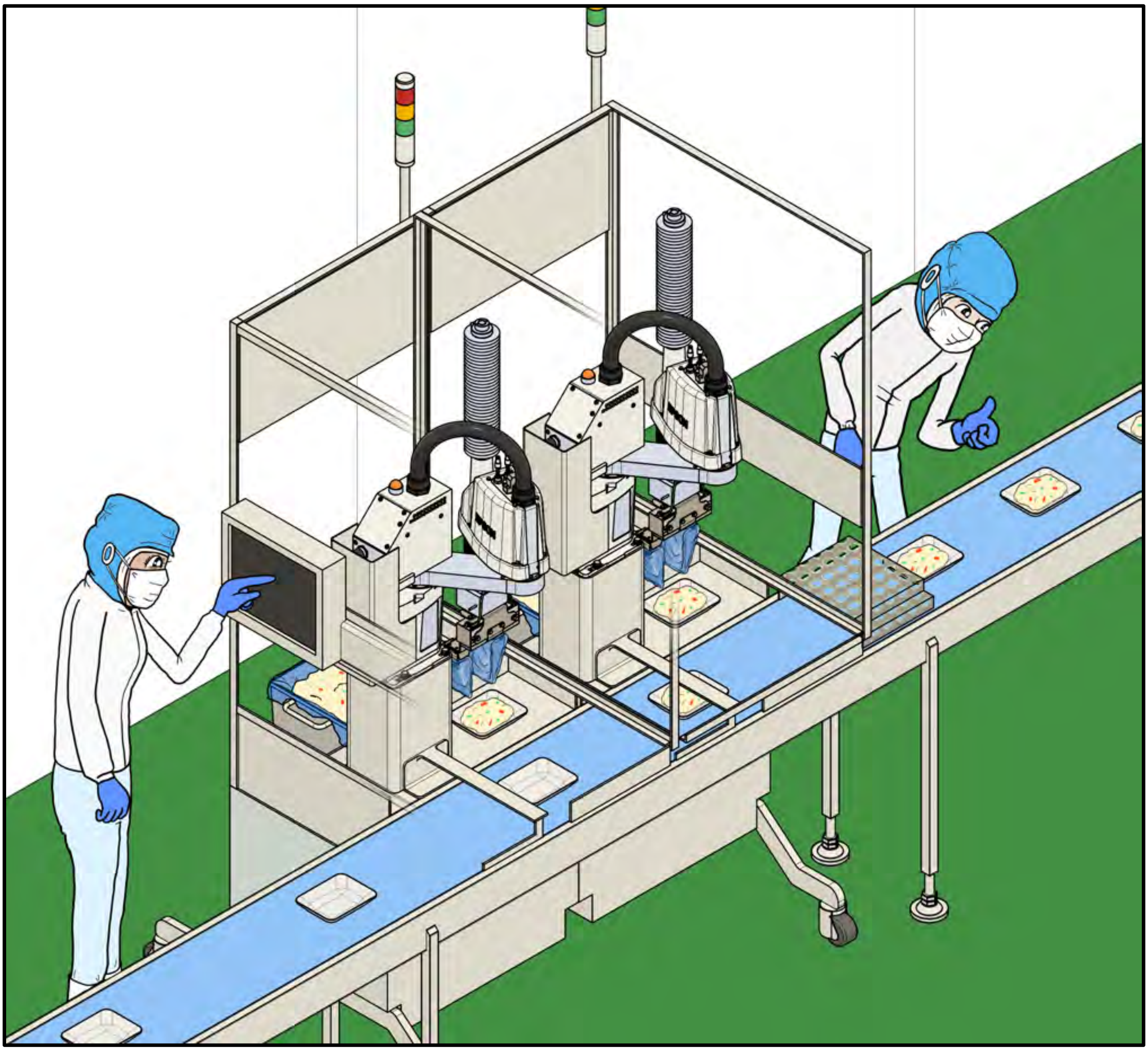
Sanitation Management Guidelines for Food Manufacturing Facilities Implementing and Operating Robots, etc.



Established in April 2024

Ministry of Agriculture, Forestry and Fisheries

Table of Contents

Introduction

There are currently about 8,000,000 individuals being employed by the food industry in Japan, of which roughly 1,300,000 individuals work in food manufacturing[1]. Generally considered labor intensive, the food manufacturing industry is facing the challenge of having to secure sufficient workforces, as the country's total labor force has been on the decline. In addition, as the workforce productivity[2] of the food manufacturing industry is at about 60%[3] relative to other manufacturing industries, the industry also needs to tackle its own issue of low workforce productivity. In addressing these issues, automation and other associated technologies, especially of robots that have advanced quite significantly in recent years, are viewed as viable solutions.
In its *Sustainable Food Systems Strategy "MIDORI"* (May 2021)[4], the Ministry of Agriculture, Forestry and Fisheries (hereinafter referred to as "MAFF") states its intent to facilitate the automation, etc. of the food manufacturing industry in order to improve its workforce productivity by at least 30% by 2030. So MAFF's general policy is to further accelerate the implementation of automation technology in the food manufacturing industry.

When it comes to implementing automation technology at food manufacturing facilities, one salient challenge is the difficulty of technology development because the items that are being processed come in various shapes and sizes and require intricate and precise handling, and the robots must also be versatile enough to adapt to a broad range of food products. Therefore, MAFF has been systematically providing support to the industry, which entails identifying the specific needs of its food manufacturing operations, conducting relevant R&D, and demonstrating, improving, and propagating developed technologies, in conjunction with the Ministry of Economy, Trade and Industry (hereinafter referred to as "METI") and the New Energy and Industrial Technology Development Organization ("NEDO").

Meanwhile, it has become mandatory since June 2021 for all food business operators, in principle, to conduct HACCP-based sanitation management under the Food Sanitation Act[5]. Accordingly, if a company has a plan to implement advanced technology such as robots, etc. at its food manufacturing facility, each system integrator (hereinafter referred to as "SIer(s)") and machine manufacturer involved in the project must also understand and conduct HACCP-based sanitation management. However, the lack of official guidelines, etc. that could be referenced by them had become a major obstacle hindering the adoption of any advanced technology that could be useful in their food manufacturing operations.

To address this situation, MAFF set out to create guidelines encompassing all key items that each food manufacturer

---

[1] *Labour Force Survey*, Ministry of Internal Affairs and Communications (FY 2021)
[2] The figure is calculated by dividing the monetary value of all value added newly created per year by the number of all individuals working in the industry.
[3] Calculated by referencing the Financial Statements Statistics of Corporations published by the Ministry of Finance (FY 2021).
[4] *Sustainable Food Systems Strategy "MIDORI": Innovation Will Enhance Potentials and Ensure Sustainability in a Compatible Manner in the Agriculture, Forestry, Fisheries and Food Sectors* (MAFF)
https://www.maff.go.jp/j/kanbo/kankyo/seisaku/midori/attach/pdf/index-10.pdf
[5] *Mandatory Implementation of HACCP-based Food Hygiene Control* (Ministry of Health, Labour and Welfare (hereinafter referred to as "MHLW"))
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/haccp/index.html

should examine in using robots and other advanced technologies at its facilities in a sanitary manner while ensuring the safety of the food products it manufactured, and formulated these Guidelines by contracting the consortium led by the Japan Ready-made Meal Association.

We hope these Guidelines will help any SIers and machine manufacturers that have not considered the food industry as part of their business domains make a successful entry into it, and will also improve food manufacturers' understanding of how to properly introduce robots and other automation technologies to their operations.

Improvement for Stable Procurement of Ingredients and Quality Management Office
Food Manufacture Affairs Division
New Business and Food Industry Department
Minister's Secretariat
Ministry of Agriculture, Forestry and Fisheries

Chapter 1 Basic Principle Underlying These Guidelines and Definitions of Key Terms

Section 1 Basic principle

These Guidelines provide comprehensive information on the essential functions that Food-Sanitation-Act-compliant (as defined in Chapter 1, 4-2-2 hereof) robots must have, and also the points to be attended when implementing any robot systems (as defined in Chapter 1, 4-2-1 hereof) incorporating robots that are not compliant with the Food Sanitation Act (hereinafter referred to as "non-Food-Sanitation-Act-compliant") at food manufacturing facilities, with a specific view to ensuring food sanitation as well as consumer health and safety.

For instructions on how to ensure worker safety when implementing a robot system, refer to other publications that are more informative on the topic, such as *Kino-anzen katsuyo jissen manual (Practical manual on functional safety utilization)* (MHLW)[1] and *Shokuhin-kojo ni okeru kyodo-robot unyo-ji no anzen kakuho guidelines (Guidelines for ensuring safety when operating collaborative robots at food factories)* (MAFF)[2], etc.

For the definitions of key technical terms, etc. used herein, refer to the glossary provided at the end of this document.

Section 2 Composition of the guidelines

Chapter	Title	Contents
Chapter 1	Basic Principle Underlying These Guidelines and Definitions of Key Terms	The Guidelines' purpose, principle, and specific terminology
Chapter 2	Procedure for Robot System Implementation	15-step implementation procedure
Chapter 3	Essential Functions of Food-Sanitation-Act-Compliant Robots Used in Robot Systems at Food Manufacturing Facilities	Explanation of the essential functions that Food-Sanitation-Act-compliant robots must have, in terms of their structures, materials, lubricants, and surface treatments
Chapter 4	Risk Of Using Non-Food-Sanitation-Act-Compliant Robots at Food Manufacturing Facilities, Hazard Factors, and Countermeasures	Description of the risk of implementing robot systems that are non-Food-Sanitation-Act-compliant, associated hazard factors, their countermeasures, and the key principle of sanitation design that must be adopted when using non-Food-Sanitation-Act-compliant robots
Chapter 5	Points to Attend, from Robot System Installation to Pre-operation	Description of action items that must be executed in food manufacturing operations, from the time of robot system installation to pre-operation
Chapter 6	Maintenance and Management after Robot Operation Start	Description of the items to be managed in day-to-day robot operations at food manufacturing facilities
Chapter 7	Training	Description of the training necessary for robot SIers and food manufacturing operation managers
Appendix	Checklist for System Integrators Implementing Robot Systems at Food Manufacturing Facilities	
Reference	①Sanitation Management Training Materials for Those Involved in the Food Industry ②Glossary ③List of Reference Materials	

[1] *Kino-anzen katsuyo jissen manual (Practical manual on functional safety utilization)* (MHLW)
https://www.mhlw.go.jp/file/06-Seisakujouhou-11300000-Roudoukijunkyokuanzeneiseibu/0000197860.pdf

[2] *Shokuhin-kojo ni okeru kyodo-robot unyo-ji no anzen kakuho guidelines (Guidelines for ensuring safety when operating collaborative robots at food factories)* (MAFF)
https://www.maff.go.jp/j/shokusan/sanki/soumu/seisansei.html

Section 3 Scope of application

These Guidelines deal with robot systems incorporating robots as are generally defined (i.e., manipulation robots capable of free movement along at least three axes, with programmable automatic control functions), which comprise a category of machine systems each having the three technological elements, namely sensors, a motor system, and an intelligence/control system (robot technologies) as defined in *the Robot Policy Committee Report* published by METI. Function-specific machines that are typically used in food manufacturing operations, such as mixers, homogenizers, fryers, food dehydrators, flash freezers, and enrolling machines are excluded from the scope of these Guidelines.

Section 4 Definitions and terms

4-1 Terms defined in ISO, JIS, etc.

1）ISO10218-1 and -2

ISO10218 (JIS B 8433) is a standard created specifically for industrial robots and robot systems, which is comprised of two parts, denoted by the suffixes "-1" and "-2." ISO10218-1 sets out the safety requirements applicable to the design and manufacture of industrial robots, mainly targeting manufacturers. Meanwhile, ISO10218-2 is a safety standard to be utilized mainly by SIers, specifying the safety requirements applicable to the integration of robot systems (encompassing their design, manufacture, installation, operation, and maintenance).

2）ISO22000:2018 (translated into Japanese by the Japan Standards Association)

〇Food safety

Assurance that food will not cause an adverse health effect on the consumer when it is prepared and/or consumed in accordance with its intended use. (partially corrected by the author)

〇Management system

A set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives.

〇Top management

A person or group of people who directs and controls an organization at the highest level.

3）CODEX General Principles of Food Hygiene 2020: *Taiyaku to kaisetsu* (Side-by-side translation and commentary). Japan Food Hygiene Association

〇Contaminant

Any biological, chemical, or physical agent, foreign matter, or other substances not intentionally added to food that may compromise food safety or suitability.

〇Contamination

The introduction or occurrence of a contaminant in the food or food environment. (The author's comment: food environment = manufacturing environment)

〇HACCP (Hazard Analysis and Critical Control Point) plan

Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business.

〇Hazard

A biological, chemical, or physical agent in food with the potential to cause an adverse health effect.

〇Hazard analysis

The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the (manufacturing) process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards. (The author's comment: raw materials = meat, eggs, and other uncooked raw materials; other ingredients = sugar, salt, phosphate, breadcrumbs, etc.)

Reference ②: Utilize these Guidelines while referencing the glossary provided herein.

4-2 Terms defined in these Guidelines

1) Robot system

A robot system does not mean a robot alone but a comprehensive system as a whole, consisting of a robot and peripheral devices that in a coordinated manner detect motion using a sensor, according to which a computer performs cognitional and determinative tasks, and sends commands to actuators to execute certain operations.

2) Food-Sanitation-Act-compliance

If a product is Food-Sanitation-Act-compliant, it means the product meets all the requirements as set forth in Article 18 of the Food Sanitation Act[1], in terms of the apparatuses, containers, and packages used relating to the product. If a company intends to manufacture robot end effectors that are Food-Sanitation-Act-compliant, it is advised to refer to the following procedure.

①For each of the parts and components used to make the robot end effectors, obtain from the manufacturer a certificate that the part or component it supplies is compliant with the Food Sanitation Act. If such a certificate is unavailable on a part or component, use a different part or component instead, on which a certificate of compliance with the Food Sanitation Act can be provided.

②If such a certificate is unavailable but the company still needs to use the part or component, the company should have a dedicated test organization test the part or component to verify its compliance with the Food Sanitation Act. Such test must verify that all materials used are on the list of materials (commonly referred to as *the Positive List*[2]) provided in Appended Table 1 of the Standards and Criteria for Foods and Additives, etc. (Public Notice of the Ministry of Health and Welfare No. 370; Act No. 46 of 2018) and that they conform to (1) general standards and (2) specific standards[3] as set forth in Section 3-D-2 of the aforementioned Public Notice; provided, however, that what type of test must be conducted in each case varies, depending on the materials used and what the intended uses are, requiring certain expertise, so it is advisable to consult a test organization whose area of expertise covers them. On the MHLW's official website, there is a section where

[1] Food Sanitation Act (MHLW)
https://elaws.e-gov.go.jp/document?lawid=322AC0000000233

[2] Positive List System relating to apparatuses, containers, and packages for food (MHLW)
Until May 31, 2025: https://www.mhlw.go.jp/stf/newpage_05148.html
From June 1, 2025: https://www.mhlw.go.jp/stf/newpage_36419.html

[3] (1) General standards and (2) specific standards under Section 3-D-2 of the Public Notice (MHLW)
https://www.mhlw.go.jp/content/000757879.pdf

the list of registered test organizations under the Food Sanitation Act[1] is provided.

[1] List of registered test organizations (MHLW)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/jigyousya/kikan/index.html

Chapter 2 Procedure for Robot System Implementation

The procedure for the implementation of food manufacturing robot systems is provided below, which is based on the general-purpose industrial robot system implementation procedure, so that any SIers can easily understand it, especially those that have little or no experience of system integration at food manufacturing facilities.

1-1 Procedure toward robot system implementation

1）Determine what the objectives of robot system implementation are

The typical objectives of implementing general industrial robot systems include labor reduction, productivity enhancement, and the improvement of work environments due to robots taking over hazardous tasks from humans. As workforce shortage has become such a major issue also in the food manufacturing industry, the most crucial object of implementing robot systems is to compensate for it.

2) Consult SIers

When small- to medium-sized food manufacturers go into the specific planning phase for robot system implementation, many of them consult external SIers because, unlike larger food manufacturers, they do not have in-house engineers with advanced expertise on production technology within their organizations.

However, when SIers are called upon by such clients, many of them lack experience in robot system implementation at food manufacturing facilities. Such SIers are advised to implement hygiene control from the perspectives of food sanitation and HACCP in accordance with these Guidelines and other literature.

Also as previously stated, the work tasks typically required in food manufacturing operations are not as uniform as those involved in the manufacture of industrial products. Therefore, merely developing and implementing such robot motions that just mimic human workers' movements might not be enough to achieve the intended objectives. Hence, it is necessary for assigned company staff and SIers working on the same project to share in advance the following types of information.

・List of the human work tasks that will be replaced by robots
・Types of work tasks
・Descriptions of the work objects (weight, viscosity, slipperiness, shape, etc.)
・Quality requirements (weight deviation, visually recognizable quality, sanitation, shelf life, etc.)
・Expected robot productivity (throughput) (e.g., similar to humans, faster processing than humans, etc.)

3）Conduct an on-site observation

On-site observation plays an important role when implementing a robot system. The specific points to be checked during such observation include worker safety measures, food sanitation safety measures, system installation space and environment, carrying-in space, and carrying-in, installation, and adjustment time schedule, etc.

・Worker safety measures

At food manufacturing facilities, workers are often present in high density. Therefore, especially when implementing such collaborative robots that do not entail safety fencing, it is important to design the system configuration while considering all the risks involved.

・Food sanitation safety measures

To determine the level of sanitation required of the robots that will be introduced, it is necessary to define the objects of mechanization for the project first, and then decide what would be the sanitation specification level for each of those objects. For this purpose, it might also be necessary to consider obtaining and applying the opinions of some sanitation management experts.

・Necessary installation space and environment, carrying-in space

Food sanitation operations often entail many workers being present near each other. Hence it is necessary to check and determine whether sufficient space is available for the robot system installation. In addition, food manufacturing environments are significantly more diverse than those of typical industrial product manufacturing, involving refrigeration, freezing, high temperatures, high humidity, large amounts of water used in washing and other processes, etc. Therefore, it is crucial to clearly define the environmental conditions of robot system usage when designing or selecting a robot system. Also it is necessary to check the availability of space through which items will be brought in to the installation site in each robot system implementation project, especially if it involves large-sized items.

・Carrying-in, installation, and adjustment time schedule

Some food manufacturing facilities operate around the clock, all year round. Therefore, it is necessary to carefully coordinate with the on-site supervisor, etc. in advance when scheduling the date and time of robot system carrying-in, installation, and adjustment.

4）Design a system concept

Once an on-site observation has been conducted, and clarifications have been made on the worker safety measures, food sanitation safety measures, and necessary installation space and environment, carrying-in space, and the carrying-in, installation, and adjustment time schedule, the next step is the development of a conceptual system design that meets all of the aforementioned requirements. For this task, preparing rough system design schematics and installation schematics is recommended, if possible, to ensure that there is no misunderstanding between the assigned company staff and SIers. So while the conceptual design that gets created at this stage becomes the grand scheme based upon which the whole project will unfold from here on out, one must be reminded that the top priority in food manufacturing operations is sanitation management. Hence, to ensure the supply of safe food products, the conceptual design of a robot system must be especially attentive to the following points.

・Its structural design must be resistant to the occurrence of microbial flora so that food poisoning or other similar events can be prevented.

・Its structural design must allow for the easy washing of its certain areas where microbial flora tends to occur.

・Its structural design must prevent the intrusion of any foreign matter.

・It must be equipped with the function to detect and remove any foreign matter that enters the food being produced.

5）Review system specifications

Once the system’s specification requirements are defined based on the conceptual system design developed in 4) above, the next step is for the assigned company staff and SIers to review and make adjustments to those requirements, and then discuss what the system’s achievable specifications might be. Because there are still many undeterminable factors that remain, it is expected that some of the specifications cannot be decided at this point. Hence it is important to minimize those factors as well as any misunderstanding that might exist among all concerned parties to the extent possible. In addition, as food manufacturing facilities sometimes already have, or will implement, other systems to manage production volumes and product traceability, intersystem coordination must also be considered. Therefore, the robot system's specifications must be decided while considering its interfacing with other systems.

6) Select robots

When it is time to select robots, the SIers must mainly lead the way in reviewing and deciding which ones might be optimal for the project, considering the work tasks involved, work object specifications and other related information, productivity requirements, etc. The main attributes of robots to be examined for this purpose are set forth below.

- Whether they are collaborative robots
- Whether they are Food-Sanitation-Act-compliant, waterproof, etc.
- Maximum moving speed
- Movable load
- Price

If a robot is selected that is Food-Sanitation-Act-compliant, refer to Chapter 3 below. If a robot is selected that is non-Food-Sanitation-Act-compliant, refer to Chapter 4 below.

7) Examine what technological elements need to be developed

Once the system specifications have been decided in 5) above, the next step is to determine what technological elements must be newly developed to achieve them. Such technological elements must be examined one by one to decide what their target specifications should be, to just sufficiently achieve the system's overall specifications, after which consensus needs to be formed between the food manufacturing company and its hired SIers.

Take robot end effectors for example, which are one of the crucial elements that usually require development. If it is a robot system implementation project whose aim is to automate the process of placing and arranging produced ready-made meals on food trays, etc., requiring a custom-made robot end effector for handling the job, the team working on the project must consider key information such as what kinds of food products will be handled by it, what will be the allowable weight deviation percentage relating to the food products that get placed onto the trays, how many seconds should be the maximum allowable takt time, and other requirements in terms of food contamination prevention, the robot end effector's cleansing property, etc., to decide its specifications.

8) Create the robot system's design

Once the system's specifications have been examined, the next step is to create its detailed design.

When a new robot system is being implemented, its design in terms of safety is usually done based on ISO10218-1 and -2 and also FMEA (failure mode and effects analysis). If the robot system is intended for use at a food manufacturing facility, its design must additionally consider the sanitation factors as previously mentioned in 4) above, to ensure the safety of the consumers that ingest the food produced using the system.

For example, such robot system design must prevent foreign matter from entering the food being produced and allow for the easy cleaning, washing, and maintenance of the robots, etc. where food remnants might attach, so no microbial flora can germinate. While the robot system design must integrate adequate sanitation measures to minimize hazard factors, it might be difficult to completely eliminate them in certain cases where a single robot system must handle different types of food and other work objects. If this is the case, the SIers, etc. must communicate to the food manufacturers the hazard factors that have been identified at this point so that they can consider how to implement their sanitation measures, which might also entail HACCP-based sanitation management.

9) Conduct a risk assessment

Even with a robot system that has been meticulously designed to manufacture safe food products, there is still a possibility of various risks occurring.

That is why risk assessment is crucial in order to identify all such risks and come up with ways to avoid them. In the case of general industrial robot systems, the main risks are on-site workers' occupational accidents, so ways to remove or reduce those risks are devised and implemented by first estimating the risks by predicting the severity and incidence of each type of such accidents that might arise from the robot operations, and then prioritizing them. Meanwhile, implementing a robot system at a food manufacturing facility entails not only the aforementioned risks that could affect the workers but also sanitation risks that must be addressed to ensure the safety of food consumers, requiring a risk assessment from all these perspectives.

10) Conduct a design review

As with general industrial robot systems, food manufacturing robot systems need design reviews from the perspective of QCD (quality, cost, and delivery), which must involve all concerned parties to determine whether there is any inconsistency in the systems' mechanical designs, all safety and productivity specification requirements are met, delivery schedules are free of issues, etc., from comprehensive perspectives not only limited to proper mechanical designs.

Of all the aforementioned perspectives that must be adopted when designing robot systems for food manufacturing operations, the one requiring special attention is food sanitation. Design reviews must be hence conducted by thoroughly examining and ensuring that the robot systems are structurally and functionally capable of protecting their work objects (i.e., food products) from foreign matter intrusion, microbial contamination, etc.

11) Manufacture the robot system

Once the design of the robot system is completed, the next step is the production phase where the robot system is manufactured according to its specifications in such a manner that all its design quality is replicated (completely achieved). This phase also requires constant attention to sanitation control in order to ensure the absence of issues, etc. until the entire system is built and ready. If the system being manufactured requires many technological elements be newly developed, it is possible that certain risks that could not be detected early on in the design phase get noticed in the production phase. Therefore, it is crucial the manufacturing and design departments maintain close and constant communication with each other. In particular, the manufacturing department should strive to comprehend all the intents and purposes embedded in the system design, while the design department should regularly check on the status of the risks that were identified during the design phase.

12) Check the robot system's basic operations

Once the robot system is built, it is time to check its whole series of operations using typical work objects. The main purpose here is to ensure that the robot system is capable of all its basic movements as intended in its design, so not too much attention should be paid to any fluctuations that may arise in its work results just yet. This is also the time to check and make sure all its safety measures are functioning properly.

13) Check the robot system's operations using actual work objects

In this step, the task is to check and make sure the robot system's operations are all fine, using the same work objects that will be used in the actual manufacturing operations. Because food items, etc. as work objects come in different shapes and sizes and also change their form when grasped, etc., defects might still occur even if the robot system is normally operating. Hence, attention must be paid to ensure not only that the robot system's entire operations are all normal but also that the robot end effectors' movements are precise and adaptive to the deformation of its work objects. So it is also crucial to consider such requirements in the system design phase. In addition, as defect and malfunction occurrences affect the system's working rate, it is important to check the system's recovery procedure, and all the methods involved. It is desirable to conduct this system operation verification in the presence of the on-site supervisor, etc.

14) Deliver the robot system (carrying-in, installation, and adjustment of the robot system)

When the project reaches this delivery phase, it is standard practice to install and make adjustments to the robot system on the actual site where it will be used. Once the system is proven to meet the conditions as described in 13) above, it is ready for delivery to the business operator. While robots are capable of executing the same movements over and over with high accuracy, their operations could be significantly affected by subtle differences in how they are set up on site (in terms of levelness and parallelism). As such, it is sometimes necessary to provide on-site training on how to teach the robots to execute their intended tasks, etc. after the system has been installed.

15) Conduct regular inspections

While general industrial robot systems only require functional inspections from time to time, food manufacturing robot systems additionally need to be inspected from the perspective of HACCP-based sanitation management.

1-2 Perspective of HACCP-based management

While the entire flow of food manufacturing robot system implementation is described above, food safety must be ensured in the actual food manufacturing operations as explained in each of the preceding sections. Accordingly it is necessary that each food manufacturing site practices HACCP-based sanitation management for accident prevention. This HACCP-based approach to sanitation management is required in every project to identify all food sanitation risks, formulate a policy for addressing them, clarify what types of risks might still remain, determine how to conduct operations so that the risks are avoided, in each of the conceptual design, detailed design, and design review phases.

1-3 Necessity of training

As described above, HACCP is a crucial management method for ensuring food safety, which is meant to be practiced mainly by those working in operations. To correctly apply HACCP at a company, its employees must first understand what HACCP-based sanitation management entails. Then they must be trained on related key topics such as basic 5S activities, proper recordkeeping, manufacturing procedure verification, CCP (critical control points), food poisoning, allergens, and other hazard factors, etc.

Chapter 3 Essential Functions of Food-Sanitation-Act-Compliant Robots Used in Robot Systems at Food Manufacturing Facilities

Because the machines used at food manufacturing facilities operate in different environments than those of the machines that manufacture general industrial products, they are required to possess different functionalities. This Chapter provides information on the essential functions of Food-Sanitation-Act-compliant robots that are incorporated into food manufacturing robot systems, in terms of their structure, materials, lubricants, and surface treatment.

For key points to be attended and measures to be implemented when incorporating non-Food-Sanitation-Act-compliant robots into food manufacturing robot systems, refer to the following Chapter.

Section 1 Structure

1-1 Waterproofness

Because the operating environment of a typical food manufacturing facility is quite humid due to the constant use of water, condiments, and cleaning solutions, waterproofness is one of the key requirements of any Food-Sanitation-Act-compliant robot that is implemented in such environment. By waterproofing robots, their inner workings and overall mechanisms become insulated from water and humidity, so they become more durable and can operate stably over extended periods.

Each Food-Sanitation-Act-compliant robot must be highly waterproof to ensure food safety and sanitation. Therefore, each robot manufacturer must implement the measures as set forth below while striving to make sure that the robots it produces can be safely operated at food manufacturing facilities. In addition, as Food-Sanitation-Act-compliant robots are meant to be used at food manufacturing facilities, their design must be attentive to such sanitation and durability that reliably lead to food safety. Hence, waterproofness is one of the crucial elements of food manufacturing robots' design, and when it comes to Food-Sanitation-Act-compliant robots, the IP code is usually the standard adopted in achieving their targeted level of protection from water.

《Compliance with the IP code》

The IP code is one of the standards set by the IEC (International Electrotechnical Commission), which defines the different levels of protection from water and dust achieved by electrical appliances, using different combinations of the letters IP and two-digit numbers (e.g., IP65).

1-2 Different types of waterproof structural components

1) Waterproof casing

Casings are a type of component used to cover any frames and adjoining sections. It is a crucial device for preventing water ingress through spaces. Waterproof casings are installed on robots to protect their electronic components and circuits from water.

2) Seal packing

Seal packings are used to make watertight any moving or stationary parts of robots, etc. They are especially used to cover robotic joints and mechanical connections so that water cannot enter.

3) Waterproof connector

Because these connectors are waterproofed, they can be used in any indoor or outdoor environment, etc. that is highly exposed to water. They are typically used around power supply units and control signal lines to protect them from water.

4) Water-resistant coating

Water-resistant coating is applied to various electronic parts, components, and mechanisms to reduce the effects of water.

5) Sealant filling

Liquid and other forms of sealants are injected into robotic joints and other mating surfaces to fill the space and enhance their insulation from water.

6) Robot protective jacket for food processing

Robot protective jackets are used to provide cover for robots. Robot protective jackets are effective at preventing water from intruding into robots.

7) Lubricant

Injection or application of lubricants into various axles, gears, and other moving parts of robots enhances their protection from water.

8) Water-resistant cable

Use of cables (electrical wiring and air piping) with high water resistance in robots prevents water ingress.

These waterproof structural components are particularly important for robots that operate underwater or in high humidity. In addition, adopting reliably waterproof structural features leads to the maintenance of robots' performance as well as the extension of their usable lifespans.

1-3 Structural features that lead to high cleanability and washability

The structural features of robots that allow for better cleanability and washability include the following.

1) Smooth exterior

Making the outer surfaces of robots smooth, with reduced numbers of corners, edges, grooves, etc. makes the task of cleaning and washing them easier. Such design feature also helps repel unwanted dirt and water droplets.

2) Detachable parts

When robot's parts are detachable, they can be removed and washed separately. This helps prevent any unwanted dirt from building up.

3) Waterproof structure

If robots are structurally designed to be waterproof, they can be washed with water and detergent. This allows for the cleaning of the entire robot.

4) Non-slip structure

If robots' legs and wheels are structurally designed to prevent slippage, they can be steadily moved around as they get cleaned. This also makes it easier to clean the robots' bottom parts as well as their installation spaces (floor, etc.).

5) High durability

If robots are made of highly durable parts, they become less prone to deformation and damage that may occur during cleaning.

6) Heat resistance

If robots incorporate parts that are resistant to high temperatures, they can be washed with hot or otherwise high-temperature water.

The features described above improve robots' cleanability and washability. When robots are properly cleaned and managed, they remain sanitary, operable for extended periods, and easy to maintain.

1-4 Measures for preventing foreign matter contamination

When implementing Food-Sanitation-Act-compliant robots and robot end effectors in food manufacturing, one of the most crucial issues is how to prevent contamination with foreign matter. If foreign matter enters food products, it not only compromises their quality but also could cause significant impairment to the consumers' health, depending on the type of foreign matter. In addition, when food products are contaminated by hard or spreading foreign matter, it not only becomes an incident requiring product recalls but also might significantly damage the reputation of the company that produced them. To avoid such incidents, it is crucial to formulate and implement meticulous prevention measures. Examples of measures that are commonly adopted for the prevention of foreign matter contamination are provided below.

1) Use of Food-Sanitation-Act-compliant materials

Each part of robots and their hands that come in direct contact with food must be made of Food-Sanitation-Act-compliant materials so the risk of foreign matter contamination leading to the consumers' health impairment can be mitigated. It is also important that robots' designs are repellent to the food items that they handle, as well as any food residues and foreign matter.

2) Dust- and water-resistant design

Making robots and robot end effectors structurally dust- and water-resistant renders them impervious to corrosion and damage, which in turn prevents food contamination with foreign matter.

3) Seamless structure

Robots of seamless structural design are less susceptible to the risk of unwanted foreign matter getting attached and dirt accumulating on them.

4) Handling operations

Robots' handling operations must incorporate such preventive design feature that ensures their hands accurately grasp the work objects and will not damage any food products or come into contact with any other unintended objects. This in turn will protect the robot end effectors themselves as well as the containers holding the work objects, etc.

5) Sensor and detection technology

Visual inspectors, X-ray inspectors, metal detectors, and other foreign matter detection machines are integrated into food manufacturing lines to flag any food products passing through that are contaminated with foreign matter.

6) Ease of cleaning

When work objects, etc. get attached to robots, they could give rise to microbial flora. To prevent this, robots' designs must allow for easy cleaning and repel foreign matter.

7) Traceability and quality management

When implementing a new robot system, it is desirable if the system is capable of traceability management relating to all production processes involved, so if any foreign matter contamination is found, the cause of the contamination can be determined, and the food product units that have been contaminated can be identified.

1-5 Risk assessment and residual risk

If robots are left insufficiently dewatered or dried, discoloration and corrosion could occur in any spaces within them as well as on outer surfaces. In terms of the procedure for conducting risk assessment on robots, it entails risk management structure implementation and risk assessment. While it is assumed to be each robot manufacturer's responsibility to formulate a risk management structure suitable for its robots, the practice of risk assessment entails the identification of hazards and other potentially harmful factors, estimation of the risks they pose, examination and implementation of risk mitigation measures, recording of their results, and sharing and communication of related information, which are similar to how risk assessment is conducted on general industrial robots whose applications are not food production. When it comes to food manufacturing robots, however, it is important to assess risks especially relating to robots' waterproofness, ease of cleaning and washing, and protection against contamination with foreign matter, for sanitation control purposes.

In terms of anticipated risks, if robots are not sufficiently resistant to water, washing them could cause the water to seep into their inner mechanisms and controllers and corrode any motors, PCBs, etc. within them. Meanwhile, robots that are difficult to clean and wash tend to accumulate food residues, etc., which gives rise to microbial flora outgrowth, food contamination with foreign matter, etc. that all negatively impact the health of the consumers, etc.

Section 2 Materials of robots' main units

2-1 Materials of robots' main units

Each material used in any Food-Sanitation-Act-compliant robot must meet the requirements as set forth in the Act. The following is the list of materials used in robots that are Food-Sanitation-Act-compliant.

1) Stainless steel

This is one of the most commonly used materials at food manufacturing facilities, which is highly anticorrosive and durable. Because it is malleable enough to be molded into various shapes and sizes, stainless steel is used in the parts of robots that come into direct contact with food as well as on their main units' surfaces.

Stainless steel is highly resistant to corrosion. In addition, as the material is typically used without any coating, it poses no risk of its coating getting detached and contaminating the food being processed, and little risk of becoming corroded and causing food contamination with any foreign matter produced by the corrosion. Hence stainless steel is used in large numbers of apparatuses, devices, etc. at food manufacturing facilities. There are two types of stainless steel that are most commonly used in food manufacturing operations.

・**Austenite stainless steel (SUS304, etc.)**

As it is not immune to the effects of chlorine ions, its resistance to salt-induced corrosion is low, which poses the risk of any items made of this material cracking. Therefore, austenite stainless steel might not be suitable for factories where any salt, soy sauce, etc. are used.

・**Ferrite stainless steel (SUS430, etc.)**

While this stainless steel's anticorrosive performance is inferior to the austenite one, it is far less susceptible to cracking, so it is widely used in manufacturing operations that involve the use of salt, soy sauce, etc.

2) Plastics

Food-Sanitation-Act-compliant plastics have come into widespread use today. As these plastics are intended for use at food manufacturing facilities, they are mostly durable, light-weight, and easy to handle. However, a robot, etc. made of a Food-Sanitation-Act-compliant plastic qualifies as *apparatus* as defined in Article 4 of the Food Sanitation Act, it must conform to the rules of the Positive List System[1]. Special attention must be paid to the materials that are used in the robot end effectors that come into direct contact with food.

3) Aluminum alloys and titanium

Aluminum alloys are light-weight and highly resistant to corrosion. However, they have certain unfavorable properties as described below, relative to stainless steel. Therefore, the use of aluminum alloys should be limited to parts of robots, etc. that must be made lighter in weight, do not directly contact food, and are not exposed to the risk of getting scratched, etc.

・Aluminum alloys are more prone to rust than stainless steel.

・Being of equal thickness, stainless steel is stronger than any aluminum alloy, so the former is a better material for making robot parts, etc. in smaller sizes.

・With aluminum alloys, tightening torque for bolts, etc. must be set lower, which makes the task of assembly more difficult.

・While titanium is more corrosion-resistant than stainless steel, it is also less pliable and more expensive.

4) Silicone elastomers

Silicone elastomers are elastomers whose main component is silicone, which are flexible, heat-resistant, chemical-resistant, etc. Therefore, they are used in a variety of applications, including O-rings, gaskets, and other sealing materials.

2-2 Chemicals used at food manufacturing facilities

A whole host of chemical agents are used in food manufacturing operations, the main purposes of which include the cleaning, washing, disinfection, and sterilization of food manufacturing equipment. The following is a list of chemical agents[2] typically used at food manufacturing facilities. In this connection, also refer to Chapter 4, 2-7,

[1] Positive List System relating to apparatuses, containers, and packages for food (MHLW)
Until May 31, 2025: https://www.mhlw.go.jp/stf/newpage_05148.html
From June 1, 2025: https://www.mhlw.go.jp/stf/newpage_36419.html

[2] *Choriba ni okeru senjo shodoku manual (Washing and disinfection manual) Part I* (Ministry of Education, Culture, Sports, Science and Technology ("MEXT").)
https://www.mext.go.jp/a_menu/sports/syokuiku/1266268.htm

2), in which related information is provided on the applications, characteristics, etc. of commonly used detergents, washing agents, etc.

1) Neutral detergents

These are suitable for removing general, minor dirt.

2) Alkaline detergents

These are suitable for removing persistent dirt, especially dirt consisting of lipids or proteins, that is difficult to address with neutral detergents.

3) Acidic detergents

These are suitable for removing mineral scale consisting of calcium, magnesium, etc. as well as limescale and other types of water-induced scale.

4) Washing and antibacterial agents

These are capable of both cleansing and microbe removal, etc., which are especially useful where microbial control is essential.

5) Aqueous sodium hypochlorite solutions

This is used to disinfect food manufacturing equipment, apparatuses, etc. after washing them. As this could corrode metallic parts if left on, it is necessary to wipe it off with a cloth wet with water after disinfection, followed by another round of wiping with a dry cloth to remove any residual water, etc.

6) Alcohol formulations

This is used for the disinfection of fingers, etc. as it quickly dries off and can be applied using a spray, etc. It is often sprayed onto food manufacturing equipment, apparatuses, etc. before use.

These chemical agents are essential items for ensuring food quality and safety in the food industry and, therefore, must conform to the applicable food regulations. In food manufacturing operations, neutral detergents, aqueous sodium hypochlorite solutions, and alcohol formulations are most commonly used as general means of washing and disinfection. However, even such chemical agents that are intended for the same applications are made of different ingredients (formulas, etc.) by different manufacturers, which naturally have varying characteristics. Hence, it is advisable to check with each food manufacturing operation in advance what types of chemical agents (product names, etc.) are being used, and also how they are used.

2-3 Materials' characteristics relating to acids, alkalis, and alcohol formulations, etc. in terms of resistance, absorptiveness, permeability, etc.

Examples of characteristics of commonly used materials in terms of chemical resistance and permeability are provided below.

1) Stainless steel

While stainless steel has generally high resistance to acids and alkalis, it could be affected by some strong acids and chlorine detergents.

2) Aluminum

While aluminum is generally resistant to acids, it could be affected by alkalis and strong acids.

3）Plastics (Food-Sanitation-Act-compliant plastics in particular)

While plastics are generally resistant to acids, alkalis, and alcohol, it could be affected by some other chemical substances.

4）Titanium

Titanium has properties that make it highly resistant to acids as well as chloride ions.

When selecting materials to be used in robots, it is necessary to consider what the characteristics and processing conditions of their work objects, etc. are. When researching the detailed characteristics of specific materials as to chemical resistance, absorptiveness, and permeability, it is important to check the technical information and specification documents that are provided by the robot and materials manufacturers.

Section 3 Materials and mechanisms of robot end effectors

There are still only a small number of cases where robot systems have been implemented to directly handle food products. Of all such cases, the robot end effectors are the constituent components that come into direct contact with the food being processed, which must be designed to perform all the functions they are supposed to perform on their processing objectives, while also attentively meeting their food sanitation needs, which are constraints. These two sets of requirements (i.e., functions and constraints) are often diametrically opposed to each other.

The functions the robot end effectors are required to execute include a whole range of processes, such as holding, measuring, transporting, placing, and arranging food items in a stable and efficient manner, without ever breaking or dropping them. Unlike the manufacturing processes for mechanical or electrical products, where most robots have been deployed to date, food manufacturing involves objects that come in various shapes and sizes, which also constantly change over the course of each process. The surfaces of the food products that the robots are tasked to handle also widely vary. While some food items that are coated with oil-rich condiments produce slippery surfaces, other products could be of highly viscous texture, like *ohagi* (a type of rice cake that is a Japanese confection), all of which robots are expected to properly handle as work objects. While the recent advancement of image processing technology has significantly improved the robots' ability to recognize the shapes of objects that come in varying forms and sizes, it is functionally left up to the robot end effectors to deal with the rest of the objects' physical characteristics. For this purpose, a whole host of technological applications are being considered for implementation, including the use of non-contact hands incorporating suctions and other adhesive end effectors, certain surface finishes (emboss, etc.) to deal with slippery objects; intermediate to advanced adaption to objects' varying shapes and sizes by adopting pliable materials, optimizing robot end effectors' drive mechanisms, and utilizing soft robotics[1] technology; and detection, monitoring, and controlling of robot end effectors' object retention status using tactile sensing technology[2].

As described above, such cutting-edge technologies that have just come out of the R&D pipelines, including soft robotics and tactile sensing manipulation[3], are used more and more in food manufacturing robotics, which calls for

[1] Soft robotics is the technological field that is focused on making robots execute gentle movements by using such compliant materials as rubber, silicone, etc. whose properties represent high elasticity and flexibility.
[2] Tactile sensing is such technology that employs sensors to perceive the objects that are being grasped by robot end effectors in a manner analogous to human hands. The information obtained by the sensors is then used as feedback to control the robots with increasing accuracy, etc.
[3] Tactile sensing manipulation is the operation (manipulation) of robots with tactile sensing technology as described above.

the implementation of adequate food sanitation measures for which there have been no precedents to refer to. Therefore, it is necessary to examine and verify what the appropriate measures might be in each instance of new technology application.

3-1 Food sanitation measures in robot end effector development

The most fundamental food sanitation measures relating to robot end effectors are as explained mainly in Section 1 “Structure” above. Additional points that are worth noting are explained below.

・Selection of materials:

When selecting materials to use in robot end effectors, one must ensure they meet the functional requirements of the robot end effectors as specified in the Food Sanitation Act[1] while adequate measures are implemented to prevent foreign matter contamination caused by the materials’ breakage, deterioration, etc. In particular, the materials that are used in the parts of robot end effectors that come into direct contact with food must conform to the rules of the Positive List System[2].

・Mechanism and structure:

In addition to implementing waterproofing and other measures aimed at protecting the robots and other apparatuses, it is advisable to also consider installing robot protective jackets, etc. over them, to redundantly prevent the risk of foreign matter contamination caused by any lubricant, robot parts such as screws, etc. accidentally getting into the food being processed, from where it is difficult to use a special lubricant for food-processing machinery. Structurally any robot end effectors, etc. must be designed such that even if any screws, adhesives, etc. come loose, they cannot possibly fall into the food being handled (i.e., by facing all screws downward, etc.). In each instance where a suction or other type of attractive mechanism is employed, it is necessary to install a filter or other device so that no food gets into the mechanism (otherwise it could lead to bacterial outgrowth).

・Washing, replacement of expendables:

It is desirable for each part of robot end effectors, etc. that comes into direct contact with food to have such a structure that allows for its disassembly, washing, and, if possible, sterilization and disinfection by leaving it submerged in a liquid having such effect. In particular, as robot end effectors and tactile sensors integrate such complex mechanisms that make it significantly difficult to disassemble and wash them, how to approach this issue must be addressed early on in the design phase. As for the rest of the parts of robot end effectors, etc. that do not come into direct contact with any food, they must also incorporate such structures that allow for easy cleaning by wiping with alcohol, etc. In the case of any parts that actuate the functions of tactile sensors or are otherwise directly linked to the sensor functions, those parts should be regarded as expendables, and accordingly a guideline must be formulated that will dictate how many times each such part can be continuously used before it must be replaced with a new one, etc.

---

[1] Food Sanitation Act (MHLW)
https://elaws.e-gov.go.jp/document?lawid=322AC0000000233

[2] Positive List System relating to apparatuses, containers, and packages for food (MHLW)
Until May 31, 2025: https://www.mhlw.go.jp/stf/newpage_05148.html
From June 1, 2025: https://www.mhlw.go.jp/stf/newpage_36419.html

・Introductory training:

Once the guidelines on sanitation measures have been decided, they must be shared in detail with each concerned food manufacturer (facility manager) to have them comprehend what the residual risks are. Likewise, it is necessary to prepare procedure manuals and guidelines on the washing, storage, and expendable replacement procedures and train the facility managers, etc. on them until sufficient understanding is achieved.

In addition to the basic measures as described above, it is necessary to take the following measures when implementing a new technological application for which there is no precedent.

- Investigate what the specification and standard requirements are in terms of the constituent materials, the shapes and structures of the parts that come into contact with food, and the shapes and structures of the parts being exposed to food dispersion. As for the requirements of the constituent materials used in food processing machinery, there are not only such major standards as ISO and JIS but also many other laws, regulations, and guidelines, etc. issued by different governments and independent organizations, including the Food Sanitation Act of Japan, the U.S. Federal Food, Drug, and Cosmetic Act, and the EU Regulations, Directives, and Decisions.
- Review other existing products for reference. Even in the absence of the exact same type of robot end effector use case involving direct contact with food, it is possible to find other food-handling products having similar moving parts and study what measures have been implemented on them.
- Seek advice from consultants, etc. that have expertise on sanitation in food manufacturing operations.
- Conduct meticulous examination and verification on the robots' durability, etc. involving repetitive tests, etc.
- If difficulty remains when making any critical determination, use any of the MHLW-registered test organizations[1], etc. to conduct quality evaluation.
- Explain sanitation measures to the food manufacturer and exhaustively identify all concerns, issues, etc. that remain.
- Periodically conduct bacterial tests through trial and normal operations.

3-2 Materials used in robot end effectors

Each of the materials used in Food-Sanitation-Act-compliant robot end effectors must meet the requirements set forth by the Food Sanitation Act. Accordingly materials such as stainless steel, plastics, etc. must be used in a manner that complies with the applicable laws and regulations, as described in Chapter 3, 2-1 “Materials of robots' main units” above. It is advisable to divide the parts of robot end effectors, etc. into the separate categories of those that come into direct contact with food, those to which food may get attached through dispersion, etc., and those that pass over food being processed, in order to determine what materials had better not be used, and what measures should be implemented in terms of structural design, etc., category by category.

In terms of the pliable materials that actuate the functions of soft robot end effectors and tactile sensing technology,

[1] List of registered test organizations (MHLW)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/jigyousya/kikan/index.html

silicone rubber and other elastomers that can ensure food safety and have high heat resistance and durability are typically used. With these particular materials, it is necessary to implement measures relating to the materials' food safety, processing methods, and quality evaluation in their molded form, unlike the case of stainless steel and other materials whose conformance to the Food Sanitation Act is already tested and verified in their machined form.

Indeed, such materials whose conformance to the Food Sanitation Act is not yet tested are usually produced based on the original formulations of the material manufacturers. Hence, while silicone is generally considered to be compatible with food safety, there is no guarantee that each instance of its use in robots, etc. meets the requirements of the Food Sanitation Act. Therefore, it is necessary to obtain SDS (safety data sheets) from the manufacturers of all materials being used and make sure that no materials that do not guarantee food safety are used in their products.

In addition, as the surface condition of each robot part, etc. changes through the molding (hardening) process, depending on the processing method used, it is necessary to conduct leaching tests to determine whether it meets the requirements of the applicable specifications and standards of food, additives, etc. pursuant to the Food Sanitation Act. Hiring independent test organizations that offer such testing service can improve the reliability of all product quality involved.

For the waterproofing of robot end effectors, packings must be applied to insulate all moving parts, while applying adhesives, etc. for the assembly of non-moving parts. Different adhesives and resins that are intended for such application and conform to the Food Sanitation Act are also commercially available. In each instance of using any such material, SDS must be obtained in a manner as described above.

As for the use of silicone rubber and other similar elastomers, special attention must be paid to addressing the risk of foreign matter contamination that may be caused by broken off parts. While the first line of defense should certainly entail enhancing the durability of each material used, adjusting how the robot end effectors, etc. contact their work objects, etc. to prevent parts breakage to the extent possible, it is also advisable to consider implementing multiple lines of defense in case any breakage should occur. For example, the materials used in robot end effectors may be colored blue, which makes it easier to detect any broken off parts that have gotten into the food being processed. Another example is to blend iron powder into the materials used in robot end effectors, etc. so that a metal detector can be used to flag a parts breakage, etc. when it occurs. In examining the feasibility of such measure, one must carefully consider what amount of metal power to put in, as using too little of it makes the task of detection nearly impossible to perform, but too much of it can reduce the durability of the parts and also cause other untended consequences, which will defeat the very purpose of mixing in the metal powder. One way to address this is to measure and record the weight of each robot end effector component, etc. before and after use, so that any change in weight can be monitored to initiate an investigation of possible breakage.

In addition, each contact point between the robots, etc. and the food being processed is exposed to the risk of bacterial propagation. Hence, they must be cleaned in accordance with the equipment management procedures as specified in the cleaning manuals, etc. that have been adopted at each food manufacturing site, in addition to periodically testing for and measuring any populations of common bacteria, coliform bacteria, etc. that may be present, to verify the validity and efficacy of each management protocol being implemented. As all these tests must physically take place at each food manufacturing facility, the sanitation managers of each site must be consulted when planning and conducting the tests.

3-3 Chemical agents used at food manufacturing facilities

Refer to Chapter 3, 2-2 and Chapter 4, 2-7, 2) hereof.

3-4 Materials' chemical resistance, absorptiveness, permeability, etc. relating to acids, alkalis, alcohol, etc.

For information on stainless steel and plastics, refer to Chapter 3, 2-3 above.

As for silicone elastomers, their compositions vary by manufacturer and by product, as described above, so it is necessary to evaluate and examine them individually. In this connection, the concentration of each chemical agent used also affects the results.

Generally speaking, aqueous hypochlorous acid solutions are known to affect elastomers. However, as long as the concentration of solutions is kept in the range (e.g., around 200 ppm) typically seen at food manufacturing facilities, deterioration will be minor in most cases, unless the parts are constantly submerged in those solutions overnight. At any rate, the first step should always be to learn what ingredients are used in each of the chemical agents being applied at food manufacturing facilities, and make specific inquiries to the elastomer material manufacturers about the chemicals and their products.

While detailed explanations have been provided above on elastomers as one of the materials commonly used in robot end effectors, it is also advisable to take a similar approach to examining the rest of the materials of which robot end effectors are made, including austenite stainless steel, ferrite stainless steel, titanium, etc.

Section 4 Lubricants

4-1 Lubricants for food processing machinery

The lubricants for food processing machinery that are suitable for robots must possess such characteristics as described below.

1) No harm to work objects or humans

Special attention must be paid to lubricants so that they do not negatively affect the work objects of robots. If any lubricant gets into food, it could cause harm to the consumers' health, depending on its ingredients. Therefore, when implementing a robot system and selecting a lubricant for it that could possibly enter the robots' work objects, it is advisable to pick one from the list of the lubricants that have been registered with NSF[1].

Class H1: Lubricants assigned to this class are considered safe even if they inadvertently get into food, although they should not come into contact with food.

Class H2: Lubricants of this class are allowed to be used in places where there is no food in the immediate surrounding and there is no contact with food.

Class H3: Lubricants belonging to this class are not meant for any use that involves contact with food. They are applied to the meat hooks used at meat processing factories, etc. for rust prevention, etc.

[1] NSF is an independent certification body that is globally recognized in the field of public safety and sanitation. https://www.nsf.org/

2) High durability

In each instance where robots are operated for extended periods, their lubricants must be highly durable also. Deteriorated lubricants could negatively impact the robots' performance.

3) Abrasion prevention

One of the key functions of lubricants is the mitigation of abrasion-induced wear in robots' moving parts. Unless suitable lubricants are applied, robots' moving parts become increasingly worn, causing their performance to decline.

4) High-temperature resistance

Robots are sometimes used in high-temperature environments. In other cases they are used in such a manner that the friction resulting from their sliding movements causes those parts to reach high temperatures. Therefore, any lubricants used in such instances must be sufficiently heat-resistant.

5) Low-temperature resistance

When robots are operated in low temperatures, the lubricants also tend to harden, making it difficult for them to properly reach the sliding surfaces of the robots' rotating parts, potentially causing excessive friction and galling. Therefore, any lubricants used in such environment must have high resistance to low temperatures.

6) Suitable viscosity for mechanical parts

For each moving part of a robot, a lubricant with just the right amount of viscosity must be selected in order to allow the robot to perform at its full potential.

Considering all the above factors, it is important to select a food-processing-machinery lubricant that is suitable for each robot, as it extends the robot's usable lifespan while maintaining its performance. In addition, each robot's and robot end effector's lubricants used in food manufacturing operations should be carefully selected while also taking into consideration the effect of their contamination of food in case they should leak out, as described above.

4-2 Robots' structure that mitigates the risk of lubricant leaks

In terms of robots' structural features that make it difficult for the lubricants to leak out, there are two types of seals commonly implemented, one of which is static seals that are applied to insulate robots' arm covers and the joints of other non-moving parts, with the other being kinetic seals that are installed to insulate the rotating shafts of robot arms. Common examples of static seals include O-rings and sheet gaskets, while examples of kinetic seals include oil seals. Typical examples of robots' structural insulation design are provided in Figure 3-1 below.

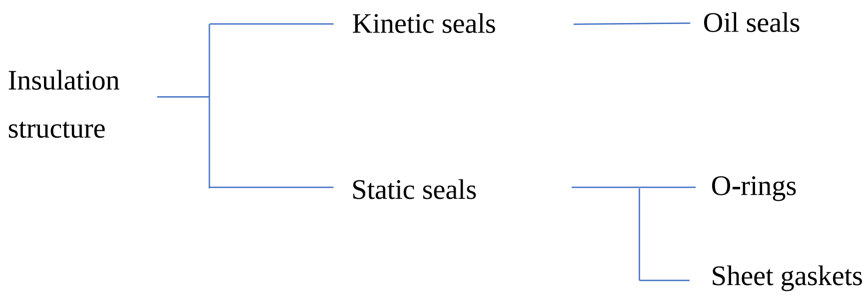


Figure 3-1: Typical examples of robots' structural insulation design that mitigate the risk of lubricant leaks

1) Oil seals and their structural features

Oil seals are a type of packings that are typically installed on the rotating shafts of mechanical parts. Installation of oil seals to robot's rotating parts can prevent lubricant leakage.

For more detailed information on oil seals, including their structural design features, it is advisable to refer to the Japanese industrial standards JIS B 2402: Oil Seals (Rotary Shaft Lip-Type Seals Incorporating Elastomeric Sealing Elements), JIS B 0116: Glossary of Terms for Packings and Gaskets, etc.[1]

2） O-rings and their structural features

O-rings are ring-shaped seals that are mostly made of synthetic rubber, having circular cross-sections. Because they are easy to install and offer excellent insulation performance, the use of O-rings has become quite widespread as liquid seals for general machinery and equipment. O-rings are mainly used in the joints of robots' non-moving parts, etc.

For more detailed information on O-rings, including their structural design features, it is advisable to refer to the Japanese industrial standards JIS B 2401: O-rings, JIS B 0116: Glossary of Terms for Packings and Gaskets, etc.

3) Sheet gaskets and their structural features

Sheet gaskets are sheets of gaskets that can be cut out into a variety of shapes and sizes that fit the connecting surfaces. Gaskets are seals for filling the space between parts, etc., the function of which is to prevent any fluids from leaking out while also shutting out any foreign matter. In the case of robots, gaskets are typically used to seal the joints of their covers, etc. that have complex shapes. For more information on the different types and shapes of gaskets, it is advisable to refer to the Japanese industrial standards JIS B 2404: Dimensions of Gaskets for Use with Pipe Flanges, JIS B 0116: Glossary of Terms for Packings and Gaskets, etc.

By applying these different structural components in combination, robots can be built such that any leakage of their lubricants is kept to a minimum. However, if the lubricants deteriorate or if any seal or oil seal insulating their interior becomes damaged, it might cause a fluid leak. Therefore it is essential to periodically perform maintenance and inspection. For more detailed information on the seals' structural features, recommended replacement frequency, etc., it is advisable to make inquiries to the robot manufacturers or SIers.

[1] These are overseen by the Japanese Industrial Standards Committee.
https://www.jisc.go.jp/index.html

4-3 Examination of robots that do not use any lubricants

Robots that operate without lubricants do not pose the risk of lubricant leaks and food contamination by them. Also they are easy to maintain and clean, relative to conventional robots that require lubricants. Examples of robots that do not use any lubricants are provided below.

1) Pneumatic robots

Robots that are powered by conventional electric motors require reduction drives, which are assemblies of gears that require lubrication to reduce the friction between the gears. On the other hand, pneumatic robots use air as the source of power for their drive systems. Because they do not have any built-in components such as reduction drives that cause friction, they do not require any lubricants.

2) Magnetic levitation robots

As magnetic levitation robots use magnetic force to levitate and move their arms, etc., they do not require any lubricants. Therefore, they are easy to clean and maintain and are suitable for use in clean rooms and other clean operating environments.

3) Robots incorporating polymer bearings

Robots that use polymer bearings are able to mitigate the friction that would otherwise occur in the sliding surfaces of their rotating parts, without requiring any lubrication. Highly resistant to high and low temperatures as well as to humidity, oxidation, corrosion, etc., they are suitable for continuous operation over extended periods.

4) Dry-run robots

Dry-run robots use carbon fiber and other high-performance materials in their moving parts. As such materials are resistant to high and low temperatures and friction, these robots do not require lubrication and, hence, are suitable for use in clean rooms and other similar environments.

Section 5 Surface treatment for preventing attachment of food, etc.

5-1 Preventing attachment of food

Take, for example, robot end effectors the main function of which is to pick, place, and arrange ready-made meals, etc. in food containers in equal amounts. Although they must always pick and hold the same amounts of food items, if food attaches to the hands, it becomes increasingly difficult for them to measure and place the exact same amounts of food each time. Therefore, the surface treatment of each robot end effector should be designed and implemented to suit the work objects it is supposed to handle.

5-2 Highly viscous food items

Examples of food items that are highly viscous and can easily get attached to robot end effectors are listed below.

- Cooked rice, *tsukudani* (Japanese dish of *kombu* kelp, small fish, etc. simmered in soy sauce, mirin, etc.), potato salad, yam, okra, *natto*, *kombu* kelp, *wakame* kelp, *mozuku* algae, *hijiki* algae, egg white, honey, etc.

5-3 Surface treatment for food attachment prevention and enhanced washability

Mitigation of food and dirt attachment to robot end effectors, etc. allows for the development of, and processing by, food manufacturing machines that are conducive to sound food quality and sanitation. The types of surface treatment that are often used for such purpose are summarized below.

1) Water-repellent coating

Application of water-repellent coating to surfaces makes it difficult for water to seep in while also improving their washability. Such water repellence also prevents dirt attachment.

2) Nanoparticle coating

This surface treatment entails such coating of surfaces with ultrafine nanoparticles that makes them non-adhesive. As nanoparticles have large surface areas and are exceedingly fine-grained, they can mitigate the likelihood of food getting attached to the robot end effectors.

3) Silicone coating

Silicone coating of surfaces can make them smooth and minimally adhesive, which in turn reduces the likelihood of food getting attached to the robot end effectors, etc.

4) Fluorine coating

Fluorine coating of surfaces can also make them smooth and minimally adhesive, which in turn reduces the likelihood of food getting attached to the robot end effectors, etc.

5) Plasma treatment

Plasma treatment of surfaces creates ultrafine irregularities that repel food that comes into contact. This surface treatment makes it easier to remove dirt by washing and improves the effects of washing in general.

6) Ozone treatment

With this treatment, ozone is used to cause a certain chemical reaction on surfaces that makes them smooth and suppresses food attachment.

The surface treatment technologies described above are widely used in the food manufacturing industry, the food packaging industry, etc. They improve the sanitary handling of food products and increase the efficiency of their production, etc. in addition to maintaining their quality and taste.

Chapter 4 Risk of Using Non-Food-Sanitation-Act-Compliant Robots at Food Manufacturing Facilities, Hazard Factors, and Countermeasures

When selecting robots for integration into robot systems for use at food manufacturing facilities, it is desirable to choose ones that incorporate the sanitation measures (waterproof structure, surface treatment, etc.) as described in Chapter 3 above. However, according to polls, 99% of all food manufacturers that contemplate robot system implementation fall into the category of small, medium-sized, and micro enterprises. Therefore, the main barrier to their implementing robots that are fully Food-Sanitation-Act-compliant is higher costs. To address this issue of expensive robot system operation, one option is to choose inexpensive robots that are not Food-Sanitation-Act-compliant.

To further elucidate this topic, this Chapter explains the risks that arise when implementing non-Food-Sanitation-Act-compliant robot systems at food manufacturing facilities that require HACCP-based sanitation management, what the attendant hazard factors and their countermeasures are, and how to approach sanitation design in such circumstances.

Section 1 Risks anticipated before use of non-Food-Sanitation-Act-compliant robots at food manufacturing facilities

1-1 Mechanism of food contamination with rust as foreign matter, and its effects on humans

Food manufacturing operations usually entail use of many different machines and cooking apparatuses that are made of metals. In such environment, rusting could typically occur under the following conditions.

・High temperature and high humidity might lead to rusting.

・Machines, etc. might get damaged during assembly or washing, whereby the damaged parts lose their antirust effect, leading to rusting.

・When food gets attached to machines, etc. and is left there for an extended period, those areas become exposed to salt and acidic ingredients, etc. of the food, leading to rusting.

・When apparatuses are washed with acidic or alkali detergents, their surfaces oxidize, leading to rusting.

In terms of specific instances of rust occurrence in food manufacturing operations, examples include any parts of robots, such as inside their main unit covers, spaces etc., that are not regularly cleaned or difficult to visually inspect from outside, where food residues build up and remain unattended for extended periods, giving rise to rust. Another example is when robot parts are washed but dried not enough so the water from the washing remains on their surfaces for long, which, after a series of repeating such cycle, could form rust. Figure 4-1 provides illustrations of food remnants, built up inside the spaces of parts’ adjoining areas.

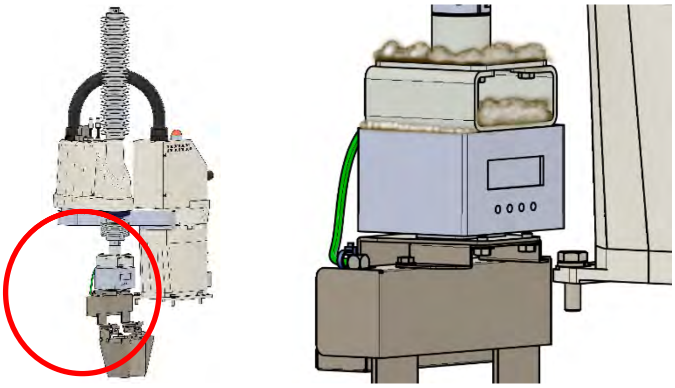


Figure 4-1: Illustrations of food remnants built-up inside the space of parts' adjoining areas

As far as HACCP-based sanitation control is concerned, rust is classified as a physical hazard, a hazard that needs to be removed from food. While its impact on human biology might vary depending on the size, hardness, etc. of the rust, it could cause health harm such as tooth breakage, injury inside the oral cavity, etc., considering rust is a metallic foreign object of sorts.

According to a published report on incidents of food contamination with foreign matter[1], which is organized by food category and level, the smallest size range of metallic foreign objects for the cooked food category has been 5.0 - 9.9 mm. However, depending on who actually ingests it, any piece of rust below this range could harm the health of the individual. Therefore, all incidents of food contamination with metallic foreign objects must be prevented.

1-2 Mechanism of material leaching and its effects on humans

In the Food Sanitation Act[2], the terms *apparatus*, *containers* and *packaging* are defined as *machines, equipment, and other articles…which come into direct contact with food or additives.* Therefore, any materials of robot end effectors and other food manufacturing apparatuses that come into direct contact with food must meet the requirements of the Food Sanitation Act. The basic ones among such requirements that apply to all apparatuses, containers, and packaging are described below.

- All such apparatuses, containers, and packaging used in conducting business must be clean and sanitary (Article 15, Food Sanitation Act).
- Apparatuses, containers, and packaging that contain or bear toxic or harmful substances and are likely to cause harm to human health, or those that come into contact with food or additives and have a harmful effect on human health and are likely to cause harm to human health must not be sold, produced or imported for the purpose of sale, or used in business (Article 16, Food Sanitation Act).

Generally speaking, if a product is said to be "compliant with the Food Sanitation Act," it often means that the product meets the applicable specifications and has successfully passed the standards as set forth in Article 18 of

---

[1] Guidance on the Formulation of Sanitation Management Planning Guidebooks by Food Business Associations (4th edition), Appendix 2 (MHLW)
https://www.mhlw.go.jp/content/11130500/000794538.pdf

[2] Food Sanitation Act (MHLW)
https://elaws.e-gov.go.jp/document?lawid=322AC0000000233

the Act. However, for a product to truly be compliant with the Act, it must not only meet the aforementioned specifications and standards but also possess all clean and sanitary qualities and be free of any toxic or harmful substance.

For more details on the specifications and standards that apply to apparatuses, containers, and packaging, it is advisable to refer to the MHLW Public Notice No. 370 entitled *Specifications and Standards of Food, Additives, etc.*, Section 3 "Apparatuses, Containers, and Packaging"[1]. In this connection, in each instance where a robot incorporates more than one material in its parts that come into direct contact with food, each of the materials must be tested and cleared. It must also be noted that a material's ease of leaching varies depending on the temperature, pH, oil content, and alcohol content, etc. of each work object that the robot end effector comes into contact. Therefore, it is advisable to consult any of the MHLW-registered test organizations[2], etc. to determine which tests must be conducted.

1-3 Effect of food contamination on humans resulting from lubricants that are not intended for food-processing machines

If a lubricant that is not designed to be used on food-processing machines accidentally gets into food, the symptoms that the consumers of the food might express vary, depending on the ingredients and the amount of the lubricant ingested. However, when such incident occurs, the symptoms that will likely appear are thought to be similar to the typical symptoms of food poisoning caused by chemical substances.

・Digestive system: Pain and numbness in the mouth and throat, nausea, vomiting, abdominal pain, diarrhea
・Nervous system: Headache, dizziness, consciousness disorder, convulsion, difficulty in breathing
・Skin: Rash, blister, itchiness
・Internal organs: Disorders of the liver, kidneys, etc.

Because any lubricants not designed for food-processing machines are chemical substances known to cause negative effects on human health, they should never be allowed to get into food under any circumstances.

To achieve this goal, the following protocol might be worth considering implementing on each section of food processing lines, where food items pass fully exposed without any cover, in the indicated order of priority: ① Do not use any lubricant that is not intended for food-processing machinery above each such section; and ② in each instance where a lubricant that is not intended for food-processing machinery must be used, select a lubricant that is permitted to come into contact with food.

Figure 4-2 below provides illustrations of lubricants leaking out of rotating shafts, etc.

[1] MHLW Public Notice No. 370. *Specifications and Standards of Food, Additives, etc.*, Section 3 "Apparatuses, Containers, and Packaging" (MHLW)
https://www.mhlw.go.jp/content/000757879.pdf

[2] List of registered test organizations (MHLW)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/jigyousya/kikan/index.html

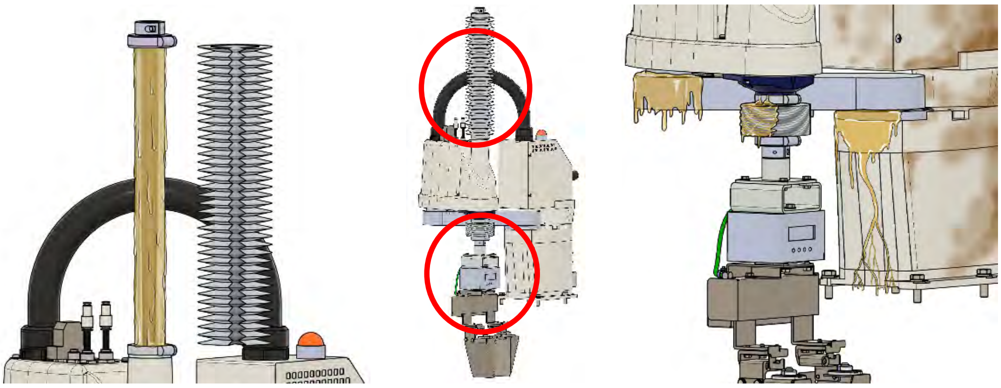


Figure 4-2: Illustrations of lubricants leaking out of rotating shafts, etc.

1-4 Mechanism of microbial propagation on irregular, rough, and cracked surfaces, and its effect on humans

Even though many of the scratches and cracks that occur on the surfaces of resin and metallic parts might seem minor to the human eye, they are significantly immense relative to the sizes of microorganisms, so they become easy entry points for microbial life. Likewise, those surficial scars and cracks let in food residues and water. Because the bristles of most brushes and other utensils typically used to wash apparatuses are larger than the scars and cracks found on apparatuses, they can hardly reach the farthest depths of them, where food residues and water gradually build up and become hotbeds of microbial propagation. Even in the absence of such scars and cracks, any surfaces that have irregularities or roughness tend not to release dirt during washing and occasionally end up becoming a breeding ground for microbes, which could lead to food contamination. If any food that is microbially contaminated is ingested, it could harm the health of those consumers. To address this risk, it is crucial to incorporate adequate measures into the apparatus washing protocol, involving foam washing (such that foam detergents remain in targeted spots), using fine-bristled brushes (such that they reach the full depth), exposing to high heat (for thermal sterilization), etc., which must be optimized to the structural features of, and materials used in, each machine, apparatus, etc.

1-5 Electrical issues that may be caused to robots by water ingress

The typical environment of food manufacturing operations, including the food as objects that they are meant to handle, is not optimal for robots as they are technically precision instruments of sorts.

＜Examples of undesirable environmental factors and potential issues that might arise＞

・Robots are washed with water, which might seep into any PCBs, etc. in their electrical circuits and cause shorts.

・Some food items as work objects might evaporate certain ingredients (acids and alkalis) and cause corrosion to PCBs, etc. in robots.

・Operating robots in low temperatures results in constant condensation, which corrodes their PCBs, etc. over time.

When robots are used in such environment day in, day out, their operational accuracy and reliability deteriorate with time and, in the worst-case scenario, they abruptly cease working. To address this risk, it is necessary to formulate and implement appropriate measures for shielding robots from their adverse operating environment. For one, comprehensive and broad application of seals all around robots not only prevents water ingress but also expands the areas of those robots that may be washed with water without issue. So this might be a desirable approach especially for workers at food manufacturing facilities. Another effective measure might be to install signage, etc. clearly indicating where the use of water is strictly prohibited, raising the alarm about such spots. Figure 4-3 below provides illustrations of how an electrical failure could be caused by water used during washing that gets through the cover of an apparatus.

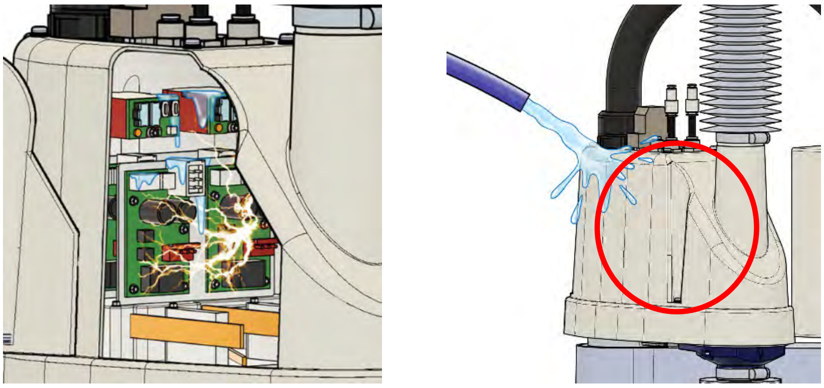


Figure 4-3: Illustrations of an electrical failure caused by water from washing that gets through the cover of an apparatus

As described above in this Section, implementing non-Food-Sanitation-Act-compliant robots at food manufacturing facilities involves a variety of risks that could lead to real operational issues. In the next Section, explanations are provided about the essential functions that any food-manufacturing robots should have (structural design, materials, lubricants, surface treatment, etc.) to avoid such risks.

Section 2 Hazard factors involved in implementing non-Food-Sanitation-Act-compliant robots at food manufacturing facilities and their countermeasures

2-1 Hazard factors to be considered when implementing non-Food-Sanitation-Act-compliant robots

The risk areas that are typically anticipated when introducing non-Food-Sanitation-Act-compliant robots at food manufacturing facilities have been classified into the three categories below.

①Robot systems
②Robot protective jackets
③Robot end effectors (points of contact with work objects)

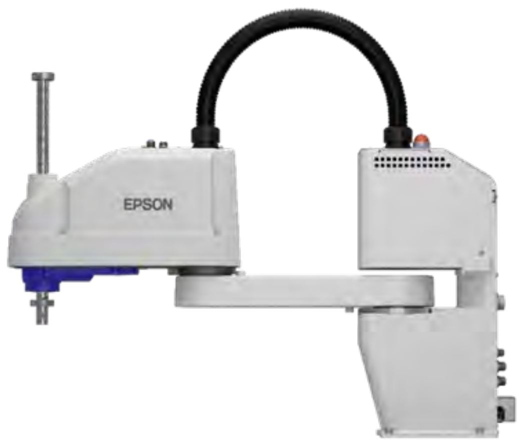
2-2 Robot systems

1) Definition of "robot system"

The term "robot system" used in this Chapter has the same meaning as defined in Chapter 1, 4-2, 1) above. Several types of robots are often used as constituents of such robot systems, including selective compliance assembly robot arms (SCARA robots), which move horizontally, vertical articulated robots, which mainly involve vertically moving arms, etc. (Figure 4-4).

While SCARA robots' operations are limited to horizontal movements, they offer the advantage of relatively inexpensive implementation costs, due to their simple structure. On the other hand, vertical articulated robots are capable of dynamic and free movements analogous to human arms, involving many rotational axes. However, because their structure is more complicated than that of SCARA, they tend to be more expensive.

In this Chapter, the focus is placed on SCARA of all general industrial robots, and also on SCARA-based robot systems, since they are affordable and less difficult to implement, easy to operate, and can be used for a wide range of applications.



SCARA

Vertical articulated robot

Figure 4-4: Multiple-joint robots

2) SCARA

SCARA (selective compliance assembly robot arms) is a type of robot whose arm only moves horizontally. As the name indicates, SCARA specializes in horizontal movements and has a shaft at the tip of its arm, which vertically moves up and down and can perform pushing and other tasks. SCARA is adept at moving its arm horizontally at a high speed and executing tasks on its work objects, using the shaft placed at the end. The use of SCARA is quite widespread today for handling various transport and assembly tasks, etc. (Figure 4-5). SCARA offers different installation options and comes in models intended for floor installation, ceiling suspension, etc., which allows for versatile robot system configurations suitable for a variety of system layouts.

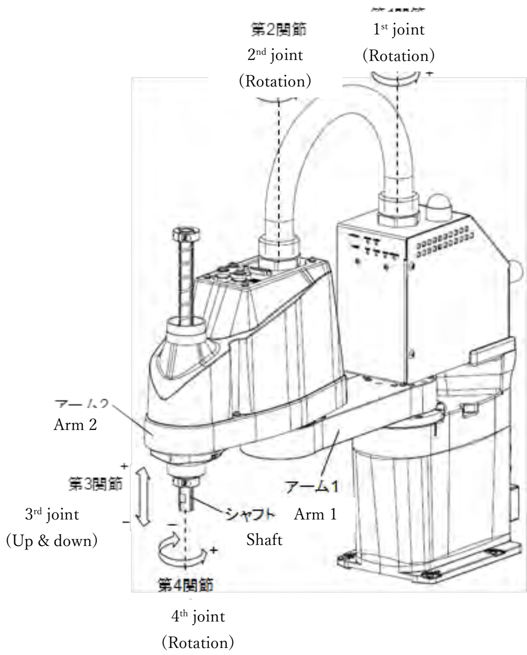


Figure 4-5: Illustration of SCARA's movement

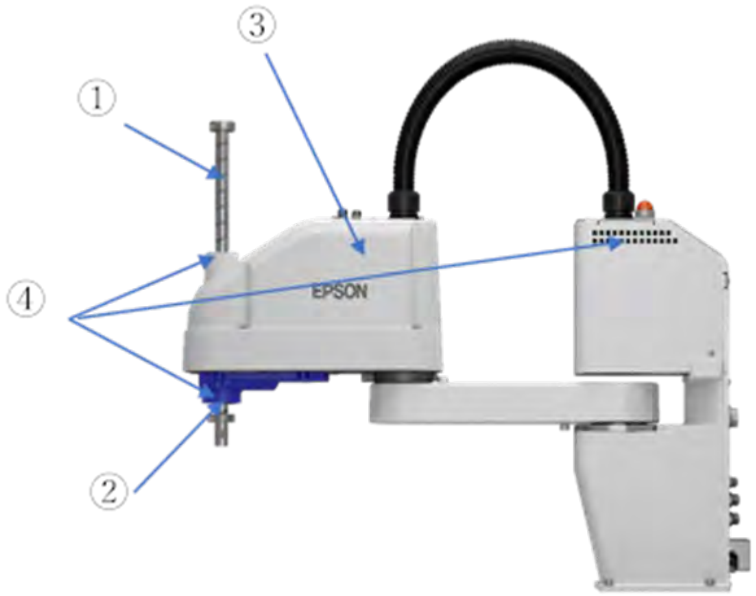
2-3 Sample configuration of a robot system incorporating SCARA (floor installation model)

When introducing a new robot to a food manufacturing facility, it must be noted that the closer its range of motion gets to the point of contact with its work object, the higher the risk becomes of its parts falling off, foreign matter contaminating the food, etc. as the robot keeps operating. To address this, it is necessary to adopt the concept of sanitation design as described below.

Basic principle: No contamination of work objects should occur, involving any substances that may be orally ingested by humans and cause harm to their health.

Countermeasures:
1. Use lubricants that are intended for food-processing machines and do not cause any negative health effects even when orally ingested.
2. In each instance where a lubricant not intended for food-processing machines must be used, implement such measures that will eliminate the chance of its leakage.
3. Install robot protective jackets for food processing, etc. to keep all lubricants from accidentally getting into the food being processed, etc.

In each area where the robot's arm possibly comes close to the food or passes over it, etc., there is a chance the lubricant enters the food, so adequate measures must be implemented to prevent such food contamination. Figure 4-6 below indicates what kinds of sanitation risks arise when the range of motion of the tip (shaft) of the arm comes close to where the work object is, and how those risks can be addressed.



Locations	Names of parts	Sanitation risks	Sample countermeasures
①	Shaft	・Dust caused by the shaft operation could enter the work objects. ・The shaft coming into contact with the work objects could cause the leaching of chemical substances.	・Place a cover over the shaft so that any dust from the shaft does not fly off. ・Such shaft cover must have such corrugated form that tracks the shaft's vertical movement. ・The material of the shaft cover must have high resistance to chemicals. ・The ring that holds together the shaft and its cover must be made of a stable metal that has high resistance to chemicals.
②	Shaft lubricant	The lubricant used on the shaft could enter the work objects.	・If the shaft comes close to the work objects, it must be applied a lubricant that is intended for food-processing machines, to ensure safety if any food contamination should ever occur with the lubricant. ・The shaft cover must be periodically inspected (for breakage, etc.).
③	Robot cover	If the robot cover has a rough surface, it could allow food residues and other dirt to build up.	・The surface of the robot cover must be smooth so that it will not retain any water residue that could lead to microbial propagation. ・The robot cover must be periodically inspected. ・The robot cover must be periodically cleaned by wiping. ・The robot cover must be made of a material that is highly resistant to chemicals so that it can be periodically cleaned by wiping.
④	Electronic components such as PCBs, electric motors, etc.	Any liquid (food, steam, etc.) dispersed from the work objects could create a moist environment, possibly letting water through the space around the cover to corrode the electrical parts inside.	None of the electric motors, PCBs, etc. should be exposed to the external environment. To ensure this, all space around the robot cover must be sealed by modifying the shape of the robot cover, with the shaft cover, etc.

Figure 4-6: Sanitation risks associated with the use of non-Food-Sanitation-Act-compliant robots and their sample countermeasures

The measures described above are examples of how sanitation management might be conducted in a set-up where the tip of the robot arm (3rd joint) and the work objects are proximate to each other. As explained above, the basic principle here is to keep the robot insulated such that no substance that could be orally ingested and cause harm to the health of consumers is let out of the robot. Therefore, it is necessary to implement proper sanitation control measures covering the entire range of the robot's movement (where the robot comes close to, or passes over, the food being processed). Figure 4-7 below provides an example of how a non-Food-Sanitation-Act-compliant robot may be implemented at a ready-made meal dish-up process, by employing the measures described in Figure 4-6 above, i.e., putting on a shaft cover, using a lubricant whose formulation is for food-processing machines, etc., as indicated with the red circles.

Figure 4-7: Example of a sanitation-controlled robot system implemented at a ready-made meal dish-up process

2-4 Sample configuration of a robot system incorporating a ceiling-mounted robot

When a ceiling-mounted robot system (Figure 4-8) is implemented at a food manufacturing facility, it is often the case that the robot is positioned right above the work objects passing through. In each such instance, it is crucial to attend to all sanitation risks that may exist across the robot's entire range of motion. The principle behind robots' sanitation design is explained below.

Figure 4-8: SCARA (ceiling-mounted model)

Basic principle: No contamination of work objects should occur, involving any substances that may be orally ingested by humans and cause harm to their health.

Countermeasures: 1. Use lubricants that are intended for food-processing machines and do not cause any negative health effects even when orally ingested.

2. In each instance where a lubricant not intended for food-processing machines must be used, implement such measures that will eliminate the chance of its leakage.

《Countermeasure 2 sample implementation》

Install a structural component (oil pan, etc.) that can catch and retain any leaked lubricant around the reduction drive and wherever else there is a possibility of lubricant leakage. Each such component must be covered up as needed to protect the work objects from contamination, in a manner suitable for the installation layout, and also must be carefully set up so that it does not interfere with the robot's range of motion.

3. Robot protective jackets for food processing, etc. must be used so that no food contamination with the lubricant will occur.

In each instance where there is a high likelihood of the work objects coming underneath the robot's main unit, any of its joints, etc., it is desirable to cover the entire robot with a robot protective jacket, etc. Specific guidance is provided in the next paragraph on how to do such robot protective jacket implementation to cover the entire robot and mitigate the sanitation risk (Figure 4-9).


Figure 4-9: Robot protective jacket for food processing installed on a ceiling-mounted robot and the robot protective jacket removed

2-5 Examination of robot protective jacket specifications

Table 4-1 below provides the guidance on robot protective jacket for food processing implementation at food manufacturing facilities, as mentioned in the preceding paragraph, detailing all potential sanitation risks, and the specification requirements of robot protective jackets for food processing for addressing those risks.

Table 4-1: Sanitation risks associated with robot protective jackets for food processing and sample specification requirements

Names of parts		Sanitation risks	Safety principles implemented as sanitation design of robot protective jackets for food processing
①	Fabric	・Thermal environment (low temperatures, high temperatures) could cause deterioration, ignition, etc. ・Chemical substances (slightly acidic or alkali) could cause deterioration. ・Evaporated substances from work objects could cause deterioration. ・Lubricants leaked from the robot's reduction drive, etc. could contaminate and deteriorate the fabric of robot protective jackets for food processing. ・Washing with detergent could deteriorate the fabric.	・Fabric's thermal resistance must cover the range between -30℃ and 150℃. ・It must conform to ISO6450 in terms of chemical resistance (detergent resistance evaluation). ＜Evaluation method＞ Prepare all solutions to be tested. Then submerge the fabric in each solution for 10 minutes to test whether it has deteriorated. The solutions must be prepared at the concentrations specified below. Hydrogen peroxide solution (Oxydol) Aqueous hypochlorous acid solution (200 ppm, 400 ppm) Aqueous sodium hypochlorite solution (0.02%, 0.1%) ・Check and make sure the fabric has not deteriorated in the lubricant submersion test. As there is a wide selection of lubricants available for reduction drives, it is advisable to determine which lubricants are being used when selecting robot protective jackets for food processing to be implemented. Then run durability tests on them, to observe their swelling, deterioration, etc. before and after being submerged in the lubricants. ・Recommended robot protective jacket for food processing washing method: Wash robot protective jackets for food processing by wiping with a cloth soaked in aqueous hypochlorous acid solution. ・When selecting robot protective jackets for food processing to be implemented after a detergent has already been selected, it is advisable to run durability tests on each candidate robot protective jacket for food processing using the detergent. Recommended tests include submersion tests to observe the jackets' swelling, deterioration, etc. before and after being submerged in the detergent.
②	Waterproof structure	Water and other liquids dispersed in food manufacturing operations, or water used elsewhere in other processes could get into the robot protective jackets for food processing.	Robot protective jackets for food processing must have water resistance of at least IP66 to be able to serve their function when exposed to water.
③	Size	Robot protective jackets for food processing coming into contact with the joints of robot arms could cause dust. Improper sizing could also intervene into the robots' operating areas and affect their repetitive movements.	Each robot protective jacket for food processing must be split into two pieces, held together with a fastener, so that no interference or entanglement occurs between any of the robot arm joints and the robot protective jackets for food processing (see Figure 4-9).

2-6 Rationale behind the specification requirements of robot protective jackets for food processing

1) Typical thermal environment at food manufacturing facilities

While the room temperature at food manufacturing facilities and the temperature of food being processed there vary depending on the types of food being handled, Table 4-2 below provides an overview of typical temperature control protocols seen at ready-made meal factories. As the actual thermal conditions of food manufacturing processes where the temperatures of food items are not specified (e.g., heating and cooking processes) change depending on the time of day and also from one season to the next, it is advisable to check and verify with each food manufacturer.

Table 4-2: Typical temperature control at ready-made meal factories

Manufacturing	Bento meals	Salads, bread with various cooked

processes		fillings, cooked noodles, etc.
Heating and cooking	Temperature could go up to around 50℃ around heating equipment in summer.	
Post-heating processing	around 20℃	around 15℃
Dish-up	around 20℃	around 15℃
Food ingredient storage	at or below 10℃ (cooked rice: around 20℃)	at or below 10℃

2) Detergents typically used, and washing methods commonly adopted, at food manufacturing facilities[1]

While a wide variety of detergents and washing agents are used at food manufacturing facilities, their ingredients (formulations, etc.) and characteristics are different even among the ones used for the same purposes, depending on the manufacturer. Therefore, it is common to decide which detergents to use after consulting the manufacturers. Table 4-3 below provides an overview of the types of detergents and washing agents that are most commonly used, as well as what their intended uses and target objects are.

Table 4-3: Commonly used detergents and washing agents

Types	Intended uses	Examples of target objects	Characteristics
Neutral detergent	Various types of food-derived dirt	Cooking utensils	Washing is performed with the effects of surfactants. Its neutrality affords significant safety.
Alkali detergent	Significant persistent oil-based dirt, scorched dirt, especially protein-based persistent dirt	Floor, walls, heating and cooking apparatuses, tableware to be washed in dishwashers	Persistent dirt that cannot be removed with neutral detergent, especially oil- and protein-based dirt, as it can be chemically dissolved by action of alkali.
Acidic detergent	Waterborne minerals-based-dirt (scale)	Washing the interior of dishwashers	Used to remove the scale that often builds up inside dishwashers.
Washing and disinfection agent	Minor food-derived dirt and microbes	Food items that are eaten raw, cooking apparatuses for heat-cooked food items	It simultaneously washes and eliminates microbes, which is useful especially when microbial control is crucial. Its sheer washing capability is slightly less than that of neutral detergents that are specialized in washing.

For the task of dirt removal from robot protective jackets for food processing, it is usually optimal to wash them with a detergent and then sanitize them with a disinfectant. However, depending on the materials of the robot protective jackets for food processing being used, wiping might be the recommended washing method in some cases. In such cases, it is desirable to also sanitize the robot protective jackets for food processing by wiping with a sanitation towel that has been soaked in alcohol or chlorine disinfectant (aqueous sodium hypochlorite solution or aqueous hypochlorous acid solution). In addition, if wiping cannot completely remove all the dirt on robot protective jackets for food processing, they must be periodically replaced with new ones. It is advisable to consult the robot protective jacket for food processing manufacturer and detergent manufacturers when deciding on the washing protocols and replacement frequency.

3) Lubricants

Generally speaking, of all the components that constitute a robot system, the reduction drive is the one that

[1] *Choriba ni okeru senjo shodoku manual (Washing and disinfection manual) Part I* (Ministry of Education, Culture, Sports, Science and Technology (MEXT))
https://www.mext.go.jp/a_menu/sports/syokuiku/1266268.htm

uses most of the lubricant given to the system. As such, lubrication is highly correlated with the reduction drives' usable lifespans, ability to repeat the same operations with high positioning accuracy (repositioning accuracy), and other performance metrics. Due to this fact, the manufacturers of reduction drives usually decide which lubricants should be used on their models, so the main ingredients of the lubricants vary among the manufacturers, which also depend on the use conditions. For example, there are two main types of oil used in lubricant formulation, namely refined mineral oil and synthetic hydrocarbon oil, etc. In addition, there are different types of thickening agents used to adjust the consistency (physical property metric indicating hardness) of lubricants, such as lithium-soap-based and urea-based agents, etc. There are some models of reduction drives available on the market that are adapted to lubricants for food-processing machines, which use calcium-sulfonate-based thickeners, etc. As described above, there are a variety of lubricants available for reduction drives. Therefore, when selecting robot protective jackets for food processing to be implemented after a lubricant has already been selected, it is advisable to run durability tests on each candidate robot protective jacket for food processing using the lubricant. Recommended tests include submersion tests to observe the jackets' swelling, deterioration, etc. before and after being submerged in the lubricant.

4) Concept of waterproofing (prevention of electrical failures caused by water ingress)

Refer to Chapter 4, 1-5 above.

2-7 Robot end effector

When examining robot end effector, it is necessary to pay attention to potential sanitation issues that may arise in the form of foreign matter, microbes, etc. getting attached to the hands because they are the points of physical contact between the food and the robots, as they grasp and hold the food, etc. While information on the materials and mechanisms of robot end effector integral to food-handling robot systems was provided in Chapter 3, 3 above, this Chapter is going to focus on providing key information on the sanitation risks that are anticipated with any robot end effector used in food manufacturing operations, and the design-based countermeasures for addressing those risks, using non-contact suction-type robot end effector, etc. as an example (Figure 4-10).

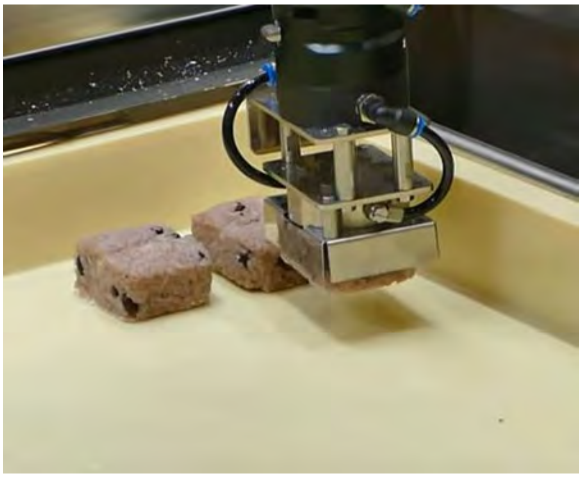


Figure 4-10: Sample non-contact suction-type robot end effector and its implementation at a food manufacturing facility

2-8 Sanitation factors causal to anticipated risks and their effects

1) Mechanism of food contamination with rust as foreign matter, and its effects on humans

Refer to Chapter 4, 1-1 above.

2) Mechanism of microbial propagation on irregular, rough, and cracked surfaces, and its effect on humans

Refer to Chapter 4, 1-4 above.

3) Sanitation measures on contacting fluids and air supply at food manufacturing facilities

Food manufacturing facilities are designed as such that optimal balance can be constantly kept between air intake and expulsion, while positive air pressure is maintained within the clean areas to prevent the entry of the air from the contaminated areas. Although it is desirable to adjust the condition of the air taken in from outside by heating or cooling and dehumidification, some facilities use the outside air without involving such process. In such cases, the air within those facilities becomes susceptible to certain hazard factors (of biological, chemical, and physical nature). For example, in the case of biological hazard factors, specific standards have been set for measuring and controlling the amounts of fallen microbes. In addition, in each instance where compressed air is used at a food manufacturing facility in such a manner that the air comes into contact with the food being processed (e.g., at conveyor belts, cooking apparatuses, etc.), it is necessary to adjust the air so that it becomes compliant with the requirements of the Food Sanitation Act.

《Fallen bacteria count, fallen fungi count》

These inspections are conducted to measure the status of contamination within indoor environments, as indicators of air cleanliness. To perform this test protocol, one must prepare Petri dishes, with growth media placed inside and the lids off, and place them at a site of investigation, and let them sit there, being exposed to the air, for a specified period, to collect and culture fallen bacteria.

Fallen microbe count (Source: *Bento oyobi sozai no eisei kihan*[1])

Contaminated work area: Fallen bacteria count may not exceed 100.

Clean work area: Fallen bacteria may not exceed 30. Fallen fungi may not exceed 10.

《Adjustment of compressed air》

・It will be ideal if an oil-free air compressor that does not require lubrication can be used.
If lubrication is required, however, be sure to use a lubricant that is formulated for food-processing machines.

・Let the compressed air pass through different filters (dehumidification, dust removal, oil removal, deodorization, disinfection) suitable for its intended uses. The filters must be periodically replaced.

4) Mechanism of material leaching and its effects on humans

Refer to Chapter 4, 1-2 above.

5) Electrical issues that may be caused to robots by water ingress

Refer to Chapter 4, 1-5 above.

---

[1] *Bento oyobi sozai no eisei-kihan (Sanitation norms applicable to bento-box meals and ready-made meals)* (MHLW)
https://www.mhlw.go.jp/web/t_doc?dataId=00ta5751&dataType=1&pageNo=1
Abolished on June 1, 2021 due to the enactment of the HACCP system.
(https://www.mhlw.go.jp/content/11130500/000787424.pdf)

6) Detergents typically used, and washing methods commonly adopted, at food manufacturing facilities

Information on the types of detergents and washing methods commonly used at food manufacturing facilities is provided in Chapter 4, 2-6, 2) above.

Provided below is a sample washing protocol for cooking apparatuses that are used to process food ingredients after they have been heat-cooked (and there is no subsequent process for addressing biological hazard factors).

①Preliminary washing (removal of food residues)

Submerge cooking apparatuses in warm water and remove food residues.

②Main washing (wash with detergent)

Wash the cooking apparatuses by scrubbing with a sponge, brush, etc. using a neutral detergent.

③Rinsing

Thoroughly rinse the cooking apparatuses with flowing water.

④Disinfection and storage

After rough dewatering, transport the cooking apparatuses to a storage space that is equipped with a hot-air disinfection function for drying and storage (30 to 50 minutes at 80 to 90℃).

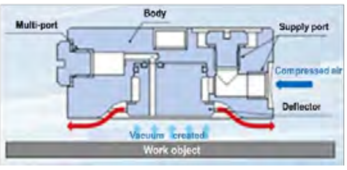
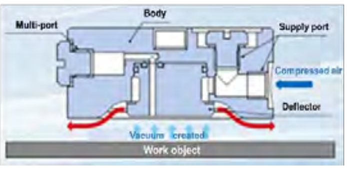
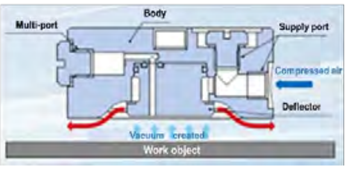
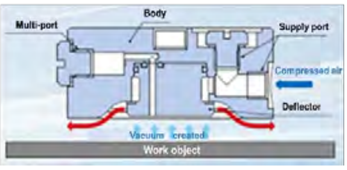
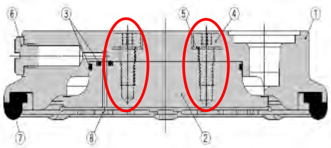
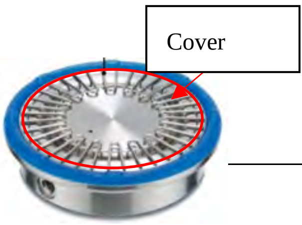
Depending on the food manufacturing operations, plastic covers are placed over their robot end effector to prevent microbial contamination that may occur due to inadequate washing, and also to shorten the time required to switch from one food item to the next, and keep out any allergens originating from other food products.

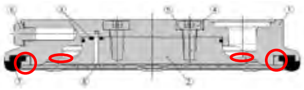
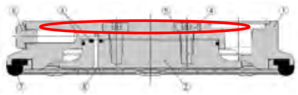
2-9 Countermeasures against anticipated risks

Any anticipated sanitation risks associated with non-contact suction-type robot end effector that could possibly arise in food manufacturing operations can be addressed by implementing the measures as described in Table 4-4 below.

Table 4-4: Sanitation risks associated with non-contact suction-type robot end effector and sample countermeasures

Names of parts	Specifications	Descriptions of anticipated sanitation risks	Examples of reliable safety attainment methods grounded in sanitation design to address the anticipated sanitation risks
① Overall		<Rust> Any metallic part could develop rust, causing corroded debris to fall off.	Use stainless steel (SUS304) as the material of each metallic part.
		<Surface roughness> Residues of work objects could attach to the surface and cause microbial propagation.	Wash periodically.
② Groove for air supply, screw holes		<Liquid retention> Liquids dispersed from work objects and also washing solutions could remain after washing and lead to microbial propagation.	Plug any air supply holes that are not used. Install while covering the installation surface. Wash periodically. Arrange air supply holes oriented in two different directions for enhanced usability.
③ Nozzle, multi-		When it comes into contact	Wash while supplying air.

	port hole		with a work object while compressed air is not supplied, residues of the work object could get in through the holes. High-pressure washing, etc. could cause a washing solution to get in.	
④	Multi-port		Work object suction creates a vacuum, and normal atmospheric pressure gets restored upon releasing it, possibly sucking in pieces of the work object.	Blow air while all work objects have been released.
⑤	Air supply area		Any part of the air supply area could come loose and let foreign matter in to cause contamination.	Apply a locking agent that is Food-Sanitation-Act-compliant.
⑥	Fluid contact		Supplied air coming into contact with the O-ring and gasket could damage them and give rise to foreign matter.	Use O-rings that are certified by the FDA (U.S. Food and Drug Administration).
⑦	Air supply		Foreign matter brought in by supplied air could contaminate the work objects or otherwise get mixed in.	Use filters that have antimicrobial, deodorization, and disinfection functions.
⑧	Adhesive		Locking agent might have been applied to the screws holding together different parts.	When using a locking agent, be sure to select one that is Food-Sanitation-Act-compliant.
⑨	Gripping part		Food could come into contact with the Coanda grip. Then its oil content could cause swelling to the silicone.	Use silicone rubber that is Food-Sanitation-Act-compliant. Remove and wash it regularly, and also replace it as needed.
			External factors could cause the Coanda grip to be detached or broken.	Use one colored blue to allow for easy color-based identification. It is advisable to select one made of a material that responds to a metal detector and X-ray inspection equipment.
⑩	Cover		Pieces of work objects could get stuck in the space beneath the cover. Insufficient washing could lead to microbial propagation.	Wash periodically.
			External factors could cause	Use a metal detector.

			the cover to be detached or broken, leading to work object contamination.	
⑪	Metal contact		Water could get into the space.	Wash periodically.
⑫	Space around the installation surface		Water could get into the space.	Install while covering the installation surface with a seal. Wash periodically.
⑬	Label		Sticker label could become loose and fall off.	Use laser printing.

Section 3 Countermeasures not related to robots' functions

3-1 Countermeasures against robot system's abnormal operations

Any robot systems could encounter unexpected malfunctions. Therefore, it is necessary to formulate countermeasures against them in advance. Main countermeasures against robot systems' abnormal operations are described below.

1) Proper maintenance

Example of malfunction: As each robot system incorporates many different parts including sensors, they could deteriorate or fail and cause a system malfunction.

Countermeasure: Perform maintenance periodically. Replace any defective parts found and also regularly adjust the sensors to prevent such malfunction.

2) System updating

Example of malfunction: Robot systems' software is constantly evolving, continuously integrating updates that improve quality as perceived by customers and better meet their requirements. If a robot system's software is not updated to its latest version, any issue found in its old version could cause a system malfunction.

Countermeasure: Constantly update the software of each robot system to its current version to avoid such malfunction. Implementing the latest technology and functions available can achieve more stable system performance.

3) Accurate calibration

Example of malfunction: Any external shock (a robot arm contacting any other part of the system, etc.) could knock the robot arm out of its correct position, etc. Also any deterioration of a sensor could cause the sensor to indicate abnormal values, etc., offsetting the robot's zero position from the normal coordinates, which in turn causes a serious negative effect on the entire system.

Countermeasure: Conduct precise calibration and check on all sensors constantly to ensure their normal operation (based on the robot's coordinate data) to prevent such malfunction.

4) Worker training and education

Example of malfunction: If a worker that is unfamiliar with the correct robot operation procedure or lacks other key knowledge operates a robot system, it could lead to a serious personal injury or the robot's failure.

Countermeasure: Provision of sufficient training and education to all workers that must handle robot system operation is the key. Make sure that they all understand how to properly operate the system, and how any malfunction can be detected so that when a malfunction occurs, it can be detected and dealt with at an early stage.

5) Back-up plan formulation

Example of malfunction: If a back-up plan that has been formulated is not sufficiently communicated to all workers to deal with a system malfunction when it occurs, they are unable to implement an effective countermeasure as planned, which in turn could lead to a serious accident.

Countermeasure: For each robot system, it is important to formulate a back-up plan if it should encounter any abnormal operation. If any unforeseen trouble arises, such plan can enable swift and effective countermeasure implementation.

3-2 Countermeasures against detachment of parts, etc.

If any part of a robot comes loose and falls off, the first priority is to find it. Once the detached part is found, countermeasures such as those described below might be worth implementing.

1) Utilization of safety functions

Some robots are equipped with safety functions. For example, a robot may incorporate a force sensor that confirms if each work object being picked by the robot is gripped securely. If such sensor is installed, an instance of any robot part detaching can be flagged by the sensor to automatically halt the robot's operation.

2) Monitoring by operators

When a robot is being controlled by an operator, it is important for the operator to constantly monitor the robot's operating status. If any of the parts is detached, it is crucial for the operator to immediately detect and properly deal with it.

3) Proper maintenance

Maintenance must be conducted on each robot periodically, during which it is important to check and make sure the status of all its parts is normal. If any of the parts is detached, it is crucial to identify it to perform a proper repair or replacement in regular maintenance.

4) Preparation of spare parts

Certain parts of a robot system are more prone to detachment than the rest, which include vacuum pads, small screws, any parts of robot end effector, etc. If any of them is detached, it is crucial to find it. Once it is found, the next necessary step is to repair or replace the part. To be able to do this, it is important to always stock their spares. Make a complete list of necessary spare parts so that any parts that go missing can be quickly replaced. It is important to stock all necessary spare parts before a need arises.

Chapter 5 Points to Attend, from Robot System Installation to Pre-operation

Section 1 Pre-operation check

After a robot system has been delivered from its SIer, the administration team assigned to oversee the robot system must check and make sure whether there is any possible nonconformity to the applicable food standards and formulate necessary system administration protocols before the system is brought into full operation.

[Examples of points to be checked]

①Make sure the robot system conforms to all its design and specifications, not only in terms of its visual appearance and operations but also concerning the materials of which its parts and components are made that come into contact with food, their disassembly procedures, whether the lubricants, etc. used on all moving parts located above the pathways of food are ones for food-processing machines, whether the system's emergency stop device functions properly, etc.

②Test the robot system being installed on the actual food processing line, simulating its full-scale operation. Then conduct analysis of all risks that could potentially give rise to nonconformities with applicable food standards. If any risks have been estimated in advance, test the robot system to determine whether or not the estimation matches the test results and there are no other risks previously overlooked. For this purpose, it is advisable to incorporate into this risk analysis the perspective of HACCP-based sanitation management encompassing the whole range of hazard factors (biological, chemical, and physical).

《<u>Examples of biological hazard factors</u>》

- Any food remnants where microbes could propagate and cause contamination (any spots where food residues could accumulate, spots that are difficult to wash, spots that are easy to overlook, etc.)
- Any space in or between moving parts and connecting surfaces of different parts, etc. where food remnants could be built up over extended periods of use. Figure 5-1 below illustrates where food remnants tend to get caught and accumulate in different spaces.
- Any spots that appear prone to dirt accumulation that might not be addressed with currently available detergents, washing tools, and washing methods.

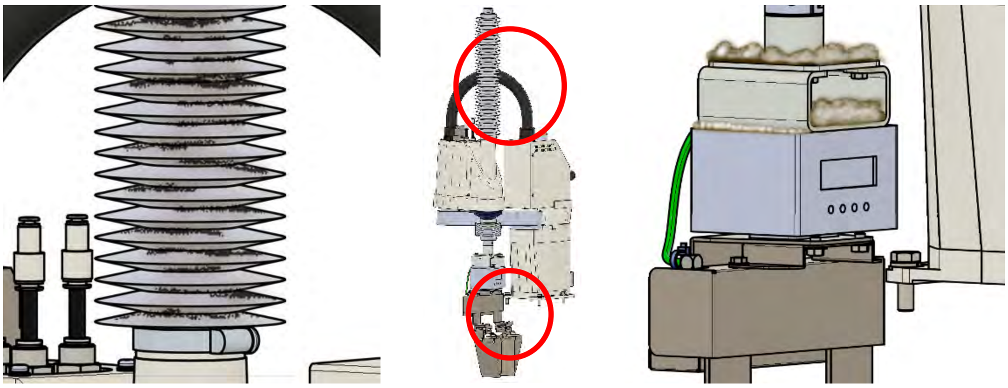


Figure 5-1: Illustrations of food remnants built up in different spaces

《Examples of chemical hazard factors》

・Any spots where chemical substances might leak or leach out of the lubricants, etc. being used in the robot system and possibly cause food contamination. Figure 5-2 illustrates how a lubricant might leak from rotating shafts.

・If the robot system is powered by compressed air, make sure the compressor is an oil-free model or is applied a lubricant for food-processing machines.

・Check the properties of each food item to be handled (pH, viscosity, temperature) and each detergent being used for washing and make sure they do not cause any negative effect (leaching of chemical substances) on the robot system (its points of direct contact with food).

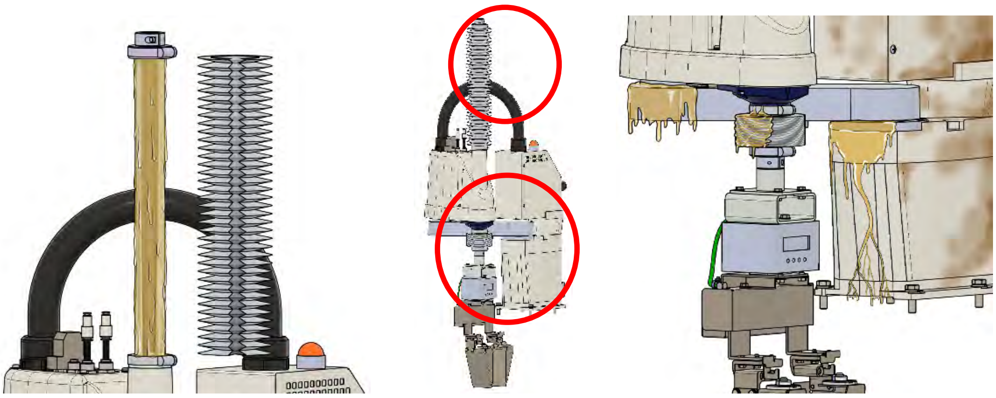


Figure 5-2: Illustrations of lubricant leaks from rotating shafts, etc.

《Examples of physical hazard factors》

・Make sure there is no risk of parts breakage during disassembly, washing, and assembly.

⇒Any large and/or heavy parts could cause damage to the interior wall of the wash sink, the poles of transport carts, etc. upon impact during assembly. Figure 5-3 illustrates how a cover might be damaged this way.

・Make sure there is no risk of parts going missing during disassembly, washing, and assembly.

⇒Small parts are more prone to getting lost, which could lead to food contamination incidents as foreign matter.

⇒Any parts being located in such places that are difficult to visually check after assembly (inside various covers, piping, etc.) are prone to being overlooked when they have not been installed at all. If the robot system is operated with any parts missing, it could get damaged.

・Check the properties of each food item to be handled (pH, viscosity, temperature) and each washing tool being used for disassembly and washing and make sure they do not cause any negative effect (deterioration or breakage) on the robot system (its points of direct contact with food).

・Check if any specific tools are required for disassembly.

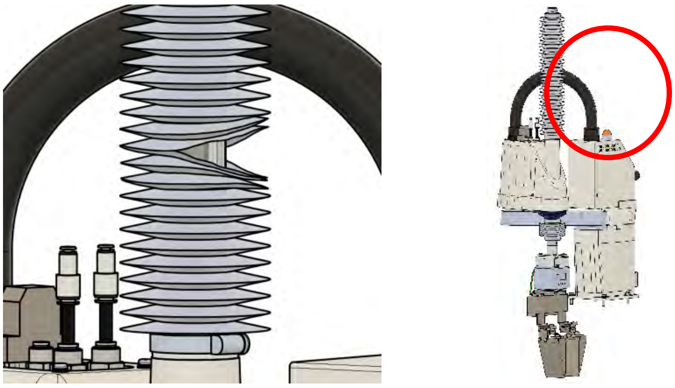


Figure 5-3: Illustrations of cover breakage

③Check and make sure that installing the robot system will not result in any surrounding environment being negatively affected by the robot system, or the robot system being negatively affected by the environment.

《Examples of possible negative effects to the surrounding environment》

・The robot system in operation might come into contact with a different robot system or a worker.
・The robot system might block any of the preexisting work flow lines.
・The air flow caused by any of the robot system's cooling fans might blow directly onto the food being processed or any part of the processing line.
・Any of its power cables or network cables might pass over another food processing line.
・If the factor has a centralized air compression management system, a drop in the robot system's air pressure might affect the operations of other robot systems.

《Examples of possible negative effects from the surrounding environment》

・If the installation space is small, the robot system could come into contact with any workers, carts, etc. that pass by.
・It might be impossible to install the robot system in a level manner if the floor is sloped.
・Any water dispersed from any of its surrounding facilities, apparatuses, etc. during washing could contaminate the robot system.
・Any vibration or electronic noise generated by any of its surrounding apparatuses, etc. could prevent the robot system from normally operating.

Section 2 Supervision and monitoring structure

2-1 Supervision and monitoring structure

It is necessary to formulate and implement a layered organizational structure of supervision and monitoring that oversees all key processes concerning each robot, from the pre-implementation review to the robot's installation, testing on the actual processing line, and normal day-to-day operation.

《Examples of organizational layers》

・Executives or food safety managers (if it is a facility that has implemented its food safety management system)
・Leaders of the robot system administration team
・Members of the robot system administration team

2-2　Functional roles and operational tasks of different organizational layers

The functional roles and operational tasks of the specified organizational layers must be defined.

[Sample functional roles of different organizational layers]

《①Executives or food safety managers (if it is a facility that has implemented its food safety management system)》

・Appoint leaders of the robot system administration team.

・Allocate all resources that are necessary for robot system administration.

《②Leaders of the robot system administration team》

・Form a team dedicated to the robot system administration.

・Manage the operational tasks being executed by the administration team.

《③Members of the robot system administration team》

・Conduct all operational tasks involved in day-to-day robot operations, from the moment of its installation, based on the instructions given by the leaders, such that no nonconformity with applicable food standards arises.

[Sample operational tasks of different organizational layers]

《①Executives or food safety managers (if it is a facility that has implemented its food safety management system)》

・Receive reports from the administration team leaders on key progresses being made, any issues that have arisen, etc.

・Allocate any additional resources that are required to address any issue that has arisen.

《②Leaders of the robot system administration team》

・Select and appoint team members.

Each administration team must consist of members that possess knowledge and experience in food sanitation, risk analysis (hazard factors), maintenance service, manufacture control, employee training, etc. Therefore, HACCP team members might be good candidates to be recruited into the administration team.

・Assign functional roles and authority to each team member.

・Periodically hold team meetings and manage the operational tasks being carried out by the team (including key operational progresses being made, whether any new issue has arisen, status of improvements being made on all existing issues, etc.).

・Report to executives any newly arising issues as needed.

[Examples of events that need to be reported to executives]

Events that cannot be handled by the administration team alone

Events that could cause material adverse effect on the health of consumers

Material violation of any applicable law or regulation concerning food safety

《③Members of the robot system administration team》

・Analyze all risks that could possibly lead to non-conformities with applicable food standards, after the robot system's installation before its operation starts.

⇒For more specific information, refer to Chapter 5, 1 above.

・Develop protocols for addressing all identified risks (or their mitigation to nonharmful level), create procedural manuals, etc.

⇒Examples of procedural manuals (including ones in audio and video formats)

Standard operating procedure (SOP)

Standard sanitation operation procedure (SSOP)

Robot system inspection manual

Verification protocols

・Once the robot system comes into full operation, check and make sure it is being operated properly according to the specified protocols, procedures, etc. on a daily basis.

⇒Examples of check methods

Observe the actual operations in person.

Interview workers.

Check available records, etc.

・If any issue arises, swiftly report it to the leader, and then conduct causal analysis and implement a remedy.

⇒Examples of factors that could give rise to issues

Any change in the installation environment

Extended operation time due to increased production

New member joining the operation team

Partial change in the raw materials or formulation of any of the food products being manufactured

Chapter 6 Maintenance and Management after Robot Operation Start

Section 1 Daily task check

1-1 Pre- and post-operation check

1) Pre-operation check

The member of the administration team assigned to the manufacturing department (or another individual appointed such responsibility) must inspect the robot system, using the pre-operation inspection sheet. If the inspector finds any abnormality, it must record it in the inspection sheet and swiftly report to the supervisor. When the supervisor receives such report, it must review it and take any action that is necessary. If any abnormality found cannot be dealt with internally at the factory, contact the manufacturer of the robot system or another external party to resolve it (by repair, parts replacement, etc.).

Once the supervisor conclusively verifies the abnormality no longer exists, it must instruct to resume the manufacturing operation.

[Examples of pre-operation check]

- How is the sanitation condition (food remnants, dirt accumulation, etc.)?
- Is the robot system free of any breakage?
- No missing parts?
- Are the operations of all moving parts normal?
- No odd noise?
- Any unnecessary items placed on or around the robot system?
- No issues found in the immediately surrounding area of the robot system?
- Are all food products being manufactured to the applicable food specifications and standards (appearance, weight, etc.)?

  *Checking methods include visual inspection, hearing the sounds, measuring, and simplified tests (wipe tests (ATP, allergens, etc.)).

  While conducting this check, any spots that are difficult to see because any moving parts (robot arms, etc.) are obstructing the view should be checked while the robots are being operated.

[Examples of anticipated abnormalities]

- Food remnants due to insufficient cleaning
- Damaged resin parts (breakage, cracks, alteration, etc.) in moving components
- Missing or loose parts, screws, and bolts after assembly
- Unnecessary items (ballpoint pen, etc.) left lying on the robot cover, etc. after being temporarily placed there
- Robot moved out of its correct installation position, causing contact with the manufacturing lines set up immediately before and after it
- Installation not level
- Dirt accumulation and condensation seen in the surrounding environment (on the ceiling, air conditioning,

etc.)

・Water puddle on the floor by the installation area

2) Pre-operation check

Staff assigned to the task of robot administration (or staff appointed such responsibility) must inspect the robot system, using the post-operation inspection sheet. If any abnormality is found, it must be swiftly reported to the supervisor.

While the points of inspection are basically the same as the pre-operation check, this post-operation check to inspect any breakage, malfunction, etc. of the robot must be conducted immediately after the manufacturing operation has ended (before its disassembly and washing). This is because there is still a chance that the robot might get damaged during its disassembly and washing. If any broken or missing part is identified by this post-operation check, it is likely that the broken off or missing part has contaminated some of the food products manufactured on the same date. In this case, it is necessary to decide whether to allow or halt the shipment of those products.

1-2 Mid-operation check

1) Check when switching from one food product to the next

This mid-operation check conducted at the time of switching from one food product to another serves as a post-operation check, in terms of the food product that has been manufactured, as well as a pre-operation check for the food product that will be manufactured after the switch. Therefore, it is advisable to decide on what points to be checked at each switching time by referring to the information provided in Chapter 6, 1-1, 1) and 2) above, while also taking into consideration whether any parts, components, etc. of the food-manufacturing machines must be changed, what the next food product is, etc. In this connection, special attention must be paid to managing the remnants of the previously manufactured food products before each switching, as it could cause allergen contamination (serious accident).

2) Interim check during continuous manufacturing operation over extended period

If a robot system must manufacture the same food product continuously over an extended period, certain risk factors increase such as microbial contamination caused by built-up food residues, system operation malfunctions caused by screws that have gotten loosen, food contamination by detached parts, etc. To address such risks, be sure to perform interim washing and inspections as needed, midway through each such extended robot system operation.

Section 2 Periodical inspection

2-1 Periodical inspection

1) Periodical inspector

As expert knowledge of robot systems is required to properly conduct periodical inspections, they must be handled by the engineering department of each food manufacturing facility or by the manufacturing apparatus manufacturers (external parties), etc.

2) Objects of inspection and inspection frequency

When it comes to any robot system that is implemented at a food manufacturing facility, it is expected that the robot system’s operating conditions would most likely be ones not suitable for, and exceedingly demanding of, any precision instruments that robots are, depending on the distinct properties of the food products the robots will manufacture, and their specific use conditions, installation conditions, etc. In addition, each manufacturing facility is made up of wide-ranging manufacturing machines and apparatuses supplied from different manufacturers, many of which are likely connected through the same local computer network. As such, it is advisable to decide what will be the points to be checked during each periodical inspection, and what its frequency should be, etc. while taking into consideration the general characteristics of each food manufacturing facility.

[Sample general characteristics of food manufacturing facilities]

- Long operating hours. Some facilities are operated non-stop around the clock, all year round.
- Some facilities are highly humid and have an environment prone to condensation.
- Room temperature in some rooms may be quite high (over 40℃) or low (15℃ or below).
- Food items with relatively low pH (acidic) are handled, e.g., dressings, sauces, etc.
- Water (or hot water) is used frequently to clean facilities, equipment, etc.
- Factories with poor sanitation control may be inhabited by unsanitary pests (insects, rats, etc.).
- Manufacturing lines may undergo change, new apparatus integration, etc. (entailing frequent layout change).
- Manufacturing line operators may change quite frequently.

[Examples of points to be inspected]

- Any wear or deterioration noticeable on any of the parts in moving components, connecting areas, etc. or on any expendables such as rubber parts, packings, etc.?
- Any rust found on any of the metallic parts (including stainless steel ones, which are not immune to rusting)?
- Any loose bolts, nuts, etc. that are holding together different parts?
- Any lubricant leaks visible?
- Any electrodes in electric circuits appear corroded?

  Any bite marks seen on wiring that might be of unsanitary pests?
- Any sign of unsanitary pests seen in relatively warm spots, e.g., inside the box of each control panel, the cover of each electric motor, etc.?
- Are the sources of power (electricity, compressed air, etc.) supplied in sufficient amounts for the system’s proper operations?
- Any vibration or electronic noise emitted from the peripheral devices causing interference with normal machine control?
- All control programs operating normally?
- Is the internal clock of each robot system indicating the correct time?
- Any built-up food residues found inside any of the covers or spaces in each robot system (by visual inspection, wipe tests (microbes, ATP))?

[Examples of inspection frequency]

・Monthly: Components that come into direct contact with food or are prone to deterioration or abrasion.

・Twice a year: Components that are considered less likely to fail or malfunction, e.g., electric motors.

・Once every few days: Check inside the covers and spaces in each robot, etc. to make sure there is no food residue built up.

2-1 Action based on inspection results and information sharing

If any issue is identified by inspection, it must be addressed by parts replacement, repair, etc. In addition, the result of each inspection conducted (including any follow-up action taken afterwards) must be reported in detail to the department overseeing the robot system. Related information must also be shared among all concerned parties.

Section 3 Record

Proper recordkeeping by a business operator attests to its good manufacturing practices, which it may also present as proof to third parties on any issues that may arise. In addition, *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application* states in Step 12 (Principle 7) that "efficient and accurate record keeping is essential to the application of a HACCP system," so it is incumbent upon each business operator that it keeps all its required operational records properly.

[Examples of records**]**

・Cleaning and washing records

・Pre-operation inspection records

・Post-inspection records

・Daily manufacturing records (robot operation records)

Operation start time and end time

Records of all numerical settings

・Records verifying that manufactured food products conformed to their applicable food standards (visual inspection, measurement data)

・Monitoring records of CCP processes

・Records of remedies implemented on nonconformities that occurred at CCP processes

・Periodical inspection records (internal records and records kept by machine manufacturers)

・Repair records

・Service records of abnormalities

・Test records (inspection results, etc.)

Section 4 Sanitation evaluation and inspection method

All sanitation evaluation and inspection methods applied to robot systems must comply with the Food Sanitation Act and the School Lunch Program Act. In addition, it is advisable to decide on the objects and points of each inspection based on the hazard factors (biological, chemical (including allergens), physical) covered in the HACCP framework.

[Examples of inspections]

・Microbe test (food inspection, wipe test, fallen microbe test)

・Allergen test (food inspection, wipe test)

・ATP wipe test

・Materials test

・Leaching test

《Applicable laws, regulations, etc.》

・Food Sanitation Act[1]

・Regulations for Enforcement of the Food Sanitation Act[2]

・Positive List System relating to apparatuses, containers, and packages for food[3]

・Standards and Criteria for Foods and Additives, etc.[4]

・Sanitation Management Standards for School Lunch Programs[5]

・Sanitation norms applicable to bento-box meals and ready-made meals[6]

---

[1] Food Sanitation Act (MHLW)
https://elaws.e-gov.go.jp/document?lawid=322AC0000000233

[2] Regulations for Enforcement of the Food Sanitation Act (MHLW)
https://elaws.e-gov.go.jp/document?lawid=323M40000100023

[3] Positive List System relating to apparatuses, containers, and packages for food (MHLW)
Until May 31, 2025: https://www.mhlw.go.jp/stf/newpage_05148.html
From June 1, 2025: https://www.mhlw.go.jp/stf/newpage_36419.html

[4] Standards and Criteria for Foods and Additives, etc. (MHLW)
https://www.mhlw.go.jp/content/000757879.pdf

[5] Enforcement of the Sanitation Management Standards for School Lunch Programs (MEXT)
https://www.mext.go.jp/b_menu/hakusho/nc/1283821.htm

[6] *Bento oyobi sozai no eisei-kihan (Sanitation norms applicable to bento-box meals and ready-made meals)* (MHLW)
https://www.mhlw.go.jp/web/t_doc?dataId=00ta5751&dataType=1&pageNo=1
Abolished on June 1, 2021 due to the enactment of the HACCP system
（https://www.mhlw.go.jp/content/11130500/000787424.pdf）

Chapter 7 Training

Section 1 Training of SIers

1-1 Training for the implementation of general robot systems

Robot SIers are business operators that provide the service of system development, mainly involving robots. System development encompasses a whole range of processes, from design and production to installation and maintenance. Therefore SIers must be knowledgeable about mechanical, electrical, and control design as well as about production systems, safety, law, etc. Table 7-1 below provides a list of subjects to be covered in SIer training that will help SIers become more competent at implementing general industrial robot systems.

Table 7-1: Training subjects and descriptions

[Design/Policy]

Subjects	Descriptions
Mechanical design	Design of overall system concept, robot platforms, robot end effectors, peripheral devices, safety fences, etc.
Electrical design	Design of systems' electrical wiring, control panels, operating consoles, etc., CAD operation
Control design	Design of system control programs (PLC, PC, etc.)
Robot program design and teaching	Design of industrial robot programs, robot teaching tasks relating to various points of movement, etc.
Robot control	Control of robots for different applications, simulation tasks
Image processing	Visual inspection and image inspection tasks
Assembly and wiring	System assembly, air piping, electrical wiring

[Legal requirements]

Subjects	Descriptions
Industrial Safety and Health Act	Law applicable to industrial robots
Ordinance on Industrial Safety and Health	Article 150-3: Rules on teaching Article 150-4: Rules on the prevention of dangers during operation Article 150-5: Rules on inspections Article 151: Rules on inspection Deregulation on collaborative robots
ISO 10218-1, 2	International standards of industrial robots

[Others]

Subjects	Descriptions
Production technology	Process analysis, production process formulation, cost-benefit analysis skills, etc.
Safety measures	Calculation skills essential to safety structural and mechanical design, electrical design skills necessary for ensuring safety, risk assessment skills, etc.

1-2 Training on food-manufacturing robot system implementation

In addition to the implementation of general industrial robot systems, the functions of the HACCP framework can be sufficiently achieved by eliminating all non-necessities and keeping all facilities, equipment, etc. in proper conditions through continuous 5S activities, and maintaining proper environments through general sanitation management initiatives, as also stated below in [Reference] ①Sanitation Management Training Materials for Those Involved in the Food Industry. Hence, this training is also necessary for robot SIers involved in the implementation of food-manufacturing robot systems.

Section 2 Training of food manufacturing facility managers

With many managers of food manufacturing facilities, it is likely that they previously worked on projects to implement new manufacturing machinery but do not have any experience of implementing robot systems at their facilities. If this applies to you, refer to Chapter 2 above for guidance on our recommended robot system implementation procedure, and also to Chapter 5 above for our recommended procedure, covering from food-manufacturing robot system implementation to its operation start. However, as initially indicated in the "Introduction" section of these Guidelines, there might be a shortage of SIers that are able to work on food manufacturing systems, or many of those might still need to gain more experience until they become fully competent at food manufacturing systems. Therefore, SIers that need to work on such robot system implementation projects must evaluate all attendant risks unique to robot systems from a HACCP-based management perspective, while paying particular attention to ensuring that each robot system is Food-Sanitation-Act-compliant, or when it is not at least necessary measures have been properly implemented on it, etc. Specific instructions on these topics are summarily provided in Chapters 3 and 4 above. Therefore, put these Guidelines to good use as you formulate and execute manager training plans.

Afterword

In these Guidelines, we have covered a whole range of topics that are essential for SIers and robot manufacturers that have operated in other industries to successfully implement robot systems at food manufacturing facilities. In terms of any topics that are not covered here but require addressing, you are advised to make the optimal decisions under each set of circumstances, based on the fundamental principles that have been described throughout these Guidelines, for which it is important that you have good understanding of food sanitation. For this purpose, additional training materials on general sanitation management and HACCP are attached below for your reference. In addition, take advantage of these Guidelines to promote understanding of essential points that must be examined or addressed to successfully implement and continuously operate a new robot system at a food manufacturing facility. Last but not least, we sincerely hope these Guidelines prove to be helpful as you work on integrating a robot system into any food manufacturing operations that concern you.

[Appendix]

Checklist for SIers Implementing Robot Systems at Food Manufacturing Facilities

The following checklist is provided as a tool for evaluating the effects that a given robot system might have on food in terms of sanitation, and also the effects that its installation environment might have on the robot system that are unique to food manufacturing operations.

In this connection, when examining any other points that do not concern worker safety, sanitation, etc., use your regular checklists for SIers.

〇Evaluation procedure

①As an SIer, conduct initial evaluation on all points that can be evaluated using this checklist, after the on-site observation (as described in Chapter 2 "Procedure for Robot System Implementation", 1-1, 3) hereof) is finished, but before moving on to the system concept design phase (as described in 4) of the aforementioned paragraph hereof).

②Moving across the checklist, from one evaluation item to the next, put "(〇)" where it is *done*, and "(×)" where it is *not done*.

③For each item on the checklist marked with "(×)," specifically identify all anticipated hazard factors that could potentially appear.

《Reference》

Anticipated hazard factors: Chapter 5 "Points to Attend, from Robot System Installation to Pre-operation" 1-1, 1) Pre-operation check process

④Focusing on each of the identified hazard factors, one by one, plug its occurrence frequency and severity into the evaluation matrix provided, to calculate what the score is, and enter the result on the checklist. In this connection, the evaluation of each hazard factor's severity may be evaluated by applying different standards where the effects would be caused to the food and where they would bear upon the robot system itself.

⑤Plug the scores calculated in ④ above into the score evaluation table, contemplate what the appropriate countermeasure might be, and enter the information on the checklist.

⑥As the robot implementation project moves from one phase to the next, keep reevaluating.

⑦Once you reach the end, review what hazard factors still remain, and report the information to the food manufacturing operation manager, so they can be addressed by those working in operations.

[Evaluation matrix (example)]

		Severity		
		A No anticipated effects on food. No anticipated effects on robot system.	**B** **Indirect** effects on food. Effects on robot system anticipated, but manufacturing operations won't be affected.	**C** **Direct** effects on food. Effects on both robot system and manufacturing operations anticipated.
Occurrence frequency	① High	**6**	**8**	**9**
	② Low	**3**	**5**	**7**
	③ Unlikely to occur	**1**	**2**	**4**

[Score evaluation table (example)]

Score	Countermeasures
7 - 9	**Highly significant risk. Robot system's specifications and design require revision.**
4 - 6	**Communicate the risk to food manufacturing operations. Have them and the SIer both examine countermeasures.** **[Countermeasures]** **1) Revise the robot system's specifications and design.** **2) Have the risk dealt with in food manufacturing operations.** **3) Both 1) and 2).**
1 - 3	**Communicate the risk to food manufacturing operations so it can be operationally dealt with.**

[Checklist (example)]

Check date: **Checker:**

Robot system being checked:

Check items	Done. <u>or</u> Not done.	Anticipated hazard factors	Occurrence frequency	Severity	Evaluation score	Countermeasures
1. Principles for the reduction of sanitation risks						
1) Select materials that do not cause foreign matter contamination, substance absorption/adsorption, etc.						
2) Select parts that are made of materials that are highly durable and difficult to break off due to abrasion, etc.						
3) Implement structural designs that do not cause substance accumulation or stagnation, and are easy to disassemble and wash.						
4) No space or opening exists, through which water could enter.						
5) Structures are in place that prevent any food residues, etc. that accidentally disperse from food-contacting parts to no-food-contacting parts cannot return to any food-contacting parts.						
6) Each closed off space, if any exists, must have an opening that can be opened and closed, so that necessary washing, cleaning, maintenance, repair, and inspection can be conducted through it.						
2. Materials of parts, etc.						
1) Robot end effectors, etc. that come into contact with food must be made of stainless steel or other anti-corrosive material. Each part that is made of resin and comes into contact with food must be Food-Sanitation-Act-compliant, in a manner suitable for the characteristics of the work objects it must handle.						
2) No parts, etc. made of glass that could break may be used.						
3) The surface of each coated area must be free of detachment, pinholes, breakage, air bubbles, warpage, etc., depending on its intended use.						
3. Mechanical elements and parts						
3-1. Bolts and other fastened parts						
1) Use of bolts, screws, etc.						
①No bolts, screws, etc. may be used in parts that come into contact with food.						
②All screwed areas where level-adjusting bolts, etc. are exposed must be covered up.						
2) Specifications (if any bolts, etc. are used in food-contacting parts)						
①No threads may be exposed.						
②Waterproof washers must be used.						
③Dome-shaped hexagon bolts must be used (hexagon-headed or slot-headed ones may be used in food-dispersion parts and non-food-contacting parts).						
3-2. Shafts and bearings						
1) Lubricants						
①Apply seals where needed to make sure no lubricant leak occurs in or to any of the food-contacting parts.						
②Use appropriate lubricants that are intended for food-processing machines.						
2) Shaft joints and bearings						
①They must be accessible for washing, cleaning, and inspection.						

3) Bearings						
①They must be located outside food-contacting parts.						
②They must be structured such that they can be washed, cleaned, disinfected, sterilized, etc. properly.						
③They must be applied lubricants for food-processing machines, or must be lubrication-free ones that do not give off abrasion dust.						
4. Waterproofness						
1) Joints and mechanical connections of the robot must adopt waterproof structures.						
2) Such structures must be adopted that protect all power supply units, electronic circuits, components, parts, etc. from water.						
5. Utilities						
5-1. Mechanical fluids						
1) Such structures must be adopted that keep all discharged liquids from entering any of the food-contacting parts.						
2) Those liquids must be positioned such that they do not enter any of the food-contacting parts even when a malfunction, breakage, or other issue occurs.						
3) All such liquids must be ones for food-manufacturing machines.						
4) Information on any repair, maintenance, inspection, etc. performed to prevent liquid leakage must be provided to the business operator, as system operation information.						
5-2. Liquid drainages						
1) Such structures must be adopted that ensure all discharged liquids directly flow into a waste liquid system or a designated drain gutter, instead of flowing onto the floor surface.						
2) The piping for waste liquids must incorporate a structure that prevents harmful small animals from coming in through any of the outlets.						
5-3. Unexpected electric power or other utility outage						
1) Even if any unexpected outage of electricity or any other utility (compressed air, steam, etc.) supplied from business operators occurs, such structures or control means must be in place to suppress all sanitation risks.						
2) Such structures must be adopted that prevent any contaminants from entering any of the food-contacting parts even if any leak or other issue occurs from any of the pneumatic or hydraulic systems. Even if any erroneous operation occurs due to a malfunction, such structures or control means must be in place to suppress all sanitation risks.						

<u>*The checklists, evaluation matrix, and score evaluation table provided herein are just samples.</u>

[Sample entries]

Check items	Done. or Not done.	Anticipated hazard factors	Occurrence frequency	Severity	Evaluation score	Countermeasures
1. Principles for the reduction of sanitation risks						
3) Implement structural designs that do not cause substance accumulation or stagnation, and are easy to disassemble and wash.	×	**As robot end effectors have grooves, food residues might accumulate there, which might lead to microbial propagation and food contamination.**	①	**C**	**9**	**Modify the hands' structural design to eliminate all the grooves, so that no food residues can accumulate there.**
3. Mechanical elements and parts						
3-1. Bolts and other fastened parts						
1) Use of bolts, screws, etc.						
①No bolts, screws, etc. may be used in parts that come into contact with food.	×	**Bolts are used in robot end effectors for fastening, which could come loose and cause food contamination.**	②	**C**	**7**	**Change the hands fastening method to one that does not use any bolts.**
3-2. Shafts and bearings						
1) Lubricants						
②Use appropriate lubricants that are intended for food-manufacturing machines.	×	**A non-food-grade lubricant is being used above the line of work objects' movement, which could leak, fall off, and cause food contamination.**	②	**C**	**7**	**Switch to an NSF-certified H1-grade lubricant.**
4. Waterproofness						
1) Joints and mechanical connections must adopt waterproof structures.	×	**Non-waterproofed area exists that is not above the line of work objects' movement, through which water could enter during cleaning and negatively affect the robot system.**	②	**B**	**5**	**Communicate to food manufacturing operations to deal with this issue by adjusting how they perform their cleaning tasks.**

[Reference]

①Sanitation Management Training Materials for Those Involved in the Food Industry

1. Training approach

When it comes to providing sanitation training for food manufacturing operations, it is necessary to optimize its contents based on the experience, positions, and nationality of the employees that will receive it. It then becomes important to meticulously formulate training plans in advance, and systematically and continuously execute them, so that all employees will eventually possess the same knowledge imparted from the training and perform their tasks accordingly.

For example, training for newly recruited employees might focus on teaching them basic knowledge on safety and sanitation, and operational rules, while training for production leaders, etc. might emphasize such contents that will promote and enhance their awareness and knowledge on sanitation. Also, if training sessions must be designed for employees some of whom are foreign nationals, it would be more effective to include many illustrations, photos, videos, etc. in the materials to promote their understanding of the subjects being taught.

2. Training methods

Training methods can be roughly divided into two different categories, namely OJT (on-the-job training) and Off-JT (off-the-job training). OJT mainly involves providing guidance to trainees in on-site actual operations. This mode of training is effective because it directly promotes their learning of essential knowledge and work execution methods, allows for easy monitoring of their comprehension levels, and develops their skills that can be quickly put to use, as it trains them while observing how actual tasks are executed. However, the training contents of OJT tend to widely vary, depending on the skills and teaching style of the employees guiding the training. In addition, as OJT is conducted simultaneously with day-to-day operations, the former's interference with the latter is a factor to be considered.

Meanwhile Off-JT is the mode of training that takes place off the trainees' usual workplace. It may be provided mainly in the form of group learning at specified times, webinars, on-demand training contents streaming, and other e-learning. Group learning allows for systematic knowledge comprehension by all trainees, as they all use the same prepared materials and take in uniform training contents. Meanwhile, its disadvantages include disparity in comprehension levels across trainees because the training contents and delivery are all uniform and concurrent, without room for optimizing the unique attributes of individual trainees, such as their professional experience, aptitude level, etc. As for webinars and on-demand learning contents streaming, the contents are usually recordings of previously held seminars, etc., so they can be accessed by any number of trainees, which is an advantage that can be utilized. However, the same issues remain as Off-JT. In terms of e-learning, it is a learning method accessed online, using assigned learning materials. By selecting different materials, each trainee can choose any training contents that are suitable for its level. Its advantages include its flexible accessibility, allowing each trainee to freely pick the time and place of its learning. E-learning also allows the training administrators to centrally check and manage the progress of each trainee's learning and comprehension. However, it does have the disadvantage of not allowing for trainees to acquire knowledge and skills through actual practice.

As such, it is necessary to carefully consider which learning methods to adopt, based on the circumstances, while it is also important to continuously offer training based on effective learning plans, according to the levels of individual trainees, and the circumstances of their workplaces.

Table ①-1 below provides a list of advantages and disadvantages specific to the training methods.

Table ①-1: Advantages and disadvantages of different training methods

Training methods		Advantages	Disadvantages
OJT	On-site training	Training can be customized to individual trainees. Since it is hands-on training, learning can be accelerated.	Training results vary depending on the trainers' levels. Training interferes with actual job execution.
Off-JT	Group learning	Common understanding among trainees can be achieved. Systematic learning is possible.	Training cannot be customized to individual trainees' levels.
	On-demand training contents streaming	Accessible from anywhere.	Levels of comprehension among trainees vary.
	e-learning	Accessible from anywhere, anytime. Management of trainees' learning progress is easy and convenient.	Difficult to learn knowledge and skills through practice.

《Sanitation management: 3 key points on employee training》

①Continuous training provision

Formulate and execute training plans so that training can be held periodically, without causing any resource shortage, comprehensively covering all essential subjects.

②Materials made easy-to-understand to the extent possible

Use uniform materials based on operational rules.

Make all materials easy to comprehend as much as possible, referencing many sample cases, etc. that the trainees can all relate to.

③Training that cultivates deep understanding

Incorporate many illustrations, photos, videos, etc. to improve understanding.

Replace difficult technical terms with easier terms.

《Sanitation management: 5 key points to incorporate into employee training》

①Understanding of 5S activities

These are activities aimed at preventing secondary contamination, foreign matter contamination, and ensuring food safety.

It must be noted that the main goal here is not the 5S activities themselves.

②Recordkeeping

Records properly kept can be used as documentary proof for HACCP, so they are highly important.

Recordkeeping must be conducted with emphasis on accuracy, authenticity, and reliability.

③Review of manufacturing procedures

It is important to constantly keep going back to what the basics are, and achieve unified understanding of all key facts, etc. among the related staff members.

Incorrect understanding could lead to unexpected accidents, troubles, etc.

④Understanding of CCP (critical control points)

Understand what are designated as CCPs and how to deal with them, which are the most important components of HACCP.

⑤Descriptions of hazard factors such as food poisoning, allergens, etc.

Obtain the latest information on food poisoning so that necessary measures can be implemented.

Also understand how cross contamination could potentially occur on manufacturing lines, which could be a blind spot in allergen monitoring.

3. Sanitation management at food manufacturing facilities

At each food manufacturing facility where foods are manufactured and shipped, meticulous sanitation management is so crucial. If there is a minor error in this respect, it could cascade into a series of food poisoning accidents that could escalate into a major catastrophe resulting in the deaths of customers in the worst case. Therefore it is necessary to constantly monitor sanitation control status, so as to ensure that all food products being delivered to customers are safe and secure.

3-1 5S Activities at food manufacturing facilities

5S activities are the basic sanitation management practices commonly implemented at food manufacturing facilities, which stand for *seiri* (sort), *seiton* (set in order), *seiso* (shine), *seiketsu* (standardize), and *shitsuke* (sustain or self-discipline). By keeping sanitary all environmental conditions, facilities, equipment, etc. at each food manufacturing facility, it is possible to prevent incidents of food contamination and foreign matter accidentally getting into any products. Almost all food manufacturing facilities practice 5S activities today to ensure food safety. In addition, while the main objective of implementing 5S activities at food manufacturing facilities is to make sure all food products being processed and shipped out are safe to consumers, the practice also yields other positive benefits in the form of improved product quality, higher productivity, reduced cost, prevention of accidents, equipment malfunctions, etc., and enhanced operational safety. Hence, 5S activities are effective operational enhancement tools all round that can continuously improve the food manufacturing operations where it is adopted.

1) Sort (*Seiri* in Japanese)

"Sort" means distinguishing necessary items from unnecessary ones, so that the latter can be removed from the site or dispose of altogether. In the case of food manufacturing operations, this entails getting rid of any and all useless items left lying in each of the areas designated for storage, manufacturing, processing, cooking, packaging, and other operational activities.

2) Set in order (*Seiton* in Japanese)

"Set in order" means reviewing the necessary items that have been *sorted* in order to decide where to store them, so that when anyone needs some of those items, they know where to find them to use them, whenever the need arises. So this process also involves deciding what is the necessary quantity of each of the necessary items. In the case of food manufacturing facilities, specific machines, equipment, tools, detergents, disinfectants, etc. must be stored in their designated locations, in the specified quantities. It is also important to make extra efforts in labeling different items and organizing them neatly on shelves, etc. to minimize the chance of mistakes. This sort-and-set-in-order approach also improves operational productivity.

3）Shine (*Seiso* in Japanese)

While it goes without saying that all trash, dirt, and dust must be constantly reduced and eliminated, no food remnants, etc. also should not be left alone for long. Keeping sanitary all work spaces and manufacturing areas always, and regularly cleaning and inspecting all machinery, equipment, etc. can not only prolong their usable lifespans but also make possible detection of any abnormality at an early stage, so that all items remain usable at all times. That is why keeping all items nice and “shiny” is an essential aspect of this initiative.

4）Standardize (*Seiketsu* in Japanese)

When the environment of a food manufacturing facility is said to have been “standardized,” it means not only that all items have been properly sorted, set in order, and made shiny but also that such clean state is always maintained as a *standard* discipline. This encompasses not only all machinery and equipment but also the internal walls, ceilings, floors, and other areas of each such factory, facility, etc., which must all be kept habitually clean. In the case of food manufacturing facilities, this component of 5S also includes washing and sterilization to prevent microbial contamination and improve food safety. Special attention must be paid when introducing a new robot to the operations, in terms of determining how to optimally wash and disinfect the food-contacting parts of the robot.

《Washing》

Use detergents, etc. to remove any food residues found stuck on the machinery and equipment and also eliminate all harmful microbes that exist within each food manufacturing facility, etc. in order to mitigate the risk of microbial contamination.

《Sterilization》

Use heat, alcohol, aqueous sodium hypochlorite solution, and peracetic acid formulation, etc. to perform sterilization so that all harmful microbes are eliminated from each food manufacturing facility.

5）Sustain/self-discipline (*Shitsuke* in Japanese)

“Sustain” or “self-discipline” means that all specified procedures, protocols, rules, etc. are correctly followed and have been habituated. It is necessary to practice this component of the initiative by constantly communicating with workers, etc. so that everyone working on site is accustomed to proper food and raw material management and operational protocols in order to ensure food safety.

In food manufacturing operations, the very training of employees to protect the safety of food is considered as this “sustain” and “self-discipline” practice. Therefore, it is important and necessary to make sure that all workers at each food manufacturing facility constantly follow the specified rules as they execute their tasks, while their training itself is this practice of “sustenance” and “self-discipline,” without getting too hung up on the specific steps involved in 5S.

3-2 Employee training on sanitation

“Sustenance” and “self-discipline” directly translate into the training of employees on the topic of sanitation in food manufacturing operations, as are also one of the components of 5S. As most of the workforces that are running the day-to-day operations at food manufacturing facilities are humans, it is important to educate them on proper sanitation control so that they can understand and put it to practice. So needless to say, those that are tasked with such employee training responsibility must thoroughly know themselves about sanitation in food manufacturing.

The key points to pay attention to when providing sanitation training to employees are threefold, namely “teach”, “practice”, and “check”. No matter how long trainees read literature on the topic of sanitation, the knowledge they read from those documents does not stick if it is not put to use.

Therefore, once the applicable rules of their food manufacturing operations have been taught, it is important to apply the knowledge to their job execution. Then check and make sure that they are performing their tasks according to the rules while observing whether their rules-based operations are all rational and executable without issue. If any issues are identified, it is important to address them in a timely manner, by facilitating communication between the site manager and the employees concerned with those issues, while constantly optimizing the rules and task execution.

It is also crucial that such sanitation training of employees is constantly evolving.

While the fundamental rules do not change so often, the employees’ adaptive capability might be needed from time to time, based on the operational circumstances. Therefore, the instructors that must formulate and provide such sanitation training to the employees must constantly communicate with the trainees working in operations to incorporate their inputs into the training to make it incrementally better. In such communication, the instructors must actively hear the opinions of the trainees, to determine if their job execution entails any inconvenient aspects and make sure their operational settings are improved by the training, etc., allowing them to do their jobs without obstacles, etc. If any issues are found through such communication, it is necessary to discuss how they might be addressed efficaciously.

On the other hand, employees that are the recipients of the training are encouraged to communicate to the instructors about any inconveniences they may be feeling, or ask any questions that have not been answered, so that improvements can be jointly made involving both sides. As described above, effective communication between employees and their managers, instructors, etc. is fairly important when it comes to their sanitation training.

3-3 Key points about sanitation management at food manufacturing facilities

When implementing 5S activities at a food manufacturing facility for sanitation management, it is important to clarify what the objectives are. Unless the goals of strict adherence to 5S are made quite clear, it is impossible for all employees to collectively and consciously do it. To raise their awareness of sanitation management, the goals must be clarified by also the facility’s top executives and managers to actively convince and motivate the employees. If managers don't work hard, why should employees?

In addition, to induce “self-discipline,” training must be offered not only to all full-time employees but also the rest of the workforce that together runs the facility’s food manufacturing operations, including temporary workers dispatched from staffing agencies, part-time workers, etc.

To achieve comprehensive sanitation control, it is important for management to proactively communicate with the employees such that the company’s entire culture will become increasingly attentive to the topic of sanitation.

Superficial initiatives to enhance sanitation management usually are not well accepted into day-to-day operations. Therefore, it is important that management constantly contemplates what might be the optimal ways to keep the employees' attention to sanitation management and to become incrementally adept at manufacturing food products in a safe and secure manner. To achieve this, it is also crucial that such environment is cultivated that both workers and managers can candidly express opinions to each other to jointly make progress on the topic.

4. General sanitation management

Implementing HACCP-based sanitation management allows for the organization, analysis and control of hazard factors that might exist in each of the food manufacturing and management processes, and mitigate the risk of health injury. However, unless "good hygiene practices" are not habituated, which is a prerequisite of HACCP, HACCP is unable to perform its functions. Therefore, once 5S activities are habituated and the operating environment has been improved by them, it is necessary to initiate good hygiene practices.

Good hygiene practices are sanitation management encompassing various on-site facilities, apparatuses, etc., employees working in operations, pest control of rats, other rodents, bugs, etc., and other non-food aspects of the site's environment.

A total of 14 items are listed as the criteria of good hygiene practices[1] in Figure ①-1 below.

Good hygiene practice criteria

1. Appointment of a food sanitation manager, etc.
Appointment of a food sanitation manager, the duties of food sanitation manager, etc.

2. Sanitation management of facilities
Cleaning, disinfection, cleanliness maintenance, etc. of facilities

3. Sanitation management of equipment, etc.
Cleaning, disinfection, maintenance, cleanliness maintenance, etc. of machinery and equipment

4. Management of water used, etc.
Water quality inspection, reservoir cleaning, maintenance of sterilization and water purification devices, etc. at least once a year if tap water or potable water is used, etc.

5. Measures against rats and insects
At least twice a year, exterminate rats, insects, etc., or conduct such pest control based on periodical biological surveys, etc.

6. Handling of waste and wastewater
Storage and disposal of waste, processing and treatment of waste and wastewater, etc.

7. Sanitation management for persons who handle food or additives
Monitoring of such persons' health conditions, determination of action when symptoms of diarrhea, abdominal pain, etc. show in such persons (diagnosis and treatment at hospital, suspension of all tasks involving food, etc.), such person's attire, hand-washing, etc.

8. Implementation of food inspection
Implementation of food inspection at large-scale cooking facilities operated by bento meal suppliers, caterers, etc.

9. Provision of information
Provision of product information to consumers, provision of information to municipal health centers, etc. concerning any health injury risks manifested or possible

10. Recall and disposal
Accountable product recall structure when the need arises, calling for consumers' attention, recall operation method, report to municipal health centers, etc., handling of recalled products, etc.

11. Transportation
Cleaning and disinfection of automobiles, containers, etc., management of temperature, humidity, time, etc. while cargo is in transit

12. Sales
Adequate procurement volumes, temperature control of products for sale

13. Education and training
Employee education and training, verification of the effects of education and training, etc.

14. Others
Keeping and storing of records on suppliers, customers, etc., recordkeeping concerning voluntary product inspections

Figure ①-1: Criteria of good hygiene practices

[1] *Regulations for Enforcement of the Food Sanitation Act, Appended Table 17 (Re: Article 66-2, paragraph (1))* (MHLW) https://elaws.e-gov.go.jp/document?lawid=323M40000100023

1）Appointment of a food sanitation manager, etc.

・Each business operator must appoint a food sanitation manager.

・Food sanitation manager must fulfill its duty of sanitation management while endeavoring to acquire new knowledge on the topic.

2）Sanitation management of facilities

・The facility and its surroundings (walls, ceilings, floors) are to be kept clean.

・Sufficient illumination must be secured within the facility.

・Temperature and humidity must be managed properly as needed. The facility must also be sufficiently ventilated.

・Clean the facility to ensure proper drainage. Perform any repair as needed.

・Keep the toilets clean always. Periodically clean and disinfect them.

・No raising of animals is allowed in areas where food is handled or stored.

3）Sanitation management of equipment, etc.

・Cleansing and disinfection of machinery, tools, and their parts are to be performed. Any malfunction or damage must be repaired.

・Detergents used for cleansing machinery and tools must be used properly.

・Thermometers, pressure gauges, and other instruments must be periodically calibrated.

・Sterilization equipment, etc. must be periodically inspected. Inspection results must be recorded.

・Detergents, disinfectants, and other chemical substances must be carefully handled. Their containers must be labeled, indicating what they each contain, to prevent food contamination.

・Cleaning utensils must be used according to their intended uses. They must be washed, dried, and stored in their designated places.

・Facilities for washing hands must be equipped with soap, paper towels, etc. and also disinfectants. They should be maintained such that fingers can be washed and dried properly always.

4）Management of water used, etc.

・For potable water, water quality inspection must be conducted at least once a year, and its results must be stored for a year. If any of the standards is not met, the use of water must be immediately suspended.

・If potable water is used, and there is sterilization equipment, etc. installed, it must be periodically checked to ensure normal operation, the results of which must be recorded.

・If a water tank is used, it must be periodically cleaned and be kept clean always.

5）Measures against rats and insects

・In and around the facility, any breeding sites of rats or inspects must be eliminated.

・Install screens, traps, etc. and also cover drainage ditches with lids to prevent their intrusion into the facility.

・Conduct extermination at least twice a year, and keep their records for a year.

・To prevent contamination by rats and insects, keep all raw materials, packaging materials, etc. in containers. Also implement additional measures on them to prevent their contamination while in storage.

6）Handling of waste and wastewater

・Specify and enforce waste storage and disposal procedures.

・Keep waste containers from other containers by making them clearly distinguishable. Keep them clean so that no dirty liquids or foul odors leak.

・No waste may be stored in the same areas as where food is handled or stored.

・Implement similar measures on wastewater treatment, etc. so that contamination does not spread.

7）Sanitation management for persons who handle food or additives

・Medical examinations of food handlers must be periodically conducted.

・If any health issue is identified with a food handler, efforts must be made to monitor its symptoms and, depending on its condition, make a decision on whether to have it get diagnosed by a physician, stop working, etc.

・If skin injury is present, cover it with a water-resistant material.

・If there is a chance that any food products might have been contaminated with vomitus, etc., discard them all.

・If anyone vomits within the facility, immediately and properly disinfect the area with disinfectant.

・Make sure that food handlers all wear work clothes appropriate for their designated tasks, along with hats, and masks.

・Food handlers must wear the specified footwear within the workplace. They may not leave the designated area without changing the footwear.

・Food handlers may not bring any decorative items, etc. that might cause foreign matter contamination of food into any facility where food, etc. are handled.

・Food handlers must cut their nails short and constantly wash their hands to keep their fingers clean.

・Food handlers must change their clothes in the designated area. Smoking and consumption of food and beverages are only permitted in the designated areas also.

・When going to a toilet, food handlers must take off their work clothes in advance.

・If any persons that are not food handlers intend to enter the facility, they must all comply with the sanitation management regulation.

8）Implementation of food inspection

・For a business operator that cooks and provides 300 identical meals at a time or 750 meals or more per day, the food is to be preserved for an appropriate period of time for each raw material and cooked food.

・When storing the food as set forth above, records of each recipient of the cooked food, the time of each serving of cooked food, and served quantities must be kept and stored.

9）Provision of information

・Each business operator must endeavor to provide necessary information to consumers so that they can safely consume the food.

・If a business operator receives from any consumer a report on health injury or other violation of the Food Sanitation Act, the business operator must endeavor to provide the information to the supervising municipal health center, etc.

・If a business operator receives any report of abnormal taste, odor, foreign matter contamination, or other event that could possibly lead to health injury, the business operator must endeavor to provide the information to the supervising municipal health center, etc.

10）Recall and disposal

・To prepare for any risk of food sanitation hazard that is attributable to food, each business operator must in advance specify an accountable system related to recall, a specific recall method, and procedures for filing a report, etc. so that the food can be promptly and properly recalled.

・All recalled products must be clearly distinguished from other food products while in storage before they are properly discarded, etc.

11）Transportation

・Vehicles, containers, etc. used for transporting food, etc. are to be cleansed and disinfected as necessary to prevent contamination of food or its containers and packaging, and maintained in an appropriate manner.

・When food, etc. and cargo other than food are loaded together, food, etc. are to be separated by storing them properly in different containers as necessary.

・In the case of food, etc. loaded in bulk, special vehicles, containers, etc. that are suitable for the food, etc. must be used as necessary.

・Temperature and humidity are to be managed carefully during transportation. Delivery times are to be set based on the temperature and humidity while in transportation and to be properly managed so as not to exceed the specified delivery time.

12）Sales

・An appropriate quantity is to be purchased per item, in anticipation of its sales volume.

・Sales must be conducted in an appropriate environment, which must be constantly managed so that no sales take place at inappropriate temperature.

13）Education and training

・Food handlers are to be provided with education necessary for sanitation management.

・The effects of the education and training provided must be verified periodically.

14）Others

・Keep records of all suppliers, customers, etc.

・If a self-inspection is conducted on any food, its record must be kept and stored.

・Organize and store all necessary records so that they can be chronologically tracked later.

5. HACCP (Hazard Analysis Critical Control Point)

HACCP is a method of risk mitigation for addressing food contamination with various hazardous substances, by organizing, analyzing, and managing all operational processes involved. It is a globally-recognized process management system necessary for maintaining proper sanitation standards for produced goods, published by the

Codex Alimentarius Commission, an international food standards committee jointly run by the WHO (World Health Organization) and the FAO (Food and Agriculture Organization of the United Nations). The acronym stands for Hazard Analysis and Critical Control Point, which is translated into Japanese to correctly signify such meaning.

5-1 How HACCP is different from conventional inspection

While sampling has been the conventional inspection method, usually involving finished goods. If any issue is found, all associated products must be discarded. However, by its own design, sampling inspection cannot allow for the inspection of all product units. Hence one of the method's disadvantages might be the reasonably high chance that some nonconforming units could be overlooked by sampling.

Meanwhile, with HACCP, all operational processes, from the procurement of raw materials to product shipment, can be inspected to identify all potential causal factors of microbial contamination and food poisoning, allowing for the determination on what control points should be continuously monitored and recorded accordingly relating to the key processes for preventing the aforementioned risks. Such HACCP-based management structure can not only prevent any nonconforming products from being shipped but also allow for the swift tracking of any product units shipped after they have been shipped, when any issue is newly identified, based on the stored records, and also the identification of when the causal factor occurred at which manufacturing process, etc. in a fairly efficient manner.

5-2 Seven principles and 12 steps for HACCP application

Step 1: Assemble HACCP team.

Assemble a HACCP team by gathering assigned staff from various concerned departments, etc. so that all necessary information for manufacturing products can be obtained. For appropriate sanitation management, it is necessary to select team members that are experts in their respective fields, including raw materials and manufacturing methods, handling of equipment, quality assurance. For this purpose, the key point is not the departments being invited to the team but a necessary group of experts in the concerned areas, even from within the same departments having separate internal job allocations, etc.

Step 2: Describe product.

To initiate sanitation management on a given product, product description document must be prepared, detailing the product.

A product description document is a document wherein all key information on the product is organized and presented, including information on its raw materials, packaging style, packaging materials, product characteristics. It is one of the essential documents required to effectively conduct hazard factor analysis. It may be prepared in any format, as long as it contains all the key information, such as a recipe, specification document. If it can also provide information on the product's microbial and chemical properties and other safety-related information that affects the product's characteristics, it will enhance the efficacy of sanitation management on the product.

Step 3: Identify intended use and users.

At this step, check what the product's intended use is, and who the consumers are. Even in the case of food container manufacture, it is necessary to check what types of food will be eventually placed in those containers, and how they would be used by the consumers.

If a product's targeted consumer demographics cover elderly people, young children, pregnant women, etc. because the product's intended use is geared toward them, etc., a need might arise for the product to be managed in a special manner.

Step 4: Construct flow diagram.

This step involves drawing up of a flow diagram, covering all processes involved in the manufacture of the product, including all their constituent tasks, from the acceptance of raw materials to product manufacturing to the delivery of product units to customers.

This flow diagram must cover the entire sequence of manufacturing and processing steps involved in the making of the product, including a description of each of the tasks performed along the way. The main purpose of this particular step is to visualize the product's entire manufacturing processes. It is crucial to make a flow diagram such that simply by glancing at it, one can tell what the necessary raw materials are to manufacture the product, and what operational tasks are involved, etc. in a comprehensive manner.

Step 5: On-site confirmation of flow diagram.

Once the flow diagram has been drawn up, it is time to travel to the site of operations and observe the movements of workers, goods, etc. If any inconsistency is found, the flow diagram must be corrected as needed. Because the flow diagram of a product provides such crucial information for the subsequent analysis of hazard factors, the document must be accurately prepared. It is advisable to involve all members of the HACCP team and the rest of concerned parties in reviewing this document in order to ensure its completeness, accuracy, etc.

Step 6 [Principle 1]: Conduct a hazard analysis (analysis of hazard factors)

Process by process, list up all hazard factors that could possibly arise due to any of the raw materials or mid-process happening, etc. Then identify what control method might be implemented to address each of those hazards.

Using the flow diagram prepared in Step 4 above, determine what biological, chemical, and physical hazards could possibly occur at each of the processes, from raw material reception to finished product delivery. Also estimate the severity of each of those hazard factors and determine what the most severe ones might be.

Step 7 [Principle 2]: Determine the critical control points (CCPs)

Focusing on the most severe hazards that could possibly occur as identified in Step 6 above, decide to what degree they should be controlled and at which process, one by one. A variety of control methods might be considered for implementation, including utilizing a heating process, if there is one, to remove or mitigate any of the hazards, using a refrigeration process to keep the hazard from propagating, etc., employing a metal detector at one of the processes to flag any food units contaminated with foreign metallic objects. Each process where such control is exercised is referred to as CCP (critical control point). There are instances where a single high-severity hazard factor is addressed not at one process but across multiple processes by a combination of measures.

Step 8 [Principle 3]: Establish validated critical limits ("CL") for each CCP

At this step, validated critical limits are established so that all the CCPs previously identified based on the hazard factor analysis can be properly controlled.

These validated critical limits (hazard control criteria) are intended to control all hazard factors and ensure food safety. Each of these limits must be a numerical metric that is grounded in science and can be continuously measured and recorded in real time (e.g., temperature, time, water content).

Step 9 [Principle 4]: Establish a monitoring system for each CCP

At this step, optimal monitoring methods are specified for ensuring that all the CLs defined in Step 8 above are continuously met across all processes. Specification of such methods must clarify all monitoring procedures involved, including the monitoring objects (e.g., temperature, time, water content), who will be monitoring, and when and how frequently the monitoring will take place.

During the actual monitoring, it is necessary for the person monitoring to record its name, the product being monitored, what are the control objects, etc. without fail.

Step 10 [Principle 5]: Establish corrective actions

This step involves specifying what corrective actions should be taken once the monitoring is completed, if some of the CLs were surpassed. The objective here is to allow for the swift identification of each instance when any of the CLs has been deviated, so that any sanitation issue can be quickly dealt with, according to predefined protocols.

Organize such corrective actions in such chronologically sequential format so that one can refer to the actions, step by step, i.e., how to remove a food unit that has just been found to have an abnormality, and then what to do with the removed food unit, and so forth.

Step 11 [Principle 6]: Validation of the HACCP plan and verification procedures

At this step, review the HACCP plan once again to make sure all the control measures formulated and implemented thus far are consistent with the plan, and whether any correction needs to be made. The specific points to check here are whether the CCP-designated processes from Step 7 are being operated according to the decisions, specifications, etc. made in Step 8 through Step 10. The plan must also be verified in terms of whether it has been continuously and properly functioning as it is supposed to. Such verification methods include reviewing of the monitoring records, checking on the precision of the measuring methods that have been used, determining whether all actions that were taken after the CLs had been deviated were all appropriate. For this purpose, it is worth considering inviting a third party that is free of any conflict of interest to partake in the aforementioned verification, as this will provide an additional objective perspective in determining the efficacy of the plan, methods, etc.

Step 12 [Principle 7]: Establish documentation and recordkeeping

This final step involves documenting all the decisions, specifications, determinations, observations, etc. made in Step 1 through Step 11 above. It is mandatory that the records of all controls exerted, and management conducted, be recorded in document form. Such records serve as proof that HACCP has been properly implemented. They can also be used to track down the management or control status of any process when an issue occurs there, so that its root cause can be investigated based on the recorded data. Hence it is crucial to decide the specifications and rules of such recordkeeping in advance, i.e., what information to be recorded, where the records should be stored, who is responsible for their management, etc.

6. Training plan formulation

The HACCP team is also responsible for formulating annual employee education and training plans, taking into account the trainees' individual education and training records, departmental affiliation, professional experience, etc. The team must then create "education plans" accordingly (consisting of education plans and records).

As previously described, the key points of sanitation education are threefold, which are "teach", "practice", and "check". Based on this cycle, it is important to gauge and determine the efficacy of the education being provided to the employees.

In addition, if HACCP-based sanitation management is properly implemented, whether that will yield the expected results is entirely up to the employees that are implementing it in actual operations.

Therefore, the education of employees is one of the major pillars that enable the company to continuously provide safe and secure high-quality products to its customers. While employee education and training can be classified into the education component aims to cultivate the employees' skills and promote their professional growth, and the training component whose sole focus is to develop the employees' ability to reliably execute their specified tasks in specified manners. Hence it is necessary to formulate and execute initiatives for each of these purposes.

In doing so, the following points become eminently important.

- What are the objectives of the employee education and development programs?
- What kinds of skills and capabilities are being targeted in those programs?
- What levels of skills and capabilities are being targeted?
- What is the time schedule of the programs?
- What is the methodology involved in the programs?

While employee education is a gradual, low-profile process, it must be also recognized that the most important goal of HACCP is the maintenance and improvement of food safety and security, and to achieve this, employee education is a crucial initiative that must be efficaciously carried out.

②Glossary

Terms	Descriptions
System integrator	Commonly represented as "SIer [usually pronounced *es-ai-er*],"this is a blend word of the initials of "system integration" and "er" as in "integrator" but with an "e." When an SIer is hired by a customer, it configures and develops such a system that the customer desires to implement, based on the customer's specific needs, which is responsible until the developed system is successfully implemented into the customer's operations.
Robot SIer	It is a specialized vendor that provides robot implementation support to factories, etc. When a robot SIer is hired by a customer to implement a machine system integrating robots, it handles a wide range of responsibilities from planning to actual system operation, encompassing system plan formulation, design, assembly, etc. It also offers comprehensive one-stop service based on the request of each customer, covering any software and hardware, including the production of jigs, tools, ancillary equipment, after-sale maintenance, supply of parts.
Work objects	They are the objects of processing. For example, think of a vegetable cutting machine used in the food industry, for which the work objects are vegetables. If it is a potato salad dish-up apparatus, potato salad is its work object.
Robot system	The term refers to an entire, comprehensive system of robots and peripheral apparatuses. Such system has built-in sensors that detect motions of objects, based on which the computer, also integrated into the system, discerns what the circumstances are and makes decisions, before issuing operation commands to actuators.
Risk assessment	Generally, it means a sequence of steps taken to identify any hazard and harmful factors present in work settings, prioritize what specific measures should be implemented to address them based on specified criteria, and remove or mitigate the associated risks. The approach is the same for robot system implementation. It aims to identify, remove, and mitigate all risk factors through sequential steps during the design phase.
Movable load	This is the maximum transportable weight of an apparatus, to the extent that its specified performance can be guaranteed. In the case of a robot, it includes the weight of all arms and other limbs. [JIS B0134-1986, D6801]
FMEA	FMEA is the initialism of Failure Mode and Effects Analysis, having the self-explanatory meaning. More specifically, it is an analysis method used to improve the reliability of products and processes while reducing the incidence of issues. It is implemented by listing all potential failures that could occur with each of the constituent parts, along with their incidence, scope of effects, magnitude, etc. so that the most critical ones can be addressed and prevented with priority.
Design review	This is an organizational activity that aims to examine the validity of a product concept, and to identify all issues that might exist with it, based on its customer requirements in terms of functions, performance, safety, reliability, operability, design, productivity, maintainability, disposability, cost, applicable laws and regulations, lead time, etc., while also taking into account all quality characteristics linked to the product's design development goals, along with any opinions provided by outside parties, so that a decision can be subsequently made on whether to proceed to the next phase of product design and development.
QCD	It is the initialism of Quality, Cost, and Delivery (lead time). These three factors are used as metrics in product evaluation. According to this means of evaluation, the ideal products and services are of high quality, that can be made or prepared at minimal cost within a short period.
Handling operations	These are robot end effectors' operational movements that are controlled by a software program.
Robot teaching	Teaching in the context of robot implementation means allowing the robot to learn its expected movements. More specifically, commands are provided that inform the robot how to execute movements, under what conditions, in what sequence. When work objects are changed, and the robot must be taught again to work on different objects, it is sometimes referred to as "re-teaching." It is worth noting that for one to perform robot teaching tasks, it must have a specific qualification that must be earned through special training.
Fluorine coating	It is a catch-all term for all types of plastics containing fluorine atoms. It has various excellent properties such as non-adhesiveness, anti-abrasion, due to which its use is widespread across different industries, including food, industrial equipment.
Silicone coating	It is an organic coating agent, which is made of silicone resin that is non-harmful to humans. It is resistant to heat and, therefore, deteriorate only very slowly. It is also known to be highly resistant to water.
Nanoparticle coating	This ultrathin coating is applied to any areas where too much thickness could cause an issue, while maintaining transparency, as well as certain other functions that may be added. It has excellent properties in terms of water repellency, waterproofness, antibacterial property, anti-

	abrasion, thermal resistance, etc.
Reduction drive	This is a component for reducing a machine's rotational speed while increasing its torque, using a set of gears. The driving force (rotational speed) generated initially by an electric motor, etc. is transmitted through interlocking gears to obtain the desired amount of torque in proportion to the reduction ratio.
Repositioning accuracy	It means a robot's ability to repeatedly position its work objects in the same manner with accuracy, which is numerically expressed based on the measurement of its positional fluctuations observed in such actual test as described above. This is also defined in the JIS standard for industrial robots.
Refined mineral oil	While lubricants are mostly made of base oil and additives, the base oil can either be refined mineral oil or synthesized one. Refined mineral oil is made by extracting from petroleum only the ingredients necessary for lubricants and refining them.
Synthetic hydrocarbon oil	Consisting of carbons and hydrogens, it is a chemically synthesized oil only containing essential ingredients for lubricants. Generally, synthetic oil tends to be superior to refined mineral oil in various aspects because of its more stable oil particle composition. However, it takes more time and labor to be properly refined, which makes it more expensive than refined mineral oil.
HACCP	HACCP is the acronym of Hazard Analysis and Critical Control Point, which is a sanitation management technique that can be employed to guarantee high food safety. It is used by food manufacturers to analyze all hazard factors that could arise at each of the series of steps involved in food manufacturing, starting with raw material acceptance and ending with finished products. By tightly managing all critical control points identified with this method, it is possible to prevent the hazard factors from occurring. It is a useful tool for guaranteeing food safety in an advanced manner across the entire sequence of all manufacturing processes.
Biological hazard factors	These are biological factors that could adversely affect the health of humans. Examples include bacteria (enterohemorrhagic E. coli, Campylobacter, Salmonella), viruses (noroviruses, hepatitis A virus), parasites (Anisakis, Kudoa septempunctata).
Chemical hazard factors	These are chemical factors that could adversely affect the health of humans. Examples include natural toxins (of blow fish, poisonous mushrooms, molds), environmental pollutants (mercury, cadmium, arsenic), remnants of used substances (agricultural chemicals, animal feed additives, veterinary pharmaceuticals), accidental chemical use (detergent).
Physical hazard factors	These are physical factors that could adversely affect the health of humans. Examples include pieces of metals, glass, rigid plastics, stones, needles, bones.
Food safety management system	This system is comprised of sets of policies, processes, and procedures, which is used by organizations to achieve food safety by addressing essential issues in a reliable manner. It has three components, namely FSM, HACCP, and GMP. Examples include ISO22000, FSSC22000, and JFS.
Standard sanitation operating procedure (SSOP)	This is a procedure manual on sanitation management, documenting all necessary action protocols, clearly specifying the when, the where, the who, the what, and the how of each required action execution.
Pre-operation check	This is the check conducted pre-operation, which generally includes inspection for any apparatus breakage, assembly condition, insufficient cleaning. If any issue is found, it is addressed before commencing operation.
Post-operation check	This is the check conducted post-operation. If any issue is found, any or all of the food products that have been manufactured up to that point could have been affected by the issue.

③List of Reference Materials

〇Strategy for Sustainable Food Systems: Innovation Will Enhance Potentials and Ensure Sustainability in a Compatible Manner in the Agriculture, Forestry, Fisheries and Food Sectors (MAFF)
https://www.maff.go.jp/j/kanbo/kankyo/seisaku/midori/attach/pdf/index-10.pdf

〇Mandatory Implementation of HACCP-based Food Hygiene Control (MHLW)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/haccp/index.html

〇Practical manual on functional safety utilization (MHLW)
https://www.mhlw.go.jp/file/06-Seisakujouhou-11300000-Roudoukijunkyokuanzeneiseibu/0000197860.pdf

〇Guidelines for ensuring safety when operating collaborative robots at food factories (MAFF)
https://www.maff.go.jp/j/shokusan/sanki/soumu/seisansei.html

〇Food Sanitation Act (MHLW)
https://elaws.e-gov.go.jp/document?lawid=322AC0000000233

〇Positive List System relating to apparatuses, containers, and packages for food (MHLW)
Until May 31, 2025: https://www.mhlw.go.jp/stf/newpage_05148.html
From June 1, 2025: https://www.mhlw.go.jp/stf/newpage_36419.html

〇(1) General standards and (2) specific standards under Section 3-D-2 of the Public Notice (MHLW)
https://www.mhlw.go.jp/content/000757879.pdf

〇List of registered test organizations (MHLW)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/jigyousya/kikan/index.html

〇Washing and disinfection manual Part I (MEXT), partial revision and addition
https://www.mext.go.jp/a_menu/sports/syokuiku/1266268.htm

〇NSF (an independent certification body that is globally recognized in the field of public safety and sanitation)
https://www.nsf.org/

〇Japanese Industrial Standards Committee
https://www.jisc.go.jp/index.html

〇Guidance on the Formulation of Sanitation Management Planning Guidebooks by Food Business Associations (4th edition), Appendix 2 (MHLW)
https://www.mhlw.go.jp/content/11130500/000794538.pdf

〇MHLW Public Notice No. 370. Specifications and Standards of Food, Additives, etc., Section 3 "Apparatuses, Containers, and Packaging" (MHLW)
https://www.mhlw.go.jp/content/000757879.pdf

〇Sanitation norms applicable to bento-box meals and ready-made meals) (MHLW)
https://www.mhlw.go.jp/web/t_doc?dataId=00ta5751&dataType=1&pageNo=1
Abolished on June 1, 2021 due to the enactment of the HACCP system.
（https://www.mhlw.go.jp/content/11130500/000787424.pdf）

〇Regulations for Enforcement of the Food Sanitation Act (MHLW)
https://elaws.e-gov.go.jp/document?lawid=323M40000100023

〇Standards and Criteria for Foods and Additives, etc. (MHLW)
https://www.mhlw.go.jp/content/000757879.pdf

〇Enforcement of the Sanitation Management Standards for School Lunch Programs (MEXT)
https://www.mext.go.jp/b_menu/hakusho/nc/1283821.htm

〇Regulations for Enforcement of the Food Sanitation Act, Appended Table 17 (Re: Article 66-2, paragraph (1)) (MHLW)
https://elaws.e-gov.go.jp/document?lawid=323M40000100023