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)

I Hygiene control in harvesting agricultural, livestock and fishery products

When harvesting agricultural, livestock and fishery products for human consumption, food-related business operators should conduct the following control.

- (1) Measures should be taken to prevent contamination caused by dirt, soil or waste water, as well as measures to prevent contamination agricultural chemicals, veterinary drugs, feedstuffs, fertilizers, faecal and other substances, by appropriately managing wastes, poisonous substances, etc.
- (2) Things apparently unfit for human consumption should be segregated.
- (3) Wastes (including waste water) should be disposed of in a way that does not affect the environment.
- (4) When harvesting, storing and transporting agricultural, livestock and fishery products, measures should be taken to prevent contamination rodents, insects, chemical substances, foreign matter, micro-organisms, etc.
- (5) Measures such as the control of temperature and humidity and other necessary measures should be taken to prevent decomposition or deterioration of food, etc.
- (6) Establishments and facilities should be maintained cleanly and properly through cleaning and appropriate repair.
- (7) Hygiene control should be performed for persons handling agricultural, livestock and fishery products for human consumption.

II Hygiene control in food handling establishments, etc.

1 General matters

- (1) Hygiene control including daily inspections should be conducted according to a plan.
- (2) In view of the structures and materials of establishments, facilities, equipment and utensils, and the characteristics of foods handled, methods of cleaning, washing and disinfecting these should be determined and, if necessary, procedures should be documented.

In preparing the procedures manual, necessary items concerning the procedures for cleaning, washing and disinfecting such as places to clean or wash, equipment and utensils, an operating manager(s), the method and frequency of cleaning or washing, the method of monitoring should be specified and, if necessary, should be drawn up in consultation with expert advisors.

- (3) Whether the methods of cleaning, washing and disinfecting as provided for in (2) above are appropriate and effective should be evaluated, if necessary.
- (4) Foods should be handled appropriately according to establishments, facilities, and human capability, etc., and orders should be managed properly.

2 Hygiene control of establishments

- (1) Establishments and surrounding areas should be cleaned regularly and always maintained without any hygiene problem during operations.
- (2) Unwanted objects, etc., should not be placed where production, processing, disposal, cooking, storage, sales or other procedures are performed.
- (3) Inner walls, ceilings and floors of establishments should always be kept clean.
- (4) Adequate natural or artificial lighting and ventilation should be provided in establishments and, if necessary, temperature and humidity should be controlled appropriately.
- (5) Windows and entrances should not be left open. If they have to be left open of necessity, measures should be taken to prevent dirt, rodents, insects, etc., from entering establishments.
- (6) Drains should be cleaned and repaired and the outflow of wastes through drains should be prevented for keeping good drainage.
- (7) Lavatories should always be kept clean, and should be regularly cleaned and disinfected.
- (8) Animals should not be kept inside establishments.

3 Hygiene control of food handling facilities, etc.

- (1) For maintaining hygiene, equipment and utensils (including those for cleaning) should be used according to the purpose of use.
- (2) Equipment, utensils and dismantled parts of them should be washed, disinfected and stored hygienically in appropriate places so as to prevent the food from contaminating from metal fragments, unclean foreign matter, chemical substances, etc.

Failed or broken equipment and utensils should be repaired promptly, and should be kept well maintained for appropriate use.

- (3) When equipment, utensils or parts of them are washed with detergent, an appropriate detergent should be used at a proper concentration.
- (4) Measuring instruments such as thermometers, pressure gauges, flow meters, etc.,

and equipment used for sterilization, pasteurization, disinfection or water purification, should be checked their functions regularly and recorded the results.

- (5) Towels, kitchen knives, chopping boards, protective clothing and others should be disinfected with hot water, steam, disinfectant, etc., and then dried. In particular, chopping boards, kitchen knives, protective clothing and others that come into direct contact with food should be fully cleaned and disinfected each time they are contaminated or after the end of the work.
- (6) Detergents, disinfectants and other chemical substances should be paid attention to the handling in use, storage, etc., and measures such as labeling the contents on their containers should be taken to prevent contaminating with foods.
- (7) Cleaning apparatus for establishments and facilities should be washed, dried, put back and stored in exclusive place every time they are used.
- (8) Hand-washing facilities should be maintained for the appropriate washing and drying of hands and fingers, and made available at all times with a sufficient water supply, appropriate soap for hand washing, nailbrushes, paper towels, disinfectant, etc.
- (9) Washing facilities should always be kept clean.
- (10) Irradiated food business operators should measure radiation dosage with chemical dosimeters once or more a day and keep the records for two years.

4 Measures against rodents and insects

- (1) Establishments and surrounding areas should be appropriately managed and maintained, breeding sites of rodents and insects should be eliminated, and measures are taken to prevent rodents and insects from entering establishments by installing wire mesh screens on windows, doors, inlets and outlets, traps, covers of drain ditches, etc.
- (2) Extermination of rodents and insects should be conducted at least twice a year and the records should be kept for one year. When rodents or insects are found, they should be exterminated at once to avoid an effect on foods.
- (3) When rodenticides or insecticides are used, these should be handled appropriately to prevent them contaminating foods.
- (4) In order to prevent contamination caused by rodents or insects, raw materials, products, packaging materials, etc., should be placed in containers and stored away from floors or walls. Items that have already been opened should be stored after taking measures to prevent contamination such as putting the content in a lidded container.

5 Handling of wastes and waste water

- (1) Procedures with regard to the methods of storing and disposing of wastes should be documented.
- (2) The waste containers should be clearly distinguished from other containers and always kept clean to prevent leakage of waste fluids or foul odors.
- (3) Wastes should not be stored in food handling or storage areas (including adjacent areas) provided this does not hinder work.
- (4) Areas for storing wastes should be appropriately managed so that they can have no adverse impact on the surrounding environment.
- (5) Appropriate methods should be used to dispose wastes and waste water.

6 Handling of foods, etc.

(1) When purchasing raw materials, business operators should endeavor to check the quality, freshness, labeling, etc., from a hygienic point of view and record the results.

No raw materials should be accepted if it is known to contain parasites, pathogenic micro-organisms, poisonous substances, decomposed matter, deteriorated matter or foreign matter which would not be eradicated or removed to an acceptable level by normal processing, cooking, etc.

(2) Appropriate raw materials should be used for foods and processed after pretreatig according to need.

Storage conditions and methods should be appropriate for said food.

- (3) The space inside refrigerators or cold rooms should be partitioned to prevent mutual contamination of materials.
- (4) Additives should be weighed precisely and used properly.
- (5) Pathogenic or other micro-organisms and their toxins should be eradicated or removed completely or to a safe level in the process of manufacturing, processing or cooking food.
- (6) Foods should be handled hygienically in due consideration of control for time and temperatures such as refrigeration in each process of cooking, storage, transportation, sales, etc., according to the nature of the foods (water activity, pH, the initial level of contamination by micro-organisms), best-before or expiration date, method of manufacturing or processing, packaging, kind of use, for example, ready-to-eat or further cooking/processing.

In establishments that have obtained the approval of the Total Hygiene Controlled Manufacturing Processes, hygiene control should be conducted based on the implementation plans.

- (7) The following processes that are considered to particularly contribute to food hygiene should be controlled with due consideration.
 - (a) Chilling
 - (b) Thermal processing
 - (c) Drying
 - (d) Use of additives
 - (e) Vacuum cooking or atmospheric packaging
 - (f) Irradiation
- (8) For avoiding the mutual contamination of foods, the following points should be taken into consideration.
 - (a) Non-heated or non-processed raw materials should be handled separately from foods to be eaten raw.
 - (b) No one except food handlers who conduct affairs in the relevant areas should enter the manufacturing, processing and cooking areas (provided, however, that this should not apply if there is no possibility of contamination of foods caused by the entry of people other than relevant food handlers to the area). If necessary, persons who enter these areas should go to a dressing room before entering, wear a hygienic clothing and shoes, and wash their hands.
 - (c) Facilities, equipment and utensils used to handle a non-heated food such as meat should be washed and disinfected before handling other foods.
- (9) Raw materials (particularly perishable materials) should be stored in a way that allows the materials to be used in proper order (first-in first-out, or the like).
- (10) Utensils, containers and packages should protect products from contamination or damage, and they can be appropriately labeled.

Reusable utensils, containers and packages should be easy to wash and disinfect.

- (11) The following items should be implemented wherever possible in manufacturing and processing foods.
 - (a) Measures should be taken to prevent contamination of raw materials and products by metals, glass, dirt, detergents, and machine oil and other foreign matter, and that inspections should be carried out whenever necessary.
 - (b) Raw materials, products, containers and packages should be controlled and recorded by lot.
 - (c) Product sheet which specifies the characteristics, manufacturing and processing procedures, raw materials, etc., by each product should be prepared and kept.
 - (d) Cut and sliced meat, etc., should be checked for foreign matter. If any foreign matter has been found, the part suspected of contamination should be

removed.

- (e) Measures should be taken to prevent allergenic substances which must not be included in raw materials from contaminating with products during the manufacturing process.
- (12) Business operators should conduct voluntary inspections of raw materials and products, confirm the conformity with the Specifications and Standards and make records of the results.

7 Management of water used, etc.

- (1) Potable water should be used in food handling establishments. However, that should not be applied to following case, and such water should be prevented from contaminating with water that comes into direct contact with foods.
 - (a) Use for purposes not directly relating to food production, such as for steam heating, fire fighting and so on.
 - (b) Use of clean sea water in a process not affecting cooling or food safety.
- (2) In using water other than running water, water quality tests should be conducted at least once a year (at least once a quarter by operators of food refrigeration or freezing businesses, margarine or shortening production businesses (except those who are exclusively engaged in shortening production) and edible fat and oil production businesses) and the records should be kept for at least one year (or a relevant period if the distribution period of a product handled in view of the before-use period is one year or more).

However, if there is a possibility of contamination of water sources caused by unforeseen disasters, water quality tests should be conducted every time the possibility arises.

- (3) If water is judged as unsuitable for drinking as a result of a water quality test, use of the water in question should be promptly suspended and adequate measures should be taken based on instructions from a public health center.
- (4) When water tanks are used, said tanks should be regularly cleaned and kept clean.
- (5) When using water other than running water, such as well water, independent water supply, etc., it should be regularly confirmed and recorded that sterilizing or water purifying devices are working properly.
- (6) Ice should be made from potable water supplied by appropriately managed water supply equipment. Ice should be handled and stored hygienically.
- (7) When water is re-used, it is appropriately treated as necessary to prevent an adverse impact on food safety.

8 Appointment of a food hygiene supervisor

- (1) Business operators (except the business operators who should appoint a food hygiene supervisor based on the provision of Article 48 of the Food Sanitation Law (Law No. 233 of 1948); hereinafter the same should apply in this paragraph) should appoint a supervisor for food hygiene (hereinafter, "food hygiene supervisor") among relevant food handlers and persons concerned in each establishment or division.
- (2) Food hygiene supervisors should regularly participate in the training sessions held by prefectural governors and the mayors of ordinance-designated cities and core cities (hereinafter, "governors, etc.") or those considered to be appropriate by governors, etc., and endeavor to acquire new knowledge regarding food hygiene.
- (3) Food hygiene supervisors should follow business operators' advice regarding hygiene control.
- (4) Food hygiene supervisors should pay due attention to the matters relating to hygiene control methods of establishments and food hygiene to prevent food hygienic hazards and provide opinions to business operators.
- (5) Business operators should respect the opinions of food hygiene supervisors pursuant to the provision in (4) above.

9 Preparing and keeping records

- (1) Business operators should endeavor to prepare and keep records on suppliers, status of manufacturing or processing, ship-to or sales-to operators or other necessary matters of foods handled, as far as it needs to prevent food hygienic hazards.
- (2) The record retention period should be decided reasonably according to the actual conditions of distribution of foods handled (including the best-before or expiration dates).
- (3) Business operators should submit relevant records if the national government or prefectures, etc., request them to prevent the occurrence of food hygienic hazards such as food poisoning.
- (4) When business operators conduct voluntary inspections of manufactured or processed products, the records of inspection should be kept.

10 Recall and disposal

(1) If a food hygiene problem caused by food products offered for sale occurs, with a view to preventing health hazards to consumers in advance, business operators should establish a system of responsibility for recall, specific measures of recall

and procedures of reporting to the public health center which have jurisdiction over the area in which the establishments in question are located, which allow operators to recall the products in question promptly and appropriately.

- (2) If a food hygiene problem caused by food products offered for sale occurs, business operators should take necessary measures to dispose of recalled products or others precisely and promptly.
- (3) Business operators should store recalled products separately from normal products and take appropriate measures such as disposal, etc., according to advice from a public health center, etc.
- (4) When performing a recall, etc., if necessary, business operators should consider announcing the recall in question to alert consumers.

11 Preparation of guidelines for control and operation

- (1) Business operators should prepare guidelines for hygiene control and operations pertaining to the handling of establishments and foods and try to keep food handlers and persons concerned informed about the guidelines.
- (2) The effect of the guidelines for hygiene control and operation prepared in conformity with (1) above should be verified by conducting regular product inspections, smear tests, etc., and confirming the state of hygiene of establishments and, if necessary, the contents should be reviewed.

12 Implementation of food testing

- (1) Among restaurant business operators, lunchers and caterers should keep test food of each raw material and cooked food for 48 hours (provided, however, that if the 48 hours extend across Sunday, a national holiday or substitute holiday, or a day when the shop is closed, food specimens should be kept until the day following that Sunday, national holiday or substitute holiday, or the day the shop is closed). Raw materials should be stored under the same condition at the purchase, with no washing or disinfecting.
- (2) In the above case, deliver-products-to operators, delivery time and the amount of products delivered should also be recorded and the records should be kept.

13 Provision of information

- (1) Business operators should endeavor to provide information concerning the safety of food products for sale to consumers.
- (2) Business operators should promptly report to the public health center the information concerning the health hazard claim from consumers arise from food

products which they have manufactured, processed or imported (in case that they are given doctor's diagnosis and confirmed or suspected that symptoms in question are caused by food products which have manufactured, processed or imported) and the information concerning food products which violate the Food Sanitation Law.

III Hygiene control of food handlers in food handling establishments

- (1) The health examination of food handlers should be carried out with attention to the health conditions necessary for hygiene control.
- (2) If a public health center instructs business operators to implement a stool examination, business operators should make food handlers take the examination.
- (3) The food handlers who show the following symptoms of illness should inform food-related business operators, food hygiene managers or food hygiene supervisors thereof. Business operators should instruct the food handlers in question not to engage in food handling work and make them undergo a medical examination.
 - (a) Jaundice
 - (b) Diarrhea
 - (c) Stomachache
 - (d) Fever
 - (e) Sore throat with fever
 - (f) Suspected case of infection among skin lesions (burns, cuts, etc.)
 - (g) Discharges from the ear, eye or nose (only that which is pathologic)
 - (h) Nausea and vomiting

When a person who has cuts or wounds on his or her skin but does not fall under item (f) above is made to engage in work, the part in question should be covered with a waterproof covering.

- (4) If it is ascertained that a food handler has a Type 1, 2 or 3 infectious disease or is an asymptomatic bacteria carrier, the business operator should instruct him or her not to engage in the work in which he or she directly touches food until he or she is no longer a carrier.
- (5) Food handlers should be provided with a hygienic uniform, cap, mask and shoes exclusively for use in the work place and should not enter a contaminated area as they are.

Food handlers should be prohibited from bringing ornaments such as rings, watches, hairpins, safety pins, etc., into food handling area.

(6) In principle, food handlers should not wear gloves whose part that touches meat

directly is made of a material that is difficult to wash and disinfect, such as a fibrous material.

- (7) Food handlers should cut their nails close and should not polish their nails. They should wash and disinfect their hands before work, after using the lavatory and after handling perishable raw materials or contaminated materials without fail. Food handlers should avoid handling foods for uncooked use after handling perishable raw materials or contaminated materials.
- (8) Food handlers should not do the following during food handling work:
 - (a) Touching the hair, nose, mouth or ears with their hand or food utensils
 - (b) Spitting or coughing out phlegm
 - (c) Smoking
 - (e) Eating or drinking in a food handling area
 - (f) Sneezing or coughing over unprotected food

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

(9) Persons who will enter food handling area other than food handlers should change their clothes to a clean uniform for exclusive use and observe the provisions for hygiene control of food handlers as provided for in this section.

IV Education and training for food handlers in food handling establishments

- (1) Food-related business operators, food hygiene managers and food hygiene supervisors should provide hygiene education such as the methods of hygienically handling foods and preventing foods from contamination, etc., for food handlers and persons concerned in order to perform manufacturing, processing, cooking, sales, etc., hygienically.
- (2) Such hygiene education should include items concerned with the procedures as described in II above (1-(2), 5-(1), 6-(6), 10-(1), 11).
- (3) In particular, for persons who handle chemicals such as detergents, education and training on safety handling should be provided.
- (4) The effects of education and training should be evaluated regularly and the programs should be reviewed as needed.

V Transportation

(1) Vehicles and haulage containers and others used for transporting foods should not be those which could contaminate foods, containers or packages. Also, their structure should make them easy to wash and disinfect. They should always be kept clean and in a proper state by repair, etc.

- (2) When foods and loads other than foods are mixed, to prevent the latter from contaminating foods, if necessary, the foods should be put in an appropriate container and separated from the other loads.
- (3) During transportation, foods should be controlled in such a way as to avoid contamination by dust or toxic gases.
- (4) When a vehicle or haulage container once used for transporting different commodities of food or loads other than foods is re-used, the vehicle or container should be washed effectively and disinfected as needed.
- (5) In the case of bulk transportation, a vehicle or haulage container exclusively for foods should be used, if necessary. In this case, the vehicle or haulage container should be clearly marked as being exclusively for foods.
- (6) Attention should be paid to the control of temperature, humidity, etc., during transportation.
- (7) Attention should be paid to the delivery route and the control of time to avoid long-time delivery.
- (8) When delivering lunches, attention should be paid to meeting the proper delivery time in consideration of the expected eating time.

VI Sales

- (1) Stock should be purchased properly allowing for the amount of sales.
- (2) Attention should be paid to the hygiene control of products so as not to expose products to the sun or unsuitable temperature for a long time.

VII Labeling

Labeling should be properly given based on the Food Sanitation Law.

As for the labeling of before-use date for lunches, if necessary, the time should also be indicated.