the deviation in a timely manner, minimize its impact as much as possible, and allow for easy corrective action, in order to isolate and evaluate the product.

3) If possible, process adjustments should be made when monitoring results suggest a tendency toward deviation at a CCP.

4) The five whos and who dictates the monitoring method are as follows:

(1) Theoretical basis (Why): Is there scientific validity in monitoring the management status of CCPs?

(2) What: Is the CCP within the acceptable range of the CL (does not deviate from the CL)?

(3) Where: Clearly identify the relevant process (CCP process).

(4) How: Is it a rapid and accurate physical, chemical, or sensory method of observation, measurement, or inspection?

Is there a frequency at which deviations are not missed, whether continuous or non-continuous?

(6) Who: Are the personnel who have received education and training on monitoring methods?

5) Simply recording measured values continuously is insufficient to control hazards. Someone other than the monitoring personnel must check the data appropriately and at a sufficient frequency.

6) When creating a HACCP plan, designate a monitoring officer. This officer must be able to take the appropriate steps themselves or be instructed to do so when monitoring indicates the need for corrective action.

7) The data obtained from monitoring will be evaluated by designated persons with the knowledge and authority to implement corrective actions.

8) All records and documents relating to CCP monitoring shall be signed or signed by the person who performed the monitoring, and the results and the time of the monitoring shall be recorded.

HACCP Step 10 (Principle 5) Corrective Actions

●Requirements

The organization shall establish a procedure for corrective actions (correction, root cause investigation, and removal of the root cause) for deviations from critical limits.

●Thinking, specific examples

1. Corrective Actions

1) Corrective action is an action taken immediately when a monitoring parameter deviates from the CL.

2) In the CCP (Critical Control Point), which is a process that requires particularly strict control to prevent the occurrence of hazards, if the monitoring parameters deviate from the CL (Critical Limit), food safety risks may arise and escalate. Therefore, it is important to establish corrective action methods and procedures in advance.
3) The HACCP plan shall specify the measures to restore the process control status, the procedures for restarting the line, and the measures to isolate affected products and determine and implement their disposal methods.
4) To minimize the likelihood of the deviation recurring, a root cause analysis should be conducted where possible to identify and correct the cause of the deviation. The root cause analysis should identify the reason for the deviation or limit the amount of product affected by the deviation.

2. Items to be included in the HACCP plan as corrective actions

1) The following items should be included in the HACCP plan as corrective actions:
(1) Measures to restore the process to its original state: Repair, adjust, or replace machinery to restore the process to a normal state of control.
(2) Actions to be taken on products manufactured during the deviation: Identify, retain, and evaluate products that do not conform to CL. Determine how to dispose of them, such as reprocessing or discarding them.

3. Person in charge of implementing corrective actions

1) The person responsible for implementation should be a responsible individual with sufficient knowledge of CCP management, a thorough understanding of the process, and the authority to make quick decisions .

4. Record of corrective action implementation

1) The corrective action record should include the following items:
(1) The nature of the deviation, the manufacturing process or location in which it occurred, and the date and time of occurrence.
(2) Name, lot number, quantity, etc. of the product subject to the action
(3) Results of investigating the cause of the deviation
(4) Actions to restore the process to its original state
(5) Actions to be taken for products manufactured during the deviation.
(6) Signature of the person in charge of implementing and recording the above items.
(7) The inspector's signature on the corrective action and the date of inspection.

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

●Requirements

> The organization shall validate a HACCP plan prior to implementation. Verification procedures shall be established to confirm whether the defined handling (HACCP Plan) 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.

●Thinking, specific examples

1. The necessity of validation

1) Ensure that the HACCP plan has the ability to control critical hazards.

Matters to be validated: Identification of hazards, CCPs, CLs, 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) The validity of the control measures and CCPs' Critical Control Points (CLs) will be verified during the development of the HACCP plan.

3) Validation includes reviewing scientific literature, using predictive models, conducting validation studies, and using guidelines developed by authoritative sources.

4) During the initial implementation period of the HACCP plan, evidence should be obtained demonstrating that consistent controls were achieved during production under the specified manufacturing conditions.

2. The need for verification

1) Evaluate the effectiveness of the HACCP plan and confirm that the HACCP system is functioning properly.

2) By recognizing the weaknesses of your HACCP system based on the results of regular evaluations, you can revise your HACCP plan to make it better.

Verification of each HACCP plan

1) Verification of the HACCP plan for each CCP shall be conducted with respect to the following matters:

(1) Calibration of measuring devices (instruments) used for monitoring.

(2) Testing and inspection of raw materials, intermediate products, or final products

(3) Measurement of manufacturing and processing conditions

(4) Verification of monitoring records, corrective action records, and verification records of CCPs.

(5) Confirmation that workers are performing their duties in accordance with the HACCP plan.

(6) Observation that control measures are being implemented in accordance with the HACCP plan.

2) Verification of monitoring includes verifying whether the monitoring is correct using other measuring instruments or methods.

For example, temperature is cross-checked using a different thermometer, and in verifying the heating process, microbiological testing is performed on the sample after the heating process to confirm that no microorganisms remain.

3) The following items should be included in the HACCP plan as part of the internal verification process:

(1) Contents

(2) Frequency

(3) Actions based on the verification results

(4) Method of recording verification results

4. Test and Inspection Methods

1) This includes evaluating and verifying whether CCPs and CLs are properly established and controlled to ensure product safety.

Verification testing and inspection methods must be valid. Visual inspection and sensory indicators can also be used as verification methods, but even in these cases, it is necessary to establish documented procedures and objective criteria using photographs or samples.

5. Verification of the entire HACCP system

1) The HACCP system will be verified periodically, as necessary, using the following procedure.

(1) Analysis of the causes of consumer complaints or recalls

(2) On-site verification to ensure that monitoring work is being carried out according to established procedures.

(3) Testing and inspection of the final product

2) Record and review the results of the verification.

6. Review of the HACCP system

1) Reviews (reviews) will be conducted annually as a general rule, and also whenever any of the following occurs.

(1) Change of raw materials

(2) Changes to the manufacturing process or system (including computers and their software)

(3) Changes to packaging

(4) Changes to the delivery system for the final product

(5) Changes to the intended specifications or intended consumer of the final product

(6) If the verification results indicate a defect or potential defect in the HACCP plan

When a new hazard is identified in the same food or the same food group

(8) When new information regarding the safety of the product is obtained

7.Reference materials

1) In some cases, it may be smoother to consider potential hazards and countermeasures from the development stage of new products, etc. Therefore, it is considered effective to consider the following countermeasures, referring to the explanation of Section FSM15 of the JFS-C standard guidelines as needed.

(1) Document and implement methods and responsibilities for the design and development of new products and for product improvements.

(2) Requirements, design and formulation, and manufacturing processes for new products will be validated and verified through line tests, prototypes, etc., to ensure safety in advance. The formulation is developed by an authorized person to meet the specified needs.

2) If necessary, perform a shell life test and confirm the following:

(1) Handling and storage requirements, including setting expiration dates and best-before dates.

(2) Microbiological criteria (if applicable)

(3) Cooking (if applicable) and storage/handling requirements

3) When transitioning to commercial production and distribution, or when changes occur to raw materials, processes, or packaging materials, the food safety team will verify and validate the new products and related processes.

4) Product formulations and manufacturing processes within the scope of certification will be reviewed when materials, raw materials, or equipment are changed.

5) The process flow of all manufacturing processes shall be designed to prevent cross-contamination based on approved formulations.

6) Maintain records of product design, formulation, label compliance, process flow, shell life testing, and approval records for new and existing products.

HACCP Step 12 (Principle 7) Documents and Record

●Requirements

Organizations must create, record, and maintain necessary documents.

●Thinking, specific examples

1. Required records

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

(1) HACCP team member list and division of roles

(2) Product Description

(3) Flow diagram

(4) Hazard factor analysis
(5) Determination of control measures (critical control points: CCPs) for important hazards that need to be controlled.
(6) Determination of control standards (CLs) and information that scientifically supports the determination of control standards (CLs)
(7) Verification of the appropriateness of the control measures
(8) Record of revisions to the HACCP plan
etc.

2) Records of activities in accordance with the HACCP plan
(1) Monitoring records
(2) Record of corrective actions
(3) Verification records
(4) Training records of the person in charge
etc.

3) Records of HACCP plan implementation
(1) Implementation of hazard management
(2) Implementation of corrective measures (improvement measures)
(3) Implementation of verification and correction

Keep records of what was done and when, including the date and time of any deviations and the nature of those events, so that this information can be easily understood later.
Furthermore, it is sufficient to record the implementation of (2) corrective actions (improvement measures) and (2) verification and corrections in a logbook.
When writing in a log, make sure to record at least what, when, and how you did it.
(1) Regarding the implementation of hazard management, the format of the records is shown in the "Industry-Specific Handbooks Created by Food Business Associations" for each industry and type of business, and can be used as a reference.

4. Examination of the sustainability of documents and records

1) To properly manage and maintain the records, they may be maintained electronically as needed.
2) To maintain the sustainability of operations, it is also effective to document "Standard Operating Practices (SOPs)," "Work Instructions (WIs)," or similar documents as needed. However, depending on the environment and scale, managing these documents may become an excessive burden, so it is desirable to consider management methods that are easier to maintain.

Ⅲ Good Manufacturing Practice (GMP)

Good Manufacturing Practices (GMP) are general conditions and activities for maintaining a hygienic environment inside and outside a business premises. They aim to reduce the likelihood of food safety hazards (hazards) identified in HACCP hazard analysis, thereby maintaining the production of safe food.
In some cases, implementing GMP (Good Manufacturing Practice) measures may be sufficient to address existing hazards.

However, some hazards cannot be controlled by general GMP practices. To properly control these hazards, some GMP practices may require greater attention.
The JFS-B standard requires that GMP4 implement measures to control such " hazards requiring enhanced control," such as increasing the frequency of monitoring and verification.

It should be noted that implementing GMP alone may not be sufficient to guarantee food safety. Significant hazards that are not controlled by GMP should be addressed through a HACCP plan.

GMP 2 Site Management

● Requirements

The organization shall establish appropriate standards for the premises of the establishment and maintain them in accordance with those standards.

●Thinking, specific examples

1. Concepts in GMP2

1) In GMP2, it is important to take measures and maintain practices to ensure that influences from the surrounding area and within the business premises do not affect the food safety risks to the products. Therefore, the following measures are required.
   (1) Understand what is present in the vicinity and on the premises of the business site.
   (2) Confirm whether the existing substances pose a food safety risk to our products.
   (3) Consider the response and maintenance of a system that will ultimately be able to prevent food safety risks to products.
   (4) While maintaining the environment, periodically check for any changes.

2. Setting and maintaining standards

1) Confirmation of property boundaries
   (1) Clearly define the boundaries of the property and confirm that they can be reliably explained.

(2) Even if the site is located within an industrial park or similar area, the organization's site must be clearly defined.

(3) In order to clearly retain the confirmed settings, it is recommended to show them in drawings or other diagrams whenever possible.

2) Check the surrounding environment

We will identify any potential issues in the vicinity of the facility that could affect food safety.

Examples include the following:

(1) Insect and bird damage related

Rivers, drainage ditches, etc.

Mountains, forests, parks, farmland, livestock farms, etc.

Garbage disposal sites, waste disposal facilities, etc.

(2) Foreign matter related

Garbage disposal sites, waste disposal facilities, etc.

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

- Regional impacts such as salt damage, strong winds, and freezing.
- Farmland where pesticides are sprayed - Livestock farms (fatting farms, etc.)
- Exhaust and smoke from other factories, etc.

3) Confirmation within the business premises

Within the facility, we will also identify anything that may pose a risk to food safety. Examples include the following:

(1) Insect and bird damage related

Green spaces, etc.

• Places where puddles form

・Drainage systems, septic tanks, rainwater tanks, etc.

- Areas for storing unwanted items or waste, etc.

(2) Foreign matter related

- Waste storage areas, processing areas, etc.

4) Addressing each impact

For each item identified as having an impact, we will consider, verify, and periodically implement measures to reduce the impact to a manageable level. Possible countermeasures include the following:

(1) Insect and bird damage related

- Removal or modification of the target, isolation, etc.
- Regularly check and address planted areas and puddles.

(If the site is subject to the Green Space Act, compliance is required, but the layout and management should be carefully considered.)

- Addressing the building (positive and negative pressure, entrances and exits, damaged areas or gaps that could be entry points, light sources, odor leaks, etc.)

- Regular monitoring by pest control companies or your own organization (exterior, interior of building, etc.)

(2) Foreign matter related

- Removal or modification of the target, isolation, etc.

Measures to prevent foreign matter contamination through flying onto buildings and adhering to workers.

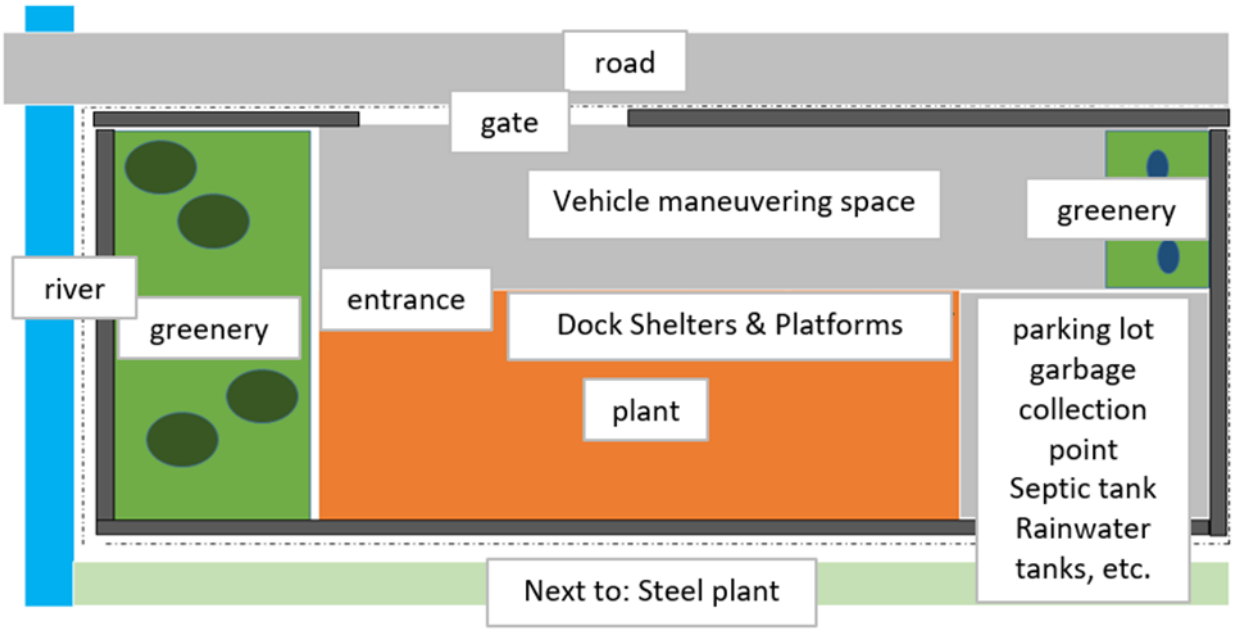
(3) Others

Agreements with stakeholders in the surrounding environment

- Measures to prevent deterioration through regular maintenance of buildings and equipment
- Regular inspection of manufacturing areas and products

[Example] Surroundings of the building

In addition to facilities within the site, we will consider environmental impacts from external facilities and the surrounding environment (outside the dotted line).



3. Reference materials

In site management, food defense elements may also be involved. Along with FSM7 procedures, the following resources may also be helpful.

- JFSM "Food Defense Implementation Support Handbook"

https://www.jfsm.or.jp/scheme/documents/index.php

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 systems and lighting) and the flows of people, materials, and operations shall be designed in accordance with their intended purposes so as to minimize food safety risks.

●Thinking, specific examples

1. Facility location, design, and layout

When designing manufacturing and processing facilities, the most important thing is to fully understand the impact on manufacturing and processing. Refer to the following when understanding the impact.

(1) Layout diagram of the manufacturing and processing area
(2) Flowchart showing the manufacturing and processing steps
(3) Equipment, personnel, methods for transporting raw materials and products, process capabilities, etc.
(4) Work divisions that match the manufacturing and processing steps

2. Movement of people, goods, and tasks

1) It is effective to include manufacturing and personnel movement patterns in the layout diagram of the manufacturing and processing area, and to consider the impact on food safety from this flow of movement (movement patterns).

2) The movement patterns include the following, with "objects" and "people" being particularly important. Manage them to minimize cross-contamination between "objects" and "people."

(1) Goods: The route from the receipt of raw materials to the shipment of the final product.
(2) Personnel: Routes for personnel to enter and exit the work area, routes for movement between work areas, routes for external workers to enter and exit
(3) Waste: Routes for transporting leftover and unwanted materials from the work site outdoors.
(4) Drainage: Drainage routes for the 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.

3. Lighting

1) The specifications should be such that maintenance and cleaning are easy and deterioration is minimal.
2) When installing electrical wiring ducts, etc., they should be designed so that dust and dead insects do not accumulate on top, installed in a location that is easy to clean, and when removing them, they should be pulled out vertically rather than horizontally to prevent dust from falling.
3) In the event that a fluorescent lamp or light bulb breaks, protective covers (of a type that does not accumulate dust) or measures to prevent scattering of debris, such as using anti-scattering tubes, shall be installed to prevent physical hazards such as fragments from affecting products or manufacturing/processing lines.
4) For windows used to let in light, choose materials that are less prone to deterioration and shattering if made of resin, or materials that are less prone to condensation if made of glass, and apply a plastic film to prevent shattering.
5) Illumination and color tone must be set to avoid causing misidentification of the work area.
6) It is necessary to provide sufficient lighting for food handlers to work safely and hygienically.
7) If the lighting in the area where visual inspections or other work is performed is insufficient, measures such as installing auxiliary lighting like desk lamps should be taken.
8) When conducting color tone inspections, etc., the color tone of the lamps should be considered in addition to the illuminance.
9) The illumination level of the work environment is stipulated in Article 604 of the Industrial Safety and Health Regulations and in JIS (Japanese Industrial Standards). The work classifications and standards shown in Article 604 are: precision work: 300 lux or more, ordinary work: 150 lux or more, rough work: 70 lux or more.

According to JIS illuminance standards, the required illumination for ordinary visual work in typical manufacturing plants is 500 lux.

4. Drainage System

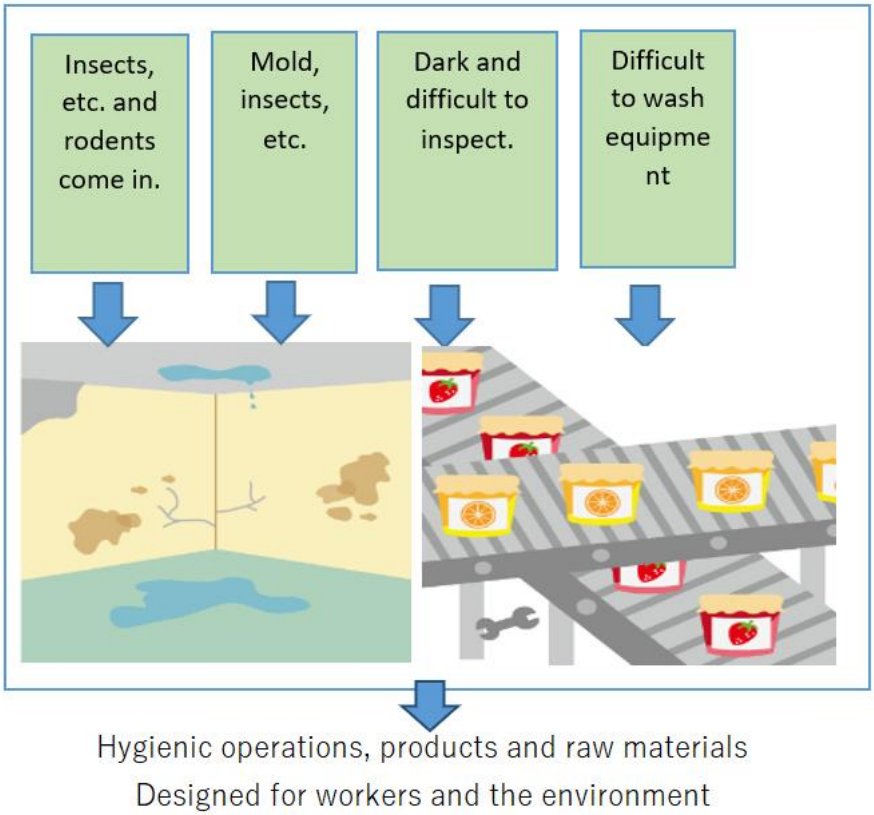
1) Drainage routes shall be designed and managed in such a way that the possibility of contamination of products, etc., is minimized.
2) The floor and drainage pit should be sloped to prevent water from accumulating and to make cleaning easier.

5. Specifications within the manufacturing area, general

1) The facility specifications will be designed to prevent secondary contamination or adverse effects on food.
2) The specifications should be such that maintenance, cleaning, and washing are easy, and the product is resistant to deterioration.
3) Durability should be considered to withstand heavy loads used in the work, wear and tear, etc.

4) The material must be able to withstand cleaning, washing, sterilization, and disinfection.

5) Drainage and wastewater systems should be designed so as not to compromise food safety.



GMP 4 Control of hazards requiring enhanced control, cross contamination and isolation

● Requirements

Based on the results of the Hazard Analysis in HACCP Step 6 (Principles 1), the organization shall establish control measures for significant hazards that require particularly enhanced controls, other than CCPs, and maintain them effectively through periodic review. The organization shall prevent physical, chemical, 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 maintained effectively through periodic review.

●Thinking, specific examples

1. Control of hazards that require strengthening.

1) This standard requires the following actions regarding potential hazards identified in HACCP Step 6 (Principle 1) Hazard Analysis, or in publicly available hazard information:

① Consider whether there are any hazards that did not result in the designation of a Critical Control Point (CCP) that require particularly strengthened management.

② If there are hazards that require particularly strong control, establish the necessary control measures, document the procedures as needed, and maintain their effectiveness through regular reviews.

2) 1) is synonymous with "GHP requiring extra attention" in the General Principles of Food Hygiene CXC 1-1969, Rev.2022 of the International Food Standards Committee (CODEX).

* Hazard factors identified through hazard analysis in HACCP Step 6 (Principle 1) that, if errors occur that fail to meet GMP management requirements, are considered to have the potential to cause serious food safety hazards, are considered to be managed under "GHP requiring more attention," and as a result, are managed under GMP4.

2. Points to note when managing hazards that require reinforcement

1) The hazards requiring reinforcement will vary depending on the type of product, manufacturing process, hazard analysis, frequency, and severity. These factors should be taken into consideration when identifying the hazards.

2) Procedures for managing hazards that require strengthening may involve not only GMP requirements but also FSM requirements. While not uniform across all organizations and products, examples of relevant requirements are provided below.

FSM 13.1 Purchasing
FSM 13.2 Supplier Performance
FSM 16 Allergen Management
FSM 19 Analysis and Inspection
GMP 3 Design, construction, layout of business site and work and product flow lines
GMP 6 Sanitation, work clothes and health management of employees, etc.
GMP 8 Housekeeping, cleaning, sterilization and disinfection
GMP 11 Air and water management
GMP 13 Pest control
GMP 18 Devices and Tools
GMP 19 Maintenance

3) When implementing the above, monitoring, corrective actions, and verification records should be established at an appropriate frequency that suits the characteristics of the product and the size of the organization. Monitoring may include the following:

(1) Definition of monitoring methods (including definition of responsible person, frequency, and sampling system if applicable)
(2) Monitoring of records to be kept

3. Examples of hazards that need reinforcement

1) Allergen Management: If the cleaning of the production line after manufacturing products containing allergens is insufficient to remove the allergens, there is a risk that the next batch of products, which should not contain allergens, may become contaminated with them.

Furthermore, if there are multiple production lines in the same manufacturing area, simultaneous manufacturing of allergen-containing products may cause cross-contact of allergens with products on other lines. To address these risks, we will strengthen our existing GMP compliance measures and control the risks.

As an example, we will strengthen our GMP compliance as follows:

(1) Lines and equipment: Establish cleaning frequency and procedures, and provide training to workers. Keep records as necessary.

(2) Worker movement: Worker movement routes should be considered and communicated to prevent cross-sectional contact between workers.

(3) Raw materials, equipment, waste, etc.: Take measures to prevent cross-contact during storage and handling, including proper placement and prevention of misuse.
think about.

(4) Prevention of scattering: Consider measures to prevent powder raw materials containing allergens from scattering during storage or handling, and to prevent cross-contact.

2) Management of Listeria: While Listeria can be dealt with by appropriate heat sterilization, for RTE foods (pre-cooked foods that do not require heating before consumption) and foods that do not undergo a heating process, the existing GMP measures will be strengthened to control the risk.

As an example, we will strengthen our GMP compliance as follows:

(1) Temperature control: Maintain temperatures within the process and during storage at 10°C or below.

Furthermore, RTE food and contact lines should be kept at lower temperatures, preferably below 4°C.

(2) Worker contact: Do not touch products or lines/equipment that come into contact with products with bare hands.

If using gloves, change them at appropriate intervals.

(3) Lines and equipment: Establish procedures for cleaning and maintenance at appropriate intervals and provide training to workers.

4. Necessary control measures

1) Refer to HACCP Steps 4, 6, 7, and 11. However, pay attention to the controls listed in "1. Control of hazards requiring reinforcement" and conduct a deeper analysis/consideration.

2) Record the results of the procedures as necessary.

5. Cross-contamination and isolation

1) Hazard factors may arise not only from those identified in the hazard analysis, but also from external influences. Examples include the following:

(1) Products that are produced using the same line, equipment, and supplies, but contain different hazards (such as allergens not present in the product)
(2) Products that are produced in the vicinity and contain different hazards
(3) Products containing different hazards should be handled by the same worker during the same time period.
(4) The influence of the surroundings when storing raw materials and work in progress

Cross-contamination and isolation for these factors are related to HACCP Steps 4 and 5 in the actual work performed.

Sources of contamination include all aspects of food safety, such as foreign objects, microorganisms, drugs, and allergens. An effective way to prevent cross-contamination (including cross-contact of allergens) is to isolate raw materials (including containers and packaging materials), semi-finished products, work in progress, reworked products, and finished products from sources of contamination or objects that may contain such sources during the manufacturing process.

Normally, the level of contamination in a product decreases as processing progresses, but in the case of pathogenic microorganisms, they tend to spread from highly contaminated areas to less contaminated areas or objects. Isolation is an effective way to prevent this contamination. When storing items that need to be isolated, it is best to designate a specific location for each item, such as a storage room or refrigerator, and use dedicated containers to prevent cross-contamination (including cross-contact of allergens).

2) Regarding contamination associated with the movement of people and goods, and cross-contamination (including cross-contact of allergens), it is also effective to identify the areas where these contaminations occur and to implement preventive measures.

6. Zoning and traffic flow improvements to prevent cross-contamination (including cross-contact of allergens)

1) When conducting evaluations and formulating plans, creating manufacturing and processing diagrams, ventilation plans, and product and raw material inflow/outflow plans will make it easier to identify control points for pollution sources.
2) The flow for zoning and improving traffic flow to prevent cross-contamination (including cross-contact of allergens) is as follows:
   (1) Clearly define the movement of people and goods, and create a movement diagram.
   (2) Considering the characteristics of the product and the potential for contamination, assess the possibility of cross-contamination (including cross-contact of allergens) associated with the movement of people and goods.
   (3) Based on the evaluation, develop control measures to prevent cross-contamination (including preventing cross-contact of allergens).

GMP 5 Personnel Facilities

● Requirements

The organization shall ensure that facilities for employees are designed and operated to minimize food safety risks, including allergens.

●Thinking, specific examples

1. Handling of employee facilities

1) Employee facilities include shoe lockers and shoe racks for changing from work shoes to indoor shoes, changing rooms, toilets, handwashing facilities, a cafeteria, a break room, a smoking area, etc. These must be kept clean at all times to prevent the introduction of sources of contamination or foreign objects into the manufacturing and processing areas.

2. changing room

1) It is desirable to install a sufficient number of lockers, etc. Lockers and changing rooms must be managed to prevent cross-contamination of clean work clothes worn in the manufacturing area with personal clothing or used work clothes.
2) Changing rooms shall be located in a place where work clothes will not be contaminated before food handlers move to the work area.

3. Handwashing facilities

1) Facilities for hygienic handwashing and drying are necessary. It is important to install a sufficient number of these facilities in appropriate locations for food handlers, and to have washing, drying, disinfecting equipment and hot water facilities as needed.
2) Maintain a sufficient supply of water (including hot water if necessary for proper handwashing), and provide appropriate liquid soap, nail brushes, paper towels, disinfectants, etc., to ensure they are clean and always ready for use.
3) To prevent re-contamination of hands after washing, faucets should be designed to be opened and closed without touching them with hands.
4) Clearly display instructions for handwashing and disinfection.
5) Handwashing facilities should not be used for washing food or machinery.

4. Toilet

1) Ensure a sufficient number of toilets with hygienic structures relative to the number of employees.
2) It is desirable that the area be sufficiently isolated from the area where food is handled.
3) Provide handwashing and disinfection facilities, as well as means of drying hands.
4) Keep the area clean at all times and perform regular cleaning and disinfection.

5. Employee cafeteria, break room, and smoking area

1) It is desirable that places where food and beverages are stored and consumed, such as employee cafeterias and break rooms, be set up in a way that minimizes the possibility of cross-contamination with the manufacturing area.

2) Keep the cafeteria clean and manage waste so that it is not left lying around and does not become a source of pests.

3) Smoking areas shall be installed and managed in a manner that prevents cross-contamination with work clothes or manufacturing areas.

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

● Requirements

The organization shall document and enforce appropriate hygiene standards for employees in accordance with the laws and regulations of the country in which the employees are working. This shall include hand washing methods and frequency, health check methods, work clothing and footwear rules, entry and exit from the manufacturing facility, food handling methods, and foreign material contamination control. These requirements shall be made known to employees and applied without exception to contractors and visitors.

●Thinking, specific examples

1. Concepts in GMP6

1) The manager shall ensure that the manufacturing environment is set up so that no contamination occurs through the actions of employees during the entire process from the start to the end of their work, and so that there are no problems with the work on site, and shall also consider appropriate education and guidance to be provided to workers. In order to ensure that the established information is accurately conveyed to all workers, documentation shall be made and measures shall be taken to appropriately maintain knowledge and awareness of food safety.

2) We will take measures to ensure that external visitors do not affect food safety.

2. Handwashing Method and Frequency

1) Specify the timing for washing and disinfecting hands (e.g., upon entering and leaving the room, after designated tasks, after using the toilet, etc.)

2) Specify the handwashing method. It is desirable to consider how to make it effective and easy to continue, such as by showing it clearly with visuals and specifying the number of seconds as needed.

3) Review records of handwashing practices as needed.

3. Methods for checking health status and procedures for responding to cases where infected individuals pose a risk to food safety.
and reporting system

1) When employees join the company, managers should explain the employee's health status and food safety risks, and ensure they understand the necessary procedures for identifying pre-existing medical conditions, responding to illness, and handling food poisoning cases.
2) Managers shall be aware of employees' pre-existing medical conditions as necessary for food safety.
3) Check the employee's health condition before they begin work. Instruct and inform employees that they must report any health problems to the on-site supervisor. If an employee reports a health problem, they will not be allowed to handle products unless it is clear that it will not affect food safety (e.g., a minor toothache).
4) If an infectious disease or food poisoning is suspected, report it to the management, food safety officer, etc. If necessary, disinfect the facility and equipment, confirm any contacts (including external visitors), and take action regarding products manufactured or shipped prior to the incident .
5) Regularly perform stool tests to confirm that there are no abnormalities.
6) When external visitors, especially those entering the manufacturing area (equipment, inspection, consultants, etc.), their length of stay, health status, and contact information should be confirmed so that they can be contacted in case of any abnormalities. Visitors (including maintenance workers), especially when entering food manufacturing, processing, or handling areas, should be instructed and supervised where appropriate, and, like employees, should wear protective clothing to prevent contamination of food and comply with other employee hygiene requirements.

Visitors should be instructed to report any illnesses or injuries that could potentially cause cross-contamination issues, through the operator's hygiene policy, before their visit.

4. Rules regarding work clothes and footwear

1) Avoid unsanitary behavior with anything that may come into contact with the product (hands, gloves, equipment, etc.).
2) Refrain from sneezing and coughing at the work site, and take particular care to prevent droplets from spreading to areas related to the product.
3) Wear the mask correctly as instructed, covering both your nose and mouth.
4) When work clothes are stored in a shared locker where individuals keep their own clothes and belongings, handle them in a way that prevents contamination.
5) Regarding the shape of work clothes and shoes, appropriate consideration will be given to prevent the shedding of hair and body hair and their contamination of products.

6) Establish and strictly enforce rules for washing and changing work clothes and footwear so that employees can wear clean and well-maintained work clothes and footwear as needed for their work, thereby preventing contamination and foreign object intrusion.
7) When using gloves, select the appropriate material according to the purpose, determine the intended use and storage method, and handle them while maintaining a clean and good condition. When using disposable gloves, check the material and strength according to the work, determine an appropriate replacement frequency, and strive to prevent damage.

5. Methods for entering and exiting the manufacturing plant

1) To prevent foreign objects from being brought into the manufacturing area, wear the designated work clothes correctly to prevent contamination with hair, body hair, etc.
2) Install air showers, adhesive rollers, etc., at designated times, and establish and publicize the implementation method. It is also considered effective to provide clear visual instructions and, if necessary, specify the number of times or duration.
3) Specify the need to change into work clothes and work shoes as necessary.
4) Record the details of the implementation as necessary.

6. Food handling methods and measures to prevent foreign object contamination.

1) Avoid unsanitary behavior with anything that may come into contact with the product (hands, gloves, equipment, etc.).
2) To prevent foreign objects from falling off and contaminating the product, do not wear any jewelry or accessories.
3) Keep your fingernails neatly trimmed short and clean. Do not wear nail polish.
4) Do not wear makeup that may flake off and potentially affect the product (e.g., glitter powder).
5) Do not use perfume .
6) Storing or consuming food and beverages in the work area is not permitted. Please adhere to the designated areas for operation.
7) Bringing unnecessary items into the workplace is prohibited. If it is necessary to bring in regular medications or other personal items, consult with the supervisor and take measures to ensure that they do not get mixed into the products.
8) Wash your hair and take baths regularly to maintain proper personal hygiene.

GMP 7 Training

● Requirements

The organization shall 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 shall be established to ensure that employees receive appropriate guidance and supervision.
This education and training shall enable employees to recognize their role in food safety and the significance of their efforts.

●Thinking, specific examples

1. food safety officer

1) The food safety officer shall improve their own knowledge, skills, and abilities, and shall establish and implement appropriate educational programs (content, timing, methods, frequency (including retraining), etc.) for food handlers, and keep records of these programs.

2. food hygiene manager

1) Refer to the explanation in FSM2.

3. education training

1) Provide and record education and training to all employees, including new hires, to acquire the necessary knowledge and skills for food safety, according to their roles in handling food.
2) Make it possible to review the current rules and procedures at any time, taking into account the opinions of food handlers on site.
3) Records created during education and training can also be used for individual evaluations, etc.
4) Provide employees with retraining (hygiene education) as needed and keep records of it.
5) Conduct HACCP training .

GMP 8 Housekeeping, cleaning, sterilization and disinfection

● Requirements

The organization shall maintain an appropriate level of hygiene at all times by conducting housekeeping, and cleaning operations throughout all processes and phases, and disinfecting where necessary. Cleaning tools, cleaning agents and disinfectants shall be used for their intended purpose and properly stored.

●Thinking, specific examples

1. Cleaning and disinfection

1) To avoid compromising the safety and appropriateness of food, hygiene should be carefully maintained during cleaning and maintenance work. In food preparation and storage areas, cleaning agents suitable for food contact surfaces should be used.

2) Cleaning removes food residue and dirt that could be sources of contamination, including allergens. The cleaning method and necessary materials depend on the nature of the food business, the type of food, and the surface to be cleaned. In particular, disinfection may be necessary after cleaning for surfaces that come into contact with food.

3) Chemicals used for cleaning and disinfection should be handled carefully and used according to the manufacturer's instructions. For example, they should be used with appropriate dilution and contact time, and, if necessary, stored away from food in clearly identified containers to avoid food contamination.

4) Care should be taken to ensure that cleaning procedures do not lead to food contamination. For example, spray from a high-pressure washer can spread contamination from dirty areas such as floors and drains over a wide area, and may also contaminate food contact surfaces or exposed food.

5) In certain operations and/or food processing areas where the possibility of microbial contamination by water is high, such as when the food being handled is low in moisture and the products are manufactured under dry conditions, the risk of microbial contamination can be reduced by controlling the amount of water used for cleaning (e.g., by performing dry cleaning to remove and collect residues and debris).

6) In order to carry out cleaning and washing systematically, create a plan and procedures as follows:

(1) A plan for cleaning and washing the facility; this plan should include the frequency of the work, the date of implementation, the person performing the work, the method of recording, etc.

(2) Procedures for cleaning and washing facilities: These should include the person responsible for the work, the target, the method, the frequency, monitoring and verification procedures,

the designation of work tools, the post-work inspection procedures, the pre-production inspection procedures, etc.

2. Employee training

1) Establish effective procedures and document them as necessary.
2) Educate food handlers on standardized methods. Effective methods include demonstrating cleaning procedures and displaying photos and illustrations of the steps. Only trained individuals should perform cleaning, washing, and disinfection.
3) Monitoring will be conducted visually to ensure that the procedures are being followed, and their effectiveness will be verified using hygiene tests such as product inspections and swab tests. The monitoring method will depend on the nature of the procedure, but will include pH, water temperature, conductivity, detergent concentration, disinfectant concentration, and other important parameters for ensuring that the cleaning and disinfection program is being carried out as planned and verifying its effectiveness.
4) Education will be provided based on the results of basic education and hygiene inspections.

3. Handling of detergents and chemicals used for cleaning, sterilization, and disinfection.

1) The following items will be implemented.
   (1) Appointment of a person responsible for management
   (2) Inventory management of pharmaceuticals, etc. (receiving, issuing, usage, inventory quantity, user and first-in, first-out)
   (3) Locking of the drug storage room and management of keys
   (4) Education for food handlers regarding the handling of chemicals, etc. (including appropriate dilution, contact time, etc.)
   (5) Preventing contamination of food with detergents and chemicals (e.g., displaying the name of the contents on the container)

4. Cleaning and storage of cleaning tools and equipment.

1) If foreign matter or microorganisms are present on equipment, facilities, or instruments used for cleaning, washing, sterilization, or disinfection, it could lead to foreign matter contamination or microbial contamination of products. Separate cleaning machines, equipment, and tools designed for their respective purposes should be used for different hygiene zones (areas), such as food contact surfaces and non-contact surfaces. Furthermore, contaminated cleaning tools and equipment can spread contamination.
2) Check the operation and any deterioration before and after use, and immediately repair or replace any defects.
3) Since dirt may remain on the back or underside of devices, equipment, and utensils, disassemble them and check them. Cleaning equipment should be kept clean, maintained, and

replaced regularly to prevent it from becoming a source of cross-contamination of contact surfaces or food.

4) Store cleaning equipment in an appropriate place to prevent contamination.

5) Store cleaning tools by hanging them up so they do not touch the floor or other surfaces, and allow them to dry properly.

6) Designate a storage location for food so that it can be used immediately by food handlers, and keep it clean. Posting a sign indicating this is also a way to maintain cleanliness.

7) Measures must be taken to prevent the misuse of cleaning and washing equipment used in contaminated areas in clean areas.

It's important to color-code items by purpose, such as using red for floor cleaning and blue for cooking utensils, or to store them in separate locations.

5. Activities related to GMP8

1) Activities that can be considered related to GMP8 include 5S and 7S activities. These activities originated in Japan and are being implemented by many companies, often with various adaptations.

One of the characteristics of 5S activities is that they are bottom-up activities in which employees can independently determine the rules and carry them out. This bottom-up approach is expected to foster collaboration beyond a top-down structure. By considering a workplace environment that encourages autonomous activities and actions by employees, it is also expected that a food safety culture will be cultivated.

Once you have established the procedures and are considering taking the next step, the following resources may be helpful.

• JFSM "Handbook for Supporting the Introduction of a Food Safety Culture"
https://www.jfsm.or.jp/scheme/documents/index.php

GMP 11 Air and water management

● Requirements

The organization shall define the required quality criteria according to the application, and regularly monitor and record the air, high-pressure gas, and water (including ice and steam) used in food production in order to minimize the effect on food safety. Water not intended for use in food production, and water that has been used but is acceptable for contact with food, shall be controlled so that it is not mixed with water used exclusively for production.

●Thinking, specific examples

1. Identifying and handling the water in question.

1) When manufacturing food products, it is possible to use different types of water depending on the intended use, and in such cases, standards appropriate to the intended use should be established.

2) The water to be used will be checked for quality through water quality tests, etc., and if necessary, it will be treated with filtration, sterilization, etc., to ensure water quality before use.

3) Where necessary, comply with local, national, or internationally recognized microbiological and water quality standards for drinking water.

4) In Japan, the water that comes into contact with food shall, in principle, be water for food production or water suitable for drinking, and water for food production refers to water that complies with applicable laws and regulations.

5) In order to reduce water costs, water other than water used for food production may be used in the manufacturing process (for primary washing of food, heating and cooling, etc.), and this water must be managed to prevent contamination of the water used for food production.

Specific examples include the following:

(1) Well water that has simply been drawn up

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

6) In some food industries, in order to make effective use of water resources, used water that is safe to come into contact with food may be reused in food production. In the same way as above, this water must be managed to prevent contamination of water used for food production.

Specific examples include the following:

(1) Water used for heat sterilization of the equipment

(2) Water used for heating and cooling packaged food

(3) Secondary washing water for cut vegetables (water used in the final stage of the washing process)

(4) Reused water from steam drain

2. Dealing with ice and steam

1) Regarding ice and steam used in food manufacturing, the following measures can be taken to minimize their impact on food safety.

(1) Ice and steam shall be made and handled in a way that does not cause contamination. In particular, the cleaning agents for ice makers and the boiler water treatment agents (chemical agents) used in boilers that generate steam shall be those approved for food use and shall not be mixed with ice or steam.

(2) The boiler cleaning agent (chemical agent) used in the boiler that generates the cleaning steam for the ice maker shall be one approved for food use and shall not be mixed with the ice or steam.

(3) Install a filtration device (filter) near the end of the water supply and steam piping of the ice maker.

(4) Confirm that ice and steam that come into direct contact with food will not have any adverse effects on the food (odor, discoloration, etc.).

3. Compressed air, carbon dioxide, nitrogen, and other gases

1) Equipment for gases used in manufacturing and filling must be designed to prevent contamination of food and be properly maintained.

2) Gases that come into contact with food shall be those approved for use in food in general as food additives.

3) Ensure that the air and gases that come into contact with food are free of dust, oil, and water.

4) Filter gases as close to the point of use as possible.

4. Air conditioning and ventilation measures

1) To prevent dust, debris, insects, etc. from entering and polluting the air, the following points should be considered when designing the air conditioning and ventilation system.

(1) The air conditioning and ventilation system must be designed to be easy to clean, wash, and replace filters.

(2) Consider the balance of intake and exhaust air in the facility.

(3) Ensure that outside air does not enter through windows, doors, or gaps.

(4) To facilitate the removal of soot and steam (to prevent condensation and mold growth, etc.).

(5) Maintain differential pressure as necessary to prevent air from flowing into the clean area.

(6) Regularly check the outside air intake for any damage, for any clogging of the filter due to the intake of dust or insects, and for any deterioration due to rust or corrosion.

(7) It is convenient to have inspection ports for both the intake and exhaust systems for inspection, cleaning, washing, and filter replacement.

2) When aiming to step up to the JFS-C standard, it is desirable to implement procedures for monitoring and managing the cleanliness of the air in areas where products that are prone to microbial growth and survival are manufactured.

GMP 12 Waste Management

● Requirements

The organization shall establish adequate systems for segregation, collection and disposal of waste. Waste placement and containers shall be controlled to prevent the attraction of pests and the development of harmful organisms and microorganisms. Waste flow lines shall be set up so as not to cause cross-contamination of food.

●Thinking, specific examples

1. Consideration of management methods

1) We will take appropriate measures to manage waste generated as a result of food manufacturing and processing (including by-products unsuitable for food use), and to prevent it from becoming a breeding ground for microorganisms, rodents (mice), insects, and other harmful organisms, and from leading to contamination of the manufacturing and processing environment.

2) Contact between waste materials, raw materials, and manufacturing/processing equipment must be avoided.

3) Designate a person responsible for the consistent management of waste (identification, collection, isolation, storage, removal, and disposal), and create a procedure manual for that management work. It is important to regularly check the status of waste management, such as whether the work has been carried out according to the procedure manual.

4) Ensure that the process is carried out promptly following the steps outlined below.

Waste generated on the manufacturing/processing line → Container for waste → Temporary storage area → Indoor/outdoor waste storage area → Collection by designated contractor → Issuance and storage of manifest slips (in accordance with the law)

5) Waste materials shall be managed and stored in a manner that does not affect products, raw materials, or materials and equipment that come into contact with products.

6) In order to prevent cross-contamination between waste and products, as a general rule, waste should not be stored in areas where food is handled or stored (excluding temporary storage during manufacturing, etc. - even in such cases, care should be taken to prevent cross-contamination with products).

7) Containers for waste and other materials should be clearly distinguishable from other containers.

GMP 13 Pest Control

● Requirements

The organization shall 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 they do not affect food products.

●Thinking, specific examples

I. Pest control measures

1) Analysis and Inspection Plan for Pests such as Rodents and Insects: Pests to be identified based on past occurrences within the facility, biological evidence, characteristics of the products handled, etc., and an inspection plan is formulated.

2) Eliminate internal sources of pests and implement measures to prevent their invasion and attraction from external sources.

3) Regularly monitor for pests such as rodents and insects to ensure that hygiene management and pest control measures are in place within the facility and that there is no evidence of pest infestation. If the monitoring results indicate that extermination is necessary, develop countermeasures that do not affect food or disrupt facility operations, and ensure that the measures are implemented by qualified personnel.

4) Identify the cause of the outbreak, take corrective measures to prevent the problem from recurring, and keep records of monitoring and extermination efforts.

5) When entrusting pest control to a professional company, confirm the above points with the professional company and proceed with the measures accordingly.

Even when monitoring and extermination are outsourced, the organization shall review the monitoring reports and, if necessary, ensure that its designated pest control personnel take corrective actions (e.g., eradicate harmful small animals, eliminate hiding places or entry points).

6) It is desirable to avoid planting flowers or fruits that attract harmful organisms such as rodents and insects, and to maintain the area in a way that does not spread the odor of waste or sewage. Regular mowing and pruning of plants should be carried out to prevent them from becoming breeding grounds for harmful organisms.

7) Places where puddles tend to form become breeding grounds for midges and other insects. For example, in unpaved parking lots, breeding can be prevented by regularly adding gravel.
It is desirable to install yellow or green fluorescent lights or vinyl curtains, which are said to make insects less visible, in outdoor lighting areas of the facility, as well as in entrances and passageways .

9) Take care to prevent birds and other animals from building nests in the eaves of the facility and around the air intake facilities. Regularly inspect the mesh and filters.

10) To prevent rodents, insects, etc. from entering the facility through openings, it is effective to install nets or water seals at the ends of drainage ditches around the factory.
11) It is desirable to seal any gaps in windows that do not open or close, and remove them if necessary. Keep employee and material access points closed when not needed. Install wire mesh screens on windows, doors, etc. that open or close to reduce the risk of harmful small animals entering.
12) To prevent dust from scattering due to air pressure when opening and closing the door, and to avoid the entry of insects, etc., measures should be taken such as installing screens on the windows of the swing doors.
13) Ensure that light does not leak to the outside around window and shutter openings. Apply light-blocking film or insect-proof sheeting to windows.
Applying adhesive is also an effective method. Make sure roll-up doors close securely against the floor.
14) The insect trap at the workshop entrance should be installed on the inside of the building in a location where it cannot be seen from the outside.

2. Measures to make facilities easier to clean

1) Insufficient cleaning can lead to the internal breeding of harmful organisms. It is desirable to create a structure that facilitates cleaning, such as by rounding the joints between walls and floors.
2) Openings and pits in floors and walls caused by damage can easily become entry points for harmful organisms and breeding grounds, so it is desirable to repair damaged areas promptly.
3) Avoid placing equipment or objects against the walls of the facility, and strive to arrange things in a way that makes inspection and cleaning easy.

3. Medication Management

1) It is important to establish procedures for pesticide management, application, and the commencement of manufacturing and processing after application.
2) The use of medications should be restricted to well-trained personnel.
3) Manage the volume of drugs entering and leaving the warehouse, and store them in a locked location, isolated from the manufacturing and processing area.
4) Record the type of pesticide used, the amount used, the concentration (dilution ratio), the date and time of application, the location of application, etc.
5) Since more efficient measures can be expected and pesticide management can be omitted, it is also considered effective to entrust the entire pest control process to a specialized company.
6) It is important to regularly inspect for the presence of entry points and internal breeding grounds for harmful organisms, such as once a week or once a month, depending on the season.
7) To prevent contamination of the product, do not use poisoned bait in the manufacturing area.

GMP 15 Transport

● Requirements

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

●Thinking, specific examples

1. Establishment of storage conditions and systems

1) The organization shall ensure that raw materials and packaging materials are free from defects before use and shall endeavor to prevent food safety risks to the product.

Products (including those in intermediate stages) are required to be guaranteed to proceed to the customer or the next process without any defects.

2) When receiving raw materials and packaging materials, those used in the manufacture of products must be in good condition before use.

3) When purchasing and using products that are already packaged, it should be permitted only if the specifications of each raw material and packaging material are checked and there are no problems with delivery under general transportation conditions such as refrigeration, freezing, or ambient temperature control, rather than using specialized vehicles.

4) If any temperature abnormalities, damage, contamination, etc. are found upon receipt, do not use the product and take necessary checks and actions such as returning the product.

5) When receiving semi-finished or work-in-progress products from related parties to be used as raw materials, if the other party uses a dedicated vehicle, the following transportation conditions will be confirmed, and a list of items to be checked upon receipt will be established so that a return or other appropriate action can be taken if there are any abnormalities.

(1) Appearance (presence or absence of damage, condition of sealing, etc.)

(2) Temperature range during transport

(3) Pallets to use

etc.

2. When transporting semi-finished goods, work-in-progress, refurbished goods, reworked goods, and finished products.

1) When shipping to a customer, check the product specifications and consider the necessary conditions for delivery without any problems. Examples include the following:
   (1) Temperature and humidity setting
   (2) Stacking and loading methods
   (3) Related to the pallets used
   (4) Shipping container
   (5) Other special conditions

2) Confirm that the delivery vehicle can handle the following conditions without any problems and that the environment is suitable for delivering products without damage or contamination.
   (1) Is it possible to set the required temperature and humidity? Also, can that temperature and humidity range be maintained even at maximum load? If not, can the maximum load be changed?
   (2) Are temperature and humidity recorded at the necessary frequency? Also, can the thermometer and hygrometer be checked periodically to ensure there are no abnormalities?
   (3) If the containers or pallets are not your own products, can you manage the frequency of cleaning, disinfection, and replacement?
   (4) Is the interior of the vehicle kept in an appropriate clean condition?
   (5) Is it possible to load products together with other items? If so, can we confirm the load capacity, the items that can be included in the total load, etc.?
   (6) Can you confirm that there was no involvement of any outsiders other than the delivery person?

3) The organization will also conduct checks as needed and strive to maintain a safe delivery environment. If any abnormalities are found, appropriate improvements must be requested.

GMP 17 | Stock Management

● Requirements

The organization shall establish a system to use raw materials(including packaging materials), semi-finished products, work-in-process products, recycled products, reworked products 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.

●Thinking, specific examples

1. Storage period

1) Raw materials (including containers and packaging materials), semi-finished products, work-in-progress, recycled products, reworked products, and finished products shall be used within the specified period by establishing an appropriate shelf life and utilizing first-in, first-out (FIFO) systems.

2) During storage, traceability (see FSM | 4) of raw materials (including containers and packaging materials), semi-finished products, work in progress, recycled products, reworked products, and finished products shall be managed so that they can be linked to records.

2. Storage location

1) Raw materials (including containers and packaging materials), semi-finished products, work-in-progress, recycled products, reworked products, and finished products must be stored in a manner that prevents contamination and deterioration. Examples of such effects include the following:

(1) Deterioration due to temperature and humidity

(2) Foreign matter contamination due to broken pieces from ceilings and walls, dust, etc.

(3) Pests (see GMP | 3)

(4) Allergens (refer to FSM | 6, GMP4)

(5) Contamination due to leaks, condensation, etc.

2) Regarding "odor transfer from other raw materials, products, etc.," in most cases the possibility of this affecting food safety is considered low, but it is desirable to take action as needed.

3. Reference materials

Inventory management may also involve elements of food defense. Along with FSM7 compliance, the following resources may also be helpful.

• JFSM "Food Defense Implementation Support Handbook"

https://www.jfsm.or.jp/scheme/documents/index.php

GMP 18 Devices and Tools

● Requirements

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

●Thinking, specific examples

1. Prevention of food safety risks originating from equipment and utensils

1) Examples of what might be considered risks include the following:

(1) Biological: Contamination due to residual food residue, etc.

(2) Chemical: Residual mold and allergens due to insufficient washing and drying, etc., and chemical damage due to residual detergent, etc.

(3) Physical: Foreign matter contamination due to damage, deterioration, detachment, etc.

We will consider how to enable production activities while ensuring that such risks are adequately prevented.

2. Selection of equipment and instruments

1) It is desirable to be able to perform "thorough washing in a washing room, etc." and "reliable drying in a drying room, etc." whenever possible.

For equipment that needs to be fixed to the floor, we will consider designs that allow for easy handling, such as allowing the cleaning area to be disassembled.

2) Prepare the necessary capacity and quantity to allow sufficient time for washing and drying, taking into account actual operation.

3) Confirm whether regular cleaning and inspection of water and residue in pipes, ducts, etc. is possible.

4) The following points will be considered regarding the specifications.

(1) Ensure that parts that come into contact with food are food-compatible and that measures can be taken to prove this.

(2) For parts that come into contact with food, ensure that they are easy to clean, inspect, and replace, and consider what level of deterioration should warrant action and whether the frequency of such action is realistically feasible.

(3) Avoid, as much as possible, any items on top of food that may detach (screws, labels, etc.), and monitor as necessary.

(4) Before first use, check carefully to ensure that there are no paint fragments, metal shavings, etc. mixed in.

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

3. After equipment installation

1) Establish procedures for washing, drying, and disinfecting as necessary.

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

(2) Drying method: Drying chamber temperature setting, temperature setting when drying with hot air, drying time required, etc.

(3) Other: Presence or absence of alcohol spray, etc.

2) It is desirable to verify whether any intended hazards remain if the procedure is carried out according to the considerations. For example, after actually washing and drying according to the procedure, it is possible to check for the remaining allergens by means of bacterial testing of swab samples, ELISA testing, etc.

3) If the established procedures require particular attention and training for workers, it is desirable to have procedure manuals, visual explanatory materials, etc.

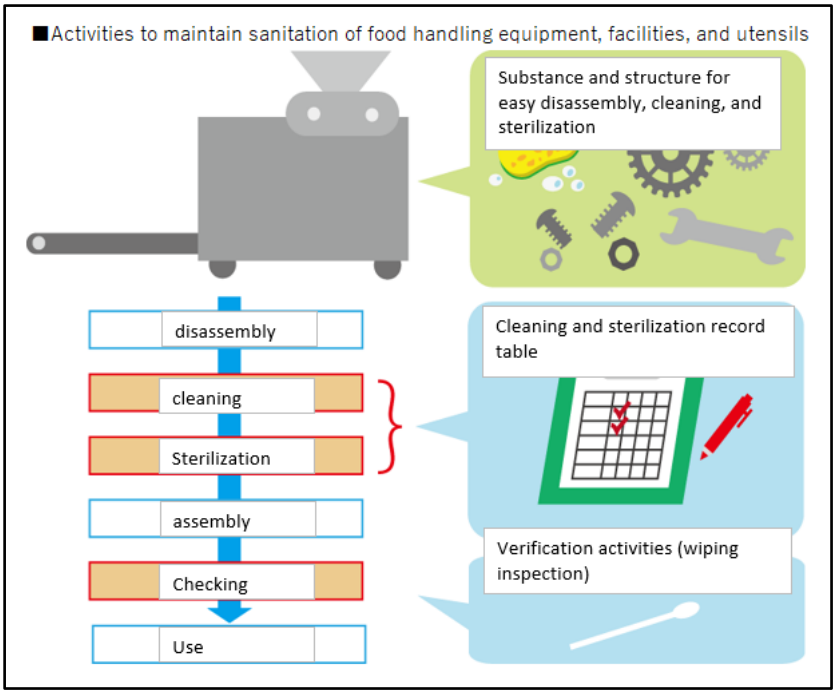
Furthermore, keeping records of areas prone to insufficient cleaning, and confirming that drying is complete, as needed, will increase the accuracy of the process.

4) Areas that are damaged, deteriorated, or otherwise pose a food safety risk should be monitored at an appropriate frequency.

When conducting monitoring, it is advisable to keep records.

5) Inform workers to report any abnormalities such as damage, parts falling off, or unusual noises.

[Reference] Activities to maintain hygiene of food handling equipment, facilities, and utensils.



GMP 19 Maintenance

● Requirements

The organization shall establish a system for the planned maintenance of all equipment and instruments critical to the safety of the product. Maintenance activities shall be performed in such a way that they do not pose a food safety risk.

●Thinking, specific examples

1. Maintenance and management of equipment and devices

1) Establish and implement procedures for the maintenance and management of all equipment and devices that are critical to the safety of the product. These procedures should include the following considerations:
   (1) Corrective maintenance: A management method in which maintenance is performed after a failure occurs, the system stops working, or its function deteriorates.
   (2) Preventive maintenance: A management method that focuses on prevention, such as inspecting equipment and replacing parts regularly.
   (3) Improvement maintenance: A management method that focuses on improvement and reinforcement to prevent failures from recurring.
2) The procedures for the maintenance and management of equipment and devices shall include the following items:
   (1) Planning of maintenance and inspection
   (2) Person in charge of maintenance and inspection
   (3) Identification of equipment and devices that require maintenance and inspection.
   (4) Frequency of maintenance and inspection
   (5) Procedures for performing maintenance and inspection (including the chemicals to be used)
   (6) Methods for confirming and recording the status of maintenance and inspections
   (7) Procedures for restoring the equipment to a state where food manufacturing is possible after maintenance (including cleaning, etc.)

2. Points to note regarding maintenance

1) Repair the area to prevent contamination of food, etc.
2) Check that the equipment and devices are not damaged and that no screws or other fasteners are missing.
3) In addition to corrective maintenance, preventive maintenance should be implemented systematically.
4) Preventive maintenance plans should include equipment for monitoring or controlling food safety.
   (For example, sieves, air conditioning filters, magnetic traps, metal detectors, etc.)

5) In the event of malfunction or damage, repair it promptly and restore it to normal operation.
6) When performing maintenance, take care not to contaminate surrounding manufacturing and processing lines or equipment.
7) Lubricants and heat transfer fluids that may come into direct or indirect contact with food should be selected to ensure that they do not compromise safety even if they come into contact with food.

Annex 1 List of documented information explicitly required by the standard

FSM6	Food Safety Policy and Goals
FSM13.2	Supplier Performance
FSM14	Traceability
FSM22	Serious Incident Management
FSM25	Corrective Action
HACCP Step 12 (Principle 7)	Record keeping
GMP6	Sanitation, work clothes and health management of employees, etc.
GMP11	Air and water management

Note: The legal provisions listed are examples of mandatory provisions in Japanese domestic laws and regulations, based on the relevant laws and regulations at the time of the guidelines' issuance.

Since laws and regulations may be amended, please check for the latest information regarding laws and regulations.

That's all.

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

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