JFS-C Standard Document

(Sector: CI, CII, CIII, CIV/K)
Version 3.2

Guideline

Edition 1.0

Japan Food Safety Management Association

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Introduction

1.1 JFS-C Standard Document

The JFS-C Standard Document (hereinafter referred to as “this Standard Document”) is a standard document developed by the Japan Food Safety Management Association (JFSM) and is intended to assist organizations to establish, operate and improve its management systems for manufacturing safe food products. In addition, this Standard Document can also be utilized to have the system of the organization (*1) evaluated by external agencies including Certification Bodies. This Standard Document is utilized by organizations that endeavor to realize a food safety management system applicable worldwide.

(*1) “Organization” refers to a business entity, group or individual to whom the requirements of this Standard Document apply.

1.2 Scope of Application

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

*Pet food is included in the following food manufacturing sector (C).

Food manufacturing sector (C)

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

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

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

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

Table 1: List of Sectors by GFSI

Code	Sector/Subsector	Code	Sector/Subsector
AI	Farming of Animals for Meat/ Milk/ Eggs/Honey	FI	Retail / Wholesale
AII	Farming of Fish and Seafood	FII	Food Broker / Agent
BI	Farming of Plants (other than grains and pulses)	H	Provision of Food Safety Services
BII	Farming of Grains and Pulses	G	Provision of Storage and Distribution Services
BIII	Pre-process handling of plant products	I	Production of Food Packaging
C0	Animal primary conversion	JI	Hygienic Design of Food Buildings and Processing Equipment (for building constructors and equipment manufacturers)
CI	Processing of perishable animal products		
CII	Processing of perishable plant products	JII	Hygienic Design of Food Buildings and Processing Equipment (for building and equipment users)
CIII	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

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

1.3 Structure of JFS-C standard document

The Standards Document consists of three elements, namely, Food Safety Management Systems (FSM), Hazard Analysis and Critical Control Point (HACCP), and Good Manufacturing Practice (GMP).

The Standard Document only specifies common requirements for the manufacturing sector, and does not cover individual hygiene requirements for individual product. Organizations shall use information appropriate for the organization (e.g. laws and regulations on food safety, standards specified by the relevant industry group, “General Principles of Food Hygiene” by the Codex Alimentarius Commission (*2), specific code of conduct), in addition to the requirements stipulated in this Standard Document.

The Standard Document is consistent with the benchmark requirement version 2024 (*3 hereafter, BR 2024) published by GFSI in December 2024. On the other hand, since BR 2024 adopts ISO22000:2018 (*4) in its scope structure and numbering structure, this Standard Document has a structure consistent with both the scope structure and

numbering structure.

In addition, the Standard Document uses a process approach that incorporates the plan-do-check-act (PDCA) cycle of ISO22000:2018 and a risk-based approach as a benchmark. The Standard Document establishes and implements a food safety management system to ensure the provision of safe food and services while meeting each applicable requirement and adopts a process approach for improving its effectiveness.

The process approach indicates that each process used for providing food and services is regarded as a system and is managed as such. In the process approach, the purpose of each process is clarified and managed in consideration of process interactions to aid the organization to effectively and efficiently achieve the intended results.

Risk (*5) in the Standard Document refers to all the factors that may hinder the achievement of the organization's food safety objectives and targets. Risk-based thinking involves "focusing on what factors may compromise the achievement of goals and objectives, identifying those factors, clarifying their effects, and considering necessary measures." By establishing a hypothesis based on risk, executing it, and performing verification based on the facts that are obtained, it becomes possible to aim to improve the accuracy of achieving the objectives and goals of the organization.

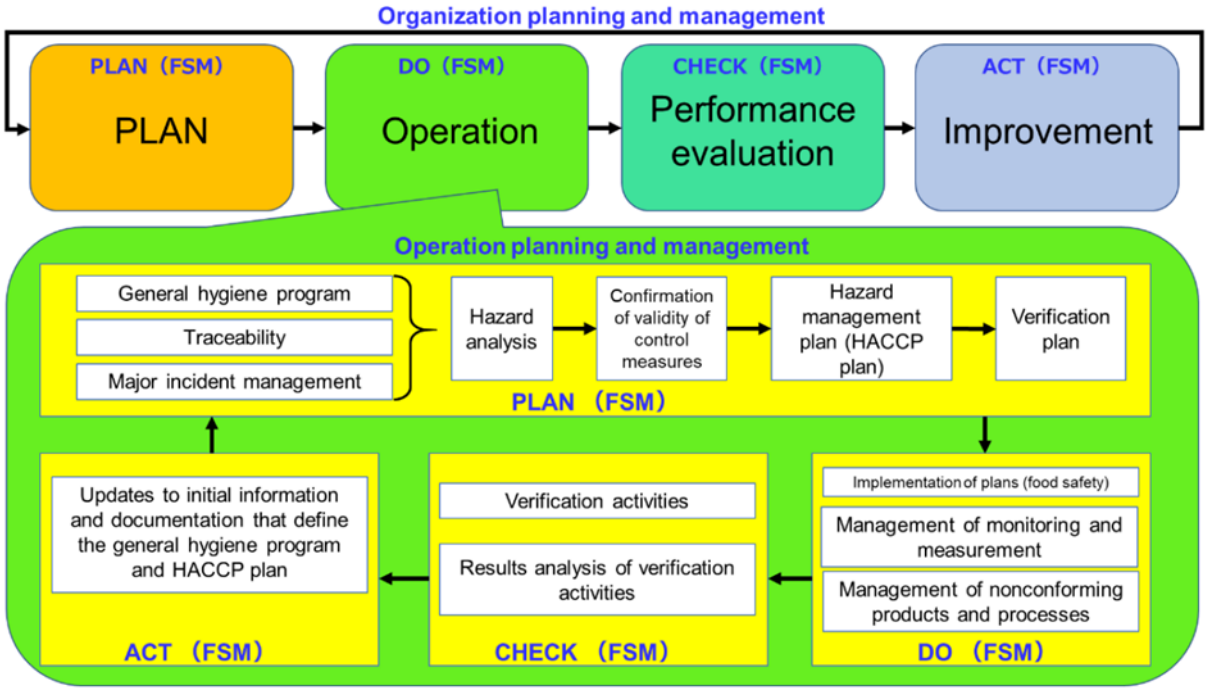
As shown in Figure 1, in the Standard Document the process approach adopts the concept of a plan-do-check-act (PDCA) cycle at two levels. The first level involves the FSM framework. The second level is targeted at the Do process within the food safety management system. For this reason, communication between the two levels is extremely important.

(*2) Codex Alimentarius Commission
"GENERAL PRINCIPLES OF FOOD HYGIENE," CXC 1-1969, Rev. 2022.

(*3) GFSI "The GFSI Benchmarking Requirements version 2024"

(*4) The International Organization for Standardization
"Food safety management systems - Requirements for any organization in the food chain" ISO 22000:2018

(*5) Unlike the risk defined in ISO22000:2018 (ISO22000:2018 3.39), the term risk is used in the JFS-C Standard Document as something limited more to food safety.



PLAN (FSM)		DO (FSM)	
FSM 1	Top Management Responsibility	FSM 7	Food defense
FSM 2	Top Management Commitment and Food Safety Culture	FSM 8	Food Fraud Prevention
FSM 4	Compliance with food safety laws	FSM 11	Procedures and Instructions
FSM 5	Food Safety Management System and General Requirements	FSM 14.1	Traceability
FSM 6	Food Safety Policy and Goals	FSM 15	Product development
FSM 9.1	Documentation procedures	FSM 16	Allergen Management
FSM 9.2	Control and storage of documented information	FSM 17	Control of Measuring and Monitoring Devices
FSM 10	Specification Control of Purchased or Provided Items and Services	FSM 19.1	Analysis and Testing
FSM 12	Resource Management	FSM 19.2	Environmental Monitoring for Food Manufacturing
FSM 13.1	Purchasing	FSM 19.3	Cleaning and Disinfection Program
FSM 13.2	Supplier Performance	FSM 22.1	Serious Incident Management
FSM 13.3	Outsourcing	FSM 23.2	Product Release
FSM 18.1	Product labeling (B-to-C products)	FSM 24	Identification of nonconformities and control of nonconforming products
FSM 18.2	Product labeling (B-to-B products, work in progress, semi-finished products)	CHECK (FSM) Performance evaluation	
FSM 23.1	Management of product specifications	FSM 3	Management Review
FSM 26	Change management	FSM 14.2	Traceability verification
		FSM 20	Internal Audit
		FSM 21	Complaint Handling
		FSM 22.2	Verification of food incident response manual
		ACT (FSM) Improvement	
		FSM 25	Corrective Action
		FSM 27	Utilization of Kaizen suggestions from personnel

Figure 1 Conceptual diagram of two PDCA cycles in the JFS-C Standard Document Food Safety Management System

At the beginning of this chapter, it was noted that the Standard Document consists of three elements: Food Safety Management Systems (FSM), Hazard Analysis and Critical Control Point (HACCP), and Good Manufacturing Practice (GMP). Instead of working independently, each of these elements influences the other. Each element has an organic function within this relationship that spirals up while interlocking. Figure 2 shows a conceptual diagram of the three elements. An understanding of this conceptual diagram will be effective for organizations that use the Standard Document for building and operating a food safety management system.

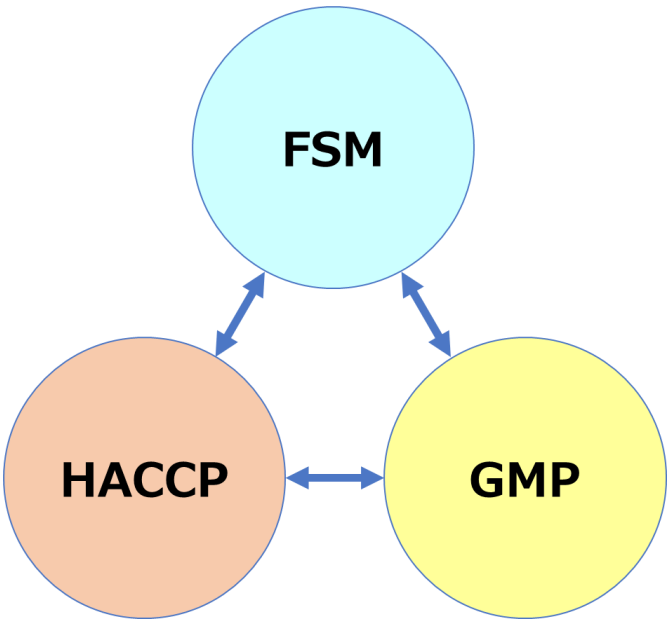


Figure 2 Conceptual diagrams of the organic functions of the three elements (FSM, HACCP, GMP)

1.4 JFS-C Standard Document Guideline

This guideline provides ideas and specific examples of what organizations should implement with regard to the JFS-C 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, products, business scale, and social background. This guideline is intended to be used as a reference for each organization to build a food safety management system suited to their own needs.

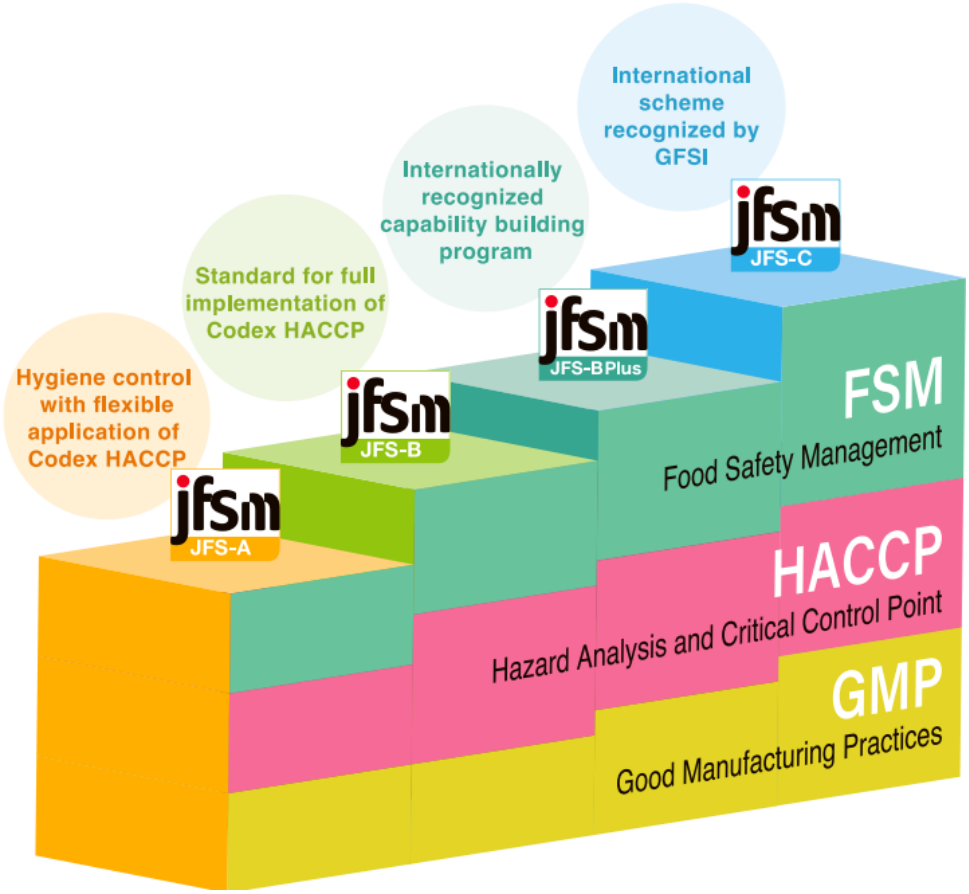


Figure 3 Overall view of JFS Standard Document and Certification Program

This guideline covers the C standards of the sector (CI to CIV/K) (Figure 3). Assuming that operators understand the basics of food safety, the guidelines omit detailed examples and focus on specific interpretations of the requirements.

This guideline consists of "Requirements" and "Concepts and Specific Examples," and provides interpretations and guidance as reference. These are only one concept, and other concepts and methods may be selected if it can be explained technically and scientifically that the requirements of the JFS standards are met. By using them together with research data and food safety theory from research institutes and industry

associations that have been published in the past, the technical information and know-how possessed by individual industries can also be utilized.

Even when management based on other approaches is adopted, it is required to ensure that the level of management is equivalent to this guideline. However, if there is any discrepancy between the requirements of the standard and the contents of this guideline, the requirements of the standard shall take precedence.

We hope that this guideline will help you understand the JFS standards.

[JFS-C Standard Guideline]

JFS-C standard (Sector: CI, CII, CIII, CIV/K)

I Food Safety Management Systems (FSM)

FSM 1 Top Management Responsibility

Requirements

Top management shall establish and operate a clear organizational structure which unambiguously defines the job functions, responsibilities, directing and reporting structure and information sharing of at least the personnel whose activities affect food safety.
There shall also be evidence that employees are made aware of them.
Top management shall appoint personnel responsible for the operation of the organization's food safety management system.

Concepts, specific examples

1. To clarify the organizational structure, the roles of the organizations and departments involved in the food safety management system shall be determined, communicated to employees.
   Use an organization chart that includes a communication system for instructions, reporting, and consultation.
2. In order to clarify the communication system for instructions, reporting, and consultation, it is easier to manage by using meeting bodies and morning meetings to determine the activities necessary for food safety. Instructions, reporting, and consultation are as follows.
   1) Instructions: The clarification of tasks and roles by a supervisor, manager, or other person.
   2) Reporting: The person who performed the work communicates the facts to a supervisor, manager, or other person.
   3) Consultation: Confirmation of appropriateness should be obtained when it is not possible to determine whether the work is appropriate, or when new activities are undertaken.
3. The following are points to be considered when establishing the organizational structure:
   1) The positions and functions included in this standard are included.
   2) The Food Safety Officer (see below) receives direct instructions from top management.

3) Quality assurance and quality control departments can objectively evaluate food handling departments such as manufacturing.

4) No double-directed structure in which instructions pertaining to food safety come from two different places.

5) It is a simple organization.

4. The term "information sharing" includes communicating information that may affect food safety to the person or department that needs that information. In particular, ensure that changes that may require changes to the HACCP plan, such as new products or changes in production lines, are communicated to the HACCP team.

5. Examples of evidence that employees are informed about the above include, but are not limited to, meeting minutes, morning meeting records, and communication notes. It can also be confirmed in communications during internal and external audits, etc.

6. Determine a Food Safety Officer as "the person responsible for the operation of the food safety management system. The competencies required of the Food Safety Officer include the ability to establish, implement, and maintain JFS standards and the HACCP system. This responsible person may be the leader of the HACCP team (*see HACCP Step 1), but the two need not be the same, and there may be a HACCP team leader under the direction of the responsible person. This responsible person can also be more than one person.

   1) The food safety Officer should have a good understanding of the food safety policies in the organization, and knowledge of food safety and knowledge and experience in the field will help create an effective system.

   2) The role of Food Safety Officer includes the following:

      (1) Sanitation, including daily inspections, will be carried out systematically in accordance with management's instructions.

      (2) In order to prevent the occurrence of food sanitation hazards, give necessary attention to matters concerning sanitation control and, when necessary, offer opinions to management.

      (3) Prepare documents concerning sanitation control of facilities and products, etc., and inform and confirm them with food handlers, etc.

7. Items to be referred to in legal provisions related to food safety (this item is applicable to the extent in Japan):

   1) Assign Food Hygiene Supervisor or Food Hygiene Manager who meets the necessary requirements.

      (1) Food Hygiene Supervisor: Appointed in accordance with Article 48 of the Food Sanitation Law. Target foods are whole milk powder, sweetened milk powder, adjusted milk powder, meat products, fish meat ham, fish meat sausage, irradiated food, edible oils and fats, margarine, shortening, and additives.

(2) Food Hygiene Manager: Unless Food Hygiene Supervisor is appointed according to the Food Sanitation Law Enforcement Regulations, each facilities that require a business license, and facilities that submit business notifications shall be placed.

2) Food Hygiene Supervisor or Food Hygiene Manager shall direct hygiene control while respecting the opinions of Food Safety Officer.

3) Food Safety Officer can also serve as Food Hygiene Supervisor or Food Hygiene Manager. If Food Hygiene Supervisor or Food Hygiene Manager is appointed separately, it is important to share information and collaborate with the Food Hygiene Officer.

Reference: "Food Hygiene Supervisor" "Food Hygiene Manager"

	Food Hygiene Supervisor	Food Hygiene Manager
laws and regulations governing	Food Sanitation Law Article 48	Food Sanitation Law Enforcement Regulations In accordance with Article 66-2 established by, designated cities, etc
Qualification	National qualification	Public qualification
Submission destination	Prefectural governor	Public health center
subject	For each licensed facility that manufactures and processes target foods and additives, etc	Each facility subject to business license and business submission
Whether qualification is renewed or not	Basically nothing. Regular attendance in practical training is recommended.	Basically nothing. Regular attendance at designated training courses is recommended.

FSM 2 Top Management Commitment and Food Safety Culture

Requirements

Top management shall demonstrate evidence of its commitment to establish direction, engage personnel, and provide sufficient resources to maintain a positive food safety culture and develop and continuously improve food safety management system shall be provided.

The organization shall establish, implement and maintain an assessment plan to identify areas for improvement to drive a positive behavior in its food safety culture. This assessment plan shall include, at a minimum, communicating with employees, responding to Kaizen suggestions, training to improve food safety, and assessing the performance of food safety activities.

And top management shall ensure that all personnel demonstrate a clear commitment to safe food production and handling.

Concepts, specific examples

1. Top management is responsible for maintaining a positive food safety culture and for establishing, implementing, maintaining and continually improving the food safety management system, and demonstrates its commitment to establishing direction, engaging personnel and providing sufficient resources through the implementation of the following:
   1) Develop a food safety policy.
   2) Communicate to employees in a timely manner the importance of compliance with laws, standards, social norms, and rules set by the organization.
   3) Review the food safety management system in a timely manner.
   4) Provide necessary resources including human resources in a timely manner.
   5) Ensure that employees are aware of factors that can influence food defense and food fraud risks. To this end, establish and maintain a system that allows the organization to constantly obtain the following information.
      - All related laws
      - Scientific and technological developments
      - Industry code of practice
      - Other information on food safety and product quality issues, etc.
   6) Engage, direct, and support employees to contribute to food safety effectiveness.
   7) Set business goals that support food safety.
   8) Provide opportunities and means for all employees involved in food safety to provide the organization with potential food safety improvements they discover. (Responding to “Suggestions for improving food safety from employees” listed in “FSM 27.”)
   9) Other matters necessary for the establishment, implementation and maintenance of food safety management systems.
2. In order to promote improvements through the food safety management system, the organization shall establish, implement and maintain an assessment plan to identify areas for improvement to promote positive action regarding the food safety culture that the top management commits to. The following are examples of the elements. (5 dimensions)

   1) Clarify the vision and mission.

      Is food safety integrated into your business strategy? (including providing resources and other support).

      Does the company provide direction and objective goals to employees and clearly state what is expected of them?

      Does it provide messaging with leadership to employees?

   2) Conduct outreach to the people.

Have the necessary stakeholders been clarified and the governance structure clarified?

Do you communicate with employees on site? (e.g., by holding meetings)

Is there an organization in place for learning and training?

Does the company have an evaluation system (incentives, rewards, recognition, etc.) for actions taken by employees?

3) Consistency.

Is the top management taking the responsibility seriously as the person who is ultimately responsible for the company?

Are employees' performances properly evaluated?

Are all processes kept in writing?

4) Adaptability.

Do they demonstrate food safety expectations while understanding the personal cultural differences of each employees?

Does the company provide prompt feedback on employee offers?

Is the business model appropriately changed to manage risks and solve problems?

5) Recognize hazards and risks.

Does the company provide risk prevention education, such as by providing basic hazard information?

Are employees involved in activities to prevent near misses?

Are hazards verified when they occur and are risks communicated?

*The Food Communication Project (FCP) site on the Ministry of Agriculture, Forestry and Fisheries website (see link below) is also a useful reference.

https://www.maff.go.jp/j/shokusan/fcp/index.html

3. Fundamental to a well-functioning food safety management system is the establishment and maintenance of a positive food safety culture that recognizes the importance of the actions of all employees involved in providing safe and appropriate food. Therefore, top management shall ensure that all personnel demonstrate a clear commitment to safe food production and handling. Reference examples are as follows.

(Reference case)

- Personal commitments such as conducting thorough visual checks of the manufacturing process after washing/cleaning and before the start of manufacturing in order to prevent contamination by foreign matter. etc.
- Signatures in the record after food safety training at the time of joining the organization or at morning meetings, etc.
- Confirmation of commitment during food safety performance assessment, etc.

FSM 3 Management Review

Requirements

Top management shall conduct management reviews on a regular basis and record them in an appropriate manner to review all elements of the overall food safety management system, including HACCP plans for managing food safety hazards and risks.
In the event of changes that have an effect on food safety, top management shall ensure that the food safety management system remains relevant and effective.

Concepts, specific examples

1. Management Review
   Management review" means that top management monitors and evaluates the adequacy, appropriateness, and effectiveness of the targets to achieve the set goals, and points out areas for improvement.
   1) The food safety manager takes the lead in collecting and analyzing information that enables top management to evaluate the food safety management system of his/her organization, and reports (input) to top management on a regular basis.
   2) Top management evaluates its own food safety management system and provides instructions for evaluation and improvement as a result of management review.
   3) Input items for management review shall include the following information:
      (1) Nonconformity and Corrective Action Information
      (2) Results of process monitoring and measurements
      (3) Results of audits and reviews
      (4) Results of supplier management
      (5) Environment surrounding the organization
      (6) Results of verifying the implementation of FSM, GMP and HACCP
      (7) Results of improving and updating the food safety management system
   4) In addition, although not explicitly stated in the requirements, input of the following information is also recommended:
      (1) Follow-up on the results of previous management reviews
      (2) Serious accidents and recoveries
      (3) Review of communication activities, including customer feedback
   5) HACCP plan reviews may be conducted by the HACCP team, the results of which are reported to top management. HACCP plan review is to review the HACCP plan from time to time due to information such as new products, line changes, accidents at other companies, and revisions to legal and regulatory requirements. In addition, periodic reviews could also be conducted.
   6) The results of the management review shall be reflected in the improvement of the food safety management system. The results of the management review shall include decisions and actions regarding the following:

(1) Any changes to the food safety management system, including resource needs
(2) Revision of Food Safety Policy and Goals

2. Verification activities and analysis for management review

1) Verify the implementation of FSM, GMP and HACCP. The verification shall confirm that the requirements are met after establishing a verification plan including objectives, methods, frequency, responsibilities, etc., in accordance with the importance of the subject matter.

For example, the following methods are used for verification:

(1) Check records (confirm that established procedures were followed and that there were no problems)
(2) Confirmation that work was performed in accordance with procedures (by witnessing the work, etc.)
(3) Confirmation that food safety is ensured as a result of work performed according to procedures (e.g., confirmation of workmanship)
(4) Confirmation of safety through testing of final products, etc.
(5) Confirmation of equipment used for monitoring, etc. (calibration, etc.)
(6) Prior to the introduction of a new procedure, etc., confirmation that the objective can be achieved with that method (validation)
(7) See HACCP Step 11 (Principle 6) for verification of the HACCP system.

2) These checks will be performed as appropriate in response to social events, changes within the organization, product or process changes, or new scientific findings that affect food safety.

3) If a problem is discovered through verification, it may be addressed through the mechanisms of FSM 24 and FSM 25. If the product has already been shipped, action may be required under FSM 22.1.

4) The results of the verification will be analyzed by the food safety manager or other person with expertise in the field. The purpose of this analysis is to clarify the overall performance of the food safety management system and to provide input to top management for reviewing the system. This analysis can also consider, for example, the following information:

(1) Records of nonconformities, customer complaints, serious accidents, and actions taken to remedy them
(2) Results of internal and external audits
(3) Review results of safe product manufacturing systems (HACCP plans, GMP controls, etc.)

5) The results of the analysis shall be recorded in an appropriate form so that they can be used in management reviews.

3. Updating Food Safety Management System

1) Top management provides direction for the continuous updating of the food safety management system and ensures that periodic and ad hoc updates of the food

safety management system are made. This is done through a process of judgment and decision making by top management during management reviews.

2) The updating of the food safety management system shall be carried out in consideration of the following:
   (1) Results of Management Review
   (2) Results of internal audits (FSM 20)
   (3) Results of verification activities and analysis of results
   (4) Changes in internal and external environment

3) The organization shall establish specific methods for updating the food safety management system, implement them on a regular and ad hoc basis, keep records, and report to top management.

FSM 4 Compliance with food safety laws

Requirements

When developing a food safety management system, the organization shall develop, implement and maintain detailed procedures to ensure that all processes and operations that have an effect on food safety are in compliance with the laws of both the country of manufacture and the intended country of sale.
In addition, records of implementation shall also be maintained.

Concepts, specific examples

1. The organization shall clarify the food safety laws and regulatory requirements for its own organization and define the methods of control. The organization shall comply not only with the laws and regulations of the country of manufacture, but also with the laws and regulations pertaining to food safety in the country of sale. When relevant laws and regulations are revised or new laws and regulations are enacted, it is necessary to grasp them in a timely manner, communicate them to the organization, and change management methods as necessary. The laws and regulatory requirements of the country of sale must also be understood. Evidence of the results of the implementation of the control procedures must be retained. An example of a record of the implementation of the procedures is a list of relevant laws, regulations, and requirements, and records of their confirmation and updating.
2. Laws, regulations, and regulatory requirements pertaining to food safety to which reference should be made (this item is applicable to the scope in Japan)

   Business operators engaged in manufacturing or processing shall assign a food hygiene supervisor or food hygiene manager who meets the necessary requirements.

   1) Food Hygiene Supervisors: These are appointed in accordance with Article 48 of the Food Sanitation Law. Target foods are whole milk powder, sweetened milk powder, adjusted milk powder, meat products, fish meat ham, fish meat sausage,

irradiated food, edible oils and fats, margarine, shortening, and additives.

2) Food Hygiene Manager: A Food Hygiene Manager is appointed for each facility that is to obtain a business license and each facility that is to submit a business notification, except in cases where a Food Hygiene Manager is appointed in accordance with the provisions of the Enforcement Regulations of the Food Sanitation Law.

FSM 5 Food Safety Management System and General Requirements

Requirements

The organization shall document the elements of the Food Safety Management Systems and shall establish, implement and maintain them appropriate to the scope of the products covered by its business activities.
In addition, the Food Safety Management Systems shall be continuously improved by properly adapting to changes in the surrounding social environment.

Concepts, specific examples

1. This requirement requires that the framework for the entire food safety management system be clarified. The JFS-C standard uses a process approach, incorporating the Plan-Do-Check-Act ("PDCA") cycle and risk-based approach of ISO 22000:2018, as the benchmark. The standard document adopts a process approach in establishing, implementing, and improving the effectiveness of a food safety management system to ensure the provision of safe food and services while meeting the respective applicable requirements. (See JFS-C Standard Document Ver. 3.1 "1.3 Structure of this Standard Document" and this Guideline Document 1.3 Structure of the JFS-C Standard Document.)
2. In the process approach, it is important to consider the interaction of each process, e.g., how management, control, monitoring, and support processes relate to each other. Processes should not be considered in isolation, but rather in relation to other processes, otherwise it may be difficult to achieve operational effectiveness, and consideration should be given to the sequence of processes, the flow of information, and the flow of goods.
3. In particular, the PDCA (Plan-Do-Check-Act) cycle, which is based on documentation, implementation, and maintenance, needs to be followed, and since changes in the social environment can affect views on food safety and hazard factors, it is necessary to constantly collect and analyze information and reflect it in improvements to the management system.
4. In establishing a food safety management system, the following items shall be considered:
   1) Clarify the scope of application of the food safety management system.

The scope of application is determined by considering areas of manufacturing, lines, processes, products, personnel within the organization, subcontracting, etc. For example, it is possible to establish a management system for only one of the two manufacturing lines, as long as the system includes all the series of activities: design and development of food products, receiving of raw materials, processing, packaging, storage, shipping, and delivery, but it is not possible to set the scope of application to cover only processing and packaging and exclude the other activities.

If part of a series of activities is not within the organization's control, such as the production of food products designed and developed by another company, or if the customer arranges for the delivery of the products, the activities may be excluded from the scope of application. (In-house activities cannot be excluded from the scope of coverage, even if they are conducted at a different business location.)

2) Extract the processes required for a food safety management system.

Organize and clarify the activities and mechanisms required to establish a food safety management system based on the JFS-C standard in terms of its functional units.

3) Establish the sequence and interrelationships of the processes.

Document the results of establishing the sequence and interrelationships of the activities and mechanisms identified in (2) above. This may be a document illustrated with figures and tables.

4) Determine the criteria and methods necessary to ensure the efficient operation and control of the process.

These criteria and methods are determined by the competence of the personnel operating in the organization and the complexity of the work.

5) Evaluate, measure, monitor and analyze the process, as well as implement the necessary measures to achieve the planned results and continue to improve.

The system is created in which the activities carried out and the information obtained from inspections and verifications be analyzed and used as input for future activity plans.

6) Have a system verification procedure to ensure the continued effectiveness of the food safety management system.

See FSM 3 and FSM 20. For verification of the HACCP plan, see HACCP Step 11 (Principle 6).

5. The organization shall prepare the documentation required by the standard and make it available to employees who need it. The table below lists the documented information explicitly required by the standard. For information other than these, each organization shall consider whether documentation of information is necessary to demonstrate conformity to this standard, and shall create such documentation as it deems necessary. The "Food Safety Management System" is a systematic

presentation of an organization's activities. Depending on the size and use of the organization, not all items requiring documentation may be described in the Food Safety Management System, but they can be managed as separate documents that can be referenced.

●List of documented information explicitly required by the standard

Clause	Content of documented information	Check
FSM 1	Records that top management has made employees aware of the defined organizational structure (at least the duties, responsibilities, instruction/reporting system, and information sharing for employees in charge of activities that affect food safety).	
FSM 3	Management review by top management	
FSM 4	Records of implementation of food legal compliance procedures	
FSM 5	Elements of the food safety management system that are deemed necessary by the organization	
FSM 6	Food Safety Policy and Goals	
FSM 7	●Assessment procedures for prioritizing responses to threats to food defense ●Food Defense Plan	
FSM 8	●Evaluation procedures for assigning predominance to food deception reduction measures ●Food Deception Prevention Plan	
FSM 9.1	●Information documentation procedure ●Records required to prove the implementation of food safety management	
FSM 10	Specifications of what is being purchased or supplied	
FSM 13.2	Supplier evaluation/approval/monitoring records	
FSM 13.3	Documents related to the management of outsourced processes	
FSM 14.1	●Documented procedures for implementing and maintaining product tracing ●The following records are required to ensure traceability: ・Identification of all externally procured raw materials (including containers and packaging materials), products, or services ・Records to identify batches, semi-finished products, work in progress, refurbished products, reworked products, finished products and packaging throughout the manufacturing process ・Record of purchasers and shipping destinations for all products supplied ・If the procedure has been updated, record it	
FSM 14.2	Trace test verification results	
FSM 16	Allergen management plan	
FSM 17	Records of actions taken if equipment or devices is found to be inaccurate	
FSM 21	Management mechanism for handling complaints and utilizing complaint data	
FSM 22.1	●Food incident management procedure ●Record of incidents that have occurred	
FSM 22.2	Product recall test verification results	
FSM 23.1	Specifications of products (raw materials (including containers and packaging materials), semi-finished products, work in progress, recycled products, reworked products, and final products)	

FSM 23.2	Product release (shipping) procedures	
FSM 24	Procedures for identifying nonconformities that impact food safety and for clearly identifying, managing, disposing of, and reworking resulting nonconforming products	
FSM 25	Procedures for determining and implementing corrective actions when nonconformities impacting food safety occur	
FSM 26	Procedures to assess, to the extent necessary, the impact of changes that may impact food safety in advance	
HACCP Step 12 (Principle 7)	Documents and records required for HACCP plan （Step 12 requires documentation of all documents and records required for the HACCP plan.）	
GMP 4.1	Necessary control measures/methodological procedures, including isolation, aimed at preventing contamination and cross-contamination (including cross-contact)	
GMP 4.2	Procedures for control measures/methods for hazards that require enhanced control (as appropriate)	
GMP 6.1	Personal hygiene standards for employees, etc.	
GMP 6.3	Health management procedures for employees, etc.	
GMP 6.4	Documents related to GMP 6.1 and GMP 6.3 applied to contracted businesses and visitors	
GMP 7	●Record of education/training implementation ●System for re-education (if necessary)	
GMP 8	Documented procedures for organizing, cleaning, and sanitizing/disinfecting	
GMP 9	Records of product rework	
GMP 10	Business site patrol/inspection results	
GMP 11	Monitoring records of air, high pressure gas, and water (including ice and steam) used in food production	
GMP 19	Systems for systematically maintaining all equipment and devices important to product safety	

FSM 6 Food Safety Policy and Goals

Requirements

The organization shall have a clear, concise and documented food safety policy statement and objectives specifying the extent of the organization’s commitment to meet the safety needs of its products. Top management shall ensure the organization to establish measurable objectives consistent with the organization’s food safety policy, formulate plans to achieve the objectives, monitor the progresses against the objectives, and to update the objectives as necessary.

Concepts, specific examples

1. The organization shall develop a written food safety policy. This policy provides direction for the organization's overall activities related to the food safety management system and includes the following:
   1) Commitment to providing safe food products and corporate philosophy
   2) Management Policy of the Organization

3) Examples of 1)~2) above are shown below.
   (1) The organization provides safe and trusted food products to consumers based on the consumer.
   (2) The organization appropriately responds to changes in the surrounding social environment, complies with laws, regulations, ordinances, fair rules, and social norms, and promotes organizational activities in line with social ethics.
   (3) Accept employee suggestions for food safety improvements and make appropriate use of employee suggestions to improve food safety awareness throughout the organization. (FSM 2)

2. This is important to ensure that all employees understand the direction of the activities and that each is aware of his or her role. Therefore, the food safety policy and the goals that are aligned with it should be prepared in a language that all employees can understand.
3. In addition, not only must the document be prepared, but it shall also be disseminated to all employees. The following are examples of methods of disseminating the document:
   1) It is always taught when training employees.
   2) Post it in a place where employees can see it on a regular basis.
   3) Employees are told in the morning meeting. etc.
4. The food safety policy is developed by or with the involvement of top management. Top management" refers to the chief executive officer of the organization, such as the president or plant manager, but it does not necessarily have to be the highest-ranking person in charge as long as he or she has overall food safety responsibility and authority, and there may also be cases where there are multiple people who qualify as managers.
5. Top management will periodically review the food safety policy for appropriateness and revise it as necessary.
6. Food safety goals should be measurable. A "judicable goal" should be a concrete numerical goal that can be measured to determine whether it has been achieved or not, for example, the number of food safety-related complaints. Even in cases where it is difficult to quantify, goals that can be evaluated as achieved or not achieved should be set.
7. In addition to top management establishing the goals, the framework could be such that the food safety officer (see FSM 1) or others establish the goals. Progress on food safety goals shall be monitored and activities reviewed as necessary.
8. It is recommended that the goals for the organization as a whole be broken down into goals for each department and individual.

FSM 7 Food Defense

Requirements

The organization shall document, implement, and record assessment procedures to identify potential and overt threats to hazards of intentional food contamination by persons within or outside the organization and prioritize response to those threats. Appropriate knowledge and expertise shall be utilized to develop and maintain an effective plan for this assessment.

The organization shall document, implement, verify and maintain a food defense plan that specifies the actions that the organization implements to mitigate or exclude the identified food defense threat.

This plan shall also be checked at intervals determined by the organization, or when a new threat is established, and reviewed, if necessary, as a result.

The organization shall also establish access controls for areas where food defense threats have been identified.

The organization shall establish and implement procedures for responding to possible intentional contamination of product.

Concepts, specific examples

1. Food defense means measures to prevent, avoid, and respond to the intentional contamination of food by persons inside or outside the organization with physical, chemical, and biological hazards.
2. In the threat assessment of food defense (analyzing threats and identifying weak points), the risks of intentional food contamination described in 1. are identified, their magnitude is evaluated, and the defensive measures are formulated as a food defense plan. In light of the above, appropriate knowledge and expertise shall be utilized to develop and maintain an effective plan for this assessment. Examples of how this can be utilized include looking at other organizations' case studies posted on government recall sites, past case studies within the organization, receiving specialized external training, and obtaining the participation and advice of external food hygiene experts. Since it is difficult to completely protect against intentional food contamination because it is a human activity, priorities are determined, documented, implemented, and recorded by contrasting the contents of each extracted threat with the management resources that can be invested.
3. Document and implement procedures for conducting threat assessments of facilities.
4. Based on the results of the food defense and facility threat assessment, document, implement, verify and maintain a food defense plan that includes methods, responsibility and authority, and decision criteria to prevent intentional food contamination, tampering, etc. This food defense threat assessment shall also be checked at intervals determined by the organization, and/or when a new threat is

established, and reviewed, if necessary, as a result. The food defense plan shall be revised/updated as necessary and shall be implemented, verified, and maintained.

5. The food defense plan includes the following elements:
   1) Personnel from each discipline with food defense responsibilities have been designated
   2) Have policies and procedures in place to record and control employees, contractors, and visitors entering and leaving the facility area
   3) Have procedures to ensure the safety of raw materials, utensils, containers and packaging materials, drugs, and food during storage and distribution.
   4) The site shall be physically secured (security)
   5) Have procedures and carry out in place for dealing with discovered or suspected intentionally contaminated or deteriorated food, packaging, or equipment
   6) Have an effective recall program (see FSM 22.1)
   7) Provide necessary education and training to personnel in accordance with the food defense plan established by the organization
6. Access controls implemented for areas where food defense **threats** are identified are also included in the food defense plan. Access controls can include guards, ID cards, or systems that limit or record access to authorized personnel.
7. Reference
   1) In addition to monitoring cameras and lock controls, communication among employees is a deterrent to food protection.
   2) Excessive reliance on hard measures of food defense may instead damage the good relationship between employees and managers. Thus, for example, an organization could explain to employees that the monitoring cameras are not installed based on suspicion of employees, but so that the company can prove the actions of employees in the event of a food accident.
   3) Food defense is not limited to physical measures of the facility; internal attacks from interested parties must also be anticipated. Ensuring that there are no short-term workers or disgruntled or disgruntled workers is particularly useful.
   4) A mechanism for examining trends in social cases, cases of other companies in the same industry, prevention cases, and predictive signs is required.
8. For specific examples of food defense, please refer to the following. (1), (2), and (3) are applicable in Japan.)
   1) Ministry of Health, Labour and Welfare "Guidelines for Food Defense Measures (for Food Production Plants)" (Draft revised in 2019)
   2) Ministry of Health, Labour and Welfare "Guidelines for Food Protection Measures for Large-Scale Events (Manufacturing Plants)" (Revision 2)
   3) Ministry of Agriculture, Forestry and Fisheries "Voluntary Action Plan for Enhancing Confidence in the Food Industry" Guidance for Formulation

-Five Basic Principles - (Revised January 2016)
(Basic Principle 1) Clarify the consumer's point of view
(Basic Principle 2) Establish compliance awareness
(Principle 3) Basis of proper hygiene and quality control
(Basic Principle 4) Establish systems for appropriate hygiene and quality control
(Basic Principle 5) Efforts to collect, communicate, and disclose information

4) FDA "Food Defense Mitigation Strategies Database (FDMSD)". https://www.cfsanappsexternal.fda.gov/scripts/fooddefensemitigationstrategies/index.cfm

FSM 8 Food Fraud Prevention

Requirements

The organization shall document, implement, and record assessment procedures to identify potential and overt food fraud vulnerabilities such as tampering with records and labeling of products and intentional dilution, and prioritize food fraud mitigation measures.
Appropriate knowledge and expertise shall be utilized to develop and maintain an effective plan for this assessment.
The organization shall document, implement, verify and maintain a plan that specifies the measures the organization implements to mitigate the identified threats of food fraud.
This plan shall also be checked at intervals determined by the organization, or when new vulnerabilities are recognized, and reviewed, if necessary, as a result.

Concepts, specific examples

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

information can be obtained, for example, from

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

2) Identify in what situations food fraud can occur.

It is also effective to assume food fraud in each production flow as follows:

(1) Fraud in raw materials used

(2) Fraud during manufacture

(3) Fraud in products after shipment (including resale of discarded defective products as food)

3) Evaluate the ease of occurrence (vulnerability).

3. Supply chains are becoming more complex, extending overseas, and the risk of food fraud is increasing. "Assessing vulnerability" means analyzing what types of food fraud are likely to occur and how likely they are to occur due to external and internal factors in the context of such changes in the environment surrounding the organization. Vulnerability assessors need to understand the potential food fraud risks, which includes knowledge of the raw materials used in the field and the concept of vulnerability assessment described above. Vulnerability assessment is conducted from two perspectives: product/supplier. In light of the above, appropriate knowledge and expertise shall be utilized to develop and maintain an effective plan for this assessment. Examples of how this can be utilized include looking at other organizations' case studies posted on government recall sites, past case studies within the organization, receiving specialized external training, and obtaining the participation and advice of external food hygiene experts.

Examples of vulnerability assessment steps include:

1) Clarify the raw materials and their specifications related to the food products handled.
2) Estimate what are the events that could cause fraud (what kind of fraud could occur).
3) Estimate the magnitude of risk for any possible fraud that may occur.
4) Estimate the magnitude of the impact of fraud on food safety.
5) Prioritize vulnerabilities by risk and magnitude of impact.

4. Based on the results of the vulnerability assessment, a management plan to reduce food fraud shall be developed after conducting an evaluation of current control measures related to food fraud. The plan shall clearly identify priorities. The following methods can be used as means to reduce food fraud:

1) Conduct appropriate monitoring in response to vulnerabilities
2) Verification of origin and labeling
3) Specification Management

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

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

FSM 9.1 Documentation procedures
FSM 9.2 Control and storage of documented information

Requirements

FSM 9.1

The organization shall document, implement, and maintain documentation procedures to manage the documented information (including records) necessary for effective operation of the food safety management system and explicit control of the process.

In addition, the organization shall keep records necessary to prove the implementation of food safety management, determine an appropriate storage period, and store them.

FSM 9.2

The organization shall provide the documented information required to demonstrate its effective operation of the food safety management system and control of processes. Documented information shall be stored for the period required by the customer or legal and regulatory requirements, or if there are no applicable requirements, for a period exceeding the shelf life of the food. In addition, the documented information shall be effectively controlled so that it is always available when it is required.

Concepts, specific examples

1. In the requirements of this standard, it is important to maintain that "necessary settings, etc., are securely retained and can be explained to a third party too" and that "records are kept without shortages and can be reviewed later". The following actions are required:
   1) The required documents have been selected. (See FSM 5)
   2) The latest versions of selected documents are kept and used.
2. "Documented information" includes "documents" and "records", details of which are as follows:
   1) Document

      Documents refer to information and the medium in which it is contained, and include not only written text on paper, but also images, photographs, diagrams, audio and video, and those stored in electronic media. Examples include specifications, documents describing procedures, drawings, reports, standards, and work procedure videos.
   2) Record

      A "record" is a document that describes the results achieved or provides evidence of activities performed.

      (1) Record keeping enables the following actions to be taken:
         ① Appropriate food safety management systems can be clearly demonstrated to third parties too.
         ② Able to analyze trends in activities over a certain period of time.

③ Information can be shared within the organization.

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

(3) Establish "rules for amending records" so that corrections such as erroneous entries will not be suspected of being "falsification. For example, "Corrections should be made with double lines, and the date of correction and the name of the person who made the correction should be written in the corrected area," etc., so that a third party can clearly understand the correction, too.

3. Documents are prepared for the following purposes:
   1) Ensure that the company's status, settings, and procedures are known to all but the preparer too.
   2) Standardize work and prevent variation in perception and understanding among individuals.
   3) By keeping a record, it is possible to trace and identify the cause if any problems occur.
   4) It facilitates correct explanations to third parties and clarifies the legitimacy of own organization.
4. The "documented information necessary for the effective operation of the food safety management system" is determined by the organization itself, taking into account its industry, business type, size, and complexity of operations, in addition to what this standard explicitly requires to be documented in FSM 5 (the list of documented information explicitly required by the FSM 5 standard).
5. "Documented information necessary to clearly define the control of the process" is a document that clearly describes the main points and cautions in controlling each stage of the manufacturing process, which enables appropriate and effective operation based on such information, and also provides evidence of such control.
   Specific examples include temperature control such as heating and cooling, specific measures to prevent contamination, and conveyor speed.
6. Documented documents must be managed so that the latest version can always be referenced and operated. For this purpose, a document management procedure should be developed and operated to make it as easy as possible to manage documents by establishing appropriate rules for modifying and storing documents. The procedure should include all of the following points:
   1) Documents are approved by an authorized person prior to issuance.
   2) Documents will be reviewed and updated as necessary.
   3) Clearly identify the changed part and the latest version of the document by attaching a setup number, obsolete number, etc. to the document.
   4) Distribute appropriate documentation so that it is available to those who need it.
   5) Documents should be legible and easily identifiable.
   6) Maintain necessary documents created externally.

7) Create a list of documents.
8) Designate where documents are to be stored.
9) Obsolete documents such as old versions should be disposed of or stored in another designated location to prevent misuse.

7. Appropriate retention periods shall be defined for documented information. The retention period is determined by the organization itself, taking into account the following:
   1) Length of time the product is on the market
   2) Product storage period
   3) Duration to be set based on the arrangement with the customer.
   4) Period required by legal and regulatory requirements
   5) Some documents, mainly records, need to be stored for a long period of time in order to enable investigation of the cause of problems when they occur. Therefore, an "appropriate storage period" should be set in consideration of the shelf life of the product, etc., and the documents should be managed so that they will not be accidentally disposed of during that period.

FSM 10 Specification Control of Purchased or Provided Items and Services

Requirements

For all purchased or provided input items and services (including raw materials and ingredients (including containers and packaging materials), equipment and tools, utilities, and services (e.g. electricity, water, transportation, maintenance)) that have an effect on the safety of final product, the organization shall ensure that documented specifications are prepared, maintained, securely retained and readily accessible when needed. Microbiological, physical, chemical and allergenic specifications shall be based on appropriate scientific principles.

The organization shall evaluate the risks and set the confirmation items (confirmation of inspection certificate, condition, temperature, display, etc.) on the items to be purchased or provided.

In addition, the organization shall define and implement a review process that includes the handling of changes in specifications and the frequency of regular reviews.

Concepts, specific examples

1. Maintain documentation of specifications for goods, equipment, tools, utilities, and services that the organization procures from external sources. Specifications requested by the organization for purchased goods, etc., or obtained from suppliers, etc., are evaluated within the organization to ensure that they are appropriate and

intended. Microbiological, physical, chemical and allergenic specifications shall be based on appropriate scientific principles.

2. It is important to maintain and control the specifications stored as documents so that they can be used as needed for verification at the time of acceptance.
3. The organization shall assess the inherent risks of the items it purchases or receives supplies from and establish checks upon acceptance (e.g., inspection certificates, condition, temperature, labeling, etc.), as well as establish procedures for these checks.
4. Inherent risks include, for example, the following hazards:
   1) In ground beef requiring adequate heat: enterohemorrhagic E. coli O-157
   2) In redfish where temperature control is not properly implemented: histamine accumulation

   This requirement calls for attention to hazard factors in purchased products based on the product characteristics handled by the organization.
5. If externally procured goods, equipment, tools, utilities, or services do not conform to specifications, procedures shall also be established to ensure that they are not misused. Procedures should be documented as necessary.
6. In addition to specific requirements for goods, equipment, tools, utilities, and services, specifications can include:
   1) Statement of compliance with laws and regulations
   2) Customer requirements (food safety is the subject of this standard)
   3) Handling of specification changes
   4) Review of specifications (e.g., frequency, timing, etc.)
   5) Whether or not to re-consign and its conditions, etc.
   6) Provide inspection items that conform to specifications and a certificate of inspection (also called Certification Of Quality or Certification Of Analysis)
7. The organization shall establish and implement a review process for this information, including the frequency of periodic reviews.
8. HACCP Steps 2 and 3 require information on the food safety of products. It is recommended that the specifications to be maintained and controlled by such requirements be organized in relation to such information.

FSM 11 Procedures and Instructions

Requirements

The organization shall establish, implement and maintain effective procedures and instructions in all processes and activities that affect food safety.
In addition, these procedures and instructions shall be understood by personnel who use different languages.

Concepts, specific examples

1. The organization shall define the roles of each employee and share procedures for all processes and operations that affect food safety.
   When considering "all processes and operations affecting food safety," reference shall be made to the following requirements, among others:
   1) Hazards known to be associated with the food.
   2) Hazards that may occur or increase during manufacturing, storage, distribution, etc.
   3) Relevant legal and regulatory requirements
   4) Requirements established by the organization in consideration of past troubles with the same or similar foods.
2. In sharing, the organization shall use documents and other means as necessary to make it easier for employees to understand.
3. On the other hand, it is not necessary to document everything, as long as the personnel involved (e.g., workers, their supervisors, personnel at the relevant management level, internal auditors who audit the procedures, etc.) are aware of the procedures and are possible to work according to those procedures.
4. Key points for establishing procedures and instructions are listed below:
   1) All processes that affect food safety are to be covered.
   2) It needs to be easy to understand so that it can be used for training when new employees start working and for retraining, etc.
   3) Clarify "when, where, who, what, and how should be done".
5. Organizations should also accommodate and document the languages used by their employees as much as possible, given the increasingly multilingual nature of their workforce.

FSM 12 Resource Management

Requirements

Top management shall determine and provide, in a timely manner, the qualified resources (including human resources, facilities and work environment, equipment, systems for operating sites (including communication technology and transportation), means of measurement and traceability, intellectual property management, etc.) that meet the standards required to implement, maintain, and improve the food safety management system.

Concepts, specific examples

1. Top management shall identify and provide to the organization in a timely manner the management resources necessary to implement, maintain and improve the food safety management system. Required management resources include the following:

1) Human resources
   (1) Define the required competencies and provide education and training to employees.
   (2) Utilize outside experts as necessary.
2) Infrastructure
   (1) Buildings, facilities, utilities (power, gas, water, etc.)
   (2) Equipment, devices, and instruments
   (3) Systems for operating the business offices
      ① Communication technology (telephone, fax, web environment, etc.)
      ② Transportation
3) Environment (In this requirement, this refers to the working environment of employees.)
   (1) Physical Factors: Provide a comfortable environment for employees by taking into consideration temperature, heat, humidity, light, air currents, and noise.
   (2) Mental Factors: Provide a comfortable environment for employees, taking into consideration discrimination, conflict among employees, and mental stress.
4) Traceability of measuring and monitoring equipment

   Where measurement and monitoring are required to assure food safety, this indicates providing appropriate means of measurement (see FSM 17) and ensuring traceability of the means of measurement (see FSM 19.1). Specific examples of ensuring traceability include the following:
   (1) Periodic calibration or verification of the means of measurement shall be performed.
   (2) Calibration or verification shall be traceable to international and national standards.
   (3) If the aforementioned standard does not exist, the basis used for calibration or verification shall be retained as documented information.
5) Intellectual resources

   The intellectual resources required to operate a food safety management system include the following:
   (1) Internal resources: Intellectual property, accumulated know-how of the organization
   (2) External resources - information from administration and customers

2. Since management resources are limited, top management is required to determine priorities, devise creative ways to maximize effectiveness, and ensure food safety in a rational manner.
3. In order to respond to changes in the manufacturing environment, it is important for top management to check that goals and plans are realistic and that employees are receiving adequate education and training.

FSM 13.1 Purchasing

Requirements

The organization shall control purchasing procedures to ensure that all externally sourced raw materials, packaging materials, and services, and equipment and tools that have an effect on food safety conform to stipulated specifications, as well as legal and regulatory requirements related to food safety.
In addition, these purchasing procedures shall also apply to raw materials, packaging materials, and services, and equipment and tools purchased from the organization's group companies.

Concepts and specific examples

1. This standard requirement requires that each organization establish and implement procedures to verify what it purchases from outside sources, depending on the magnitude of the risk to food safety.
2. Verification methods refer to determining whether or not what is purchased from outside sources conforms to the specifications set forth in FSM 10, and specifically include the following:
   1) Inspection of a sample representative of the lot of what you are purchasing
   2) Acceptance inspection of items to be purchased
   3) Conformity with specifications in Certificate of Quality and Certificate of Analysis
3. The ultimate responsibility for food safety when making a purchase rests with the purchasing organization.
4. FSM 13.1 requires control over what the organization purchases from external sources (raw materials, containers, packaging materials, services, equipment and tools), whereas FSM 13.2 requires control over their suppliers (suppliers and providers).
5. FSM 13.2 mentions the case of receiving supplies from unapproved suppliers in an emergency, but this only allows for emergency measures: raw materials, containers, packaging materials and services from approved suppliers, it is assumed that are purchased. (For more information on services, see FSM 13.3).
6. In some cases, purchasing procedures are exempted from application when purchasing from (or accepting) intra-group companies. However, this requirement requires that the same purchasing procedures be applied when purchasing from an intra-group company as when purchasing from an external source.
7. Food safety statutory and regulatory requirements to refer to:
   1) Raw material requirements
      (1) Packaging materials shall be sufficient to protect the product from contamination and damage, and shall allow for appropriate labeling.
      (2) Purchase properly controlled raw materials.

(3) Management of agricultural, forestry, livestock and fisheries products (primary products) as raw materials includes the following:
① Prevention of contamination by dust, soil, or sewage during the production stage.
② Appropriate management of waste, toxic substances, etc. at the production stage.
③ Prevention of contamination from pesticides, veterinary drugs, feed, rodents and insects, foreign substances, microorganisms, fecal matter, etc. during the production stage.
④ Facilities in the production phase are clean and properly maintained through cleaning and appropriate repairs.
⑤ Prevent contamination by rodents, insects, chemical substances, foreign substances, microorganisms, etc. during collection, storage, and transportation.
⑥ Separating out items that are clearly unsuitable for eating.
⑦ Prevent spoilage and deterioration of food through temperature and humidity control and other necessary measures.
⑧ Hygiene management of handlers is carried out.

(4) If it is clear that the raw material contains parasites, pathogenic microorganisms, pesticides, etc., or foreign substances, and these cannot be killed or removed to an acceptable level by normal manufacturing and processing, such raw material shall not be accepted.

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

(1) Use appropriately controlled products that are manufactured and processed in accordance with the Standards and Regulations for Foods, Additives, etc. (1959, Ministry of Health and Welfare Notification No. 370) and similar laws and regulations, and whose safety is assured.

(2) When selecting packaging materials, select those that are suitable in terms of gas barrier performance, tensile and puncture strength, etc., depending on product characteristics (strong odor, distribution temperature range, etc.), expiration date, size, capacity, etc.

(3) Select materials and surface-treated materials that will not peel off or erase labeling due to condensation or friction during distribution and storage.

(4) When reusing packaging materials, prepare a procedure for reuse in advance and manage it so as not to contaminate the product. Discontinue use and dispose of the product if it is damaged or significantly contaminated.

(5) Packaging containers and packaging gases shall be non-toxic and not impair the safety and suitability of the product for storage and use.

(6) Reusable packaging materials and containers/packaging shall be durable, easy

to clean and wash, and disinfectable.

(7) Raw materials that do not conform to acceptance criteria shall be handled according to documented procedures to avoid accidental use.

(8) In order to further enhance the safety of synthetic resin food utensils, containers, and packaging, a positive list system was introduced for food utensils, containers, and packaging under the Law for Partial Revision of the Food Sanitation Law, etc. promulgated on June 13, 2008, which allows only substances that have been evaluated for safety to be used. (Enacted on June 1, 2020 by the Ministry of Health, Labor and Welfare)

3) Requirements for equipment and tools used with food

(1) Ensure that the intended use and sanitary design specifications are met for the products handled.

FSM 13.2 Supplier Performance

Requirements

The organization shall document, implement, and maintain procedures for the evaluation, approval, and continual monitoring of suppliers, which have an effect on food safety.

Supplier evaluation shall include measures for food defense and to prevent food fraud.

When accepting raw materials, packaging materials, and services from unapproved suppliers in an emergency (such a natural disaster), the organization shall confirm that the products meet the required specifications by an evaluation, inspection, visit, etc. before use.

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

Concepts, specific examples

1. This requirement requires organizations to establish and implement documented procedures to control suppliers (suppliers/providers) of raw materials, containers, packaging materials, and services that affect food safety, based on risk assessment.
2. If supplies are received from unapproved suppliers in an emergency, this is only an acceptable emergency measure and assumes that raw materials, containers, packaging materials, and services are purchased from approved suppliers. (For services, see FSM 13.3)
3. Controls required of the organization include establishing and implementing procedures for supplier evaluation, approval and monitoring, which are described in detail below.

1) Evaluation

After determining the person responsible for the evaluation, collect relevant necessary information and carry out conduct the evaluation, by referring to the following methods and contents.

(1) Evaluation Method

① Oral Hearing

② Document and record checks

③ Visit and on-site verification or audit

(2) Evaluation details

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

② Information on delivery method: delivery date, delivery location, delivery condition (temperature, humidity, and special environment), etc.

③ Whether there are any cases of food fraud in the origin/supplier of raw materials

④ Whether there are conditions that are likely to cause fraud (extremely lower prices of suppliers used than market price, skyrocketing raw material prices, tight supply, frequent advance shipment times, rapid increase in order volumes, and understaffed production systems).

(3) Qualifications and Competencies of Evaluator

Supplier evaluations shall be conducted by personnel who are knowledgeable about the matters described in the specifications and applicable laws and regulations, and who have received audit training.

2) Approval

The organization shall determine who approves suppliers based on the evaluation results. Then, the organization shall establish the rules and process for the approver to do so and the method of sharing information with the HACCP team as procedures.

3) Monitoring

Establish rules (e.g., method, frequency, timing, etc.) for periodic reassessment of suppliers as a procedure. Monitoring also includes activities related to follow-up, such as suspending business with a supplier or providing guidance to a supplier if there are any problems in response to the results of a series of evaluations of the supplier.

4. This requirement refers to the supplier's food protection and anti-food fraud efforts, but it does not require a level of supplier compliance with FSM 7 and FSM 8, rather than it allows an acceptable level where suppliers have established their own applicable scope of applicability and have initiated food defense and food fraud prevention efforts.

5. In emergency situations (e.g., natural disasters), it is anticipated that an immediate decision may be required when evaluating unapproved suppliers. Under the requirements of this standard, it is not permissible to omit the point at which suppliers are evaluated under normal circumstances, but it is acceptable to shorten the period of time required for verification, provided that equivalence is recognized in the method used.
6. In addition, it includes maintaining objective evidence of the equivalence of products made with raw materials, containers and packaging materials, and services purchased from unauthorized suppliers with normal products at the time of product shipment (release).

FSM 13.3 Outsourcing

Requirements

The organization shall ensure, when the organization chooses to outsource any process that that may have an effect on food safety (including contract manufacturers, service providers for existing process, and other service providers), that it complies with the customer requirements and takes into account the JFS-C standard requirements required for food safety risk management.
Control of such outsourced processes shall be identified, documented and monitored as a part of the food safety management system.
Changes to the contract content shall be approved by both parties and communicated to the relevant personnel.

Concepts, specific examples

1. Outsourcing is the process of outsourcing an organization's own processes to another organization. The organization approves the outsourced contractor and periodically monitors and verifies the outsourced process to ensure that the results of the outsourced process do not pose a food safety problem to the organization's products. These processes are risk-based and shall take into account the following:
   - ●Risks to product safety and quality
   - ●Compliance with specific legal requirements
   - ●Potential risks to product security (i.e., vulnerabilities, and risks identified in the food defense assessment)
2. This outsourcing includes not only the manufacturing of products or the dispatch of personnel by contractors, but also the provision of services. The services provided by the provider include transportation and storage (see GMP 15 and 16), preventing insects and rodents from breeding, and sanitation consultants, sanitation of offices and facilities, maintenance of facilities and equipment, cleaning of work clothes, and provision of meals for employees.

3. When outsourcing, the final responsibility for the food safety management system lies with the organization that commissioned the work. (Legal responsibility is subject to the laws and regulations of each country.)
4. Any changes to the contractual content shall be approved by both parties and communicated to the parties involved.
5. Eligible outside contractors include contract manufacturers and service providers.
   1) Contract manufacturers agree and contract on all terms and conditions related to food safety, customer requirements, merchandising, shipping, etc. Contract manufacturers shall develop and implement an organization to comply with the terms of the contract.
   2) The contracted service provider documents and contracts for specifications of services that affect food safety.
      The contract shall include training of the personnel involved in the provision of services, as well as clarification of the services.
6. Controls according to FSM 13.3 shall be described in the flow diagram required by HACCP Step 4, if necessary, and control methods shall be determined through the hazard factor analysis required by HACCP Step 6 (Principle 1). In addition, an evaluation of suppliers shall be conducted in accordance with FSM 13.2.
7. To ensure the appropriateness of outsourcing, the following details shall be performed as necessary:
   1) Confirmation of food safety management system
   2) Confirmation of product process control system
   3) Verify accuracy and results of in-process inspections
   4) Periodic verification of the final product
   5) Ensuring food safety from a physical and chemical aspect
   6) Confirmation of competence of personnel and education and training system
8. Regarding the operation of HACCP, when outsourcing CCP processes, etc., the management system, process control, and conformance of the final product shall be equivalent to the food safety management system established by the own organization.

FSM 14.1 Traceability

Requirements

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

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

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

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

●Records of all product suppliers and recipients

●If the procedure has been updated, record it

Concepts, specific examples

1. In the event of a serious product accident or food fraud, traceability records are important in verifying the manufacturing process of the subject product and in guaranteeing the safety of the food.
2. The "recipient" in this requirement basically means the purchaser one step later in the food chain, and does not necessarily include the final consumer of the product. The "recipient" may also refer to a wholesaler or retailer that handles the shipped product.
3. Shipped products are not always delivered to the purchaser, but may be delivered to a warehouse or other location designated by the purchaser. Therefore, this requirement requires that the owner of the product and the "recipient" where the product is actually placed be known so that speedy action can be taken in the event of trouble. Raw materials, containers and packaging materials, services, and outsourced processes purchased from outside (hereinafter referred to as "raw materials, etc.") are also basically subject to traceability up to one step before.
4. Each organization is required to reliably identify the product from the supplier (at least one step before) to the recipient (at least one step after). It is also required to continuously identify the product (by labeling, etc.) throughout the entire manufacturing process and distribution. By connecting these organizations, it is possible to trace the entire supply chain.
5. The maintenance and provision of record information necessary for traceability is as follows:
   1) Maintenance of traceability
      (1) Depending on the product, document procedures related to traceability (including raw materials purchased from outside sources, container and packaging materials, and outsourced processes, each of which shall be identified in the notation).
      (2) Identify the status of raw materials, etc. (when, from where, what, and how much) at all product stages (including primary processed products).
      (3) Establish units for product and raw material lots, as necessary.

(4) Procedures for preparing records of incoming and outgoing shipments based on (1) through (3) and procedures for storing records shall be established and implemented.

(5) Ensure that traceability is functioning, including work-in-process, recycled products, reworked products, and finished products.

(6) Keep product samples for each lot, if necessary.

2) Provision of records related to traceability

(1) Establish and implement procedures for the preparation of records and the retention of records. (See FSM 9.2)

(2) Submit records related to traceability when requested by the administration.

(3) Examples of traceability records

The main examples of records required to ensure traceability are as follows:

Examples of records required for process and traceability

	Acceptance	Manufacturing	Storage	Shipping
Product Information	· Raw Material Information · Food Safety Information · Acceptance Inspection Records	· Daily production reports · Inspection records · Process records	· Product temperature records · Inventory records	· Product Shipping Information · Destination Information
Environmental Information	· Delivery vehicle temperature records · Delivery vehicle sanitation records	· GMP-related records · Information about personnel	· Temperature records inside the warehouse	· Delivery vehicle temperature records · Delivery vehicle sanitation records
sampling information	· Pre-sampled product record	· Quality Control Inspection and Acceptance · Semi-finished product samples (for storage) · Calibration records for	· Calibration records of thermometers for quality control · Calibration records for measuring and monitoring	· Product samples (for storage)

		measuring and monitoring equipment	equipment	

FSM 14.2 Traceability verification

Requirements

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

Concepts, specific examples

The organization shall document the procedures for implementing and maintaining tracing, verify them at least once a year to ensure that the procedures are working effectively, and update them as necessary.

※The results of the verification shall be recorded. (See FSM 9.2)

FSM 15 Product development

Requirements

The organization shall establish, implement and maintain product design and development procedures to ensure that new products or products whose specifications and manufacturing processes have changed are manufactured safely and in accordance with legal and regulatory requirements.

These development procedures shall clearly confirm that the products and services provided conform to specifications, and after identifying all the hazards of food safety, shall include a review to evaluate and approve the adequacy of food safety assurance in the design and development.

Concepts, specific examples

1. These requirements pertain to the design and development procedures for new products or products with changes in specifications, manufacturing processes, etc., and include the following requirements:
   1) Establish, implement and maintain product design and development procedures.
   2) In the procedure, a review is conducted to evaluate and approve the adequacy of food safety assurance in design and development.

1) Product design and development procedures

Design and development include not only the development of new products, but also changes to the specifications and manufacturing processes, etc., of existing products, and ISO 9001:2015 8.3 shall be used as a reference in establishing the procedures.

In the development of a new product or a product with a modified manufacturing process, unexpected problems can sometimes occur. The developer of a new product shall take into consideration the hazards of the product and compliance with laws and regulations. Specific issues to consider during product development include the following:

(1) Are product-specific hazard factors fully considered and designed to minimize risk?
(2) Are product shelf life tests conducted with sufficient frequency in advance to ensure product safety?
(3) Are considerations given to the flow of products, the layout of machines, the characteristics of machines, etc. so as not to affect the products?
(4) Are cross-contamination and allergen cross-contact considered?
(5) Are there any legal restrictions on the raw materials used and the content of the labeling?
(6) Is the product labeled in a way that would lead to misuse of the product, or is the product form unreasonable?
(7) Have the personnel developing or designing the product been trained in hazard factors and safety?

2) On the review process for evaluation and approval

(1) In demonstrating conformity to the requirements of this standard, a process is required for a person or department other than those in charge of development to objectively evaluate and approve the adequacy of safety assurance for new products or products whose manufacturing process has been changed. This evaluation and approval process may also be conducted by a HACCP team or a group of several departments.
(2) However, it is important that the person or department in charge of development is most familiar with the hazard analysis of the developed product. Even if there is a process to evaluate the adequacy of the safety of the developed product, the person or department in charge of the development is the main subject of the hazard analysis.
(3) The person, position hierarchy, and department responsible for conducting the evaluation and approval review required by this standard requirement should be clearly stated in the rules for division of duties.

FSM 16 Allergen Management

Requirements

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

- Control procedures to properly assess the risk of allergen cross-contact and, based on that assessment, reduce, or eliminate the risk of cross-contact.
- Procedures for handling raw materials (including containers and packaging materials), semi-finished products, work in progress, reworked products, and final products to prevent cross-contact with allergens during all processes from manufacturing to shipping.
- Cleaning procedures and verification procedures for areas that come into contact with food.
- Procedures for identifying and displaying allergens that shall be controlled in all processes from manufacturing to shipping.

The plan shall also ensure that all products containing or potentially containing allergens that are shipped and offered for sale are labeled in accordance with the laws and regulations of the country to which they are expected to be shipped, and appropriate customer requirements.

Concepts, specific examples

1. Allergens to be controlled
   The substances that cause allergies are called allergens. Worldwide, there are eight main allergens: cereals including gluten, crustaceans, eggs, fish, milk, peanuts, soybeans, and tree nuts. Organizations need to consider accidents caused by allergens in consumers.
   *Reference cases in Japan（Source : Consumer Affairs Agency Website）
   https://www.caa.go.jp/policies/policy/food_labeling/food_sanitation/allergy/
   (For the latest version, please check the relevant website.)
2. Organizations need to manage allergens from the following three perspectives:
   1) Preventing or minimizing the possibility of allergen cross-contact.
   2) Information identifying allergens in food products shall be clear and accurate. In particular, for purchased raw materials, suppliers are required to demonstrate appropriate allergen controls and their requirements.
   3) Ensure that allergens contained in food are communicated to each stage of the logistics process after shipment.
3. Allergens to be controlled in all processes from manufacturing to shipping shall be identified, and a written allergen control plan shall be established, implemented, and properly maintained:
   1) Identify allergens that may be contained based on the specifications of the raw

materials used.

2) Differentiate the receiving and storage areas for each different allergen.
3) Identify allergens to be controlled according to the production plan, so that they can be checked on each production line.
4) Distinguish between machinery and equipment used in the weighing room.
5) Identify areas in the manufacturing facility where allergen powder is dispersed and implement measures to prevent dispersal.
6) To handle line changeovers (powders, oil and fat products (chocolate, spreads, etc.)) where water cannot be used for cleaning.
7) Control the labeling and use of allergens in recycled and work-in-process products.
8) Implement measures to prevent incorrect labeling.
9) In controlling allergens, the laws and regulations of the country of sale (allergen labeling regulations) shall be observed.

4. Develop control procedures to reduce or eliminate the risk of cross-contact. Examples of control procedures include the following:
   1) Containers and utensils used in production (plastic bags, scoops, etc.) shall be identified for each allergen to be controlled and avoid use in mixed.
   2) Determine control procedures to prevent cross-contact through work clothes, gloves, etc.
   3) To prevent cross-contact by powder, physically demarcate the area with walls, partitions, curtains, etc. Air conditioner and dust collector filters shall be regularly inspected and cleaned.
   4) Develop procedures for handling raw materials (including containers and packaging materials), semi-finished products, work-in-process, reworked products, and finished products to prevent allergen cross-contact at all stages of production and shipment.
   5) Determine procedures and verification methods for cleaning and washing methods for manufacturing processes to prevent cross-contact.
   6) When producing different products on the same production line, plan production in order of the number of allergens present, from lowest to highest, if possible.
5. During the development of products containing allergens, check the validity of controls by line testing, etc.
6. When preparing product labeling, allergens shall be indicated in accordance with the laws and regulations (allergen labeling regulations) of the country in which the product is supposed to be sold.
7. If verification (e.g., analysis) is required, establish and implement procedures, and record and store the verification results.
8. All employees involved in food production shall be trained on allergens. This includes temporary and maintenance personnel.

9. Related items include FSM 4 (Compliance with food safety laws), 13.1 (Purchasing), 13.2 (Supplier Performance), 13.3 (Outsourcing), FSM 15 (Product development), FSM 18.1 (Product labeling (B-to-C products)), FSM 18.2 (Product labeling (B-to-B products, work in progress, semi-finished products)), GMP 3, 4.1, 4.2, 5, 6.1, 6.2, 7, 8, 9, 11, 13, 14, 15, 17 (requirements related to contamination in manufacturing processes, etc.) see also.
10. For more information on examples of "Allergen Management", see CODEX Alimentarius, Code of practice on food allergen management for food business operators (CXC 80-2020).

FSM 17 Control of Measuring and Monitoring Devices

Requirements

The organization shall identify measuring and monitoring devices that are parameters critical to ensure food safety.
In addition, the specified equipment and devices shall be calibrated regularly.
This calibration shall be performed in accordance with national or international standards concerned, or by a reasonably accepted traceable method.
The organization shall take appropriate action when equipment and devices are found to be inaccurate, and these actions shall be recorded.

Concepts, specific examples

1. First, measuring instruments and devices to measure essential parameters affecting food safety, including CCPs, shall be identified as objects of control. The measuring instruments and devices to be controlled here shall be capable of measuring the parameters necessary to assure food safety and have the appropriate range and accuracy for the target of measurement. Specific measuring instruments and devices include metal detectors, X-ray inspection equipment, weighing instruments, and thermometers.
2. In measuring parameters to assure food safety, another measuring instrument and device may be used to set and measure alternative parameters. For example, a weighing instrument may be used as an alternative to a thermometer or in conjunction with a thermometer to control the amount of water fed into the boiling tank or the weight of ingredients in order to ensure the center temperature of the food during the boiling process. Note that measuring instruments and equipment used for such applications shall also be subject to control. When setting alternative parameters, it is important to confirm their validity through scientific evidence (literature and experimental results). (See HACCP Step 8 (Principle 3))
3. Second, identify the monitoring methods for the measurement instrument and device that are to be controlled.

4. Third, each of the measuring instruments and devices under control requires calibration. Calibration" of measuring instruments and devices is one of the means to confirm the validity of the measurement of numerical parameters and is a form of verification. It includes internal calibration, etc., in addition to calibration performed by an external contractor.
5. Calibration shall be performed and recorded according to legal requirements, manufacturer's recommended schedule, and schedules determined by the organization.
6. Calibration shall be performed to national or international standards in question or by a reasonably accepted traceable method. If necessary, a traceability system chart or other documentation should be obtained. However, if no international standard or method exists, as an alternative, the adequacy can and shall be proved by a reasonable method that has been objectively validated and verified by the company or an industry organization, or if there is a warranty by the manufacturer on the measuring instrument, etc., the adequacy can and shall be proved based on the contents of that warranty.
7. If no official standards exist, the standards used for calibration or verification shall be retained as documented information.
8. Calibrated measuring/monitoring, testing, and inspection instruments and devices shall be controlled to prevent damage or adjustment miss.
9. If measuring, monitoring, testing, or inspection instruments and devices are found to be inaccurate, their records shall be kept, and procedures shall be established and implemented to evaluate and take appropriate action on potentially affected products. The actions taken shall be recorded.

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

Requirements

The organization shall ensure that all product labels or attached information to enable the safe handling, display, storage, preparation and use of the product in the food supply chain or by the consumer.
The finished product shall be labeled according to the applicable food regulations in the intended country of sale.

Concepts, specific examples

1. Organizations shall give sufficient information about food hygiene so that the consumers are aware of the following:
   1) Recognize the importance of reading and understanding information on labels or other media.

2) Include information about allergens and make choices appropriate for each individual.
3) Prevent contamination and the growth and survival of foodborne pathogens by correctly storing, preparing, and using food.

2. For B to C products (products that are in the form being sold to general consumers), obtain information on labeling (allergens, food additives, etc.) as specified in the laws and regulatory requirements of the countries in which they are manufactured and sold, and accurately label them.
3. The following items shall be clarified for food safety when labeling products:
   1) Users and target consumers of the sales destination, etc.
   2) Product-specific eating conditions, such as for eating raw or for cooking
   3) Usage of raw materials, seasonings, etc.
   4) Basis for setting expiration dates and best-before dates
   5) Handling temperatures and methods
4. Information required for the product shall be printed or attached to the packaging materials based on the product specifications.
5. Establish procedures to check that the contents of the labeling are correct.
6. Establish procedures to prevent mismatch between products and labeled packaging, etc.
7. It is important that the information to be labeled on the product shall be checked against the documented information in HACCP Step 2 "Product Description" and Step 3 "Identification of Intended Use".

■Check expiration date labeling

● Make sure that the date is correct.

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

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

(Partially quoted from "The Next Section of the Explanation of the Advanced Infrastructure Development" (Food Industry Center, Japan).

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

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

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

⇒

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

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

(Partially quoted from "The Next Section of Explanation of the Advanced Infrastructure Development" (Food Industry Center, Japan).

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

Requirements

The organization shall define and implement procedures to provide information, such as on primary processed foods, commercial ingredients, or intermediates in the processing process, so that customers or consumers can be informed about product safety, even if the information is not labeled on or attached to the product.

Concepts, specific examples

1. Organizations shall provide sufficient information on food Hygiene so that consumers are aware of the following:
   1) Recognize the importance of reading and understanding labels or other media information.
   2) Include information about allergens and make choices appropriate for each individual.
   3) Prevent contamination and the growth and survival of foodborne pathogens by correctly storing, preparing, and using food.
2. Similarly, information on labeling (allergens, food additives, etc.) required by the laws and regulations of the country of manufacture and the country of sale for B to B products, work in process, and semi-finished products (products other than those sold to general consumers) and provide accurate product labeling and necessary information, etc. to suppliers in a manner consistent with laws and regulations.
3. The following items shall be clarified for food safety when labeling or providing information:
   1) Product-specific eating conditions, such as for eating raw or for cooking
   2) Uses of raw materials, seasonings, etc.
   3) Basis for setting expiration dates and best-before dates
   4) Handling temperatures and methods
4. Establish procedures to check that the labeling or information provided is correct.

5. Establish procedures to avoid discrepancies between the product and information on the product's safety.
6. It is important that the information on product safety shall be checked against the documented information in HACCP Step 2 "Product Description" and Step 3 "Identification of Intended Use".

FSM 19.1 Analysis and Testing

Requirements

The organization shall establish, implement, and maintain procedures to ensure the analysis of raw materials, semi-finished products, finished products, manufacturing environments, etc. that affect food safety.
The analysis and testing shall be conducted by a competent analysis institution or testing laboratory institution using appropriate sampling and analytical / testing methods.
The testing that has a significant effect on food safety shall be conducted in accordance with the applicable requirements of ISO/IEC 17025.
In addition, the organization shall establish and implement analysis and testing procedures (methods, standards, etc.) to confirm that the product meets product specifications within its shelf life.

Concepts, specific examples

1. This standard requirement requires that organizations establish and implement testing procedures to ensure that testing of raw materials, semi-finished products, products, and manufacturing environments that affect food safety is conducted in a systematic manner. It also requires that analysis and testing procedures (methods, criteria, etc.) be established and implemented to verify that products meet specifications during the shelf life of the products. The scope and level of documentation or record keeping required by this standard requirement is based on FSM 9.1 and FSM 9.2.
2. These tests are required to be "conducted using appropriate sampling and analytical methods," but these methods can be determined by the organization itself, taking into account its industry, type of business, size, and the complexity of its work.
3. It requires that these tests be performed by sampling and analytical methods determined by the organization, and is allowed to be performed by external analysis agencies as well as internal inspection departments.
4. The scope of "tests with significant impact on food safety" includes, as specific examples, verification of CCPs, acceptance tests of purchased products, and tests related to shipping decisions, the scope of which shall be determined by the organization, taking into consideration the characteristics of the product. Tests related to quality are not included in the scope of this requirement.

5. It is important for food safety that traceability of test results as well as raw materials and products (see FSM 14.1) be ensured, too. This is to ensure that when a trouble occurs, including one related to food safety, the cause is promptly investigated.
6. ISO/IEC 17025 is the standard for accreditation of the competence of testing and calibration laboratories by accreditation bodies.

   This standard requirement requires that testing performed internally and externally by the organization be conducted in accordance with ISO/IEC 17025, which states:

   1) The inspection department or external analysis organization (hereinafter referred to as "testing organization") shall specify the competence required for test administrators and have competent, educated, trained test administrators perform the tests. (ISO/IEC 17025 6.2 Reference)
   2) The testing organization shall have an environment that does not affect the reliability of the test results. (ISO/IEC 17025 6.3 Reference)
   3) The testing organization shall have objective evidence that the equipment involved in the test is functioning properly. For example, this includes records of inspection, calibration, adjustment, and maintenance practices. (ISO/IEC 17025 6.4 Reference)
   4) The testing organization shall identify the necessary equipment and substances, and establish and maintain metrological traceability of the measurement results obtained from them. This indicates that calibration is performed using standards or reference materials that are ensured to be traceable to the International System of Units (SI) so that the same measurement results can be obtained even if the location and personnel change. (ISO/IEC 17025 6.5 Reference)
   5) Where externally provided products and services are incorporated into the activities of the testing organization, are provided to customers in an as-is condition, or affect testing operations, the testing organization ensures that only appropriate ones are used. (ISO/IEC 17025 6.6 Reference)
   6) The testing department in the organization should perform validation to ensure that the methods and procedures used and any modifications to them are suitable for the intended use. Examples of validation include checking the limits of detection, reproducibility, linearity of calibration curves, and the appropriateness of pretreatment of test samples, etc., and these should be confirmed through investigation, indicating that objective evidence and rationale should be confirmed.

      In addition, when the methods and procedures used conform to official methods or are commonly used, etc., it is acceptable to monitor whether appropriate test results are obtained during verification activities, based on official methods or past literature (ISO/IEC 17025 6.5, 7.2 References).
   7) The testing department in the organization shall have procedures for monitoring the validity of test results. Specific methods include the following This program

is not required to be conducted once a year, but it is acceptable to check all test items once a year in principle, or once every three to four years for less important tests, based on the organization's risk-based assessment of the importance of the test. (ISO/IEC 17025 7.7 Reference)

(1) Including monitoring the testing capabilities of each test item by cross-checking its own test results with the results of at least one other testing organization accredited by ISO 17025, etc. on the same sample for each test item, establish and implement the program.

(2) Participate in proficiency tests accredited by ISO/IEC 17043:2023(Conformity assessment -- General requirements for the competence of proficiency testing providers), etc. (where available and suitable for the intended purpose)

FSM 19.2 Environmental Monitoring

Requirements

The organization shall establish, implement and maintain a microbial environmental monitoring program to reduce the risk of food contamination.
This program shall consider microbial risks specific to the manufacturing process and facility environment and include evaluation methods tailored to the risks.

Concepts, specific examples

1. The identification of risks in the manufacturing process and how to control those risks are linked to the steps for establishing CCP in HACCP Step 6 (Principle 1) and Step 7 (Principle 2). On the other hand, this requirement requires organizations to identify contamination risks to products not only in the manufacturing process but also in the food manufacturing environment (on-site), and to develop an environmental monitoring program including verification measures.
2. Environmental monitoring refers to the control of microorganisms, etc. that may become hazardous factors when exposed to the environment during the processing of prepared foods and other products.
3. In particular, it is important to develop environmental monitoring programs in such areas where products that are pre-packaged after heating or where ready-to-eat foods are handled exposed, because the risk of contamination is high and sufficient consideration shall be given to these areas.
4. For specific examples of environmental monitoring program development, see:
   1) Identification of food poisoning-causing bacteria, etc. that are likely to be contaminated from the manufacturing environment and can be hazards
      Examples: Listeria monocytogenes contamination of dairy and meat products derived from the manufacturing process, Listeria monocytogenes

contamination of ready-to-eat foods, Salmonella contamination of room temperature processed foods

2) Determination of sampling method and location

Examples: Before packaging, swab tests are performed on raw materials, semi-finished products, work-in-progress, intermediate processed products, and surrounding equipment through which the finished product passes, and collection of fallen and airborne bacteria is performed.

3) Determination of sampling frequency per location
4) Determination of methods to check for the presence or absence of microorganisms that may be hazards
5) Determination of alert levels and develop action plans
6) Conducting sampling, and recording and reporting of results

FSM 19.3 Cleaning and Disinfection Program

Requirements

The organization shall establish, implement, and maintain a cleaning and disinfection program. The Cleaning and disinfection Program shall include measures to verify the effectiveness of this program.

Concepts, specific examples

1. FSM 19.3 requires the establishment, implementation, maintenance and verification of effectiveness of the cleaning and disinfection program, while GMP 8 requires specific implementation details for housekeeping, cleaning, sterilization, and disinfection.
2. The cleaning and disinfection program shall clarify the areas to be covered, the method and frequency of work, the detergents and tools to be used, the method for confirming effectiveness, the method for recording, etc.
3. For details on implementation procedures, etc., refer to GMP8.

FSM 20 Internal Audit

Requirements

The organization shall establish, implement and maintain documented internal audit procedures for all applicable food safety management systems (including HACCP plans, food defense plans, and food fraud prevention plans).

The procedures shall include at least the following content.

a) Timing of internal audits. Schedules including frequency of at least once a year.

b) Corrective action for nonconformity.

c) Rules that ensure the objectivity and fairness of internal audits.

The organization shall maintain a record of the performance of the internal audit as evidence.
The organization shall specify the competence required for internal auditors and provide training for internal auditors.

Concepts, specific examples

1. Internal audits are one of the verification activities of the overall food safety management system, and the results serve as input information for management reviews. Internal audits shall be conducted at predetermined intervals throughout the food safety management system (including all HACCP systems and GMP), and may also be conducted on an ad hoc basis as needed.
2. Internal audits are conducted to verify the following:
   1) The food safety management system established by the organization complies with legal and regulatory requirements.
   2) The organization's activities comply with the procedures, etc., set forth in the food safety management system.
   3) Food safety management systems are effectively implemented and maintained.
3. In addition to a) through c) listed in the requirements, the internal audit procedure should include the method of implementation, audit responsibilities, audit criteria, etc.
4. Individual audits shall be conducted by preparing a specific audit plan in accordance with the audit procedures. The audit plan shall be prepared in consideration of the following:
   1) Materiality of the processes and areas to be audited
   2) Previous Audit Results
   3) Status within the organization, such as changes to the food safety management system
   4) Food safety-related situations outside the organization

   When preparing the audit plan, for example, the audit criteria and scope are determined, the audit objectives are set, the schedule is adjusted, auditors are appointed and their scope of responsibility is determined, and the audit methodology is reviewed.
5. Internal audits are important activities to review and improve the organization's activities, and quality audits can further enhance the value of the management system. In order to conduct good audits, the following should be considered:
   1) Prior to the audit, confirm the scope of one's own audit and prepare checklists, etc.
   2) There are two methods of auditing: checking according to the requirements of the standard and the requirements of the system, and checking according to the

organization's workflow. By changing the method of checking, it can be easier to detect problems.

3) Review the suitability and effectiveness of the system and activities based on it, keeping in mind that the system can be improved if necessary. (Changes to the system are not considered taboo.)
4) Problems found in the audit, including the reasons for them, shall be explained to the audited department and reported after obtaining their consent.
5) The auditor should identify and report not only the inadequacies of the audited department, but also the good points that can be used as a reference by other departments.
6) In addition to checking the organization's activities through records and other means, the audit can also check the work site.
7) Upon completion of all planned audit activities, the results shall be summarized and reported to the audited department and the audit client (top management), and audit records shall be prepared. Audit results shall include responses to the audit objectives
8) For problems identified in the audit, corrective actions, corrections, and system improvements should be taken as nonconformities, if necessary. In such cases, it is recommended to use mechanisms such as FSM 3, 24, 25, etc.
9) When corrective actions, etc. are taken, the responsibility for such actions rests with the person in charge of the audited department. The internal audit personnel shall conduct follow-up audits to confirm that responses to audit results (corrective actions, etc.) have been properly implemented, and report the results.
10) The internal audit personnel shall monitor and review the overall audit progress and make suggestions to improve subsequent audits. These suggestions can include the content of the audit plan, auditor competency requirements, and resources needed for the audit.

6. "Competence of internal auditors" is indicated by knowledge, skills, work experience, audit experience, etc. There are no general standards for competence. Each organization shall develop its own standards that it deems necessary for its own audits, and shall train its personnel to meet the standards it has established. For example, the following skills and knowledge:

1) Skills required to perform audits
   (1) Ability to interview (communication skills. appropriate language skills for each level)
   (2) Ability to take notes and prepare reports (ability to prepare reports that can express nonconformities)
   (3) Presentation skills
   (4) Ability to prepare audit plans

(5) Time management skills
(6) Information gathering and risk identification skills (ability to identify risks and gather audit evidence from interviews, on-site observations, and document review results)
(7) Risk analysis and assessment capability (ability to analyze the severity of identified risks and evaluate nonconformities)

2) Knowledge related to food safety management systems
(1) Knowledge of the organization's situation (organizational structure, issues in the organization from an external perspective)
(2) Knowledge of this standard
(3) Knowledge of HACCP
(4) Knowledge of GMP
(5) Knowledge of food safety hazards (biological, chemical, physical) and related legal and regulatory requirements
(6) Knowledge of products and manufacturing processes

7. As a way to ensure objectivity and impartiality of internal audits, if it is difficult to assign auditors who are independent from the subject of the audit, it is recommended that the organization make provisions, so that they do not audit their own work, for example, to form audit teams with personnel from other departments, etc.
8. Internal auditors (candidates) should attend third-party audits to the extent possible, learn how auditors conduct audits and how they view the system, and use this as a reference when conducting their own audits.
9. To improve the competence of internal auditors, it is possible to receive training outside the company. JFSM recommends attending the JFS-C internal auditor training course. It is also effective to refer to ISO 19011 as a guideline for internal audit activities.

FSM 21 Complaint Handling

Requirements

The organization shall document, implement, and maintain a system of management to respond to complaints and utilize complaint data to identify, correct, and manage omissions and deficiencies in food safety efforts.
Control procedures shall include analyzing complaints, evaluating the magnitude of the impact threatening food safety, and implementing corrective action as necessary.
Additionally, organization must record and maintain complaints, investigation results, and corrective actions.

Concepts, specific examples

1. Complaints shall be distinguished between food safety-related events and other events, for example, quality-related events. This section covers food safety-related events. However, the term "complaint" is used in various definitions (e.g., claim, offer, suggestion, inquiry, etc.) by different organizations. To avoid terminological confusion, this standard uses the term "complaint" to refer to a variety of terms.
2. In responding to complaints, what may seem to be a minor event can lead to the discovery of a serious food safety-related defect. Therefore, it is important to collect a wide range of information in the initial stages of complaint handling. Then, the complaint shall be analyzed and its impact on food safety shall be evaluated in order to clarify that it is a food safety-related event.
3. The key to promptly resolving complaints from business partners and consumers is to create a system that allows for proper identification and prompt response.
4. Organizations shall establish and implement a documented management system for responding to complaints and utilizing complaint data. The established system shall be reviewed, and it shall be revised as necessary. Elements to be included in the management procedures pertaining to complaints include the following:
    1) Establish a manual and system for handling complaints from business partners and consumers.
    2) Employees shall recognize their responsibility for handling and investigating complaints from business partners and consumers.
    3) To understand as accurately as possible what the complainant wants in response to a complaint from business partners or consumers. If the complainant wants answers to his/her questions regarding the cause of the complaint (including presumptions), the responses to the product, the measures to prevent recurrence, etc., the organization shall inform the complainant that the information will be provided appropriately. At that time, if necessary, the complainant shall be given an estimated date for a response. (When it is found during the investigation process that the cause of the complaint is not the organization, the complainant shall be informed of this as soon as possible. If the complaint is a false accusation or is motivated by money, the organization should consider other ways to deal with the situation.)
    4) With regard to complaints from business partners and consumers, the details of the investigation and response in 3) shall be responded to complainants.
    5) Record and maintain the details of the complaint, the results of the investigation, and corrective actions.
    6) For complaints received, the relevant department shall classify those that can pertain to food safety and those that do not.
    7) For complaints that can be related to food safety, the HACCP team, etc., shall take the lead in promptly investigating the cause of the complaint and its relevance to GMP and HACCP systems, involving the departments related to the

complaint, and investigate the cause. For other complaints, the relevant department shall investigate the cause.

8) When nonconformities are found based on complaints, correction shall be taken and corrective actions shall be taken as necessary in accordance with procedures in FSM 24 and 25. The results of both correction and corrective actions shall be recorded. Examples of specific actions are as follows:
(Correction) Recall of product / (Corrective action) Change of manufacturing and cooking procedures / (Sequentially, depending on the situation) Report and public announcement to the administration
9) Determine a person responsible for confirming the termination of complaints and confirm the termination.
10) Analyze complaint trends, provide input to management reviews, and conduct reviews.
11) Accumulate and utilize complaint data to help continuously improve the food hygiene system.

FSM 22.1 Serious Incident Management

Requirements

The organization shall document food incident management manual, implement it in the event of an accident, and maintain it in effect at all times. This manual shall also describe the methods for product withdrawal and product recall and include tests to ensure that product recalls are carried out reliably.
It shall also include systems and procedures for providing necessary information to customers, consumers, and relevant authorities.
Incidents that occur shall be recorded and evaluated.

Concepts, specific examples

1. Serious incident refers to a food incident that has the potential to affect food safety and does not include incidents that do not affect food safety but may affect quality.
2. Since it is often not possible to determine whether an incident is serious at the time it occurs, it is advisable to work with a worst-case scenario when an incident occurs.
3. Procedures for responding to serious incidents include the following, but are not limited to:
   1) In the event of a serious incident, respond in accordance with relevant management procedures such as nonconformity response (FSM 24) and complaint response (FSM 21)
   2) Determine who in management is responsible for decision-making and practical handling of serious incidents
   3) Appointment and training of incident response team

4) Create and maintain up-to-date emergency contact lists (customers, consumers, relevant authorities, and internal stakeholders)
5) Securing information sources that get advice on legal and regulatory requirements and professional advice
6) Determining who is responsible for handling internal communications and communications with the relevant authorities and relevant external organizations, and methods how to communicate with them
7) Determining who is responsible for providing information to consumers and the media and methods how to communicate with them

4. Record and evaluate the incident to establish the severity of the incident and whether there is a risk to the customer. The record of the incident shall include the following:
   1) Related products, manufacturing location
   2) Quantity of products that have affected
   3) Range of products that have affected (lot, batch, etc.)
   4) Manufacturing records
   5) Quantity and location of shipments made
5. Establish deciding criteria for product recall or removal implementation in advance.
   The relationship between "recall" and "removal" of products in this requirement is summarized below.
   "Recall" refers to the removal by a supplier from the supply chain of a product that has been sold or is being sold to end consumers and is deemed to be unsafe.
   "Removal" refers to the removal by a supplier from the supply chain of a product before it is offered for sale to the final consumer and is deemed unsafe.
   The supply chain used in this standard requirement refers to a series of production and distribution processes from primary production to consumers, and is synonymous with the food chain. (See JFS-C Standard Document Version 3.1 Annex, Definition of Terms)
   Generally, the word "recall" is used for "collect" and "removal" is used for "pull-back" or "distribution recall," but since this is not the case for some industries or organizations, please refer to the "Definitions of Terms" in the appendix of the standard document for interpretation. (Reference: JFS-C Standard Document Version: 3.1 Annex Definitions of Terms)
6. In order to promptly recall or remove a lot of a product that has already been shipped if it is determined to be unsafe, procedures shall be established to implement the following:
   1) Top management shall appoint an employee to direct the product recall or removal and an employee to conduct the collecting.
   2) The organization shall specify and document the following:
      (1) Notification of stakeholders (e.g., regulatory agencies, customers or consumers, distribution)

Reference Information (Scope of this item applies in Japan)
Based on the revised Food Sanitation Law and the revised Food Labeling Law, it will be mandatory to notify the government of any food recalls. (Effective June 1, 2021)
See Law for Partial Revision of the Food Sanitation Law, etc. (promulgated on June 13, 2008)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000197196.html
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/kigu/index_00011.html

(2) Handling of products that have been recalled or removed and products that have not yet been shipped
(3) A series of actions to be taken
(4) Identifying the cause leading to the recall or removal, the scope of the recall or removal, and recording all results

3) A review shall be conducted when the recall or removal is converged, and the results shall be used as input information for the management review.

7. Ensure that product recalls or removed products are identified and quarantined until it is confirmed that they are safe.
8. In the event of a product recall, the organization shall promptly contact the certification body and JFSM after the initial response is implemented. (Reference: JFS-C Certification Program Document Version 3.2 5.2.5 Notification of information that affects an organization's certification status)
9. Recall procedures for food allergens should include the following (see FSM 16)
   ●In the event of a food allergen incident (e.g. an allergic reaction to an undeclared allergen), procedures and processes shall be established and implemented to facilitate a review of traceability along the food chain, from the supplier (at least one step before from own organization) to the recipient (at least one step after from own organization).

FSM 22.2 Verification of food incident management procedure

Requirements

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

Concepts, specific examples

1. Conduct mock recall tests to verify and record the effectiveness of the recall program at least once a year. Based on the results of the verification, review the recall program as necessary, and also verify and revise as necessary the food incident management procedure that contains it.

1) In this test, it is required to be carried out under the assumption that the product is available on the market. However, for organizations that manufacture products on a contract basis (OEM manufacturing) or that conduct business-to-business (B to B) transactions, there are situations in which it is difficult to imagine that the organization will be the subject of a market recall. The recall test in this situation indicates that the recall test should be performed assuming that the products containing the organization's products have been distributed to consumers. In other words, the organization shall imagine a situation in which a consumer had purchased these products and conduct tests to verify whether information about the traceability of the target products can be identified from this situation, from the supplier one step before to the shipping destination one step after.
2) In this test, it is easy to imagine if you assume that allergens are mixed in.

FSM 23.1 Management of product specifications

Requirements

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

Concepts, specific examples

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

   This requirement calls for attention to hazard factors in purchased products based

on the product characteristics handled by the organization.

5. If externally procured goods or services do not conform to specifications, procedures shall also be established to ensure that they are not misused. Procedures should be documented as necessary.
6. When providing specifications to business partners in business transactions, it is necessary to have a system in place that allows the provision of the latest information at all times.
7. In addition to specific requirements for goods and services, specifications may include:
   1) Statement of compliance with laws and regulations
   2) Handling of specification changes
   3) Review of specifications (e.g., frequency, timing, etc.)
   4) Whether or not to re-consign and its conditions, etc.
   5) Providing inspection items that conform to specifications and a certificate of inspection (also called Certificate Of Quality or Certificate Of Analysis)
8. The organization shall determine and implement a review process for these information, including the frequency of periodic reviews. In addition, the organization shall have a system for communicating changes to product specifications both within the organization and to external parties that require those specifications. The organization shall designate a person responsible for managing product specifications. (The person responsible for managing specifications may be a person who not only manages the specifications themselves, but also evaluates and approves them; the scope of the person responsible is determined in accordance with the organization's management system. See FSM15 1. 2) (3).)
9. HACCP Steps 2 and 3 require information on the food safety of products. It is recommended that the specifications to be maintained and controlled by this requirement be organized in relation to such information.

FSM 23.2 Product Release

Requirements

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

Concepts, specific examples

1. For product release (shipment) decisions, the procedures specified below shall be documented, implemented, and maintained:

1) Complete inspections of raw materials (including containers and packaging materials), semi-finished products, work-in-process, reworked products, and finished products to confirm that the products conform to the product specifications.
2) Ensure that not only the product specifications but also process management are carried out properly.
3) The authorized person shall make the decision of acceptability.
4) Maintain records of product release decisions.

2. The following information shall be confirmed prior to releasing products:
1) Releasing procedures are up-to-date and available to engaged personnel.
2) Specifications for raw materials, ingredients, additives, packaging materials, and finished products are clear, and the process for ensuring that recycled and reworked products are consistent with the final product specifications is also clear.
3) The final releasing decision maker is clear.
4) Procedures are in place to confirm that releasing products conform to product specifications and that proper process controls have been implemented.

FSM 24 Identification of nonconformities and control of nonconforming products

Requirements

The organization shall document, implement, and maintain effective procedures for raw materials (including containers and packaging materials), semi-finished products, work in progress, recycled products, reworked products, and final products to identify nonconformities affecting its food safety and to clearly identify, control, dispose of, and rework nonconforming products resulting from such nonconformities in order to prevent misuse and mis-shipment of nonconforming products affecting food safety.
The organization shall also determine who will be responsible for managing nonconforming products.

Concepts, specific examples

1. This requirement is responsible for setting up a barrier at each step along the way to the final product to stop any nonconformity, and documenting the procedure in advance.
2. When nonconformity occurs in raw materials (including containers and packaging materials), semi-finished products, work-in-process products, recycled products, reworked products, and finished products, determine whether or not there is a risk of affecting the safety of the finished products. If there is a possibility of affecting safety, the scope of the effect is to be identified and the response to the nonconformity is to be implemented according to pre-designed procedures. The

organization shall determine the person responsible for the management of the nonconforming product and manage it in accordance with the procedures to ensure that the nonconforming product is not used unintentionally or shipped incorrectly.

3. Nonconformities can be detected not only by inspection activities, but also by business activities or customer complaints, and can include nonconformities in manufacturing processes as well as nonconformities in JFS standard requirements.
4. It is effective to have well-defined manufacturing and inspection procedures in place in advance to detect nonconformities in each process.
5. It is important to recognize that being able to detect nonconformities means that the process is under control. If the occurrence of nonconformity is perceived as a bad thing, it will be difficult to get reports from the field.
6. Clearly identify and isolate nonconforming products found so that they cannot be misused or used in an unintended manner. In identifying the scope of nonconforming products, appropriate judgment shall be made to ensure that nonconforming products are not mixed in with compliant products.
7. Non-conforming products shall be discarded or reworked and clearly identified and traceable. The rework shall be clearly documented in the HACCP flow diagram. (See GMP 9)
8. If preventing recurrences of non-conformity is required, FSM 25 shall be Implemented.
9. If a product shipped is determined to be unsafe, the organization shall conduct a recall or removal. (See FSM 22.1)
10. When a nonconformity occurs, a release decision shall be made after confirming the contents of the nonconformity and that food safety is ensured regardless of whether or not the correction is implemented. Such a decision can require a different authority than that for a normal release decision.

FSM 25 Corrective Action

Requirements

The organization shall define, implement, and maintain the document of procedures for the determination and implementation of corrective actions in the event of any nonconformities arising relating to food safety.
In case of deviation or violation, the organization shall identify the root cause, take measures to prevent recurrence, and review the effectiveness for the series of corrective actions.

Concepts, specific examples

1. The organization shall establish, document, implement and maintain procedures to ensure the elimination as quickly as possible of the causes of detected nonconformities affecting food safety and to prevent their recurrence.
2. Personnel with the competence to analyze causes and plan countermeasures shall plan and implement corrective actions.
3. The following flow of corrective actions shall be addressed:
   1) To ascertain the actual status of nonconformity (including customer complaints).
   2) Identify causes of nonconformity.
   3) Implement necessary measures to prevent recurrence of nonconformities.
   4) Review the effectiveness of corrective actions taken.
   5) Record the sequence of actions related to corrective actions.

FSM 26 Change management

Requirements

The organization shall document, implement, and maintain procedures to evaluate the impact to the necessary extent in advance when changes occur in all processes and operations (including equipment and devices) that affect the safety of the final product. The organization shall also determine who will be responsible for change management.

Concepts, specific examples

1. In operating a food safety management system, it is important to manage changes in all processes and operations (including equipment and tools) that affect the safety of the final product, and it is necessary for organizations to reliably establish and address the process of such changes. Therefore, procedures shall be documented, implemented, and maintained to assess the impact of changes to the extent necessary before they occur. (FSM3, 10, 15, 20, 23.1, and HACCP Step 11 (Principle 6) are relevant for responding to changes that occur. FSM26 also includes these procedures for responding.)
2. The key points in establishing and operating the above procedures are as follows:
   1) The organization shall determine the "definition of change" appropriate for the characteristics of the products it handles and its own business activities, and describe it in the procedures. (Referring to the examples below, determine the scope of change and management appropriate for own organization.)

Managed subject	Examples of changes
Person	New hires/reassignments/return to work
Equipment and Tools	New installations/repairs and specification changes/restarting idle equipment
Raw materials	New adoption/change in specifications/use after a long time

Methods	First time manufacturing, inspection, and management / Changes in manufacturing, inspection, and management / First time in a long time manufacturing, inspection, and management
Environment	Factory transfers/seasonal changes/extreme weather

2) In addition to planned changes, there may be unexpected changes (such as in response to customer complaints). The definition of such unexpected changes and how to respond to them shall be also described in the procedures as much as possible.
3) To ensure control of the change, its "change flow" shall be clarified and described in the procedure. The main contents of the "change flow" are as follows:
   - Application for change ⇒ Preliminary evaluation of change ⇒ Trial operation ⇒ Judgment/permission ⇒ Check of effectiveness ⇒ Completion

   Based on this process, it is important to create a record of the entire process from application to completion of the change.
4) If changes are implemented, new and different risks may arise. (For example, if equipment in one process is changed/modified, equipment in another process can also need to be changed/modified.) Therefore, it is important to verify the risks associated with this change from multiple perspectives during the "Preliminary evaluation of change".
5) During the "Trial operation," a plan shall be developed and implemented to evaluate the change work, including the criteria necessary for subsequent "Judgment/permission". The number of samples required, etc., shall also be determined in advance.
6) After the "Judgment/permission" is completed and the product is successfully transferred to mass production, the "Check of effectiveness" is conducted for the change. The main items to be checked are as follows:
   - Does what's changed function without any problems?
   - Are the intended results being achieved continuously? etc.
7) The person responsible for change management shall confirm up to the "Check of effectiveness" step above and make a final pass/fail decision. If it passes successfully, it is complete.

FSM 27 Utilization of Kaizen suggestions from personnel

Requirements

The organization shall establish and implement a system to properly utilize food safety Kaizen suggestions from personnel.

Concepts, specific examples

1. This requirement calls for organizations to establish and implement a system for effective for improvement activities by bottom-up. This incorporates employee improvement activities, which have long been emphasized in Japan, into the food safety management system, and is a feature of this standard.
2. Suggestions for improvement made by employees should not just be adopted as is. Since some suggestions may have negative side effects for food safety efforts, the content of the suggestions should be professionally verified before being adopted. In addition, the results should be communicated not only to the proposer but also to the entire organization.
3. It is most important that food safety initiatives be properly implemented by front-line employees, and to motivate them to do so, it is effective for front-line employees to think for themselves and make suggestions for improvement.
4. Encouraging suggestions by educating each personnel on how they can contribute to food safety can be included in establishing systems of the "Training" section of GMP 7.
5. This initiative, like any other initiative, shall function substantially. In addition, there shall be daily communication between supervisors and subordinates.
6. Note the relevance of FSM 2 and FSM 27, as FSM 2 requires that top management commitments include this requirement as part of the food safety culture component.

II Hazard Analysis and Critical Control Point (HACCP)

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 Sanitation 2020: (Reference) Japan Food Sanitation Association 2021 Translation First 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 to identify the scope of the HACCP system and the applicable GMPs. The scope shall be documented what products and processes are covered by which HACCP plan. Additionally, appropriate knowledge and expertise shall be utilized in developing an effective HACCP system.

Concepts, specific examples

1. By forming the HACCP team with people with as many specialized skills as possible from the manufacturing/processing department, quality assurance/quality control department, and the maintenance department responsible for the maintenance and preservation of facilities and machinery used in manufacturing, it is possible to eliminate blind spots in hazard analysis and facilitate communication. The HACCP team leader (food safety officer) should be a food hygiene officer or food hygiene manager who has knowledge of the product and specialized skills, and knowledge of the product's characteristics and processes, furthermore, has strong communication skills and is able to summarize opinions within the organization.
   When the Food Safety Officer and the HACCP team leader are different personnel, it is necessary to ensure that they communicate with each other.
2. Depending on the size of the business, there are many cases in which various tasks are performed holding multiple positions, and for this reason, the top management himself may be the team leader, or one person may be responsible for all food safety-

related actions, etc. However, it is important to try to ensure the cooperation of employees within the organization to the extent possible.

3. If the number of employees is small, the team does not necessarily need to be composed of several people. It is also possible to utilize outside resources.
4. If the organization lacks in-house knowledge or expertise, it can be also effective to receive external training or to obtain the participation and advice of external food hygiene experts.
5. The HACCP team shall identify the scope of the HACCP system and appropriate GMPs (PRPs in ISO 22000). Examples of documentation of products and processes covered by the HACCP plan include inclusion in product manuals.
6. The main roles of the HACCP team, other than the above No.5, are as follows:
   1) Preparation of HACCP Plan
   2) Establishment of GMP
   3) Preparation of sanitation standard operating procedures
   4) Education and training for personnel in charge of HACCP plan implementation
   5) Implementation of HACCP system and GMP verification
   6) Review, amendment or change of the HACCP plan based on verification results
   7) Identification of changes in raw materials, product composition, manufacturing processes, etc. and review of HACCP plans accordingly
   8) Review, improve, or modify HACCP plans as needed based on new food hygiene information
   9) Response to external inspections
7. The HACCP team is responsible for managing food safety efforts within the organization.

HACCP Step 2 Product Description

Requirements

The organization shall document product specifications.
The document shall describe all product information necessary to conduct hazard analysis.
Scope of the HACCP system shall be defined per product or product group and per process line or process location.
This system should be systematic and comprehensive and take into account legal and regulatory requirements related to food safety.

Concepts, specific examples

1. In order to clarify the characteristics of the product, describe the specifications and characteristics of the final product, divided into necessary items, as follows:

1) Specifically, for the final product, describe the name and type of product, the intended use/purpose of the product, product characteristics, names of raw materials, names of additives and standards for use, form of packaging, units and quantities, materials of containers and packaging, expiration date or best before date and storage method, distribution method, internal targets for controlling hazards in the product (Ingredient standards for bacteria specified in the Food Sanitation Law, etc.), including the standard criteria specified by the recipient.
2) In facilities that manufacture multiple products, it can be effective to group foods together for purposes of developing HACCP plans, depending on similar characteristics and processing steps.
3) If allergens are included, or if there may be cross-contact of allergens in the same facility, this shall also be noted.

HACCP 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.

Concepts, specific examples

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

HACCP Step 4 Construction of Flow Diagram

Requirements

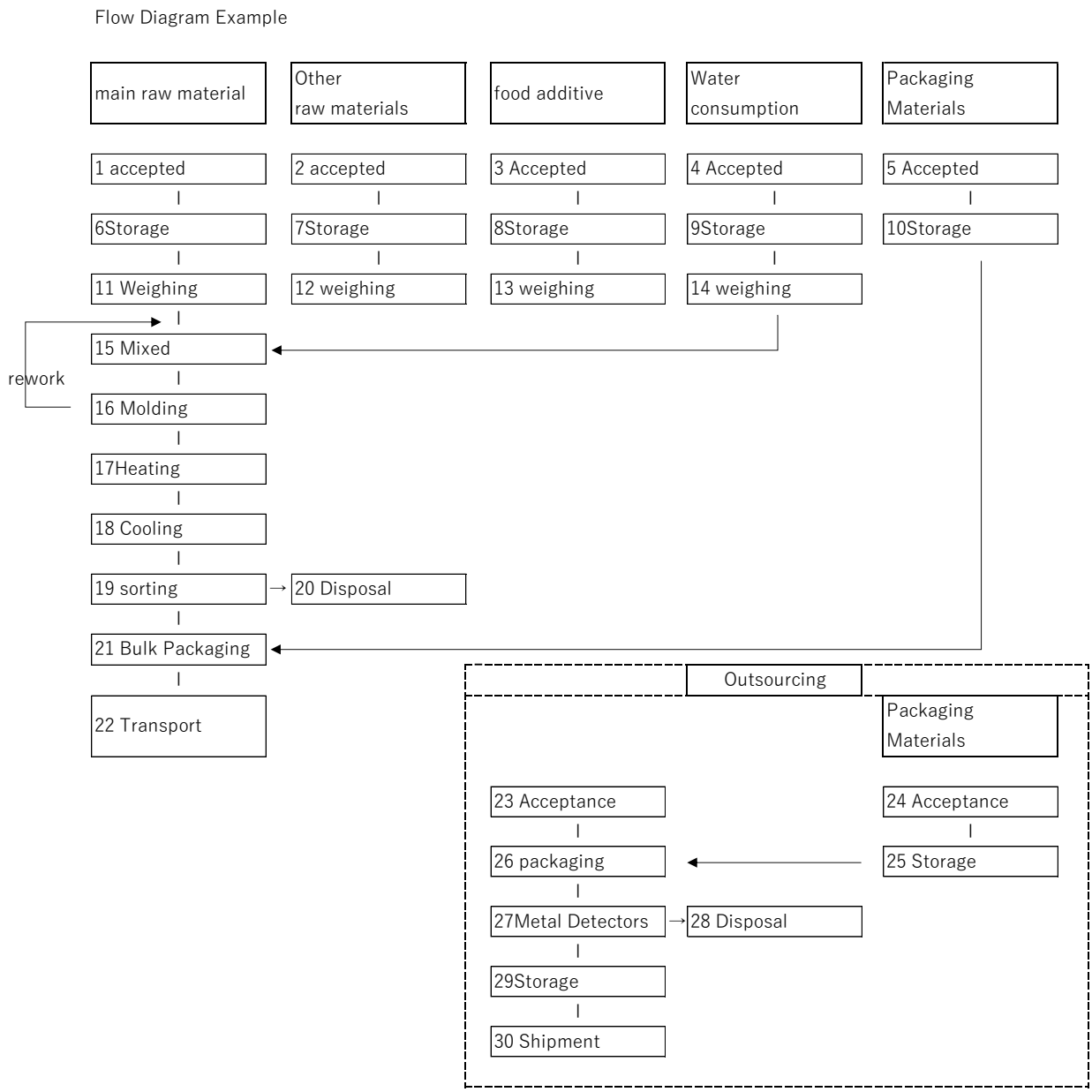
The organization shall construct the flow diagram that covers all steps in the operation.

Concepts, specific examples

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

【Creating a flow diagram】

4. The flow diagram shall be created according to the following procedure:
   1) Briefly list all processes and operations from receipt of raw materials to shipment of final products and applicable rework.
   2) The listed raw materials and processes shall be enclosed in a frame, the frames are connected with arrows, and the process is numbered in order. For raw materials, food additives, water and packaging materials used, gas (only if used), and other materials that come into contact with the product shall be also written down, and these shall be written in a box in the same row, and arrows shall be connected to the process in which they are used.
   3) In the course of raw material processing, if waste is generated or it becomes a processed raw material to be used in other products, it shall be clearly stated.
   4) In the process, if there are processes with pass/fail judgment, reprocessing, reusing or reworking, etc., it shall be clearly stated so that it can be controlled.
   5) The process being outsourced shall also be clearly stated.
5. By drawings of the facility showing the outline of each process and the planar and three-dimensional layout of the facility, it is possible to identify process key points and areas where cross-contamination is possible, which can aid in hazard analysis.



HACCP Step 5 On-site Confirmation of Flow Diagram

Requirements

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

Concepts, specific examples

1. A person with sufficient knowledge of the process shall verify on-site that the process is clearly defined in the flow diagram so that the hazard analysis in HACCP Step 6 (Principle 1) can be sufficiently performed. At that time, the on-site verification shall be performed as follows, while checking against the site layout diagram:

1) At the site, verification shall be carried out step by step from the upstream process, to check that appropriate processes are shown, including temporary storage of products and management of semi-finished products.
2) If a process or activity is inconsistent with the flow diagram at the site, check with the responsible person for the correct control method and correct the documentation.
3) Verification shall be observing the work during various work periods to ensure that the flow diagram matches the work.

HACCP Step 6 (Principle 1) Hazard Analysis

Requirements

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

Concepts, specific examples

1. Hazard analysis is to identify potential hazards to be controlled by the HACCP plan, determining critical hazards, and clarifying control measures for each critical hazard. For this purpose, information is first collected on potential hazards and the conditions under which they can occur throughout the entire process from raw materials, manufacturing and processing, storage and distribution to consumption, and the likelihood of occurrence of the hazards and the severity of the hazards when they do occur are identified.
   1) Hazards shall be specific and shall explain the cause or reason for their presence. The potential misuse of the product by potential consumers that would make the food unsafe, as well as any unintended uses that could be known from known cases, shall also be considered.
   2) Hazards should also be identified and considered whenever possible. Examples are provided below:
      (In the case of metallic foreign bodies, which are physical hazards)
      ●A certain part A in the manufacturing process is subject to routine maintenance, but it has been missing in the past, and since there is a possibility that it may get mixed into the product in the future and cause injury to consumers who eat it, it is identified as a major hazard and management measures are required.
      ●On the other hand, a certain part B in the manufacturing process is managed through daily maintenance, and there have been no cases in the past of it being missing and contaminating the product, so it is considered to be controlled

through general hygiene management and is not identified as a significant hazard.

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

《Steps to prepare the Hazard Analysis Sheet》

6. The steps for creating the Hazard Analysis Sheet are explained using the "Example Hazard Analysis Worksheet" given in the International Commission on Food Standards (CODEX) Committee's General Principles of Food Safety CXC 1-1969, Rev.2022.

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

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

[Step 1] (Column (1) of "Example of Hazard Analysis Worksheet")

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

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

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

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

This guideline describes the method in 1).

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

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

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

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

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

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

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

8) Potential for food to become unsafe as a result of its intended use, and/or mishandling of the product by the consumer

9) Conditions leading to the above

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

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

An example of the concept of 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 "Example of Hazard Analysis Worksheet")

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

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

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

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

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

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

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

Example of Hazard Analysis Sheet

Product name: Catering Bento

(1)	(2)	(3)	(4)	(5)
Ingredients/Process	Hazards expected to occur in (1)	Is it an important hazard that needs to be reduced or eliminated from the food supply?	Basis for decision in column (3)	Control measures for hazards identified as important in column (3)
Refrigerated (Vegetables)	Organisms: Presence of pathogenic Harmful Microorganisms			
	Salmonella spp.	NO	Contamination is possible due to unsanitary handling during manufacturing and processing, but can be controlled by adhering to hygienic handling of food and other products.	
	Pathogenic Escherichia coli			
	Staphylococcus aureus			
	Heat-resistant spore bacteria			
	Clostridium botulinum	NO	Contamination is possible due to unsanitary handling during manufacturing and processing, but the bacteria are anaerobic and cannot grow during storage.	
	Welch bacillus			
	Bacillus cereus	NO	Possible contamination due to unhygienic handling during manufacturing and processing, but can be controlled by adhering to hygienic handling of food and other products.	
	Chemical: None			
	Physical: Presence of metallic foreign bodies	YES	Possible presence of metallic foreign matter due to improper handling during manufacturing and processing	Controlled by metal detection (NO.9)

Product name: Boiled soba noodles

(1)	(2)	(3)	(4)	(5)
Ingredients/Process	Hazards expected to occur in (1)	Is it an important hazard that needs to be reduced or eliminated from the food supply?	Basis for decision in column (3)	Control measures for hazards identified as important in column (3)
Buckwheat	Organisms: Presence of pathogenic Harmful Microorganisms			
	Salmonella spp.	6	May be more contaminated than soil	Can be controlled in the sterilization
	Pathogenic Escherichia coli	6	May be more contaminated than soil	Can be controlled by Sterilization
	Heat-resistant spore bacteria			
	Bacillus cereus	7	May be more contaminated than soil	Can be controlled by cooling (NO.33)
	Welch bacillus	19	Not likely to proliferate since not placed under anaerobic conditions thereafter	
	Clostridium botulinum	15	No possibility of proliferation, as the material will not be placed under anaerobic conditions thereafter.	
	Chemical: Residual pesticides	17	Inspection certificate is issued once a year to confirm that the product has passed the inspection.	
	Physical: Presence of foreign matter			
	Hard foreign body	13	Can be eliminated by visual check at weighing (NO.14)	
	Metallic foreign body	18	Can be eliminated by visual check at weighing (NO.14)	

HACCP Step 7 (Principle 2) Critical Control Points

Requirements

The organization shall determine Critical Control Points (CCPs).

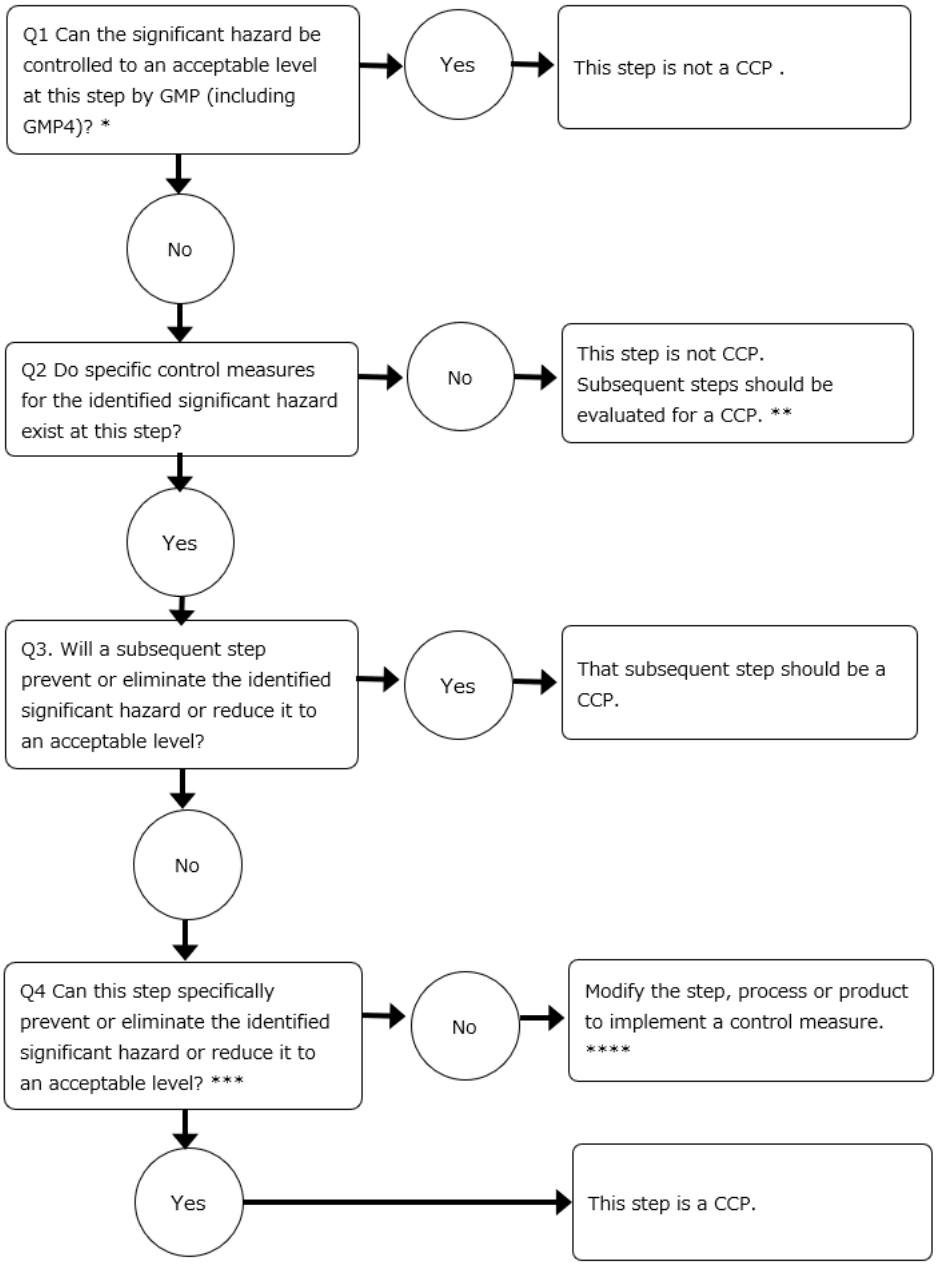
Concepts, specific examples

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

   See the figure below for the procedure / The main points are as follows:
   1) The requirements for CCPs are that it can be monitored continuously or with a reasonable frequency using a pre-defined monitoring method, and if the parameter deviates critical limit (CL), production can be stopped immediately and process control can be restored to the original state in a short period of time, and food produced during the period of deviation can be identified and isolated.
   2) Only those processes for which significant hazards are identified in the hazard analysis are subject to Decision Tree application.
   3) Consider the significance of the hazard (i.e., the likelihood of its occurrence and the severity of the effect of the hazard in the absence of controls) and whether it can be adequately controlled by the GMP. A GMP can be a normal GMP, or it can be a GMP that requires greater attention (e.g., monitoring and recording) to control the hazard (so-called GMP 4.2). (See *)
   4) If CCPs were not identified in Q2-Q4, review the process and control measures again and re-conduct the hazard analysis. (See **)
   5) Determine whether a control measure at a process where a significant hazard has been identified is used in combination with a control measure at another

process to control the same hazard, in which case both processes should be considered CCPs (See ***).

6) If there are no specific and special control measures, the process and control measures should be reviewed again and the hazard analysis shall be re-performed. (See ****)



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

3. Specific examples of CCPs

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

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

(2) Cooling: Prevention of pathogen growth through appropriate temperature control
(3) Refrigerated storage: Prevention of pathogen growth through appropriate temperature control
(4) Weighing of food additives: Prevention of over-additives

2) Examples of CCPs that eliminate hazards include the following:
(1) Heating process or sterilization process with chemicals: Sterilization of pathogenic bacteria
(2) Metal detection: Detection by detector and elimination of metal fragments

3) Examples of multiple CCPs that control a single hazard are as follows:
(1) Control patty thickness and heating time/temperature to kill non-spore-forming pathogenic microorganisms in hamburgers.
(2) The heating process can be a CCP to kill vegetative cells of spore-forming pathogens, and the cooling process can also be a CCP to prevent spore germination and growth.

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

HACCP Step 8 (Principle 3) Critical Limits

Requirements

The organization shall stipulate Validated critical limit(s) for each CCP.

Concepts, specific examples

1. What is the Critical Limit (CL)?

1) CL is a monitoring criterion that distinguishes between acceptable and unacceptable conditions of a control measure of hazards and is an observable or measurable criterion that distinguishes between acceptable and unacceptable conditions of food in relation to the control measures applied as a critical hazard (CCP). A CL can have one or more parameters.
2) Since incorrectly set CL can lead to the occurrence of hazards, they shall be validated based on scientific data and set appropriately.
3) Deviations from the CL require corrective action.
4) The CL shall meet the following conditions:
(1) The most appropriate parameters for ensuring that hazards are prevented, eliminated, controlled or reduced to acceptable levels, and whose value is scientifically proven
(2) Criteria using parameters that can be determined in real time whenever possible

If it is found that the control condition is not appropriate, corrective measures shall be taken immediately, so it is desirable for this to be indicated by parameters that can be judged in real time.

5) CL is usually the minimum or maximum value of a critically important parameter related to the control measure and can be used, such as temperature, moisture, time, pH, water activity (Aw), available chlorine, contact time, conveyor belt speed, viscosity, conductivity, flow rate, etc, or sensory indicators (color, gloss, odor, taste, viscosity, physical properties, foam, sound, etc.) or observed pump settings, etc.

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

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

2. How to set CL

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

HACCP Step 9 (Principle 4) Monitoring System

Requirements

The organization shall establish monitoring procedures for each CCP.

Concepts, specific examples

1. What is monitoring?

1) To ensure that CCP is properly controlled and to keep accurate records for later verification, monitoring is the comparison with CL, and, to do the observation,

measurement, or test inspection based on a schedule established in the HACCP plan.

2) In the management of CCP, the act of watching to ensure that there are no deviations from CL is called monitoring.
3) Any deviation from the CL requires corrective action.
4) Monitoring records are also used when verifying the HACCP plan.

2. How to monitor

1) The monitoring method shall meet the following conditions:
   (1) To be carried out continuously or with reasonable frequency.
   (2) The method shall provide rapid results (physical and chemical measurements are usually chosen over microbiological tests).
2) It is important to monitor to be conformed the control measures against hazards for all products. This shall be done continuously or with reasonable frequency to enable monitoring that the CL is met for every product, from the first one to the last one, or for every batch. When deviations from the CL occur, they shall be done in a manner that minimizes the impact as much as possible and in a way that allows easy corrective actions to be taken.
3) If possible, process adjustments should be made when monitoring results indicate a trend toward deviation in the CCP.
4) The [5W1H] that defines the monitoring method means the following:
   (1) Rationale (Why): Is there scientific validity for monitoring the control status of CCP?
   (2) What (What): Is the CCP within the acceptable range of the CL (does not deviate from the CL)?
   (3) In which process (Where): Clarify the applicable process (CCP process)
   (4) How (How): Is it a rapid and accurate physical, chemical, or sensory observation, measurement, or inspection method
   (5) Frequency (When): Is it continuous? Or, if not, is there a frequency of not missing deviations?
   (6) Who (Who): Personnel trained in monitoring methods
5) Continuous recording of measured values is not enough to control hazardous factors. They shall be checked by someone other than the person in charge of monitoring at an appropriate and sufficient frequency.
6) When the HACCP plan is developed, a monitoring person shall be identified. This person should be able to implement by oneself or implement by instructed on the appropriate procedures that need to be implemented when monitoring indicates the need to take corrective action. To take corrective action, data obtained from monitoring should be evaluated by a designated person with the knowledge and authority.

7) All records and documents related to CCP monitoring should be signed or initialed by the person conducting the monitoring, and the results and the time of the monitoring should be recorded.

HACCP Step 10 (Principle 5) Corrective Actions

Requirements

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

Concepts, specific examples

1. What is corrective action?
   1) Corrective action is the immediate action taken when monitoring parameters deviate from the CL.
   2) In CCP, which is a process that should be especially strictly controlled to prevent the occurrence of hazards, it is important to determine the methods and procedures for corrective action in advance because any deviation of the monitoring parameters from the CL may result in the occurrence and escalation of food safety risks. (See FSM 24, 25, GMP 9)
   3) In the HACCP plan, the actions to restore process control and procedures for restarting the line, as well as the actions to isolate affected product and determine and implement its disposition, shall be defined.
   4) To minimize the likelihood that the deviation will recur, the cause analysis shall be performed to identify and correct the cause of the deviation, if possible. The cause analysis shall identify the reason for the deviation or limit the amount of product affected by the deviation.
2. Items to be included in the HACCP plan as corrective actions

   Items to be included in the HACCP plan as corrective action are as follows:
   1) Action to restore the control status of the process
      - Repair, adjust, or replace machinery, etc., to return the process to a normal state of control.
   2) Treatment for products manufactured during the deviation
      - Identify and withhold products that deviate from the CL and evaluate them.
      - Decide on treatment methods, such as reprocessing or disposal.
3. Person in charge of implementing corrective actions

   Shall be done by an authorized person in charge who has sufficient knowledge of CCP management, understands the process well, and can make quick decisions.
4. Corrective Action Implementation Records

   The corrective action implementation record shall include the following items:

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

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

Requirements

The organization shall validate HACCP plan prior to implementation.
Verification procedures shall be established to confirm whether the defined handling (HACCP Plans) is carried out as specified and to judge whether it is necessary to modify the defined handling.
Verification shall be carried out considering the design of equipment, change in processing method and technology development in the manufacturing process.
HACCP system shall be reviewed regularly and updated when there is a significant change that could introduce new hazards and/or control measures.

Concepts, specific examples

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

1. validation
   1) Validation is the assurance that the HACCP plan is capable of controlling the critical hazards and shall be performed before the HACCP plan is implemented. Items for which validation should be performed include the following:
      ⇒ Identification of hazards, and CCP, CL, control measures, frequency and type of CCP monitoring, corrective actions (improvement measures), frequency, and type of verification and type of information to be recorded, etc.
   2) Validation of control measures and CL of CCP shall be conducted during the development of the HACCP plan.
   3) Validation involves reviewing the scientific literature, using predictive models, conducting validation studies, and using guidelines developed by authoritative sources (e.g., Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 - 2008)).

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

2. Implementation of HACCP Plan

Implement activities in accordance with the established HACCP plan.

3. Verification

1) After implementation of the HACCP plan, evaluate its effectiveness and verify that the HACCP system is functioning properly. Verification is basically conducted once a year, or as needed. For verification of the overall food safety management system, please refer to FSM5.

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

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

(1) HACCP plans for each CCP

① Verify the HACCP plan for each CCP. The cases to be covered are as follows:

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

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

iii. Measurement of manufacturing and processing conditions

iv. Review CCP monitoring records, corrective action records, and verification records

v. Confirmation that operators are working in accordance with the HACCP plan

vi. Observation that control measures are operated according to the HACCP plan

② Verification of monitoring also includes verifying that the monitoring is correct by using a different measuring instrument or method. For example, for temperature, cross-checking with another thermometer or measuring the center temperature if the steam temperature of the heater is monitored instead of the center temperature, and for verification of the heating process, conducting a microbiological test on the sample after the heating process to confirm that no microorganisms remain in the sample.

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

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

i. Contents

ii. frequency

iii. Action based on verification results

iv. Method of recording the results of the verification

④ Verification should be performed by someone other than the person performing monitoring and corrective action.

(2) Entire HACCP system

① Verification of the entire HACCP system shall be conducted on a regular basis using the following procedures as needed:

i. Analysis of consumer complaints or cause for recall

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

iii. Testing and inspections to verify product safety

② The results of the verification are recorded, inspected, and the HACCP system is reviewed as necessary.

4. Re-validation of the HACCP system

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

1) Change in raw materials
2) Changes in manufacturing processes or systems (including computers and their software)
3) Change of packaging
4) Change in final product delivery system
5) Changes in the intended specifications or the intended consumer, of the final product
6) When verification results indicate deficiencies or potential deficiencies in the HACCP plan
7) When a new hazard is identified in the same food or in the same food group
8) When new information regarding product safety becomes available

※. Requirements for testing and inspection methods used for verification are as follows:

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

HACCP Step 12 (Principle 7) Documents and Record

Requirements

The organization shall prepare and maintain necessary documents.
These documents shall contain documents related to the standard operating procedures (SOP) and the work instructions (WI) necessary and applicable to the scope of certification of the organization.

Concepts, specific examples

What documents and records are required?

1. Documents and records required by the 12 steps of HACCP include the following:
   1) HACCP Team Member List and Role Assignment
   2) Product Description
   3) Flow diagram
   4) Hazard Analysis
   5) HACCP Plan
   6) Determination of CCP
   7) Determination of CL and information providing scientific support for the CL
   8) Validation of control measures
   9) HACCP plan revision records, etc.
2. Records of activities according to the HACCP plan include the following:
   1) Monitoring records
   2) Corrective action records
   3) Verification records
   4) Training records of the person in charge, etc.
3. Records of HACCP plan implementation
   This is important to provide evidence to prove control (scientific literature used during validation, minutes of HACCP team meetings, etc.) as well as to address deviations when they occur. Records can be maintained electronically, if necessary.
4. The organization shall document standard operating procedures and work instructions covering the scope of certification.
5. "Standard Operating procedures (SOPs)" are documented procedures for performing standard tasks.
6. "Work Instructions (WI)" means documents that instruct employees what work is to be performed.

III Good Manufacturing Practice (GMP)

GMP 1 Facility Environment

Requirements

The organization shall locate and maintain their business site in a location where pollution can be prevented and products can be safely received, stored, manufactured and delivered.

Concepts, specific examples

1. If a new business establishment is being built, the location shall be surveyed to ensure that there are no contamination risks that would affect the food safety of the organization. In the case of an existing establishment that does not meet this requirement, relocation is not necessarily required.
2. The contamination risk in the vicinity of the site must be considered relative to the contamination risk measures taken by the organization, and if sufficient measures are in place to address the contamination risk that exists, then it can be said that the site is "located in a location that will produce safe products.
3. When taking measures to address contamination risks that exist in the vicinity of a business establishment, it is necessary to be able to explain what is considered to be a contamination risk, what is being done to address it, and that the contamination risk is being controlled by the measures being taken. If a new contamination risk arises in the vicinity of the business establishment after the aforementioned measures have been taken, the assessment and countermeasures shall be made again.
4. Examples of surrounding environments to be aware of include waste disposal facilities, ranches and poultry farms, and chemical handling facilities.

GMP 2 Factory premise environment

Requirements

The organization shall establish and maintain appropriate standards for the area around and on the premises of the business so that contamination can be prevented, and safe products can be made accordingly.
These Standards shall include the management of waste and unnecessary materials on the premises.

Concepts, specific examples

1. Concept in GMP2
   In GMP2, it is important to take measures to ensure that "influences from around and on the premises do not affect the food safety risk to the product" and to maintain them. To this end, the following actions are required.

1) Identify what exists in the vicinity and premises of the business site
2) Check whether they pose food safety risks to own products
3) Consideration of measures to be taken and maintained so that the system can ultimately be capable of "preventing food safety risks to products.
4) Regularly check for changes in the environment, in parallel with carrying out maintenance measures

2. Confirmation of site boundaries
   1) Ensure that the boundaries of the site are clear and in a condition that can be reliably accounted for.
   2) Even if the site is located in an industrial park or other location, the organization's own site shall be clearly identified.
   3) It is recommended that as much as possible, drawings or other means be used in order to clearly maintain the confirmed settings.
3. Confirmation of the surrounding environment

   Identify any food safety concerns regarding the area surrounding the facility. One example can include the following:
   1) Insect and bird damage related
      - ●Rivers, drainage ditches, etc.
      - ●Mountains, forests, parks, agricultural land, livestock, etc.
      - ●Garbage dumps, waste disposal sites, etc.
   2) Foreign body related
      - ●Garbage dumps, waste disposal sites, etc.
   3) Others (impact on buildings, odor, chemicals, etc.)
      - ●Regional effects of salt damage, strong winds, freezing, etc.
      - ●Agricultural lands where pesticide spraying is conducted - Livestock industry (feedlots, etc.)
      - ●Exhaust and smoke emissions from other factories, etc.
4. Confirmation of business premises

   Identify any food safety concerns that can also be present in the facility. One example can include the following:
   1) Insect and bird damage related
      - ●Green space, etc.
      - ●Areas where puddles can form
      - ●Drainage, septic tanks, rainwater tanks, etc.
      - ●Unnecessary items, waste storage, etc.
   2) Foreign body related
      - ●Waste storage, treatment areas, etc.
5. Response to each impact

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

Possible measures include the following:

1) Insect and bird damage related

- ●Removal or modification of the subject, isolation, etc.
- ●Periodic check, maintenance and repair of plantings and water ponding areas (If the site is subject to the Green Space Act, compliance is required but proper consideration shall be given to placement and management)
- ●Maintenance of the building, including repairs (positive and negative pressure, entrances and exits, damaged areas and gaps that serve as entry points, light sources, odor leaks, etc.)
- ● Periodic monitoring by insect control contractors or own organization (perimeter, building interior, etc.)

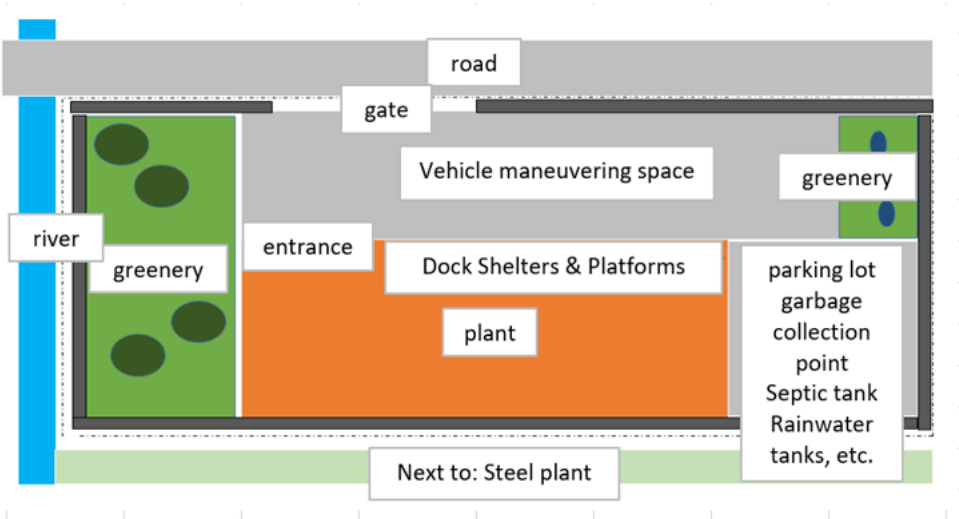
2) Foreign body related

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

3) Others

- ●Arrangements with stakeholders in the surrounding environment
- ●Deterioration countermeasures through periodic maintenance of buildings and facilities
- ●Periodic verification of production areas and products

[Example] Building Surroundings
(facilities on the site as well as outside facilities and environment (outside the dotted line)).



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

Requirements

The organization shall design, construct and maintain the factory buildings and facilities (storage area, raw material and product handling area, preparation area, packaging and storage area, etc.) of the business site both outside and inside the plant to minimize food safety risks.

In addition, the equipment layout (including drainage system and lighting) and the flow lines of people, goods, and work shall be designed in accordance with the principles of hygienic design outlined in food safety laws and regulations to meet the intended purpose and minimize food safety risks.

The organization shall set the lighting necessary for food safety to an appropriate level of illuminance.

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

Concepts, specific examples

1. The first half of this requirement requires that food manufacturing facilities within the factory buildings and facilities, at the business site that are used to produce food be designed, constructed, and maintained to minimize food safety risks, and these are primarily hardware measures.
   Factory buildings and facilities" include roads, fences, and other structures on the premises.
   On the other hand, the second half of the requirements call for equipment layout and lines of flow of people, goods, and operations to be designed to minimize food safety risks, and these are mainly soft measures. The equipment layout and the flow lines of people, goods, and work shall be designed in accordance with the principles of hygienic design outlined in food safety laws and regulations of the food manufacturing country, technical information magazines on food factory buildings and facilities, know-how provided by food facility manufacturers, and know-how on facility installation accumulated within the company, etc. to meet the intended purpose and minimize food safety risks. (refer to FSM 4)
2. The following points shall be considered in the design, construction, and layout of factory buildings and facilities:
   Factory buildings and facilities
   1) It is appropriately located on the site and is of appropriate size and construction for the intended use.
   2) The structure is easy and feasible to maintain, clean and wash.

3) Select durable materials that can handle the weight of work equipment, wear, etc.
4) The material is capable of withstanding cleaning and washing.
5) When designing manufacturing and processing facilities, refer to the following and fully identify impacts to manufacturing and processing:
   (1) Layout diagram of manufacturing and processing area
   (2) Flow diagram showing manufacturing and processing processes
   (3) Equipment, personnel, methods of transporting raw materials and products, process capabilities, etc.
   (4) Work classification commensurate with the manufacturing and processing process
   (5) Install appropriate cleaning facilities for food handling equipment and utensils, etc., in the facility.
6) Structures in food facilities shall meet the following specific requirements, as necessary:
   (1) Wall, partition, and floor surfaces: use materials that are easy to clean, can be sterilized as needed, and are impervious to water and dirt.
   (2) Walls and partitions: to be suitable heights for operation and smooth surfaces.
   (3) Ceilings and overhead fixtures (including lighting): constructed to be shatterproof where necessary and finished to minimize dirt and condensation buildup and particle falling.
   (4) Windows: installed for ease of cleaning and to minimize dirt buildup, with removable and cleanable insect screens installed as needed.
   (5) Doors: smooth, non-permeable surface, easy to clean and can be disinfected as needed.
7) In particular, the following measures shall be implemented to deal with foods containing allergens. (For details, see FSM 16.)
   (1) For example, if separate production lines are used in the manufacture of foods that do not contain a particular allergen and foods that do, the potential for allergen cross-contact from one line to another be prevented or minimized to a level that does not affect food safety.
   (2) To prevent food from spilling from one line to another, eliminate intersections or implement means to contain or defend food.
   (3) To prevent or minimize cross-contact of allergens by workers, consider the placement of handwashing sinks in appropriate locations and facilities that allow workers to change protective clothing, depending on the situation.
   (4) Equipment, tool containers, and utensils that come in contact with allergen-containing foods shall be designed and constructed to effectively eliminate allergens.

Lighting

1) Provide brightness that allows food handlers to work safely and hygienically. Illumination and color tones shall not cause misidentification in the work area.
2) If there is insufficient illumination in the area where work such as visual inspection is performed, take measures such as installing supplemental lighting such as electric stands.
3) When conducting color tone inspections, etc., lamp color tone shall be considered in addition to illuminance.
4) Lighting shall be of specifications that facilitate maintenance and cleaning and minimize deterioration.
5) When installing ducts for electrical wiring, etc., the structure shall be such that dust and dead insects do not accumulate on the top, and the ducts shall be installed in a location that is easy to clean. When removing the ducts, they shall be pulled out vertically rather than horizontally to prevent dust from falling out.
6) To prevent physical hazards such as debris from affecting products or manufacturing and processing lines in the event of damage to lighting fixtures, protective covers (dust-proof type) shall be installed or anti-scattering measures shall be taken with anti-scattering film, etc.
7) For windows used for lighting, select materials that are resistant to deterioration and shattering if they are made of resin, and materials that are resistant to dew condensation if they are made of glass, and provide shatterproof measures such as shatterproof film.
8) Illuminance of the working environment (this item is applicable to the scope in Japan)

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

(See Article 10, Paragraph 1 of the Office Sanitation Standards Regulations: Enforcement date: December 1, 2022)

Illuminance Standards in Business Establishments

Work Classification	standard
General office work	More than 300 lux
Incidental clerical work	More than 150 lux

Drainage System

1) Drainage routes shall be designed and controlled to minimize the possibility of

contamination of products, etc.

2) The floor and drainage basins shall be designed, with a slope to prevent puddles, and to make cleaning easy.

Temperature control

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

Air (air conditioning and ventilation) in the manufacturing environment

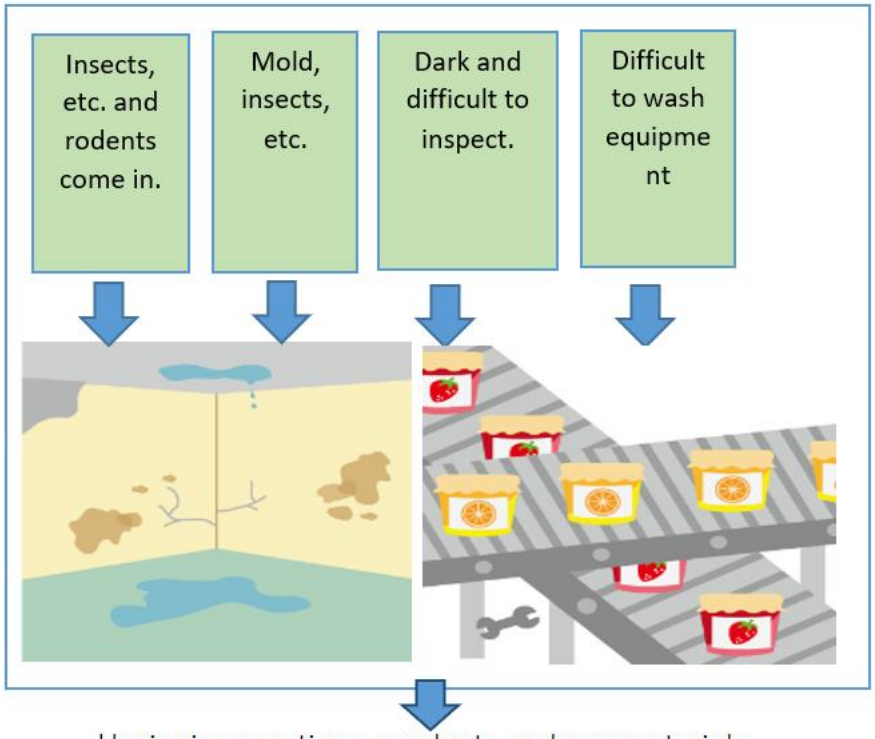
1) Provide appropriate means of natural or mechanical ventilation, especially for:
   - Minimize airborne contamination of food by aerosols and condensation droplets, etc.
   - Assistance in controlling ambient temperature
   - Control of odors that can affect food conformity
   - Control humidity to ensure food safety and suitability. (e.g., to prevent moisture gain in dried foods that can allow microbial growth and the formation of toxic metabolites)
2) Ventilation systems shall be designed and constructed so that air does not flow from contaminated areas to clean areas. Systems shall be easy to maintain and clean.

3. In this standard, "flow lines of people, goods, and operations" refers to the flow of people, goods, and operations taken as a whole, rather than individually, and is described as process design. Efforts to ensure that the flow of people, goods, and operations minimizes food safety risks include the following:
   1) Describe manufacturing flow lines, personnel flow lines, etc. on layout drawings of manufacturing and processing areas, and analyze risks to food safety from these flow lines.
   2) Flow lines shall be separated as much as possible so that they do not intersect. Lines of flow include the following. "Goods" and "people" are the most important among them. Control "goods" and "people" as much as possible to avoid cross-contamination.
      (1) Goods: Routes from receipt of raw materials to shipment of final products
      (2) People: Routes for personnel to enter and leave the work area, routes for movement between work areas, and routes for outside workers to enter and leave the work area
      (3) Work: Routes between each process to receive and deliver work
      (4) Waste: Routes for transporting workshop residues and unwanted materials outside

(5) Drainage: Routes of drainage in the work area

(6) Utilities: Routes of utilities such as steam, compressed air, carbon dioxide, nitrogen and other gases, air conditioning and ventilation, lighting, water, etc. used directly or indirectly in manufacturing and processing

3) Areas that implement different levels of sanitation control (e.g., raw material and finished product areas) are separated to minimize cross-contamination by means of physical separation (e.g., walls, partitions) and/or location (e.g., distance), goods or people flow (e.g., unidirectional production flow), air flow, or temporal separation, and are properly cleaned and sterilized between uses.



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

Requirements

The organization shall prevent physical, chemical (including allergens), biological contamination, and cross-contamination (including allergen cross-contact) of raw materials (including containers and packaging materials), semi-finished products, work in progress, reworked products, and finished products.

The necessary control measures, including isolation, shall be established to cover all aspects of food safety, and these procedures shall be documented and maintained effectively through periodic review.

Concepts, specific examples

1. This standard requirement is related to HACCP Steps 4 and 5 in the actual work performed.
2. As sources of contamination, all aspects of food safety are covered, including foreign substances, microorganisms, chemicals, and allergens.
3. An effective way to prevent cross-contamination (including allergen cross-contact) is to isolate raw materials (including containers and packaging materials), semi-finished products, work-in-process, reworked products, and finished products from the sources of contamination or objects that can contain such sources of contamination as described in Section 2 during the manufacturing process. Normally, the degree of product contamination decreases as processing proceeds, but in the case of pathogenic microorganisms, they have a tendency to spread from highly contaminated to less contaminated locations and objects. Isolation is effective in preventing this contamination. When storing the above-mentioned objects to be isolated, it is recommended that each object be placed in a specific location, such as a storage room or refrigerator, and that dedicated containers be used to protect the objects from cross-contamination (including allergen cross-contact).
4. For contamination associated with the movement of people and objects, as well as cross-contamination (including allergen cross-contact), it is also effective to identify the areas where it occurs and establish preventive measures.

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

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

GMP 4.2 Control of hazards that require enhancement

Requirements

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

Concepts, specific examples

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

      Necessary control measures be established, those procedures documented as necessary, and those procedures be maintained effectively through regular review.
   2) 1) is synonymous with "GHPs requiring more attention" in CXC 1-1969, Rev. 2022, General Principles of Food Hygiene of the International Commission on Food Standards (CODEX).

      * Hazards identified by the HACCP Step 6 Hazard Analysis that are considered to have the potential to cause significant food safety hazards if mistakes are made that do not meet the requirements for control by GMP, are considered to be "GHPs that require more attention " and consequently are considered to be controlled by GMP 4.2.
2. Points to note for controls according to GMP 4.2
   1) Depending on the type of product, manufacturing process, hazard analysis, frequency and severity, etc., the hazards controlled in GMP 4.2 will vary. These should be considered and identified. The matrix in HACCP Step 6 (Principle 1) and other information can be used as a reference.
   2) Control procedures according to GMP 4.2 can involve not only GMP requirements, but also controls according to FSM requirements. Although they vary depending on the industry and products of an organization, examples of relevant requirements are provided below:

      FSM 13.1, 13.2, 13.3 Purchasing, Supplier and Outsourcing Management

      FSM 16 Allergen Management

      FSM 19.2 Environmental Monitoring

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

      GMP 6.1, 6.2, 6.3 Personal hygiene criteria, Workwear and Health management of personnel

GMP 8 Housekeeping, cleaning, sterilization, and disinfection
GMP 11 Air and water Management
GMP 13 Pest control
GMP 18 Equipment and Tools
GMP 19 Maintenance

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

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

● Monitoring of records to be kept

3. Examples of Hazards Controlled by GMP 4.2

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

2) Management of Listeria monocytogenes:
If RTE foods (ready-to-eat foods that do not require heating before consumption) after heat sterilization are contaminated with Listeria monocytogenes from lines, utensils, or the environment, they can multiply even at temperatures below 10° C, and food poisoning can occur if stored for long periods. Therefore, lines and utensils that come into direct contact with RTE food products shall be monitored carefully. In addition, it is necessary to set up lines so that RTE foods and contact lines are kept at lower temperatures (preferably 4°C or lower).

4. Required control measures

1) See HACCP Steps 5, 6, and 11.
2) However, in-depth analysis/consideration shall be conducted by paying attention to "Controls according to GMP 4.2" listed in "1".
3) Records of the results of the implementation of the procedures shall be kept as necessary.

GMP 5 Personnel Facilities

Requirements

The organization shall design, install, and manage personnel facilities, including changing rooms, washbasins and toilets, and applicable shared facilities to minimize food safety hazards including allergens.
The organization shall separate toilets and areas where food and drinks are stored and consumed such as cafeterias, and break rooms, from areas where food is manufactured, packaged, and stored.

Concepts, specific examples

1. Facilities for employees include the following, which must be kept clean at all times to prevent the introduction of sources of contamination or foreign materials into the manufacturing or processing site:
   1) Shoe boxes or shoe lockers (to change from commuting footwear to on-premises footwear)
   2) Changing rooms
   3) Toilet and hand washing facilities
   4) Dining room, rest room, smoking room
2. Changing rooms
   1) Provide a sufficient number of lockers, etc. In lockers and changing rooms, clean work clothes worn in the production area shall be kept from cross-contamination with personal clothing or used work clothes.
   2) Changing rooms shall be located so that food handlers' clothing does not become contaminated before moving to the work area.
   3) Changing rooms, if necessary, shall be suitable facilities for employees to change clothes for the work they perform.
3. Hand washing facilities
   1) The facility shall be capable of washing and drying hands in a sanitary manner.
   2) It is important to have a sufficient number of facilities in appropriate locations based on the number of food handlers, and to have washing, drying, sterilization, disinfection facilities, and hot water facilities, as needed.
   3) Sufficient supplies of tap water and water for food production shall be maintained, and soap, paper towels, disinfectants, etc. suitable for hand washing shall be provided, clean, and ready to use at all times. Hand disinfectants shall not be used as a substitute for hand washing, but shall only be used after hand washing.
   4) To prevent re-contamination of washed hands after hand washing, the faucet should be designed so that it can be opened and closed without touching it by hand.
   5) Post easy-to-understand hand washing and disinfection procedures.
   6) Hand washing facilities shall not be used for washing food or mechanical

equipment.

4. Toilet
   1) The toilet shall be of hygienic construction.
   2) Install a sufficient number of them for the number of employees.
   3) The area shall be sufficiently separated from the area where food is manufactured, packaged, and stored. However, if sufficient isolation can be achieved, zoning (such as using separate rooms) is not required.
   4) Establish hand washing and disinfection facilities and means to dry hands, and determine and display procedures for hand-washing and disinfection.
   5) Always keep the area clean, and clean and disinfect it regularly.
5. Dining room, rest room, smoking room
   1) Dining rooms, rest rooms, etc., and places where food and drink are stored and consumed shall be sufficiently isolated from areas where food is manufactured, packaged, and stored to minimize the possibility of cross-contamination. (Pay particular attention to the bringing in of hard foreign objects and allergens.) However, if sufficient isolation is possible, zoning, such as separate rooms, is not required.
   2) Dining rooms, rest rooms, etc., and other areas where food and drink are stored and consumed shall be kept clean, and food, drink, and waste must be controlled to be not left lying around to prevent them from becoming a source of harmful organisms.
   3) Smoking areas shall be located and controlled so that there is no cross-contamination with work clothes or production areas.

GMP 6.1 Personal hygiene criteria for personnel
GMP 6.2 Personnel workwear
GMP 6.3 Health management of personnel
GMP 6.4 Application to subcontractors and visitors

Requirements

GMP 6.1
The organization shall establish, implement, and maintain appropriate hygiene standards that be assessed and documented product-specific hazards to minimize food safety hazards, for its employees in accordance with the laws and regulations of the countries in which they work.
The criteria shall include provisions of hand washing and toilet facilities, ways and frequency of hand washing, medical screening procedure to identify conditions impacting food safety, proper protective clothing, rules on the clothing and footwear, rules on accessing production area, ways of food handling, and control measures for

foreign materials, and management procedures and reporting system in the event of an infected person that poses food safety risks.
These hygiene criteria shall also be understood by personnel who use different languages.
GMP 6.2
The organization shall evaluate product-specific risks and provide appropriate work clothing and footwear to minimize food safety risks.
GMP 6.3
The organization shall develop, implement and maintain health care procedures that evaluate and document product-specific risks to minimize food safety risks.
These shall include procedures for personnel suspected of illness to promptly report illness or symptoms to their superiors according to the laws and regulations of the country in which personnel are working.
The organization shall also determine who will be responsible for managing personnel with health conditions.
GMP 6.4
The organization shall ensure that GMP 6.1, 6.2, and 6.3 are well known to personnel who have an impact on food safety, and apply them to subcontractors and visitors without exception.

Concepts, specific examples

1. Personal hygiene criteria for personnel

   Hygiene control of workers shall be implemented at all times, and care shall be taken to prevent them from becoming a source of contamination. Personal hygiene standards for employees shall be documented and implemented, according to the characteristics of the products handled, and the laws and regulations of the country in which the employees are engaged in the work, and taking into consideration the following items as well as work clothes and health care. To this end, training shall be provided to employees. The personal hygiene standards for employees shall also include procedures and reporting systems in the event of an outbreak of an infected person that poses a risk to food safety. In addition, to ensure that the personal hygiene standards are properly communicated to all employees, if there are employees who use different languages, the standards can be provided in multiple languages as necessary.

   In determining the extent of training required, factors to be considered include:

   ● Nature of the hazard associated with the food. Growth characteristics of pathogenic or spoilage microorganisms, presence of potential physical contaminants or known allergens

   ● Methods of manufacturing, processing, handling, and packaging food, including the possibility of contamination

- Degree of processing and cooking of food before consumption
- Conditions under which food is stored
- Estimated time until the food is consumed
- Use and maintenance of food-related equipment and instruments

1) Establish and document "basic hygiene rules for a series of operations from the start of work to the end of work" in each organization according to the characteristics of the products handled, and provide explanations at the time of employment, etc., to ensure that employees' personal hygiene levels are properly aligned and maintained.
2) Documented sanitation standards describe the standards and behaviors required of employees in processing, packaging, and storage areas.
3) Establish and post a list of goods (positive list) that can be brought into the manufacturing and processing area. Education shall also be provided as appropriate.
4) The following are "examples of employee hygiene practices". It is necessary to set them appropriately by discarding them or considering unique items depending on the organization's situation.
   ① Wash and disinfect hands at designated timing. Examples of designated timing are as follows:
   ●At the start of food handling operations
   ●When returning to work after a break
   ●Immediately after using the toilet
   ●After handling contaminants that can contaminate other foods, such as waste or unprocessed food
   ●After handling foods with different allergen profiles and foods that can contain allergens
   ② Do not act in an unhygienic manner with objects (hands, gloves, utensils, etc.) that can come into contact with the product.
   ③ On the site, refrain from sneezing or coughing, and make efforts to prevent splashing, especially in areas where the product is involved.
   ④ Masks shall be worn correctly as specified, covering the nose and mouth.
   ⑤ To prevent the introduction of foreign substances into the production area, the designated work clothes shall be worn properly to prevent hair and body hair from being mixed in. Also, air showers, adhesive rollers, and other measures shall be taken at designated timing.
   ⑥ Do not take any actions that can result in contamination, such as carelessly going outside the production area while wearing work clothes or work footwear.

⑦ Do not wear any equipment other than those permitted (glasses, hearing aids, etc.). Do not wear any ornaments, etc. to prevent foreign objects from falling off and becoming mixed in.

⑧ Fingernails shall be properly short, clean and trimmed. No manicures. False nails and false eyelashes are also prohibited.

⑨ No makeup that can fall off and affect the product (e.g., lame powder, etc.).

⑩ No use of perfume.

⑪ No food or beverages are allowed to be brought into, stored in, or consumed in the work area (especially areas where products, raw materials, and primary packaging are exposed). These shall be done at designated areas. Refer to FSM 16 for allergen control plan.

⑫ When work clothes are stored in a common locker with personal clothing and belongings, they shall not be handled in such a way that they can be contaminated. And lockers shall not be used to store unsanitary items (including exposed food) or equipment or devices that come in contact with products, etc.

⑬ Bringing unnecessary items to the work site is prohibited. If there is a need for regular medication, etc., consult with the manager and take measures to ensure that contamination of products is prevented.

⑭ Wash hair and bathe regularly and maintain proper personal hygiene.

⑮ Immediately report to the supervisor, if a deviated condition is found that was attached to you is missing, etc.

⑯ Do not engage in inappropriate behavior that could contaminate food. Examples include:

- Smoking or e-cigarettes
- Spitting
- Chewing (gum, etc.), eating, drinking
- Touching the mouth, nose, or other potentially contaminated areas
- Sneezing or coughing on unprotected food
- Touching hair, nose, mouth, or ears, with hands or equipment for handling products, etc.

5) In Japan, in addition to the Food Sanitation Act, the following national guidelines shall be used as a reference:

(1) Guideline for Management and Operation Standards to be implemented by food business operators

(2) Sanitation Management Manual for Large-Scale Food Preparation Facilities

(3) Various hygiene norms developed by the Ministry of Health, Labor and Welfare

2. Personnel workwear

Food handlers shall maintain a high degree of personal cleanliness and, if necessary, change into or out of work clothes, head and beard covers, and footwear that are clean and in good condition for the intended purpose.

1) Appropriate consideration shall be given to the shape of work clothes and footwear to prevent hair and body hair from falling out and getting mixed in with the product. In addition, materials suitable for the working environment shall be used.
2) Prevent contamination and the introduction of foreign matter by establishing rules for washing and changing work clothes and footwear so that employees can wear clean and good condition work clothes and footwear for their work, as needed, and ensure that these rules are followed.
3) Work clothes handling food shall only be worn when working in the facility.
4) Hairnets and masks used by food handlers to ensure food hygiene are also maintained in a sanitary condition that prevents contamination of products.
5) Do not enter contaminated areas, including toilets, while wearing sanitary work clothes, hats, masks, or special footwear for the workplace.
6) Hats shall be worn that are designed to completely cover the hair of the head (including the sideburns).
7) When using gloves, select the material according to the purpose, specify the use and storage method, and handle them in a clean and good condition to prevent secondary contamination.
8) When disposable gloves are used, check the material and strength according to the work to be performed, establish an appropriate replacement frequency, and strive to prevent damage. Establish and implement rules for hand washing before wearing.

3. Health management of personnel

Depending on the product-specific risks, health management procedures shall be developed, taking into account the following items:

1) In advance, determine a manager who shall be responsible for the management of employees with health conditions in case they arise.
2) The manager shall explain the health conditions and food safety risks to employees when they join the company, etc., and seek their understanding of identifying illnesses to the extent necessary, what to do in case of illness, what to do in case of food poisoning, etc., and take actions to ensure that they maintain appropriate knowledge and awareness of food safety.
3) The manager shall ascertain the employee's illnesses as needed for food safety.
4) Have them undergo periodic medical examinations.
5) Conduct periodic stool analysis to confirm that there are no abnormalities.

6) Check the health condition before work and record the results. Employees are to be trained and informed that they shall report any abnormalities in their physical condition to the person in charge of the work site, etc. If an employee reports an abnormality in his/her physical condition, he/she should not be allowed to work handling products unless it is clear that the abnormality does not affect food safety (e.g., minor tooth decay, etc.). The following are examples of illness symptoms that shall be reported to the person in charge of the site, etc:
   ●Jaundice / diarrhea / vomiting / fever / sore throat with fever / visible infected skin lesions (furuncles, cuts, etc.) / discharge from ears, eyes, or nose.
7) If there is a suspicion of infection or food poisoning accompanied by fever, diarrhea, vomiting, etc., or if there is a suspicion of infection among skin injuries (burns, cuts, etc.), etc., report the problem to management, food safety manager, production manager, etc., and have them refrain from engaging in work handling the product and receive medical advice. If necessary, disinfect the facility, equipment, etc., check on the persons (including external visitors) who came in contact with the product, and take action regarding products manufactured or shipped prior to that time.
8) A response procedure should be developed in case an employee becomes ill while working and there is a risk of infection or food poisoning. Procedures should include cleaning the facility as needed and contacting other employees, contractors, visitors, etc. with whom they came in contact.
9) There are some illnesses for which it is appropriate to prohibit entry to the processing area even after symptoms have resolved. In such cases, seek the results of a physician's diagnosis, if necessary.
10) Persons with cuts or wounds shall be assigned to work in areas where they can not be in direct contact with food, if necessary. If the employee is allowed to continue working, the cut or wound shall be covered with an appropriate waterproof bandage and gloves shall be worn when appropriate. Take appropriate measures to ensure that the bandage does not become a source of contamination. (e.g., color-coded, detectable by metal detectors)
11) For contracted businesses and visitors, contact information shall be obtained in advance in preparation for the above-mentioned emergencies.
12) Do not ship food that can have been touched by workers with health conditions until you have confirmed that there are no safety issues. See FSM 24. If the food has already been shipped before confirming that it is not unsafe, follow the procedures in FSM 22.1.

4. Application to subcontractors and visitors

For external visitors such as contractors, outsourced contractors, suppliers, and construction workers, employee personal hygiene management, work clothes, and health management shall be applied without exception. In particular, when entering the manufacturing site (equipment, inspection, consultants, etc.), the time spent there, health condition, and contact information shall be confirmed, and confirmation shall be made in the event of an abnormality.

GMP 7 Training

Requirements

The organization shall ensure that all personnel, including new personnel and temporary workers, be trained in their appropriate language on food safety (including management, culture, HACCP, GMP) and be a system for each personnel to deepen their understanding, implement, and maintain food safety in their respective work, commensurate with their activity.

The organization shall keep records of the implementation of education and training. Additionally, the system for retraining as necessary shall be documented and implemented.

This education and training shall enable employees to recognize their role in food safety and the significance of their efforts.

In addition, there shall be a system to improve comprehension by repeating the training as necessary after evaluating competence.

Scope of the above education and training shall include relevant subcontractors, and their management shall be carried out in accordance with FSM 13.3.

Concepts, specific examples

1. This requirement requires that the organization ensure that all employees, including new personnel and temporary workers, receive education and training in food safety.
2. The organization shall determine, systematically implement, and record training programs (contents, implementation timing, methods, frequency (including retraining), etc.) for employees according to their respective roles. It is important to periodically review the training programs and update them as necessary so that food handlers, maintenance staff, and other personnel involved in food operations continue to be aware of all procedures necessary to maintain food safety and suitability (see FSM 2).
3. Ensure that current rules and procedures can be reviewed at any time, incorporating the opinions of on-site food handlers.

4. As food manufacturing employees are becoming increasingly multilingual, the organization shall make training and education tools available in the appropriate language for training and educating employees whenever possible.
5. This education and training is not intended to be a one-time effort, but shall be based on an evaluation of the competence of each employee in his or her role, and shall be a system to improve understanding through repeated efforts.
6. Under this system, employees shall develop an understanding of the procedures pertaining to food safety in their respective jobs until they are able to implement them as prescribed.
7. The important idea is not to remove employees who lack the skills from their work, but to educate and train them within this system so that they can acquire the skills they need.
8. In addition, education and training not only contributes to food defense (FSM 7), but can also be used for the individual evaluation of each employee. This is important for building a food safety culture in an organization because it also relates to communication with employees and performance evaluation of food safety activities, which are part of the elements of food safety culture (FSM 2).
9. Specific actions that the organization will take in its educational program include the following:
    1) Relate each employee's work procedures to food safety policies and goals (FSM 6).
    2) Demonstrate that adherence to operational procedures contributes to ensuring food safety.
    3) It is not that "deviation" or "nonconformity" is a bad thing that occurs in the course of business, but it indicates "what kind of thing" or "what kind of state" is a deviation or nonconformity, and how to take measures and actions (reporting, communication, and consultation) after the occurrence of a deviation or nonconformity.
    4) Within each job, procedures pertaining to food safety shall be provided and trained until they can be implemented.
    5) At a minimum, train HACCP team members to a level that they can build the organization's HACCP plan.
    6) Employees who monitor CCPs shall be educated and trained to a level where they understand and can implement correction and corrective actions to be taken in the event of a deviation from the CL.
    7) In addition to the above, the educational program shall include, at a minimum, the following items:
        - ●Product reliability, including food fraud
        - ●Product Characteristics
        - ●Food Defense

- ●Food-related legal requirements
- ●Product/process changes
- ●Feedback from previously documented training/instructional programs

8) Establish and implement training programs for all personnel, including new personnel, to obtain the necessary knowledge and skills according to their role in handling food products.

9) Ensure that the current rules and procedures for each job can be reviewed at any time, with input from employees. (See FSM 27)

10) Records created in education and training can be used for individual evaluation and other purposes. (See FSM 2)

11) Based on an evaluation of the employee's competence, education and training shall be repeated as necessary. This retraining system shall be established and implemented in writing.

12) Scope of the above education and training shall include relevant subcontractors who perform processes that can affect food safety (such as contract manufacturers, labor suppliers, and service providers), and their management shall be carried out in accordance with FSM 13.3.

GMP 8 Housekeeping, cleaning, sterilization, and disinfection

Requirements

The organization shall identify product-specific risks based on a hazard analysis throughout all processes and stages and establish, implement, and maintain documented organization, cleaning, sterilization, and disinfection procedures.
In these procedures, the organization shall include steps to verify that product-specific risks have been minimized.
Cleaning tools, cleaning agents and disinfectants shall be suitable for their intended purpose, clearly identified and stored in areas separated from areas where food is manufactured, packaged, and stored.
Food safety information on potentially harmful chemicals shall be obtained and confirmed.

Concepts, specific examples

1. Establish procedures based on hazard analysis

1) Tidying, cleaning, sterilization and disinfection procedures shall take into account product-specific risks throughout all processes and stages, and effective procedures shall be developed and documented. Since cleaning shall remove food residues (including allergens), this procedure shall include the target facility, equipment, areas of the facility, cleaning tools, detergents, procedures, disassembly, monitoring, and actions for food in case of deviation from the

procedure, as required by the scope of the food operation. The procedure shall be reviewed periodically to reflect changing conditions, and revised as necessary.

2) It is important that cleaning equipment, cleaning agents, and disinfectants themselves be risk-assessed and selected before use to ensure that they do not pose hazards. In addition, they shall be clearly identified and stored in areas separated from food manufacturing, packaging, and storage areas. However, if sufficient separation is possible, zoning (such as separate rooms) is not required.
3) In establishing procedures, the required frequency of tidying, cleaning, sterilizing and disinfecting shall be included according to the manufacturing environment and product characteristics.
4) Cleaning shall remove food residues and contaminants that could be a source of contamination, including allergens. Containers and other items that have been exposed to allergens shall be cleaned as soon as they are emptied. Cleaning methods and materials required depend on the nature of the food business, the type of food, and the surfaces to be cleaned. Some surfaces, especially those in contact with food, can require disinfection after cleaning.
5) Attention should be paid to sanitation during cleaning and maintenance operations so that food safety and appropriateness are not compromised. In food preparation and storage areas, use cleaning agent materials appropriate for food contact surfaces.
6) Chemicals used for cleaning and disinfection shall be handled with care and used according to the manufacturer's instructions. For example, they shall be used at the appropriate dilution and contact time and, if necessary, stored away from food in clearly identified containers to avoid food contamination.
7) Care should be taken to ensure that cleaning procedures do not lead to food contamination. For example, it could happen that spray from high-pressure washing could spread contamination from dirty areas such as floors and drains over a large area. It could also contaminate food contact surfaces or bare food.
8) In some operations and/or food processing areas where water increases the potential for microbial contamination, such as when handling low-moisture foods and manufacturing products under dry conditions, controlling the amount of water used in cleaning (e.g., implementing dry cleaning to remove and collect residues and debris) can reduce microbial risks.

2. Education and Implementation

1) Educate food handlers on standardized methods. It is also effective to educate them by showing them the actual cleaning process, or by posting pictures or illustrations of the procedures. Trained personnel shall perform cleaning, washing, and sanitizing. Educate those who handle cleaning agents and other potentially risky chemicals, including methods for handling them.
2) Whether cleaning and disinfection shall be implemented according to the rules is

monitored by visual inspection, and its effectiveness shall be verified by using hygiene tests such as product testing and wipe testing. Monitoring methods can depend on the nature of the procedure, but can include pH, water temperature, conductivity, detergent concentration, disinfectant concentration, and other parameters important to ensure that the cleaning and disinfection program is being carried out as planned and to verify its effectiveness.

3) Education shall be provided based on the results of basic education and hygiene inspections.

4) To cleaning and washing shall be implemented planned accordingly, a plan and procedures shall be created as follows:

(1) Plan sheet for cleaning and washing facilities

① Include in the plan consideration of areas that are easily overlooked for contamination, such as the backs and bottoms of equipment, facilities, and fixtures.

② Describe the frequency of the work, the date it is performed, who performs it, and how it is recorded.

(2) Written procedures for cleaning and washing facilities

① Describe the person responsible for the work, the target, the method, the frequency, the monitoring and verification procedures, the work tools to be used, the inspection procedures after the work is completed, and the inspection procedures before production begins, etc.

3. Selection and maintenance of chemicals used for cleaning and sterilization

1) In selecting chemicals to be used for cleaning, sterilization, and disinfection, not only shall the chemicals be suitable for the intended use, but also their effects on the product and safety for employees shall be evaluated, and if necessary, safety data sheets (SDS) shall be obtained and their contents confirmed before making a decision on their use.

2) The following items shall be implemented for the handling of detergents and chemicals used for cleaning, sterilization and disinfection:

(1) Appointment of a person in charge of management

(2) Inventory management of chemicals, etc. (stock receipt, stock withdrawal, usage amount, stock quantity, user and first in, first out)

(3) Locking and key management of chemical storage cabinets

(4) Maintenance of procedures for formulating detergents and chemicals from undiluted solutions

(5) Education for food handlers regarding handling of chemicals, etc. (including proper dilution, contact time, etc.)

(6) Preventing detergents and chemicals from being mixed into food (e.g., labeling containers with the names of their contents)

4. Management of cleaning tools, washing equipment, etc.

1) Selection, inspection and maintenance

(1) If foreign matter or microorganisms adhere to equipment, facilities, or utensils used for cleaning, washing, sterilization, or disinfection, it can lead to contamination of products with foreign matter or microorganisms. Separate cleaning machinery, equipment, and utensils designed for different sanitation zones (areas), such as for food-contact surfaces and non-contact surfaces, shall be used for different purposes. Contaminated cleaning tools and washing equipment can also spread contamination.

(2) Check operation and deterioration, etc. before and after use, and immediately repair or replace any defects.

(3) Since dirt remains on the undersides and bottoms, etc. of equipment, facilities, and utensils, disassemble them and check them. Cleaning equipment shall be kept clean, maintained, and replaced regularly so as not to become a source of cross-contamination of contact surfaces or food.

(4) Separate facilities shall be provided for cleaning fixtures of highly contaminated areas such as restrooms, wastewater treatment and waste areas. As needed,

- ●Separate facilities for washing food and washing cooking utensils.
- ●Separate sinks for hand washing and washing food.

2) Storage

(1) When selecting a storage location, select an appropriate location that does not pose a risk of contamination to products or the manufacturing environment.

(2) Cleaning tools shall be stored properly to prevent contamination of the tools themselves, for example by hanging them so that they do not touch the floor, etc.

(3) Designate a storage location and keep it clean so that it is readily available to food handlers.

(4) Posting of indicating the storage location.

3) Identification

(1) Measures shall be taken to prevent the misuse of cleaning and washing equipment used in contaminated areas in clean areas. It is important to color-code equipment according to its use, such as "red" for floors and "blue" for cooking utensils, or to store them in separate locations.

(2) Allergen-specific cleaning utensils (sponges, cloths, cleaning solutions, etc.) shall be designated and used for allergens only.

*FSM19.3 requires the establishment, implementation, maintenance and verification of effectiveness of the cleaning and disinfection program, while GMP8 requires specific implementation details for housekeeping, cleaning, sterilization, and disinfection.

GMP 9 Rework

Requirements

The organization shall control product rework in a traceable manner with minimal food safety risk.
The food safety risks involved in rework shall be evaluated and included in HACCP flow diagrams.
Records shall be maintained as evidence of control.

Concepts, specific examples

1. Rework can occur when nonconformity occurs in raw materials (including containers and packaging materials), semi-finished products, work-in-process products, reworked products, and finished products.
   In this standard, the term "correct" includes the meaning of "fix product" and "eliminate nonconformities" in this standard requirement (see HACCP Step 10 (Principle 5)) as well as the meaning of "correct records".
   To avoid confusion, this standard uses the term "rework" when referring to "fix product".
2. Rework is required to be managed so that procedures are established according to the requirements of FSM 24 and do not impact legal and regulatory requirements and food safety in the final product. In addition, it is required to make it possible to trace reworked products by recording and maintaining the rework process.
3. Food safety risks associated with rework shall be evaluated according to GMP 4.1 and 4.2, documented in the HACCP plan flow diagram, and control procedures should be established and implemented. It shall be ensured that reworked products do not have any impact on food safety before they are released.
4. The following items shall be considered in the management of rework:
   1) Competence of personnel involved in rework
   2) Identification methods in rework operations (In particular, for reprocessed products containing allergens, food allergen information shall be appropriately displayed to prevent the possibility of contamination of different products or to a level that does not affect food safety.)
   3) Criteria and procedures for pre-release inspection and release determination of products for which rework has been performed
5. The following items are included in the record of rework management:
   1) What was conducted (when, where, what, how)
   2) Quantity of products made compliant by rework
   3) Personnel involved
   4) inspection results

GMP 10 Patrol and inspection of the site

Requirements

The organization shall establish a patrol plan and regularly inspect the environment, facilities, and process design (people, goods, workflow lines) of the entire site.
Records shall be maintained as evidence of the inspection.
The patrol plan shall ensure that the workplace is maintained in an appropriate state according to its activities and that food safety is ensured.

Concepts, specific examples

1. This requirement requires the establishment of an inspection plan to be conducted at a specified frequency and actual patrols of the site to confirm whether the business is in a suitable state to safely produce food, and the patrols cover the environment, equipment, and process design (people, materials, and work flow).
2. This requirement also aims to identify food safety problems and lead to improvements (FSM 27) through these patrols, and during the patrols, it is important not only to observe conditions, but also to communicate with employees and gather information about actual problems and concerns at the site.
3. As a result, this requirement is closely related to the establishment of a food safety culture, as it results in increased food safety awareness among employees, which leads to an environment that encourages employees to take action on food safety issues themselves and facilitates management's consolidation of this information.
4. The following are examples of how patrols and inspections are conducted:
   1) Report problems to the organization's management using small group activities such as QC circles.
   2) Establish a mechanism for information sharing across the organization through mutual patrol activities among other departments.
5. The following items are listed as viewpoints for patrols and inspections:
   1) Facility flow lines and risk management status of cross-contamination (GMP 3, GMP 4.1, GMP 12)
   2) Status of employee hygiene management (GMP 5, GMP 6.1, GMP 6.2, GMP 6.3)
   3) 5S implementation status of employees and workplaces (GMP 8, GMP 12, GMP 16)
   4) Status of pest monitoring (GMP 13)
   5) Status of facility management (GMP 11, GMP 18, GMP 19)

GMP 11 Air and water management

Requirements

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

Concepts, specific examples

1. Air, high-pressure gases, and water (including ice and steam) used in food production can cause physical/chemical/biological contamination of food depending on their use. To minimize the impact on food safety, it is essential to establish standards required for each application, establish procedures for regular monitoring, and keep records of such monitoring.
2. When manufacturing food products, it is possible to use different types of water for different purposes, in which case standards shall be established for each application.
3. The quality of water to be used shall be checked by water quality tests, etc., and if necessary, filtered, sterilized, or otherwise treated to ensure water quality before use.
4. Where appropriate, municipality, national or internationally recognized microbiological and water quality standards for drinking water shall be followed.
5. In Japan, water that comes in contact with food is, in principle, water for food production or water suitable for drinking, and water for food production means water that complies with applicable laws and regulations.
6. In Japan, it should be referred to in legal and regulatory requirements:
   1) Water quality standards based on the Water Supply Law (51 items): Ministerial Ordinance on Water Quality Standards (May 30, 2003, Ministry of Health, Labor and Welfare Ordinance No. 101)
   2) Water for food production: Specifications and Standards for Foods, Additives, etc. (26 items) (Ministry of Health and Welfare Notification No. 370, 1959)
   3) Water fit for drinking: Regulated by the Food Sanitation Law Enforcement Regulations following the revision of the Food Sanitation Law (enacted on June 1, 2020). (Reference: Appended Table 17 of the Food Sanitation Law Enforcement Regulations, July 14, 2020)
7. In order to reduce the cost of water, there are cases where water other than water for food production is used in the manufacturing process (e.g., for primary washing of food, heating and cooling), and these waters must be controlled to prevent contamination with water for food production. Specific examples include the following:

1) Well water that has simply been pumped
2) Water that has not been sterilized with hypochlorous acid or chlorine, etc.

8. In addition, in some food industries, water that has been used but is acceptable for contact with food can be reused for food production in order to make effective use of water resources, as in 6. above, these waters shall also be controlled to prevent contamination to water used for food production. Specific examples include the following:
   1) Water used to heat and sterilize facilities
   2) Water used to heat and cool prepackaged foods
   3) Secondary washing water for cut vegetables (water used in the final stage of the washing process)
   4) Steam condensate reuse water
   5) Allergens, or water that has come in contact with food containing allergens
9. In addition to water, ice, steam, air, and high-pressure gases used in food production shall also be taken measures to minimize their impact on food safety. These include the following:
   1) Ice, steam
      (1) Ice and steam shall be made and handled in a way that does not contaminate them. In particular, cleaning agents for ice makers and boiler cleaning agents (chemical agents) used in the boilers that generate steam shall be approved for food use and shall not be mixed into the ice or steam.
      (2) Install a filtration device (filter) in the water supply section of the ice maker and near the end of the steam piping.
      (3) Confirm that ice and steam that come into direct contact with food, etc. do not have any adverse effects (odor, coloration, etc.) on food, etc.
   2) Compressed air, carbon dioxide, nitrogen, and other gases
      (1) Equipment for gases used in manufacturing and filling shall be of specifications that do not present a risk of contamination of food products, and shall be properly maintained.
      (2) Gases that come in contact with food shall be approved for use in food in general as food additives.
      (3) Ensure that air and gases in contact with food are free of dust, oil, and water.
      (4) Gases shall be filtered as close to the point of use as possible.
      (5) When gases are produced in facilities within the business premises, standards shall be established and monitored to ensure that there is no contamination.
      (6) Piping, etc. used shall be marked for identification purposes.

10. Air Conditioning and Ventilation
    1) To prevent dust, debris, insects, etc. from entering the building and contaminating the air, the following points shall be considered in the air conditioning and ventilation system:
        (1) The air conditioning and ventilation systems are constructed in a way that makes them easy to clean, wash, and replace filters.
        (2) Consider the air balance between intake and exhaust air in the facility.
        (3) Avoid inflow of outside air through windows, doors, and crevices.
        (4) To facilitate the elimination of soot and steam (to prevent condensation and mold formation, etc.).
        (5) If necessary, maintain differential pressure to prevent air from entering the clean area.
    2) Periodically check the outdoor air intake for damage, clogging of the filter due to dust, insects, etc., and deterioration due to rust or corrosion, etc.
    3) Inspection ports for both intake and exhaust for inspection, cleaning and washing, and filter replacement would be convenient.
    4) Monitor and control the cleanliness of the air in areas where products are manufactured that are prone to the growth and survival of microorganisms, in accordance with procedures.

GMP 12 Waste Management

Requirements

The organization shall establish, implement and maintain adequate systems for segregation, collection and disposal of waste (including wastewater) to ensure they do not pose any food safety hazards.

The flow lines of waste shall be established so as not to cause cross-contamination of food.

Locations and containers for placing waste shall be controlled to prevent attraction of pests or growth of harmful organisms/micro-organisms. Containers for storing waste materials (including by-products not suitable for food use) shall be clearly distinguished from other containers.

Concepts, specific examples

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

surrounding environment and attraction of pests due to overflowing waste (including by-products not suitable for food use) in waste containers in factories and outdoor waste storage areas, as well as outbreaks of sanitary pests and microorganisms due to long-term storage, etc.

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

4) Ensure that effluent does not flow from highly contaminated areas (e.g., restrooms and production areas) to areas where finished food is placed.

GMP 13 Pest control

Requirements

The organization shall establish, implement and maintain procedures to control or remove food safety risks caused by pests (pests and vermin) on the premises and in the facilities.
These procedures shall be implemented using the following cycle.
1. Understanding of the pest outbreak situation and formulation of monitoring plans.
2. Implementation of pest control and invasion prevention.
3. Pest monitoring and dissemination of results to personnel.
The organization shall establish procedures for eliminating pests and vermin as necessary. If chemicals are used, handling procedures shall be established to ensure that food is not affected.
Pest control shall be carried out by persons with the necessary competence.

Concepts, specific examples

Procedures to control or eliminate the risks to food safety posed by pests shall be accomplished in cycles described in the requirements, the details of which are as follows:

1. Identification of pest outbreaks and development of monitoring plans
   This step includes the following efforts:
   1) Collect and understand information about the occurrence status (type, number, location, etc.) of harmful organisms (rodents, insects, etc.) within the facility.
   2) The target pests shall be identified based on past occurrences in the facility, biological evidence, and the characteristics of the products handled, and a monitoring plan shall be developed.
   3) It is important that pest control, including surveys and monitoring plans, is carried out frequently enough and appropriately by competent personnel with the necessary skills. It is also effective to obtain the cooperation of external pest control contractors with expertise in the field.

2. Implementation of control and infestation prevention of pest
   This step includes the following efforts:
   1) pest control
      (1) Remove internal sources of pests. (e.g., Cleaning areas that slime around water areas, and work footwear storage areas, etc.)

(2) Design the layout and specifications of the facility to make it easy to clean. Examples are as follows:

●Sloping the floor to drain water, installing R skirting at the joint between the wall and the floor, etc.

●Openings and pits caused by damage in floors and walls can easily become entry points or internal breeding sites for pests, so repair damaged areas as soon as possible.

●Keep equipment and objects away from the walls of the facility to make inspection and cleaning easier.

(3) Plantings on the site shall be avoided plants that bear flowers or fruit that attract pests, and regularly weed and prune.

(4) Since puddles are a source of chironomid and other fungi, measures shall be taken to prevent their occurrence, such as frequent grading of unpaved parking lots.

(5) Maintain the area so as not to spread the odor of waste and sewage.

(6) Install yellow or green fluorescent lights or vinyl curtains that do not attract insects, in outdoor lighting near indoor areas such as shipping entrances, and in entranceways and walkways.

(7) Be careful not to allow birds and other animals to nest in the eaves of the facility and around the air intake facilities. Inspect mesh and filters regularly.

2) Intrusion Prevention

(1) It is advisable to keep the facility free from negative pressure to prevent insects and other infestations.

(2) Take care to cover the ends of air intake and exhaust vents, drains, etc. around the factory with netting or water seals to prevent pests from entering the facility through openings.

(3) Ensure that lighting does not leak outside around windows and shutter openings in the facility. Placing shading film or insect repellent sheets on windows is also an effective method. Roll-up doors shall be closed tightly against the floor.

(4) Windows that do not open and close should be gap-filled and removed as necessary. Ensure that entrances and exits for employees and objects are closed except when necessary. Wire mesh screens shall be installed on windows, doors, etc. that open and close to reduce the risk of entry by harmful small animals.

(5) To avoid dust dispersal and insect infiltration due to wind pressure when opening and closing the doors, take measures such as installing screens on swing-door windows.

(6) Insect traps at the entrance to the work area shall be placed in a location inside the building where the light cannot be seen from outside.

3. Monitoring for pests and disseminating results to employees
   This step includes the following efforts:
   1) Regularly monitor pests according to the plan in 1. to see if the control activities implemented in 2. were effective, and record the results.
   2) The results of monitoring shall be communicated to employees and each employee shall be involved in pest control activities.
   3) Analyze monitoring results and improve monitoring plans.

4. If the intended effect cannot be achieved in the cycle from 1. to 3. above, extermination shall be performed. When extermination is performed, a work plan that does not affect food or interfere with facility operation shall be developed and implemented by personnel who have secured competence. When extermination is conducted, the following shall be taken into consideration:
   1) Have established procedures for chemical control, spraying procedures, and procedures to take measures both after spraying and before starting manufacturing and processing.
   2) Ensure that drug use is restricted to well-trained personnel.
   3) Control the amount of chemicals received and shipped, and store them in a locked location isolated from the manufacturing and processing areas.
   4) The type of chemical used, the amount and concentration (dilution ratio) used, the date and time of application, the location of the application, and so on shall be recorded.
   5) The entire pest control can be outsourced to a specialized contractor. (For reasons such as more efficient measures, omission of chemical control, etc.)
   6) Inspect if there are any points of pest entry or internal infestation, such as once a week or once a month, depending on the season, regularly.
   7) In principle, the use of poisonous bait is prohibited in the production area.
      *To ensure that the use of poisoned bait does not pose a food safety risk, a special container shall be used that cannot be easily removed when use.
   8) Do not use allergens (e.g., peanut butter, cheese) as bait for traps. When contracting pest control service providers, make them aware of the possibility of allergen cross-contact and do not allow them to use allergens.

5. Pest control and eradication activities can require specialized knowledge and skills, and it is acceptable for some organizations to outsource part or all of their pest control activities to pest control contractors. However, this requirement does not allow pest control activities to be left to the contractor, and the organization that outsources pest control activities shall be the main body of the pest control activities.

The organization that outsources pest control activities and the outsourced contractor shall develop and share a pest management program that includes the activities described in 1. through 4. above and the following, and the organization that outsources pest control activities shall take the initiative in evaluating the performance of the outsourced contractor. (See FSM 13.3)

1) Identify methods and responsibilities for developing, implementing, and maintaining a pest management program.
2) Record pest sightings for the purpose of chemical (insecticidal and rodenticidal agents) use and indicate trends in pest activity frequency.
3) Outline the methods used to prevent pests.
4) Outline methods of eliminating pests.
5) Outline how often to check for pest status.
6) Include the type of chemical to be set (chemical intended to kill insects and rodents), its number, and a diagram of its placement.
7) Clarify and store chemicals used in accordance with Safety Data Sheets (SDS).
8) Clarify and educate employees on anthelmintic control procedures (handling, shipping and receiving control, storage, etc.) and what to do if they come in contact with placed anthelmintic.
9) Outline employee education and training on the use of pest control chemicals and pesticides.
10) Measure the effectiveness of the program to assess the effectiveness of targeted pest elimination.

GMP 14 Acceptance of purchased items

Requirements

The organization shall establish, implement, and maintain acceptance procedures for all externally sourced raw materials, packaging materials and services that influence food safety. In addition, in order to ensure that the safety of the final product is not compromised and that the materials are suitable for the intended use, verification of raw materials, containers and packaging materials shall be carried out.

Concepts, specific examples

Organizations need to ensure that raw and packaging materials are free of abnormalities before use to prevent food safety risks to their products.

1. The organization shall document (see FSM 10) all specifications of all raw materials, packaging materials, and services, including raw materials and additives (but not limited to these), that are purchased from external sources and that can affect the safety of the final product, and keep them up to date at all times.
2. All raw materials, packaging materials, raw material ingredients, etc. shall comply with the relevant laws and regulations of the country of manufacture and the country of sale.
3. Verification of raw materials, packaging materials, raw material ingredients, etc. to ensure that the safety of the final product is not compromised and that the materials are suitable for their intended use.
    1) With regard to items used in the manufacture of products, they shall be in a condition free of abnormalities prior to use. When purchasing or using items that are already packaged as ready-to-use products, this should be allowed only if the specifications for each raw material and packaging material are confirmed and no problems arise when delivering the product under general transportation conditions, such as refrigerated, frozen, or ambient control, rather than in a specialized vehicle.
    2) If the temperature is abnormal, damaged, or contaminated at the time of receipt, do not use the product, checking necessary, take measures such as returning the product.
    3) In regarding semi-finished products and work-in-progress received from related parties to be used as raw materials, if the counterparty uses a dedicated vehicle, confirm the transportation conditions, establish items to be checked upon receipt, and be able to take action such as returning the product if there is any abnormality.
4. Verification shall include a certificate of conformity, certificate of analysis, inspection of extracted samples, etc.
5. All packaging materials that come in direct contact with food shall be checked for the following:
    1) A register of specifications and labels for raw materials and packaging materials shall be maintained and kept current.
    2) Obtain a certificate of compliance with either food-related regulations or approval standards.
    3) In the absence of a certificate of conformity, certificate of analysis, or certificate of guarantee, testing/analysis shall be performed and records maintained to verify that there is no possibility of chemical migration from the packaging material to the food contents.

4) With regard to 2) and 3) above, in order to further enhance the safety of synthetic resin food utensils, containers, and packaging, a positive list system was introduced under the Law for Partial Revision of the Food Sanitation Law, etc. promulgated on June 13, 2008, which allows the use of only substances whose safety has been evaluated for food utensils, containers, and packaging. (Enacted on June 1, 2020 by the Ministry of Health, Labor and Welfare) (Scope of this item applies in Japan)

6. The contract manufacturer/contract service provider shall confirm compliance with the contract by performance management (see FSM 13.2 and 13.3) of the purchasing party.

GMP 15 Transport

Requirements

The organization shall ensure that all containers and transport vehicles used to transport raw materials (including packaging materials), semi-finished products, work-in-progress, recycled products, and finished products (including final packaged and packed perishable foods) that can affect food safety, are designed, constructed, monitored, and maintained to minimize risks.

These containers and transport vehicles, including contracted vehicles, are suitable for the intended use, maintained in good repair and clean, protected from contamination, and transported within its intended temperature range.

Concepts, specific examples

The organization is required to ensure that products (including intermediate stages) are delivered to the customer or proceed to the next process without any abnormalities.

1. When transporting semi-finished products, work-in-process, recycled products, reworked products, and finished products
   1) When delivering to the destination, check the product specifications and consider the necessary conditions for a trouble-free delivery.
      Examples: temperature and humidity settings, stacking and loading methods, pallet-related items used, delivery containers, and other special conditions.
   2) Confirm that the delivery vehicle can handle the set conditions without problems and that the environment is such that the product can be delivered without damage or contamination.
      (1) Can the required temperature and humidity be set? Also, can the required temperature and humidity range be maintained even when the vehicle is fully loaded? If not, can the maximum load be changed?
      (2) Is the temperature and humidity recorded at the required frequency? Also,

is it possible to check that there are no abnormalities with the thermometer and hygrometer as appropriate?

(3) If containers that come into direct contact with products, lorry tanks (including associated hoses, air pipes, air intake filters, truck pumps, etc.), pallets, etc. are not the company's own, check the frequency of cleaning, disinfecting, and replacement.

①It is desirable to be able to verify that a validated cleaning program is being implemented for lorry tanks, including their associated parts (this includes the lorry tank body and associated parts).

(4) Is the interior of the vehicle kept in proper clean condition?

(5) Confirmation of whether mixed loading with non-products is allowed, and if so, the loading capacity, items that can be loaded, etc.

(6) Prevention of fraud through the use of sealing or other agreed upon devices or systems to ensure that no outsiders other than the person in charge of delivery are involved.

2. On the organization, too, if necessary, check and make efforts to maintain the delivery environment. If any abnormalities are found, it shall be necessary to request appropriate improvements.

3. The following are points to be considered in transportation equipment:

1) Transport vehicles

(1) Vehicles and containers used to transport products shall be clean and constructed to prevent external contamination.
Carry carts, etc. used on site are not considered vehicles under this item, and their management shall be conducted in accordance with GMP 18.

(2) Controlled by temperature and humidity according to the characteristics of the products to be transported, and equipped with refrigeration/freezing and dehumidification functions when necessary.

(3) If products are transported refrigerated or frozen, be sure to regularly inspect and record the instrumentation of the thermometer in the vehicle.

(4) Use vehicles with sufficient capacity for the items and quantities of food handled, and that can be effectively separated in the vehicle.

(5) Cross-check thermometers (e.g., install two different types of thermometers and confirm that there is no difference between them) as appropriate to ensure that accurate temperatures are maintained.

(6) Do not allow unauthorized persons to enter the loading area, and do not place unnecessary items, etc. in the loading area.

(7) For pallets used for transportation and storage, avoid using wooden pallets from the viewpoint of pest generation/contamination, and damage.

(8) When transportation is outsourced, manage it with reference to FSM 13.3 (Outsourcing Management).

①For lorry tanks, it is advisable to enter into a contract that includes documentation of cleaning frequency and methods, cleaning records, and maintenance schedules.

2) Containers for transportation

(1) Containers used to transport food are designated and labeled for food and used only for that purpose.

(2) To maintain cleanliness, the materials shall be washable, and they shall be washed and disinfected regularly. If stains or unusual odors are observed, clean immediately.

(3) If the container serves as both a shipping container and a storage container, check for damage during transportation, and take action if any leaks, etc. are found.

GMP 16 Storage

Requirements

The organization shall hold or store foods (raw materials, semi-finished products, work in progress, recycled products, reworked products, and final products) at designated locations, and manage them under appropriate conditions to minimize food safety risks.

Concepts, specific examples

Design, construct and operate appropriate storage facilities for the safe and hygienic storage of food products (raw materials, semi-finished products, work-in-process products, recycled products, reworked products and finished products).

1. Food storage facilities shall be designed and constructed with the following in mind
   1) Prevent pests from entering and living in the area.
   2) Specifications shall effectively protect food and prevent contamination. (Contamination includes cross-contact of allergens.)
   3) The environment shall minimize deterioration of food due to temperature and humidity.
   4) Non-food chemicals (including cleaning agents, lubricants, fuels, etc.) should be stored in a secure storage facility separate from food.
2. Food storage facilities shall be operated with the following in mind:
   1) Control the product in consideration of pre-sterilization, post-sterilization, distribution temperature (ambient, chilled, frozen), expiration date, and best-before date.
   2) Establish procedures to avoid mixing the test product with the genuine products.
   3) Distinguish between raw and cooked foods.
   4) Distinguish between foods that contain allergens and those that do not.

GMP 17 Stock Management

Requirements

The organization shall establish, implement and maintain a system to use raw materials and ingredients (including packaging materials), partially processed products, work in progress, recycled products, reworks, and finished products in a designated order and within the defined expiry period, and shall store these materials under the proper conditions to avoid contamination and deterioration.
Storage facilities and equipment shall be designed to allow food to be stored under appropriate storage conditions.

Concepts, specific examples

1. Storage period
   1) Raw materials (including containers and packaging materials), semi-finished products, work-in-process, recycled products, reworked products, and finished products shall be used within a specified period by establishing an appropriate shelf life and utilizing first-in, first-out, etc.
   2) During storage, the traceability (see FSM 14.1) of raw materials (including containers and packaging materials), semi-finished products, work-in-process, recycled products, reworked products, and finished products shall be managed so that they can be linked to the records.
2. Storage location
   Facilities and equipment for storing food shall be designed to store the food under appropriate conditions according to the specifications of the food.
   1) Raw materials (including container and packaging materials), semi-finished products, work in progress, reworked products, and finished products shall be stored in storage facilities, that are not contaminated, and do not deteriorate due to temperature, humidity, etc. This is related to GMP 4.1 and 4.2.
   2) Storage conditions that do not degrade means storing the product under appropriate conditions that ensure the required specifications.
3. For storage of containers and packaging materials, the following shall be considered in addition to food storage conditions:
   1) Container and packaging materials whose manufacturer is clear and suitable for the intended use
      Ensure that specifications and history can be identified and food safety can be guaranteed, such as that the manufacturer is not using potentially unsanitary ingredients.
   2) Locations where containers and packaging materials are stored and their appropriate management
      (1) Avoid dust and dirt by covering the product when not in use.

(2) Establish procedures for handling aseptic packaging materials and glass containers. (Including procedures in case of glass container breakage)
(3) For containers and packaging materials stored for long periods, establish procedures to confirm that they comply with specifications.
(4) Storage location and proper management of container packaging materials and products
(5) To allow for inspection and cleaning of container and packaging materials, they are stored off the floor and there is space between pallets.
(6) Avoid areas where condensation can occur.
(7) Returnable containers used for storage shall be clean and not contaminated.
(8) Also be careful of contamination caused by sterilization, rodenticides, and fumigation.
(9) Isolate from chemical storage areas to prevent contamination.
(10) When storing, check laws and regulations, etc. related to containers and packaging (especially synthetic resin).

GMP 18 Equipment and Tools

Requirements

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

Concepts, specific examples

1. Concept of Equipment and Tools
   1) Organizations are required to prevent food safety risks from equipment and tools. The following are examples of hazards:
      - Biological: Contamination by residual food residues, etc.
      - Chemical: Residual mold and allergens due to insufficient cleaning and drying, etc. and chemical damage due to detergent residues, etc.
      - Physical: Foreign matter contamination due to breakage, deterioration, dropout, etc.

      Consideration shall be given to sufficiently preventing these hazards before allowing production activities.
   2) "Suitably for the intended use" means meeting specifications that ensure and maintain food safety (e.g., temperature setting of heating and cooling equipment, ease of cleaning, etc.).
2. Design, selection, installation, and operation of equipment and tools

   Equipment (facilities) and tools for manufacturing and processing shall be designed and selected to be effective against product hazards (biological, chemical, and physical), taking the following points into consideration. In addition, sufficient

number and capacity shall be secured according to the amount of manufacturing/processing, and they shall be properly installed and operated in consideration of their handling methods, flow lines, etc.

1) Design and selection

(1) The structure shall be easy to clean, wash, disinfect, and maintain, and if water is used, shall be designed to drain as well as possible.

(2) Select that do not cause contamination of foreign materials (paint, etc.).

(3) If necessary, use that can be disassembled for maintenance, cleaning, washing, disinfection, and monitoring.

(4) Ensure that food contact surfaces are durable and easy to maintain, clean, inspect, replace, wash, sanitize, and monitor, and consider how much deterioration should be addressed and how often it can realistically be addressed.

(5) It is important that surfaces in contact with food be made of materials that do not be affected by leaching of ingredients due to interaction with food or by cleaning and washing. Confirm that the material is compatible with food products and take action to ensure that it is provable.

(6) Whenever possible, surfaces in contact with food shall be impervious and, if made of metal, of materials that are resistant to rust and corrosion, and shall be monitored for rust and corrosion, if necessary.

(7) It is important that equipment and tools be made of materials that do not adversely affect the product.

(8) Parts and components, etc. attached to equipment and instruments are to be checked to ensure that they do not affect the safety of the product.

(9) Items that can fall off (screws, labels, etc.) shall be avoided from the top of the food whenever possible, and monitoring shall be carried out as necessary.

(10) Check carefully before initial use to ensure that there are no paint chips, metal chips, etc. mixed in.

(11) Equipment used for cooking, heating, cooling, storing, or freezing food shall be designed to achieve the required food temperature as quickly as necessary, to maintain food temperature effectively, and to monitor and control temperature as needed. Monitoring equipment used to monitor temperatures shall be calibrated, if necessary, to ensure that the food temperatures in the process are accurate.

(12) Equipment monitoring food control conditions should have effective means of controlling and monitoring humidity, air flows, and other characteristics that can affect food safety or suitability, as necessary.

2) Installation

(1) When cleaning/cleaning piping (pipes and ducts), ensure that there is good drainage, no difficult-to-clean areas, and no unused branch pipes.

(2) As much as possible, it is desirable to be able to "wash everything in a washing room, etc." and "dry thoroughly in a drying room, etc.". For equipment that needs to be fixed to the floor, consider making it possible to handle this without difficulty, such as by making the parts to be cleaned disassembled.

(3) Prepare the necessary capacity and quantity to allow sufficient time for washing and drying, assuming actual operation.

(4) Confirm that periodic cleaning and checking is possible for water and residue on pipes, ducts, etc.

3) Operation

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

① Washing methods: washing tools used, water temperature during washing, whether or not detergents are used, etc.

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

③ Others: Alcohol spraying or not, etc.

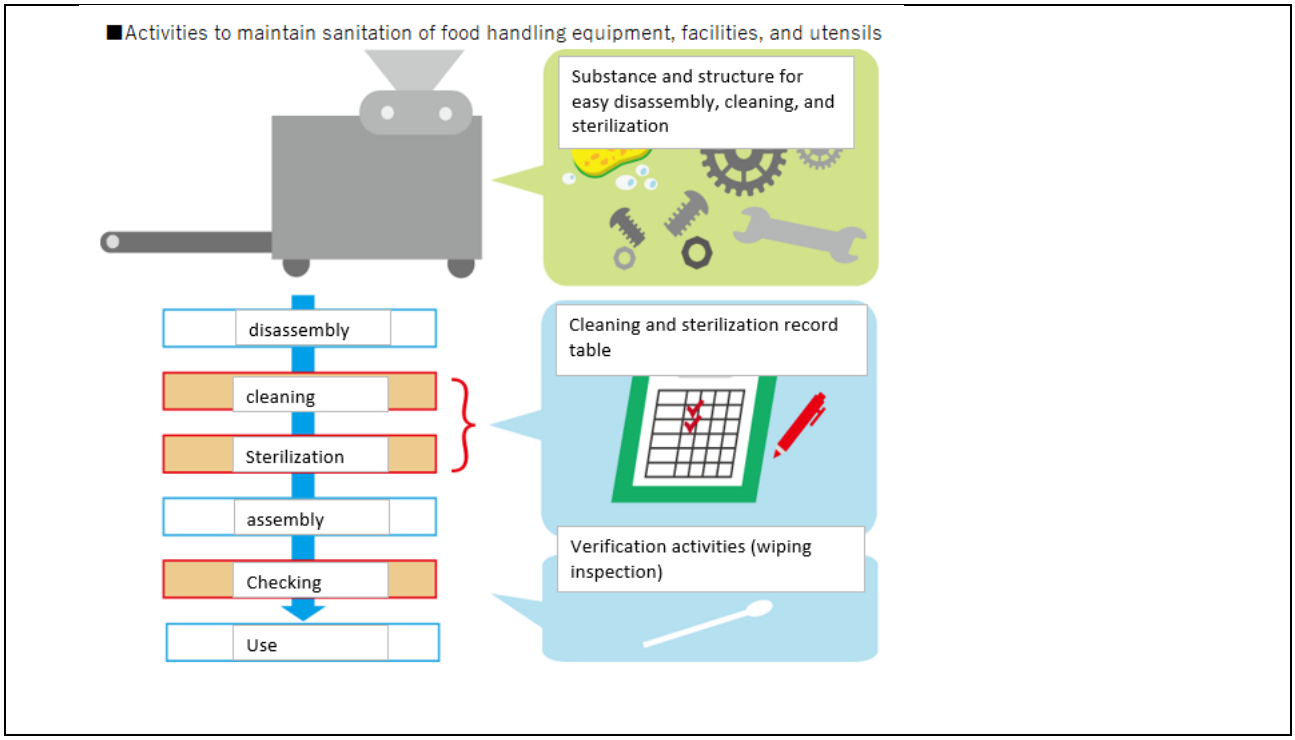
(2) It is desirable to verify whether there is no residual of the intended hazards if the procedure is implemented as studied. As an example, after actual washing and drying according to the procedure, the residual allergens could be confirmed by means of a bacterial test of wiped specimens, ELISA test, etc.

(3) If the established procedures require special training and education of workers, it is desirable to have a procedure manual or visual explanation materials. In addition, it is recommended that records be kept to confirm areas that are prone to insufficient washing, to record that drying has been completed, etc., as necessary, to increase certainty.

(4) Monitor for damage, deterioration, and other areas of food safety risk concern at an appropriate frequency. When monitoring is conducted, it is desirable to keep records.

(5) Make sure workers are aware of the need to report any abnormalities they notice, such as damage, missing parts, or strange noises.

(6) Carts, etc. shall be kept clean between uses to prevent contamination and/or allergen cross-contact with subsequently used foods, tools, etc.



GMP 19 Maintenance

Requirements

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

Concepts, specific examples

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

2) Procedures for the maintenance of facilities and equipment shall include the following items:
   (1) Developing a maintenance and inspection plan
   (2) Person in charge of maintenance and inspection
   (3) Identification of facilities and equipment requiring maintenance and inspection
   (4) Frequency of maintenance and inspection
   (5) Procedures for performing maintenance and inspections (including chemicals to be used)
   (6) Methods for checking and recording the status of maintenance and inspection
   (7) Procedures for restoring food production to a condition ready for use after maintenance (including cleaning, etc.) Procedures for restoring food production to a condition where it can be performed after maintenance (including cleaning, washing, sterilization, etc.)

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

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