

Prerequisite Programs (Related to Article 5)

I. Food (including food additives) manufacturing and processing businesses, Health-functional food manufacturing businesses, Food sales business for facilities providing meals¹⁾ or livestock slaughter houses/related businesses

A. Premises

Food processing area

1. Food processing area shall be located away or separated (by walls, floors, etc. into different rooms or areas) from non-food facilities.
2. The structure of processing area shall be suitable to exclude pests, rodents, water, and any other contaminants by doors, windows, walls, ceilings, etc.
3. Processing areas shall be divided into general/clean areas (clean area can be additionally divided into clean/semi-clean areas, if needed), and areas can be continuously divided or separated depend on properties of products or processes.

Floor, wall, and ceiling

4. Floors, walls, ceilings, doors, windows, etc. of raw material handling, food manufacturing/processing, and food packaging rooms shall be constructed of water-proof or heat-resistant materials depending on properties of products. Floors shall have no cracks and crevices, and be in a dry condition (except for moist condition of processing/manufacturing). If tiles which have grooves are used for floors, walls, ceilings, etc., they shall be maintained in a sanitary condition to prevent accumulation of dust, mold, or foreign materials, etc.

Drainage and plumbing

5. Processing area shall provide adequate floor drainage without any sediments. Plumbing shall be maintained to prevent backflow.

Entrance

6. Work clothes wearing notices shall be posted at the entrance of each processing area. Hand-washing, drying and sanitizing facilities shall be provided, and all employees shall

remove contaminants by washing, sanitizing, etc. before starting work.

Aisle

7. Employee traffic patterns shall be indicated in processing areas, and aisles shall be unobstructed.

Window

8. Raw materials and packaging materials shall be maintained in a manner that protect against contamination in case of window glass breakage.

Lighting

9. Brightness shall be 220 lux or more in working areas using natural or artificial lightings. The illuminance shall be maintained above 540 LUX for screening and inspection area that requires visual confirmation.
10. Skylights and light bulbs shall be corrosion-resistant. Adequate protective equipment shall be installed to prevent contamination caused by breakage or any fallen down foreign materials from skylights or light bulbs over exposed food.

Auxiliary facilities

- Restroom, dressing room, etc.
- 11. Adequate ventilation equipment shall be provided for internal air out. Walls, floors, ceilings and doors of restroom shall be corrosion-resistant and water-proof. Washing, drying and sanitizing equipment shall be provided at the entrance of toilet rooms.
- 12. Work clothes (including work shoes) shall be stored separately in a manner that protect against cross-contamination from personal clothes (including personal shoes) in dressing room.

B. Hygiene

Operation environment

- Traffic pattern plan and prevention against contamination between processes
- 13. Plans for traffic patterns of employee and food product shall be established and complied with, from receipt of raw materials to release of finished products.
- 14. Prevention plan against contamination with foreign materials shall be established from receipt of raw materials, manufacturing, processing, storing and to transportation, and if necessary, facilities or equipment shall be installed to implement the plan.
- 15. Hygiene program (including standards for entry, clothes, cleaning, sanitation, etc.) for each area (general/clean) shall be established and implemented.

¹⁾ Businesses selling food products or meals for meal service to facilities or groups such as to schools, childcare, or senior center.

Temperature and Humidity

16. Temperature control plan shall be established for every step of process (processing, manufacturing, packaging, storing, etc.), and indicating thermometer shall be installed and maintained. If necessary, humidity control plan shall be established and implemented to ensure food safety.

Ventilation facility

17. Ventilation facilities shall be installed to emit odors and vapors (including noxious fumes, harmful gases, and steam, etc.) in areas where they may cause food contamination.

Pest control

18. Adequate screen or filter, etc. shall be installed for the intake and exhaust port open outside.
19. Processing area shall be maintained in a manner that exclude pest to prevent infestation or propagation of pests and rodents using insect repellent and the inflow shall be checked regularly.
20. An appropriate protective procedure shall be followed within a range that does not affect the integrity of the products and safety of the foods in accordance with established hygiene rules when performing extermination of pests or rodents. Any residue shall be eliminated by thorough cleaning after extermination.

Personal hygiene

21. All persons working in processing area shall wear suitable, clean outer garments or uniforms, foot wear, and hair restraints, and remove personal jewelry and cosmetic items.

Waste treatment and disposal

22. Operating systems for waste/waste water treatment and disposal shall be installed and operated isolated from processing area. Waste containers shall be kept in a manner that prevent odor and leaking water formed by waste. Waste shall be disposed or taken away as planned. The records shall be maintained.

Cleaning and sanitation

23. Facilities or equipment for cleaning and sanitizing of machines, equipment, utensils, and containers shall be installed.
24. Guidelines or procedure for proper hand-washing shall be posted on appropriate place around cleaning/sanitizing facilities for employees.

25. Standards of cleaning or sanitation shall be established for followings:

- Employees
- Work clothes, caps, shoes etc.
- Around processing area
- Inside of each processing area
- Food manufacturing equipment (including transfer conveying belt or tube)
- Freezers and refrigerators
- Water storage facilities
- Storage and transportation facilities
- Vehicles, equipment and containers for transportation
- Monitoring and testing devices
- Ventilation (including filters, screening, etc.)
- Waste disposal equipment and containers
- Cleaning and sanitizing equipment
- Any items requiring cleaning and sanitation

26. Cleaning or sanitation standards shall include :

- Cleaning or sanitation parts for each objects
- Method and frequency for each cleaning or sanitation areas
- Person in charge
- Appropriate instructions for cleaning and/or sanitizing equipment
- Appropriate instructions for detergent and disinfectant (general name and common name)

27. Cleaning and sanitizing equipment and utensils shall be stored in designated area.

28. Cleaning and sanitation shall be conducted in accordance with the plan, and the effectiveness shall be verified.

C. Manufacturing/processing facility/equipment

Maintenance of manufacturing facility, equipment and device

29. Manufacturing, processing, sorting, and treatment equipments shall be properly arranged according to the flow of the process to avoid cross contamination between handling. Risk management plan shall be prepared to prevent contamination from hazardous factors in the case of direct or indirect use of compressed air or lubricant that may affect the product.
30. Food-contact facilities and equipment shall be made of nontoxic corrosion-resistant and water proof materials, and shall be adequately cleanable with hot water, steam, cleaning compounds and sanitizing agents. Equipment and utensils shall be used and stored according to their designated uses.
31. Temperature shall be checked and recorded on a regular basis, and controlled in accordance with the plan by installation of indicating thermometer,

temperature-measuring device, or temperature-recording device on heating or cooling facilities.

32. Food handling equipment and facilities shall be checked regularly and kept in repair, and the results shall be maintained.

D. Refrigerator and Freezer maintenance

33. Refrigerator shall have an internal temperature of 10°C or less. (However when specific temperature guideline for storage is regulated such as for fresh foods, smoked salmon or poultry meat which shall be stored at 5°C or less or as designated.) Freezer shall be kept below -18°C, and temperature sensor shall be located where the highest temperature are detected.

E. Water Management

34. Water used for food manufacturing, processing, or washing equipment that may come into direct contact with foods and washing employees must be suitable for the standard of drinking water quality in accordance with Article 5 of the 「Drinking Water Management Act」. When using groundwater, the intake source should be managed in a manner to prevent cross-contamination of other groundwater caused by toilets, wastes, wastewater treatment facilities, breeding farms etc. and if necessary, a sanitation or disinfection device shall be installed.
35. Following examination shall be conducted for water used for manufacturing/processing and cleaning of facility, equipment, utensil, container, and employee that may contact food.
- For groundwater, examine shall be conducted in accordance with the standard for quality of drinking water more than once a year (Once a half year if groundwater is for producing directly drinking products such as beverages).
 - Test for microorganism in accordance with the standard for quality of drinking water shall be conducted more than once a month (Only when using groundwater, or when tap water is used for cleaning of raw materials or for production of non-thermal food), and it may be conducted internally using simple test kit.
36. Water storage tank and plumbing shall be made of unarmful material, locked to protect against contamination, and checked regularly for leakage and contamination.
37. Cleaning and sanitation shall be conducted for water storage tank either by employee or water-tank cleanup agency more than once a half year. The result shall be documented and maintained.
38. Each plumbing that carry drinking-water and non-drinking water shall not be cross-connected with adequate signs to distinguish.

F. Storage and Transportation

Purchasing and receiving

39. Incoming raw materials and packaging materials shall satisfy the facilities' specification by certification of analysis provided by supplier or facility's self inspection.

Supplier control

40. Operator must review supplier's sanitary condition and document the result. However, the process can be exempted when supplier is HACCP-applied business in accordance with 「Food Sanitation Act」 or 「Livestock Sanitation Management Act」.

Transportation

41. Foods shall be treated in a way to prevent contamination from delivery vehicle (including fork lift).
42. Refrigerated Delivery vehicles shall maintain its compartment temperature 10°C or below. (However when specific temperature standard for transport is regulated such as poultry meat which is between -2 and 5°C, comply with the standard.) Freezer unit shall be maintained -18°C or below, and a temperature indicating device should be attached to monitor the temperature change from the outside.
43. Raw materials and finished products shall be rotated using First-in, First-out (FIFO) method and records shall be maintained.
44. Raw materials, packaging materials, semi-finished products and finished products shall be stored separately and shall be stored off the floor and wall.
45. Non-conforming raw materials, packaging materials, semi-finished products and finished products with distinct identification attached shall be stored in designated area, and adequate action shall be taken such as return or dispose. The result shall be documented and maintained.
46. Toxic substances, flammable and/or non-edible chemical shall be stored and handled separately in a well-ventilated designated area isolated from the food handling area.

G. Inspection

Product Test

47. Product test shall be conducted by facility's own laboratory according to established test plan or by external testing agency.
48. Test results shall contain following information:
- Name of product
 - Production date or expiration date (best before date)
 - Date of test
 - Test items, criteria and results
 - Evaluation results and date

- Signature of personnel who conducted test and evaluation
- Any other required information

Inspection of facility equipment

49. Temperature control devices shall be calibrated once a year at least. Tools for inspection shall be calibrated regularly. The results shall be recorded and maintained when calibration performed by itself. The results shall be kept when calibration done by externally accredited national calibration agency.
50. Air-borne microorganism shall be tested according to established plan to maintain cleanliness of processing area. However in case the environment of processing area does not affect food product the test be may be omitted; for example if production line is automated, food is not exposed, or handled in packed condition, etc.

H. Recovery Program

- 51 A recovery program including procedures or methods that describes the steps to be taken for non-conforming or returned products shall be established and operated.
52. It is necessary to record information such as production place, date, and manufacturing line by product to identify and verify non-conforming products. Appropriate verification plan shall be established such as code display or lot management for product tracking.

II. Meal service facilities¹⁾, food service businesses (catering service businesses) and transportation of meal services (individual or bulk package)

A. Premises

Food processing area

1. Food processing area shall be located away or separated (by walls, floors, etc. into different rooms or areas) from non-food facilities.
2. The structure of processing area shall be suitable to exclude pests, rodents, water, and any other contaminants by doors, windows, walls, ceilings, etc.
3. Processing areas shall be divided into general/clean areas (clean area can be additionally divided into clean/semi-clean areas, if needed), and areas may be separated or divided according to the properties and processes of products.

Floor, wall, and ceiling

4. Floors, walls, ceilings, doors, windows, etc. of raw material handling, food manufacturing/processing, and food packaging rooms shall be constructed of

water-proof or heat-resistant materials depending on properties of products. Floors shall have no cracks and crevices, and be in a dry condition (except for moist condition of processing/manufacturing). If tiles which have grooves are used for floors, walls, ceilings, etc., they shall be maintained in a sanitary condition to prevent accumulation of dust, mold, foreign materials, etc.

Drainage and plumbing

5. Processing area shall provide adequate floor drainage without any sediments. Plumbing shall be maintained to prevent backflow.
6. The connection part between plumbing pipes shall be made of materials that are harmless to the human body and it shall be treated with a heat insulating material to avoid condensation.

Entrance

7. The entrance door connected to the outside of the food processing area shall be equipped with a buffer zone or insect repellent double doors to exclude dust or pest.
8. Work clothes wearing notices shall be posted at the entrance of each processing area. Hand-washing, drying and sanitizing facilities shall be provided, and all employees shall remove contaminants by washing, sanitizing, etc. before starting work.

Aisle

9. Employee traffic patterns shall be indicated in processing areas, and aisles shall be unobstructed.

Window

10. Raw materials and packaging materials shall be maintained in a manner that protect against contamination in case of window glass breakage.

Lighting

11. In areas where visual inspection is needed such as places where food is sorted, examined, etc., adequate lighting shall be provided (540 lux or more).
12. Skylights and light bulbs shall be corrosion-resistant. Adequate protective equipment shall be installed to prevent contamination caused by breakage or any fallen down foreign materials from skylights or light bulbs over exposed food.

Auxiliary facilities

- Restroom

13. Adequate ventilation equipment shall be provided for internal air out. Walls, floors,

ceilings and doors of restroom shall be corrosion-resistant and water-proof. Washing, drying and sanitizing equipment shall be provided at the entrance of restroom.

- Dressing room, employee break room etc.

14. Work clothes (including work shoes) shall be stored separately in a manner that protect against cross-contamination from personal clothes (including personal shoes) in dressing room.

B. Hygiene

Operation environment

- Traffic pattern plan and contamination prevention between processes

15. Plan for traffic patterns of employee and food product shall be established and observed from the receiving of the raw and subsidiary materials to distribution.
16. Hygiene program (including guidelines for entry, clothes, washing, and sanitation, etc.) for each area(General/ Clean) shall be established and implemented.

- Temperature and humidity

17. Temperature of food processing area shall be controlled for every step of process (processing, manufacturing, packaging, storing, etc.), and indicating thermometer shall be installed and maintained. If necessary, humidity shall be controlled to ensure the safety of food products.

- Ventilation facility

18. Ventilation facilities shall be installed to minimize odors and vapors (including noxious fumes, gas, and steam) in areas where they may cause food contamination.
19. Adequate screen or filter and retractable facility, etc. shall be attached to the intake and exhaust port and hood, etc. that are open from outside, and they shall be cleaned, washed or replaced in accordance with the plan.

- Pest Control

20. Processing area shall be managed to prevent infestation or propagation of pests and rodents using insect repellent and the inflow shall be checked regularly.
21. The use of insecticide or rodenticide shall be permitted only under precautions and restrictions that will protect against the contamination of food. Residues shall be removed by cleaning after extermination activities.

Personal hygiene

22. All persons working in processing area shall wear suitable, clean outer garments or

uniforms, foot wear, and hair restraints, and remove personal jewelry and cosmetic items.

Work hygiene

- Preventing cross-contamination

23. Cooking utensil, such as knives and cutting boards, containers, aprons and rubber gloves, etc. shall be used separately by food material or by designated area to prevent cross-contamination in the cooking process.
24. Food handling procedure shall be performed 60cm or above from the floor to avoid contamination.

- Preparation

25. Thawing shall be performed under running water, microwave, or refrigerated condition(1 0°C or below).
26. Once thawed, food shall be used immediately. If it is not used immediately, it shall be refrigerated condition until cooking and discard any unused parts which shall not be re-frozen.

- Cooking

27. Foods that require cooling after heated cooking shall be chilled rapidly to avoid contamination during the cooling procedure. Cooling time and duration shall be established and the record shall be maintained.
28. Only a small portion of food shall be handled at a time when handling refrigerated foods, such as cutting and subdividing, etc., so that the temperature of the food does not exceed 15°C as much as possible. After such treatment, food shall be stored in the refrigerator.

- Management of finished products

29. Temperature control during storage shall be established until served and consumed. Monitoring system for expiration date and storage condition shall be established and maintained for store-bought products.
 - Temperature 28°C or below: complete consumption within 2-3 hours after finished cooking
 - Keep food warm at 60°C: complete consumption within 5 hours after finished cooking
 - Keep food cold at 5°C or below: complete consumption within 24 hours after finished cooking

Serving

30. The temperature control standard for serving of refrigerated and heat storage foods shall be established and maintained for both.

- Stored refrigerated: refrigerated foods are kept at 10°C or less (However, in the case of foods for which the storage temperatures have been specified, such temperature shall be followed. For example, fresh-cut products and smoked salmons shall be stored at 5°C or less.)
- Stored heated: heated foods are kept at 60°C or more

31. Single-use gloves and clean utensils (tongs, ladle, etc.) shall be used. When serving foods. Do not mix the food being served with the cooked foods.

- Examination of cooked foods

32. Dietitian shall conduct an examination to check the taste, temperature, foreign substances, odor, cooking status, etc. of the cooked food just before the food is served. However, the main cook may perform the examination if dietitian is not available.

- Preserve sample

33. One portion of cooked food shall be stored in a sanitized container that is used exclusively for preserve samples or sterilized plastic bag for at least 144 hours at -18°C or less each time.

- Waste treatment and disposal

34. Operating systems for waste/waste water treatment and disposal shall be installed and operated isolated from processing area. Waste containers shall be kept in a manner that prevent odor and leaking water formed by waste. Waste shall be disposed or taken away as planned, and the records shall be maintained.

Cleaning and sanitation

35. Facilities shall have sufficient equipment for washing, disinfecting machinery, equipment, tools, and containers.

36. Guidelines or Instructions for appropriate hand-washing shall be posted on appropriate place around cleaning/sanitizing facilities for employees.

37. Standards of cleaning or sanitation shall be established for followings:

- Employees
- Work clothes, caps(hair restraints), shoes etc.
- Around processing area
- Inside of each processing area
- Freezers and refrigerators
- Water storage facilities
- Storage and transportation facilities

- Vehicles, equipment and containers for transportation
- Monitoring and testing devices
- Ventilation (including filters, screening, etc.)
- Waste disposal equipment and containers
- Cleaning and sanitizing equipment
- Any items requiring cleaning and sanitation

38. Cleaning or sanitation standards shall include :

- Cleaning or sanitation parts for each objects
- Method and frequency for each washing and/or disinfection areas
- Person in charge
- Proper instructions for washing and sanitizing equipment
- Appropriate way of use for detergent and disinfectant (general name and common name)

39. Detergent, disinfectant, cleaning/sanitizing equipment or utensils shall be stored in designated area.

40. Cleaning and sanitation shall be conducted in accordance with the plan, and the effectiveness shall be verified.

C. Management of Manufacturing, Processing facility, and treatment equipment

41. The cooking area(kitchen) shall be equipped with an ultraviolet or electric sterilizer for disinfecting kitchen utensils, or equipped with a hot-water-washing-disinfection facility (a facility where pathogenic microorganisms that cause food poisoning can be sterilized).

42. The parts that come into direct contact with food shall be made of corrosion-resistant and water proof materials that are easy to clean, and shall be adequately cleanable with hot water, steam, cleaning compounds and sanitizing agents.

43. Monitoring unit shall be cleaned and sanitized before and after each use to prevent cross-contamination.

44. Food handling units and equipment shall be inspected and maintained regularly. The results shall be stored.

D. Refrigeration and Freezer Management

45. Refrigerator, freezer and cooling chamber shall have sufficient space for storage of refrigerated food ingredients, thawing frozen food ingredients, and cooling and refrigeration of heated cooked food.

46. Refrigeration unit shall have an internal temperature of 10°C or less. (However when specific temperature guideline for storage is regulated such as for fresh foods, smoked salmon or poultry meat which shall be stored at 5°C or less, or as designated.)

Freezer shall be kept below -18°C , and temperature sensor shall be located where highest temperature is detected.

E. Water

47. Water used for manufacturing, processing and cleaning of facility, equipment, utensil, container, and employee that may contact food shall be tap water or groundwater that complies with the standard for quality of drinking water pursuant to Article 5 of the 「Drinking Water Management Act」. In case of using groundwater, its source shall be maintained in a manner to prevent contamination caused by toilet, waste and wastewater treatment facility, breeding farm, etc. If necessary, sterilizing or disinfecting equipment shall be installed.
48. Following examination shall be conducted for water used for manufacturing/cooking and cleaning of facility, equipment, utensil, container, and employee that may contact food.
 - a. For groundwater, examination shall be conducted in accordance with the standard for quality of drinking water more than once a year (Once a half year if groundwater is for producing directly drinking products such as beverages).
 - b. Test for microorganism in accordance with the standard for quality of drinking water shall be conducted more than once a month, and it may be conducted internally using simple test kit.
49. Water storage tank and plumbing shall be made of unharmed material, locked to protect against contamination, and checked regularly for leakage and contamination.
50. Cleaning and sanitation shall be conducted for water storage tank either by employee or water-tank cleanup agency more than once a half year. The result shall be documented and maintained.
51. Each plumbing that carry drinking-water and non-drinking water shall not be cross-connected with adequate signs to distinguish.

F. Storage and Transportation

Purchasing and receiving

52. Incoming raw materials and packaging materials shall satisfy the facilities' specification by certification of analysis provided by supplier or facility's own inspection
53. Non-conforming raw materials and packaging materials shall be returned or disposed of in accordance with proper procedure.
54. The inspection zone shall be secured for receiving inspection, and the inspection stand shall be equipped with necessary equipment, such as a thermometer, and maintain cleanliness.
55. Inspection of raw materials and packaging materials shall be carried out immediately upon delivery, and if the inspection is delayed, it shall be kept at the refrigerated and

frozen temperature determined for each raw and packaging material.

Transportation

56. Foods shall be treated in a way to prevent contamination from delivery vehicle (including folk lift).
57. Refrigerated delivery vehicles shall maintain its compartment temperature 10°C or below. Freezer unit shall be maintained -18°C or below, and a temperature indicating device shall be attached to monitor the temperature change from the outside.
58. Foods being transported shall be handled separately from non-food, etc. to prevent cross-contamination.
59. Vehicles, equipment and containers that are used for transportation shall be washed and sanitized in accordance with the plan.

Storage

60. Raw materials and finished products shall be rotated using First-in, First-out (FIFO) method and records shall be maintained.
61. Raw materials, packaging materials and finished products shall be stored separately and shall be stored off the floor and wall.
62. Raw materials and packaging materials shall be covered or packed. Raw food and heated food shall be stored separately to prevent cross-contamination.
63. Raw materials and packaging materials that do not comply with the inspection criteria, products that have exceeded the expiration dates during storage and products with damaged packaging shall be stored with clearly identifiable markings in a separate designated place. After taking measures such as returning and discarding these products, the results shall be recorded and maintained.
64. All toxic chemicals, flammable materials, and inedible chemicals shall be handled and stored separately from food handling area with adequate ventilation.

G. Test

Product test

65. Product test shall be conducted by facility's own laboratory according to established test plan or by external testing agency.
66. Test results shall contain following information:
 - ・ Name of product
 - ・ Production date or expiration date (best before date)
 - ・ Date of test
 - ・ Test items, criteria and results
 - ・ Evaluation results and date

- Signature of personnel who conducted test and evaluation
- Any other required information

Test for facility, equipment, device, etc.

67. Calibration shall be performed more than once a year for temperature-measuring devices of refrigerator, freezer, heating facility, etc., and regularly for other measuring devices. The result shall be recorded and maintained in case of internal calibration, and the calibration report shall be maintained in case of calibration through accredited agency.
68. Air-borne microorganism shall be tested according to established measurement and management plan to maintain cleanliness of processing area. However, in case of the processing area where food is not exposed or handled in packed condition, the test be may be omitted.

H. Recovery plan (only for packaged products distributed and sold on the market)

69. The business operator shall document and keep the business name and contact information necessary to recall the product by identifying the distribution route, targeted consumer and scope of seller of the product.
70. A Recovery plan including procedures or methods that describes the steps to be taken for non-conforming or returned products shall be established and implemented.
71. Product verification information such as place and date of production, production line, etc. shall be documented and maintained. For the traceability, adequate plan such as lot control shall be established.

III. Other food sales business

A. Reception (unloading, inspection)

1. Only foods that meet the facility's own receiving standards and specification shall be received. The following shall be confirmed for each food group.
 - Agricultural/forest/fishery products and their simply treated products : deterioration, freshness, labelling, etc.
 - Processed foods : Appearance status, such as Labelling, damaged packaging, etc.
 - Refrigerated or frozen foods : Monitor transportation temperature (5°C or less for fresh-cut products and smoked salmon, 10°C or less for refrigerated foods, -18°C or less for frozen foods, checking the temperature record of the transport vehicle, etc.)

B. Storage

2. Refrigerated and frozen food shall be stored at an appropriate temperature as soon as they

are received, and they shall not be left outside.

3. Unpackaged agricultural/forest/fishery products, etc. shall be stored separately to avoid cross-contamination.
4. Stored food shall be loaded on a pedestal so that does not touch the floor and wall directly.
5. The temperature of the refrigerated warehouse shall be kept at 10°C or less (However, in the case of foods for which the storage temperatures have been specified, such temperature shall be followed. For example, fresh-cut products and smoked salmons shall be stored at 5°C or less.), and the temperature of the freezer shall be kept at -18°C or less.
6. The cooling rod of the temperature device installed in the refrigerated warehouse and freezer shall be placed at the location where the highest temperature is measured from the coolant source.
7. Refrigerating and freezing facility and equipment shall be checked and kept in repair in accordance with the plan, and the result shall be recorded and maintained.
8. Non-conforming foods (defective or damaged foods or foods with damaged label, etc.) shall be clearly labelled and then stored.

C. Work management (Processing area for agricultural/forest/fishery products)

Personal hygiene

9. Washing and sanitizing facilities shall be installed in the processing area for personal hygiene control of employees.
10. Personal hygiene guidelines including work access, uniform, washing and sanitation for employees shall be established and maintained.
11. Hand-washing instruction shall be posted where visible to employees in washing station.
12. Employees in processing area shall wear suitable, clean outer garments or uniforms, foot wear, and hair restraints, and remove personal jewelry and cometic items.
13. Employees with the disease or has the risk of the disease which unable the engagement in the businesses as prescribed by the 「Enforcement Rule of the Food Sanitary Act」 are not be allowed to work. Health examination shall be conducted at least once a year under the 「Food Sanitation Act」 or 「Code of practice: Guidelines for Employees of Sanitary Sectors」. However, those who engage in transporting or selling completely packaged foods are exempted.

Access of processing area

14. Washing and sanitizing facilities shall be provided at the entrance of processing area for person hygiene control, and the entrants shall remove any contaminant through washing, sanitizing, etc. before entering the processing area.

Hygienic management of facility, equipment, tools and processing area

15. The structure of processing area shall be suitable to exclude pests, rodents, water, and any other contaminants by doors, windows, walls, ceilings, etc.
16. Facilities or equipment for cleaning and sanitizing of equipment and containers shall be installed inside the processing area.
17. The processing area, tools, etc. shall be cleaned and sanitized regularly in accordance with the internally established plan.
18. Ventilation facilities shall be installed to remove odors generated in the processing area.
19. Processing area shall maintain an appropriate temperature and be equipped with a thermometer to measure it.
20. Processing area shall establish a management plan for pest control and check for pest inflow on a regular basis.
21. In case the groundwater, not tap water, is used for washing foods or used as washing water for employees, work tools etc, it shall comply with the standard for quality of drinking water pursuant to Article 5 of the 「Drinking Water Management Act」. Inspection should be conducted at least once a year, and it shall be inspected at least once a year.
22. Operating systems for waste treatment and disposal shall be installed and operated isolated from processing area. Waste containers shall be kept in a manner that prevent odor and leaking water formed by waste. Waste shall be disposed or taken away as planned, and the records shall be maintained.
23. The lighting facilities in the processing area shall be equipped with protective device, etc. to prevent them from being mixed into the product in case of breakage.

Hygiene during processing

24. Work tools, such as knives, cutting boards, and storage containers directly in contact with food, such as cutting and storing of agricultural/forest/fishery products, etc., shall be used separately by color, and shall be kept clean after washing and sanitation at the completion of work.
25. Employees in the processing area shall wash their hands and change aprons, etc. frequently before, during and after the work.

D. Packaging

26. Agricultural/forest/fishery products processed for direct consumption shall be managed hygienically to prevent contamination from foreign substances or pathogenic microorganisms during packaging.
27. When packing agricultural/forest/fishery products, the packing date or shelf life shall be indicated, and the packing date or shelf life shall not be arbitrarily changed.

E. Displaying and sales management

28. Processed food, etc. with a specified storage temperature shall be displayed and sold in accordance with the specified storage standards. Those foods (agricultural/forest/fishery products) whose storage temperature is not separately specified shall comply with the storage standards set by themselves.
29. A thermometer shall be installed on display shelves for refrigerated and frozen foods, and refrigerated food shall be kept at 10℃ or less (However, when specific temperature standard for storage is regulated such as fresh-cut products, smoked salmon, or poultry meat which shall be stored 5℃ or less, comply with the standard.), and frozen food shall be kept at -18℃ or less.
30. Display shelves for refrigerated and frozen foods shall be loaded according to their capacity and shall be cleaned and sanitized periodically.
31. Non-conforming foods (defective, damaged foods or foods with damaged label, etc.) shall not be sold or displayed for sale. Foods shall not be displayed or sold past the expiration date or the sell-by date set by the business, etc.
32. Water and ice for display in aquarium shall comply with the recommended standards for microorganisms for food service businesses in Chapter 5 of Food Code.
33. Cooking utensils, etc. used for tasting shall be cleaned and sanitized before and after use, and shall be kept hygienically in a separate place.

F. Return process and Recovery

34. If there is a consumer's request for return or exchange of non-conforming food (defective, damaged foods or foods with damaged label, etc.), actions shall be promptly taken in accordance with the relevant regulations.
35. Return procedures for non-conforming foods (defective or damaged foods or foods with damaged label, etc.) shall be determined and managed.
36. Risk information related to recovery shall be collected periodically, and ensure that the relevant food products are not sold and measures are taken promptly in accordance with the relevant regulations.

IV. Small Businesses, etc.

1. The processing area shall be managed hygienically to prevent the inflow of contaminants and pests from outside.
2. Processing areas shall be divided into general/clean areas (clean area can be additionally divided into clean/semi-clean areas according to the characteristics of food). In this case, the additional facilities, such as toilet rooms, shall be separated so as not to affect the work area.
3. Employees shall remove foreign objects by using foreign object removal tools when entering

the processing area, and must not carry personal items such as personal jewelry and cosmetic items

4. Employees must clean and sanitize their hands, foot wear, etc. and wear clean work clothes when entering the processing area.
5. The number of rodents and bugs captured by bug Zapper, rat traps, insect trapping tapes, etc. shall be checked at a regular interval.
6. The inside of processing area shall be cleaned and sanitized in accordance to the plan.
7. Drainage and any parts of manufacturing facilities and tools directly in contact with food during shall be cleaned and sanitized according to the planned as planned schedule.
8. In the event of consumer complaints related to food safety, such as contaminants or foreign substances, etc., corrective action shall be implemented, and measures shall be taken in accordance with the requirements prescribed by the 「Food Sanitation Act」, such as recording and maintaining the results.
9. Monitoring tools (such as thermometers) that come into direct contact with food shall be cleaned and sanitized before and after use.
10. Manufacturing equipment that are damaged or not operating correctly shall not be used, and shall be managed in accordance with the facility standards set by the 「Food Sanitation Act」. In such cases, compressed air, lubricants, etc. used in manufacturing process which may directly affect or are likely to affect the product shall be managed hygienically by establishing a management plan to prevent contamination from hazards.
11. Thermometers in heaters and refrigerated warehouse and freezer shall be inspected and calibrated on a regular basis.
12. The temperature of a temperature-controlled warehouse such as cold and frozen storage shall be properly managed.
13. Water used for manufacturing, processing, cooking, sorting and treating, and cleaning of facility, equipment, utensil, container, and employee that may contact food shall be tap water or groundwater that complies with the standard for quality of drinking water pursuant to Article 5 of the 「Drinking Water Management Act」. If necessary, sterilizing or disinfecting equipment shall be installed. In addition, if a water storage tank is installed and used, it shall be cleaned and sanitized on a regular basis.
14. Upon receipt of raw materials and packaging materials, the test report shall be reviewed or a visual inspection shall be conducted.
15. Raw and packaging materials, semi-finished and finished products shall be loaded and stored in a designated place so that they do not adhere to the floor or wall, and shall be managed to prevent cross-contamination and stay clean.
16. Food and live stock products in transit shall be separated from non-food products to prevent cross-contamination, and shall be maintained and managed at 10℃ or lower for refrigeration and -18℃ or below for frozen items. (however, a specified standards for

poultry to deliver at -2~5℃ shall be followed detailed standards.)

17. The inspection of the finished products shall be carried out according to a planned schedule. Only the products conforming to the standards and specifications shall be manufactured and sold. Recovery management of non-conforming products shall be performed.