Guidelines on Management and Operation Standards to be Observed by Food-Related Business Operators

(Annex to Notice Shoku-an No. 0227012 of February 27th, 2004. Final revision; Notification No. 1 of Shoku-an 1014, as of October 14, 2014)

The management and operation standards to be observed by food-related business operators are to be one of those listed in the following items.

I Standards when using the hazard analysis and critical control point method

Section 1 Sanitary management upon harvesting agricultural and marine products

Upon harvesting agricultural and marine products for human consumption, the following managements shall be conducted.

(1) Measures shall be taken to prevent contamination caused by dirt, soil or waste water, as well as to prevent contamination with agricultural chemicals, veterinary drugs, feedstuff, fertilizers, and feces by appropriately managing wastes and poisonous substances.

(2) Segregate what is unsuitable for human consumption.

(3) Dispose of wastes (including waste water) in a way that does not affect sanitation.

(4) Upon harvesting, storing, and transporting, measures shall be taken to prevent contamination from rodents, insects, chemical substances, foreign matter (such as glass and metal fragments which can be of potential harm to the human; the same shall apply hereinafter), and microorganisms.

(5) Prevent the decomposition and deterioration of food using temperature and humidity control and other necessary measures.

(6) Facilities are maintained clean and appropriately with cleaning and appropriate repair.

(7) Sanitary management of personnel who are handling agricultural and marine products for human consumption shall be conducted.

(8) Water used for washing shall be microbiological and chemically suitable for their intended use.

Section 2 Sanitary management in food handling facilities

1 General matters

(1) Sanitary management including daily inspections shall be conducted according to a plan.

(2) Taking into consideration the structures and materials of the facility equipment and machinery utensils as well as the characteristics of the food to be handled, an appropriate method of cleaning, washing, and disinfecting these items shall be established and a procedure manual shall be prepared as necessary.

Upon preparation of the procedure manual, for the procedure of cleaning, washing, and disinfecting, necessary items such as the place to be cleaned or washed, machinery utensils, operating manager, method and frequency of cleaning and washing, and method of confirmation shall be described, and opinions of experts shall be consulted as necessary.

(3) The method of cleaning, washing, and disinfecting provided in (2) shall be
evaluated as necessary whether it is appropriate and effective.

(4) Food shall be handled depending on facility, equipment and human capacity, and appropriate order management shall be conducted.

2 Sanitary management of the facility

(1) The facility and surrounding areas shall be cleaned regularly and it shall be maintained so as not to affect sanitation at all times while the facility is under operation.

(2) Unnecessary objects shall not be placed in the areas of production, processing, preparation, cooking, storing, and sales.

(3) The inner walls of the facility, ceilings, and floors shall be kept clean at all times.

(4) Lighting, illumination, and ventilation inside the facility shall be sufficient, and the temperature and humidity shall be controlled appropriately as necessary.

(5) Windows and entrances shall not be left open. If they must be left open, measures shall be taken to prevent dirt, rodents, and insects from entering.

(6) Wastes shall be prevented from going down the water drain so the waste water will flow out well, and the drain shall be cleaned and repaired.

(7) Lavatories shall be kept clean at all times and cleaning and disinfecting shall be conducted regularly.

(8) Animals shall not be kept inside the facility.

3 Sanitary management of the food handling equipment

(1) In order to maintain sanitation, use machinery utensils (including machinery utensils for cleaning) according to their intended purpose.

(2) To prevent contamination of foods with metal fragments, dirty foreign matter, and chemical substances, machinery utensils and the machinery utensil parts which have been dismantled shall be washed and disinfected, and stored in its designated place in a sanitary manner. When broken or damaged, it shall be promptly repaired and kept maintained for appropriate use at all times.

(3) When detergent is used for washing machinery utensils and machinery utensil parts, the proper detergent shall be used at a proper concentration.

(4) Instruments such as thermometers, pressure gauges, and flow meters and equipment used for sterilization, killing bacteria, disinfecting, or water purification shall be inspected regularly for its functions and the results shall be documented.

(5) Wash cloths, knives, cutting boards, and protective gear shall be disinfected with hot water, steam, and disinfectants and then dried. In particular, cutting boards, knives, and protective gear which come into direct contact with food shall be fully washed and disinfected after each contamination or after working.

(6) Extra care shall be taken for the handling of detergents, disinfectants, and chemical substances, such as its use and storage, and the contents shall be shown on the container when necessary to prevent its contamination of foods.

(7) Cleaning utensils of the facility equipment shall be washed with each use, dried, and stored in its designated place.

(8) Hand washing equipment shall be maintained so that washing and drying of the hands and fingers can be performed appropriately, as well as being able
to provide sufficient water, and supplied with soap appropriate for hand
washing, nailbrushes, paper towels, and disinfectants, and in a condition in
which it can be used at all times.

(9) Washing equipment shall be kept clean at all times.
(10) In food irradiation operations, radiation dosage shall be checked more than
once a day using chemical dosimeters and the record of the results shall be
retained for 2 years.

4 Management of water used
(1) The water used in the food handling facilities shall be potable water.
This may not apply to the following cases, but such water shall be prevented
from contaminating the water which comes in direct contact with food.
   i) Use for purposes not directly related to food production, such as steam
      heating and firefighting.
   ii) Use of clean sea water for cooling or a process not affecting food
      safety.
(2) When using water other than tap water, a water quality inspection shall be
conducted more than once a year (more than once in 4 months for freezing
or refrigeration operations of food and margarine or shortening production
operations (not including those which exclusively conduct shortening
production) or edible oil production operations), and the results shall be
retained for more than 1 year (or the relevant period when the distribution
period of the food in question is more than 1 year in consideration of its
best-before date).
However, when the water source may have been contaminated due to
unforeseen disasters, a water quality inspection shall be conducted at each
time.
(3) When the water is determined to be unsuitable for drinking as a result of the
water quality inspection, immediately terminate its use and appropriate
measures shall be taken based on instructions from the director of the public
health center.
(4) When using water reservoirs, it shall be cleaned regularly and kept clean.
(5) When using water other than tap water such as well water and private water
supplies, the sterilization device or the water purification device shall be
checked regularly to be working properly and documented.
(6) Ice shall be made from potable water supplied by an appropriately managed
water supply system.
   Ice shall be handled and stored in a sanitary manner.
(7) When reusing water, necessary treatment shall be performed so food safety
is not affected, and the treatment process shall be appropriately managed.

5 Measures against rodents and insects
(1) Breeding sites of rodents and insects shall be eliminated by appropriately
maintaining the facility and surrounding areas in good condition at all times,
and rodents and insects shall be prevented from entering inside the facility
by installing wire screens on windows, doors, inlets and exhaust outlets and
traps and covers of water drains.
(2) Extermination of rodents and insects shall be conducted at least twice a year
and the records shall be retained for 1 year. However, if the method is able to
infallibly achieve the goal with measures based on the combination of
effective and appropriate technologies possible for the building and the
habitation research results of the rodents and insects, it can be conducted
in the method and frequency depending on the condition of the facility. When
rodents or insects are found, they shall be exterminated immediately to
avoid effect on foods.

(3) When rodenticides or insecticides are used, they shall be handled with
adequate care to prevent contamination of foods.
(4) In order to prevent contamination caused by rodents or insects, raw
materials, products, and packaging materials shall be placed in containers
and stored away from the floor and walls. Items that have been opened shall
be stored by taking measures to prevent contamination such as storing in
containers with lids.

6 Handling of wastes and waste water
(1) A procedure manual shall be prepared for the method of storage and
disposal of wastes.
(2) Waste containers shall be able to be clearly distinguished from other
containers and kept clean at all times to prevent leakage of waste fluids or
foul odors.
(3) Wastes shall not be stored in areas where food is handled or stored
(including adjacent areas) provided it does not interfere with work.
(4) The storage of wastes shall be appropriately managed so that there is no
negative impact on the surrounding environment.
(5) Wastes and waste water shall be disposed of appropriately.

7 Appointing a food sanitation supervisor
(1) The business person (not including a business person who must appoint a
food sanitation manager in accordance with the provisions of Article 48 of
the Food Sanitation Act (Law No. 233 of 1948); hereinafter the same shall
apply in this paragraph) shall establish a supervisor regarding food
sanitation (hereinafter referred to as “food sanitation supervisor”) for the
facility or for every department from the relevant food handlers and persons
involved.
(2) The food sanitation supervisor shall regularly attend seminars conducted by
the prefectural governor, mayor of the designated cities, or mayor of the core
cities (hereinafter referred to as “governors”) or seminars which are
approved as appropriate by the governors, and endeavor at all times to
acquire new knowledge regarding food sanitation.
(3) The food sanitation supervisor shall follow the instructions of the business
person for sanitary management.
(4) The food sanitation supervisor shall pay necessary attention to the method
of sanitary management of the facility and issues regarding food sanitation,
and endeavor to provide opinions to the business person in order to prevent
food sanitation hazards.
(5) The business person shall respect the opinions of the food sanitation
supervisor prescribed in (4).

8 Organization of a team to conduct sanitary management using the hazard
analysis and critical control point method
When conducting sanitary management using the hazard analysis and critical
9 Preparation of product manuals and production process charts
(1) Product manuals for the products describing the composition of the raw materials, physical and chemical characteristics (water activity and pH), sterilization and bacteriostatic treatment (heating treatment, freezing, salting, and smoking), packaging, preserving property, and necessary items regarding safety of storage conditions and method of distribution shall be prepared. Possible methods of use and consumer demographics shall be described in the product manuals.
(2) Production process charts describing all of the production processes for the products shall be prepared.
(3) The production process chart shall be compared against the actual production process and the layout of the facility equipment to confirm whether it is appropriate or not, and when inappropriate, the production process chart shall be revised.

10 Handling of foods
With the following method, all of the underlying substance which may cause hazards in the food production process shall be listed, and the substances which may cause hazards identified by the hazard analysis shall be managed.
(1) A list of all of the substances which may cause hazards that may occur for each production process (hereinafter referred to as “list of causes of hazards”) shall be prepared, and with consideration to the possibility of being hazardous to the health and the product properties described in 9 (1), substances which may cause food sanitation hazards in each production process shall be identified.
(2) For the substances which may cause food sanitation hazards identified in (1), measures to prevent the relevant substances which may cause food sanitation hazards and the relevant hazards from occurring (hereinafter referred to as “control measures”) shall be investigated for each process in which hazards may occur, and described in the list of causes of hazards.
(3) In order to prevent hazards from occurring due to the substances which may cause hazards identified in the list of causes of hazards, the production processes in which the implementation status of the control measures associated with the relevant process need to be checked continuously or at a fair frequency (hereinafter referred to as “monitoring”) shall be determined (hereinafter referred to as “critical control point”), and when a critical control point is not determined, a document stating the reason shall be prepared. Consideration shall be taken for the possibility that there may be multiple critical control points to control the same substance which may cause hazards.
hazards. Upon determining the critical control point, if the control measures of the critical control point to be determined cannot adequately control the substances which may cause hazards, the product or the production process shall be reviewed so that appropriate control measures can be set at the relevant critical control point or the process before or after.

(4) For individual critical control points, criteria in order to reduce to an acceptable range or eliminate the substances which may cause hazards (hereinafter referred to as “control criteria”) shall be established. The control criteria is a criteria regarding substances which may cause hazards to be determine whether they are acceptable or not, and shall consist of temperature, time, moisture content, pH, water activity, effective chlorine, as well as measurable indexes or sensual indexes such as appearance and texture.

(5) Methods of confirmation of the compliance with the control criteria and the monitoring to prevent the shipment of products which passed through production processes not compliant with the control criteria shall be established and conducted at an adequate frequency. All records of the method of monitoring shall be signed by the person in charge of the monitoring and the supervisor.

(6) Measures which shall be taken when control measures regarding the critical control point is found upon monitoring not to be properly taken (hereinafter referred to as “improvement measures”) shall be established for the critical control point and appropriately conducted. Improvement measures also include the appropriate disposal of products which were affected by not complying with the control criteria.

(7) Verification to confirm that food sanitation hazards are appropriately prevented shall be conducted at an adequate frequency for the hazard analysis and critical control point method of the product.

11 Preparation of the management and administration outline
   (1) A management and administration outline for the sanitation regarding the facility and the handling of foods shall be prepared and food handlers and relevant parties shall be kept informed.
   (2) By conducting wiping examinations regularly and checking the sanitation condition of the facility, the effect of the management and administration outline prepared in (1) shall be verified, and if necessary, the contents shall be reviewed.

12 Preparation and retention of records
   (1) Records on the hazard analysis of 10 (1) and (2), the determination of the critical control point of 10 (3), and the determination of the control criteria of 10 (4) shall be prepared and retained.
   (2) Records on the verification of the monitoring of 10 (5), improvement measures of 10 (6) and 10 (7) shall be prepared and retained.
   (3) The records regarding suppliers, conditions of production or processing, shipment or sales customers, and other necessary items for the foods handled shall be prepared and retained when possible, as necessary for the prevention of food sanitation hazards.
   (4) The record retention period shall be determined reasonably according to the actual distribution conditions of the foods handled (expiration or best-before
dates).

(5) Relevant records shall be submitted when the national government or prefectures requests to prevent food sanitation hazards such as food poisoning.

13 Recall and disposal
(1) Upon the occurrence of food sanitation issues resulting from food for sale, from the viewpoint of preventing health hazards of consumers from occurring, the responsibility system regarding the recall, the specific method of recall, and the reporting procedures to the public health center under the jurisdiction of the area where the relevant facility is located shall be determined, so as the product of concern can be recalled quickly and properly.

(2) Upon the occurrence of food sanitation hazards resulting from food for sale, the disposal and other necessary measures regarding the recalled product shall be performed accurately and quickly.

(3) The relevant product being recalled shall be stored where it is clearly distinguished from normal products, and appropriate measures such as disposal shall be taken according to the instructions of the public health center.

(4) Upon recalling, public announcements regarding the relevant recall shall be considered as necessary, in order to notify the consumers.

14 Conducting food inspection
(1) Among restaurant business operations, lunchers and caterers shall store samples for each raw material and cooked food for more than 48 hours (provided, however, that if the 48 hours extend across Sunday, a national holiday, a substitute holiday, or a non-business day, they shall be kept until the day following that Sunday, national holiday, substitute holiday, or non-business day).

Raw materials shall not be washed or sterilized and be kept in the condition which it was purchased.

(2) In the above case, the delivery address, time, and amount of the products shall be documented and records shall be retained.

15 Providing information
(1) Information regarding the safety of food for sale shall be provided to the consumers when possible.

(2) Information on health hazard claims from consumers regarding food products which were produced, processed, or imported (cases in which the physician diagnoses that the relevant symptoms are or suspected to be caused by food products which were produced, processed, or imported) and foods which are in violation of the Food Sanitation Act shall be promptly reported to the public health center.

(3) Complaints received from consumers, etc., about cases that involve abnormal taste, abnormal odour, foreign matter contamination, etc. of food products produced, processed, or imported, and pose possible health risks shall be promptly reported to the public health center.

Section 3 Sanitary management of the food handler in food handling facilities
(1) The medical checkup of the food handler shall be performed in regards to the health conditions necessary for food sanitation.

(2) If a public health center requests to have a stool examination conducted, the food handler shall be made to take the examination.

(3) Food handlers who show the following symptoms shall inform the food-related business operator, food sanitation manager, or the food sanitation supervisor, shall not engage in food handling operations, and shall visit a physician for a diagnosis.
   i) Jaundice
   ii) Diarrhea
   iii) Abdominal pain
   iv) Fever
   v) Sore throat with fever
   vi) Skin wounds which are suspected of infection (burns and cuts)
   vii) Discharges from the ear, eye or nose (limited to those that are pathological)
   viii) Nausea and vomiting

When having a person with a skin wound and not applicable to above vi) engage in work, the relevant region shall be covered with a waterproof cover.

(4) When food handlers are found to be an infectious disease patient or a disease carrier who has no symptoms prescribed in paragraph 1 under Article 18 of the Act on Prevention of Infectious Diseases and Medical Care for Patients with Infections Diseases (Act No. 114 of 1998), based on paragraph 2 of the same article, they shall not engage in work which comes in direct contact with food.

(5) Food handlers shall wear a sanitary uniform, cap, and mask, and use shoes exclusive for the work space not to be worn in the contaminated area (including rest rooms). Accessories such as rings, wrist watches, hair pins, and safety pins shall not be taken inside the food handling facilities.

(6) Food handlers shall not, in principle, wear gloves in which the portion of the glove directly touching the ingredients is fiber and other material which are difficult to wash and disinfect.

(7) Food handlers shall cut their nails short at all times and shall not polish their nails. Hands and fingers shall always be adequately washed and disinfected before work, after using the rest rooms, and after handling fresh raw materials or contaminated materials, and disposable gloves shall be changed when they are used.

It is preferable that foods which are eaten unheated are not handled after handling fresh raw materials or contaminated materials.

(8) Food handlers shall refrain from the following actions during food handling work.
   i) Touching the hair, nose, mouth, or ears with the hands or utensils for handling food
   ii) Spitting or coughing out saliva during work
   iii) Smoking
   iv) Eating or drinking in a food handling area
   v) Sneezing or coughing over unprotected food

Food handlers shall not change their clothes, smoke, and eat or drink
outside the designated area.

(9) When persons other than food handlers enter the facility, they shall change their clothes to a clean and exclusive uniform and observe the provisions for the sanitary management of the food handlers shown in this section.

Section 4 Education and training for food handlers in food handling facilities

(1) Food-related business operators, food sanitation managers, or food sanitation supervisors shall conduct sanitation education toward food handlers and relevant parties regarding necessary items for food sanitation, such as the sanitary handling methods of foods, methods to prevent food contamination, and appropriate hand washing methods, so that the production, processing, cooking, and sales are done in a sanitary manner.

(2) This sanitation education shall include items regarding the procedures described in above Section 2 (1 (2), 6 (1), 10, 11, 13 (1)).

(3) Education and training on its safe handling shall be conducted especially for those who handle chemical substances such as detergents.

(4) The effects of education and training shall be evaluated regularly and the programs shall be revised as necessary.

Section 5 Transportation

(1) Vehicles and containers used for transporting foods shall not be those which will contaminate foods, containers, or packages. By using those with a structure in which washing and disinfecting can be easily done, keeping clean at all times, and performing repairs, it shall be kept in an appropriate condition.

(2) When foods and cargo other than foods are mixed, in order to prevent contamination from the cargo other than foods, foods shall be put in an appropriate container and separated from the other cargo as necessary.

(3) Foods shall be managed during transportation so that there is no contamination from dirt or toxic gases.

(4) When vehicles or containers once used for transporting different commodity items of food or cargo other than foods is used again, they shall be washed in an effective method and disinfected as necessary.

(5) When transporting in bulk, vehicles or containers exclusively for foods shall be used, if necessary. In this case, vehicles or containers shall be clearly marked as being exclusively for foods.

(6) Attention shall be paid to the management of temperature, humidity, and other conditions during transportation.

(7) Attention shall be paid to the delivery route and the management of time so that delivery time does not extend to long hours.

(8) Attention shall be paid to making the delivery time appropriate for box lunches, such as delivering in consideration to the expected time to eat.

Section 6 Sales

(1) Appropriate sales shall be conducted, such as purchasing stock according to the expected sales volume.

(2) Attention shall be paid to the sanitary management of products so as not to expose products to direct sunlight or conduct sales under inappropriate temperature for a prolonged period of time.
II Criteria when conducting sanitary management without using the hazard analysis and critical control point method

Section 1 Sanitary management upon harvesting agricultural and marine products
This shall be in accordance with Section 1 in I.

Section 2 Sanitary management in food handling facilities
1 General matters
This shall be in accordance with 1 of Section 2 in I.
2 Sanitary management of the facility
This shall be in accordance with 2 of Section 2 in I.
3 Sanitary management of the food handling equipment
This shall be in accordance with 3 of Section 2 in I.
4 Measures against rodents and insects
This shall be in accordance with 5 of Section 2 in I.
5 Handling of wastes and waste water
This shall be in accordance with 6 of Section 2 in I.
6 Handling of foods
   (1) Upon purchasing raw materials, those managed appropriately shall be purchased, and the quality, freshness, and labeling shall be checked from a sanitary point of view and the results shall be documented when possible. No raw materials shall be accepted if it is known to contain parasites, pathogenic microorganisms, agricultural chemicals, veterinary drugs, poisonous substances, decomposed matter, deteriorated matter, or foreign matter which cannot be eradicated or removed to an acceptable level by normal processing and cooking.
   (2) For foods which will be used as raw materials, those that are appropriate shall be selected, and shall be processed after pretreatment as necessary. Preservation shall be done in conditions and methods which are appropriate for the relevant food.
   (3) The inside of the refrigerator (room) shall be partitioned for preservation to prevent contaminating one another.
   (4) When using additives, they shall be weighed precisely and used properly.
   (5) In the production, processing, or cooking of the foods, pathogenic or other microorganisms and their toxins shall be eradicated or removed completely or to a safe level.
   (6) Foods shall be handled in a sanitary manner with sufficient consideration to the time and temperatures of each process of cooking, production, storing, transportation, and sales, such as preserving with refrigeration according to the characteristics of the relevant product (water activity, pH, and microorganism contamination conditions), expiration or best-before dates, method of production and processing, package presentation, and usage method such as eating it raw or cooked.
   (7) The following processes which are considered to particularly affect food sanitation shall be managed with sufficient consideration.
      i) Cooling
      ii) Heating
      iii) Drying
      iv) Use of additives
v) Vacuum cooking or gas flush packaging
vi) Irradiation

(8) In order to prevent foods from contaminating one another, the following points shall be taken into consideration.
i) Unheated or unprocessed raw materials shall be handled separately from foods to be eaten raw.

ii) No one except food handlers who work in the areas of production, processing, or cooking shall enter the relevant areas (provided, however, that this may not apply if there is no possibility of food contamination with the entry of persons other than the relevant food handler).

Persons entering these areas shall go to a dressing room when necessary to change into sanitary clothes and shoes and wash their hands.

iii) Equipment and machinery utensils which have handled unheated foods such as meat shall undergo necessary washing and disinfecting prior to handling other foods.

(9) Upon storage of raw materials (especially fresh goods), consideration shall be taken so that they are used in proper order according to expiration date (so-called first-in first-out order).

(10) Utensils, containers, and packages which protect the products from contamination or damage and can be properly labeled shall be used. For utensils, containers, and packages able to be reused, those which are easy to wash and disinfect shall be used.

(11) The following items shall be implemented when possible for the production or processing of foods.
i) Measures shall be taken to prevent contamination of raw materials and products with foreign matter such as metals, glass, dirt, detergents, and chemical substances such as machine oil, and inspections shall be conducted when necessary.

ii) Raw materials, products, containers and packages shall be managed and documented according to lot.

iii) Product manuals describing the characteristics, procedures for production and processing, and raw materials for each product shall be prepared and retained.

iv) Meat which are cut and sliced shall be checked for contamination with foreign matter. When foreign matter is found, dispose of the portion which is possibly contaminated.

v) Measures shall be taken to prevent contamination with allergenic substances which are not used as raw materials during the production process.

(12) Voluntary inspections on raw materials and products shall be conducted to check compatibility with the specifications and standards, and results shall be documented when possible.

(13) Foods which are possibly contaminated with vomited matter shall be disposed of.

(14) When vomiting occurs in the facility, immediately disinfect properly using disinfectants.

7 Management of water used
This shall be in accordance with 4 of Section 2 in I.

8 Appointing a food sanitation supervisor
This shall be in accordance with 7 of Section 2 in I.

9 Preparation and retention of records
   (1) The records regarding suppliers, conditions of production or processing, shipment or sales customers, and other necessary items for the foods handled shall be prepared and retained when possible, as necessary for the prevention of food sanitation hazards.
   (2) The record retention period shall be determined reasonably according to the actual distribution conditions of the foods handled (expiration or best-before dates).
   (3) Relevant records shall be submitted when the national government or prefectures requests to prevent food sanitation hazards such as food poisoning.
   (4) When voluntary inspections of produced and processed products are conducted, the records of inspection shall be kept when possible.

10 Recall and disposal
This shall be in accordance with 13 of Section 2 in I.

11 Preparation of the management and administration outline
This shall be in accordance with 11 of Section 2 in I.

12 Conducting food testing
This shall be in accordance with 14 of Section 2 in I.

13 Providing information
This shall be in accordance with 15 of Section 2 in I.

Section 3 Sanitary management of the food handler in food handling facilities
This shall be in accordance with Section 3 in I.

Section 4 Education and training for food handlers in food handling facilities
This shall be in accordance with Section 4 in I.

Section 5 Transportation
This shall be in accordance with Section 5 in I.

Section 6 Sales
This shall be in accordance with Section 6 in I.