

Food Sanitation Act

(Act No. 233 of December 24, 1947)

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Chapter I General Provisions

Article 1 The purpose of this Act is to prevent sanitation hazards resulting from eating and drinking by enforcing regulations and other measures necessary from the viewpoint of public health for ensuring food safety, thereby protect the people's health.

Article 2 (1) The national government, prefectures, cities specified by Cabinet Order based on the provisions of Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (referred to below as "cities with public health centers") and special wards must take the necessary measures to disseminate the correct knowledge concerning food sanitation through educational and PR activities, collect, consolidate, analyze, and provide information on food sanitation, promote research on food sanitation, enhance capabilities on inspection of food sanitation, and develop human resources to be involved in the improvement of food sanitation, and enhance their capabilities.

(2) The national government, prefectures, cities with public health centers, and special wards, must coordinate closely with each other so that measures concerning food sanitation are implemented comprehensively and promptly.

(3) The national government is to develop a system for collecting, consolidating, analyzing, and providing information on food sanitation, conducting research, and making inspections for food sanitation on imported food, additives,

apparatus, and containers and packages, take necessary measures to ensure international cooperation, and provide prefectures, cities with public health centers and special wards (referred to below as "prefectures, etc.") with the technical assistance necessary for them to pursue their responsibilities referred to in the preceding two paragraphs.

- Article 3 (1) A food business operator (meaning a person or corporation that is engaged in collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives, or manufacturing, importing, or selling apparatus, or containers and packages, or a person or corporation that continuously provides food to a large number of persons or unspecified persons at schools, hospitals, or other facilities; the same applies below) must endeavor to ensure the safety of the food, additives, apparatus, or containers and packages that they collect, produce, import, process, cook, store, transport, sell, provide to a large number of persons or unspecified persons, or use for business (referred to below as "food for sale, etc.") on their own responsibility, and endeavor to obtain the knowledge and skills for ensuring the safety of food for sale, etc., ensuring the safety of raw materials of food for sale, etc., conducting voluntary inspections of food for sale, etc., and take other necessary measures.
- (2) A food business operator must endeavor to make a record of necessary information such as the name of the person who has sold food for sale, etc. or raw materials of food for sale, etc. to the food business operator and preserve the record, to the extent necessary for preventing food sanitation hazards resulting from food for sale, etc.
- (3) In order to prevent food sanitation hazards resulting from food for sale, etc., a food business operator must endeavor to appropriately and promptly take necessary measures such as providing the record prescribed in the preceding paragraph to the national government or prefectures, etc. and disposing of the food for sale, etc. that caused the food sanitation hazards.

- Article 4 (1) The term "food" as used in this Act means all foods and drinks; provided, however, that this term does not include pharmaceutical products, quasi-pharmaceutical products, and regenerative medicine products specified in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960).
- (2) The term "additives" as used in this Act means substances that are used by the method such as adding, mixing or being infiltrated into food in the process of producing food or for the purpose of processing or preserving food.
- (3) The term "natural flavoring agents" as used in this Act means substances obtained from animals or plants, or mixtures of those substances, which are used for flavoring food.

- (4) The term "apparatus" as used in this Act means tableware, kitchen utensils, and machines, equipment, and other articles that are used for collecting, producing, processing, cooking, storing, transporting, displaying, delivering, or consuming food or additives, and come into direct contact with food or additives; provided, however, that this does not include machines, equipment, and other articles used for harvesting food for agriculture and fisheries.
- (5) The term "containers and packages" as used in this Act means articles that contain or wrap food or additives and are handed over as is when delivering or receiving food or additives.
- (6) The term "food sanitation" as used in this Act means sanitation for eating and drinking concerning food, additives, apparatus, and containers and packages.
- (7) The term "business" as used in this Act means collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives, or manufacturing, importing, or selling apparatus, or containers and packages, in the course of trade; provided, however, that this does not include the food collection business in agriculture and fisheries.
- (8) The term "business operator" as used in this Act means a person or corporation that engages in business.
- (9) The term "registered conformity assessment body" as used in this Act means a corporation that has obtained a registration from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 33, paragraph (1).

Chapter II Food and Additives

Article 5 Collecting, producing, processing, using, cooking, storing, transporting, displaying, and delivering and receiving of food or additives to be sold (including their provision other than sales to a large number of persons or unspecified persons; the same applies below) must be made in a clean and sanitary manner.

Article 6 The following food and additives must not be sold (including cases other than providing them to a large number of persons or unspecified persons; the same applies below), or collected, produced, imported, processed, used, cooked, stored, or displayed for the purpose of selling:

- (i) those that are rotten or have deteriorated, or are unripe; provided, however, that this does not apply to those that are unlikely to harm human health in general and are found to be suitable for eating and drinking;
- (ii) those that contain toxic or harmful substances or are adhered with those substances, or suspected to contain or adhered with them; provided, however, that this does not apply when the Minister of Health, Labour and Welfare specifies that they are unlikely to harm human health;

- (iii) those that are contaminated with pathogens or suspected to be contaminated with them, and are likely to harm human health; and
- (iv) those that are likely to harm human health due to contamination or addition of foreign substances, or due to other reasons.

Article 7 (1) When things that have not been generally served for human consumption and have not been proved to be unlikely to harm human health, or things that include them are newly sold as food or come to be sold as food, the Minister of Health, Labour and Welfare may prohibit those things to be sold as food, after hearing the opinions of the Health Science Council, when the Minister finds it necessary for preventing the occurrence of food sanitation hazards.

(2) When the Minister of Health, Labour and Welfare finds that there is no positive proof that the things that have been generally served for human consumption and are served in a method significantly different from the normal method for those things are unlikely to harm human health and that it is necessary for preventing the occurrence of food sanitation hazards, the Minister may prohibit those things to be sold as food, after hearing the opinions of the Health Science Council.

(3) When serious damage to human health suspected to have been caused by food has occurred, and it is suspected that the food contains things that have not been generally served for human consumption and are likely to cause harm from the conditions of the damage, the Minister of Health, Labour and Welfare may prohibit the sale of the food, after hearing the opinions of the Health Science Council, when the Minister finds it necessary for preventing the occurrence of food sanitation hazards.

(4) When the Minister of Health, Labour and Welfare has made a prohibition of sales under the provisions of the preceding three paragraphs and finds that there is no likelihood of food sanitation hazards caused by things or food related to the prohibition to occur based on the application from a person having an interest in the prohibition, or as required, the Minister is to revoke the prohibition in whole or in part, after hearing the opinions of the Health Science Council, pursuant to Order of the Ministry of Health, Labour and Welfare.

(5) When the Minister of Health, Labour and Welfare has made a prohibition of sales under the provisions of paragraphs (1) through (3), or has revoked the prohibition under the provisions of the preceding paragraph, the Minister is to issue public notice in an Official Gazette to that effect.

Article 8 (1) When a business operator that handles food containing ingredients or substances that require special attention from the viewpoint of preventing

food sanitation hazards and the Minister of Health, Labour and Welfare and the Prime Minister have designated (referred to as "food containing designated ingredients, etc." below in this paragraph) after hearing the opinions of the Food Sanitation Standards Council (referred to as "designated ingredients, etc." in paragraph (3) and Article 70, paragraph (5)) obtains information that the food containing designated ingredients, etc. handled by them causes or may cause harm to human health, they must notify a prefectural governor, a mayor of the city with public health centers or a mayor of the special ward (referred to below as the "prefectural governor, etc.") of that information without delay pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) When a notification under the provisions of the preceding paragraph has been given, the prefectural governor, etc. must report the matters related to the notification to the Minister of Health, Labour and Welfare.
- (3) Physicians, dentists, pharmacists, and other relevant persons must endeavor to grasp the state of damage to human health suspected of being caused by the ingestion of designated ingredients, etc., and when the prefectural governor, etc. conducts investigation of the damage to human health suspected of being caused by the ingestion of designated ingredients, etc. to prevent food sanitation hazards, and requests necessary cooperation for the investigation, they must endeavor to provide information on the damage or other necessary cooperation, in response to the request.

Article 9 (1) If for specific food or additives collected, produced, processed, cooked, or stored in a specific country or region, or those collected, produced, processed, cooked, or stored by a specific person, as a result of the inspections under the provisions of Article 26, paragraphs (1) through (3), or Article 28, paragraph (1), when it is found that food or additives falling under the following items are likely to be contained to a considerable extent, in light of the fact that a considerable number of food or additives falling under the following items have been discovered and the situation of food sanitation management at the production site or other grounds specified by Order of the Ministry of Health, Labour and Welfare, and taking into account the extent of risk of causing damage to human health and other matters specified by Order of the Ministry of Health, Labour and Welfare, the Minister of Health, Labour and Welfare finds that it is particularly necessary for preventing food sanitation hazards caused by the specific food or additives, the Minister may prohibit the specific food or additives from being sold, or collected, produced, imported, processed, used, or cooked for the purpose of selling, after hearing the opinions of the Health Science Council:

- (i) food or additives stated in each item of Article 6;

- (ii) food prescribed in Article 12;
 - (iii) food or additives that do not conform to the standards established pursuant to the provisions of Article 13, paragraph (1);
 - (iv) food that use additives by a method that does not conform to the criteria established pursuant to the provisions of Article 13, paragraph (1); and
 - (v) food prescribed in Article 13, paragraph (3).
- (2) When the Minister of Health, Labour and Welfare intends to make a prohibition under the provisions of the preceding paragraph, the Minister must consult with the heads of the relevant administrative organs in advance.
- (3) When the Minister of Health, Labour and Welfare has made a prohibition under the provisions of paragraph (1) and finds that there is no likelihood of the specific food or additives related to the prohibition to cause food sanitation hazards based on the application from a person having an interest in the prohibition, or as required, the Minister is to revoke the prohibition in whole or in part, after hearing the opinions of the Health Science Council, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) When the Minister of Health, Labour and Welfare has ordered a prohibition under the provisions of paragraph (1), or has issued a revocation of the prohibition under the provisions of the preceding paragraph in whole or in part, the Minister is to issue public notice in an Official Gazette.

Article 10 (1) The meat, bones, milk, organs, and blood of livestock (meaning livestock defined in Article 3, paragraph (1) of the Slaughterhouse Act (Act No. 114 of 1953) and other animals specified by Order of the Ministry of Health, Labour and Welfare; the same applies below) that have contracted or are suspected to have contracted a disease stated in item (i) or (iii), have an abnormality stated in item (i) or (iii), or have fallen dead, or the meat, bones, and organs of poultry (meaning poultry defined in Article 2, item (i) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Act No. 70 of 1990) and other birds specified by Order of the Ministry of Health, Labour and Welfare; the same applies below) that have contracted or are suspected to have contracted a disease stated in item (ii) or (iii), have an abnormality stated in item (ii) or (iii), or have fallen dead, must not be sold as food, or collected, processed, used, cooked, stored, or displayed as food for the purpose of selling, excluding cases specified by Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply to the meat, bones, and organs of livestock or poultry that have fallen dead which the ministry's officials find unlikely to harm human health and are suitable for eating and drinking.

- (i) disease or abnormality stated in the items of Article 14, paragraph (6) of the Slaughterhouse Act;

- (ii) disease or abnormality stated in the items of Article 15, paragraph (4) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act;
 - (iii) disease or abnormality other than one stated in the preceding two items which are specified by Order of the Ministry of Health, Labour and Welfare.
- (2) The meat, milk, and organs of livestock, and the meat and organs of poultry, and their products specified by Order of the Ministry of Health, Labour and Welfare (referred to as "livestock meat, etc." below in this paragraph) must not be imported as food for the purpose of selling, unless they are attached with a certificate issued by a governmental organization of an exporting country or its copy stating that they are not the meat, milk, or organs of livestock, or the meat or organs of poultry, or their products that have contracted or are suspected to have contracted a disease stated in each item of the preceding paragraph, have an abnormality stated in each item of that paragraph, or have fallen dead, and state other matters specified by Order of the Ministry of Health, Labour and Welfare (referred to as "matters on sanitation" below in this paragraph); provided, however, that this does not apply to livestock meat, etc. imported from a country specified by Order of the Ministry of Health, Labour and Welfare, and the matters on sanitation for the livestock meat, etc. have been sent from a governmental organization of the country via a telecommunications line to a computer used by the Ministry of Health, Labour and Welfare (including an input and output device) and have been recorded in a file stored on the computer.

Article 11 (1) The food and additives specified by Order of the Ministry of Health, Labour and Welfare as those that require measures to control particularly important processes for preventing food sanitation hazards to be taken, must not be imported for the purpose of selling, unless they have been produced or processed in a country or region, or facilities specified by the Minister of Health, Labour and Welfare as being certain that those measures have been taken.

- (2) The food and additives specified by Order of the Ministry of Health, Labour and Welfare as those that require proof of the state of food sanitation management at the production site to confirm that they do not fall under any of the food and additives stated in the items of Article 6 and confirm other matters specified by Order of the Ministry of Health, Labour and Welfare, must not be imported for the purpose of selling, unless they are attached with a certificate issued by a governmental organization of the exporting country, and state those matters, or its copy.

Article 12 Additives (excluding natural flavoring agents and things that have been generally served for human consumption, and are used as additives) and

formulations and food containing those additives must not be sold or be produced, imported, processed, used, stored, or displayed for the purpose of selling, unless the Prime Minister specifies them as those unlikely to harm human health after hearing the opinions of the Food Sanitation Standards Council.

Article 13 (1) The Prime Minister may establish the criteria for the method of producing, processing, using, cooking, or preserving food or additives to be sold, or the standards for the ingredients of food or additives to be sold, from the viewpoint of public health, after hearing the opinions of the Food Sanitation Standards Council.

(2) When the criteria or standards have been established pursuant to the provisions of the preceding paragraph, food or additives must not be produced, processed, used, cooked, or preserved using a method that does not conform to the criteria, food or additives that do not conform to the criteria must not be sold or imported, and food or additives that do not conform to the standards must not be produced, imported, processed, used, cooked, preserved, or sold.

(3) Food in which agricultural chemicals (meaning agricultural chemicals defined in Article 2, paragraph (1) of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948), the same applies in the following Article), substances that are used by being added, mixed or infiltrated into feed (meaning feed prescribed in Article 2, paragraph (2) of the Act on Safety Assurance and Quality Improvement of Feed (Act No. 35 of 1953)) or are used by other methods for the purpose of usage specified by Order of the Ministry of Agriculture, Forestry and Fisheries based on Article 2, paragraph (3) of that Article, and substances that are ingredients of pharmaceuticals defined in Article 2, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and are to be used for animals (including substances generated by chemical change of that substance, and excluding those specified by the Prime Minister as those clearly not likely to harm human health) remain in a quantity exceeding the quantity that the Prime Minister has specified as being unlikely to harm human health after hearing the opinions of the Food Sanitation Standards Council, must not be produced, imported, processed, used, cooked, preserved, for the purpose of selling, or be sold; provided, however, that this does not apply when standards for the ingredients of food referred to in paragraph (1) have been established concerning the limit of the amount of residue of those substances in the food.

Article 14 When the Prime Minister establishes a limit on the amount of substances (including substances generated by the chemical change of those substances) that are ingredients of feed additives defined in Article 2,

paragraph (3) of the Act on Safety Assurance and Quality Improvement of Feed, or pharmaceuticals defined in Article 2, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and are to be used for the purpose of using solely for animals (referred to as "agricultural chemicals, etc." below in this Article) which remain in food, as standards for the ingredients of food referred to in paragraph (1) of the preceding Article, and specifies the scope of meat, milk and other products of the target animals (meaning the target animals prescribed in Article 14, paragraph (2), item (iii), sub-item (b) of that Act pursuant to Article 83, paragraph (1) of that Act following the deemed replacement of terms) for which regenerative medicine products defined in Article 2, paragraph (9) of that Act which are to be used for the purpose of using solely for animals (referred to as "animal regenerative medicine products" below in this Article) have been used, and in other cases the Prime Minister finds to be necessary, the Prime Minister may request the Minister of Agriculture, Forestry and Fisheries to provide materials on the ingredients of the agricultural chemicals, etc. or the component cells and transgenes of the animal regenerative medicine products, or other things specified by Cabinet Office Order, and provide other necessary cooperation.

Chapter III Apparatus, and Containers and Packages

Article 15 Apparatus, and containers and packages used for conducting business must be clean and sanitary.

Article 16 Apparatus, or containers and packages that contain toxic or harmful substances, or to which those substances are adhered and likely to harm human health, or apparatus, or containers and packages that come into contact with food or additives and likely to harm to human health due to having a harmful effect, must not be sold, manufactured or imported for the purpose of selling, or used for business.

Article 17 (1) If for specific apparatus, or containers and packages that are manufactured in a specific country or region, or manufactured by a specific person, a considerable number of apparatus, or containers and packages falling under the following items have been discovered as a result of inspections under the provisions of Article 26, paragraphs (1) through (3) or Article 28, paragraph (1), and it is found likely that apparatus, or containers and packages falling under the following items are contained to a considerable extent due to the status of food sanitation management at the production site and other grounds specified by Order of the Ministry of Health, Labour and Welfare, and the

Minister of Health, Labour and Welfare finds it particularly necessary for preventing food sanitation hazards caused by the specific apparatus, or containers and packages, taking into account the level of risk of harming human health and other matters specified by Order of the Ministry of Health, Labour and Welfare, the Minister may prohibit the sales of the specific apparatus, or containers and packages, manufacturing or import of the specific apparatus, or containers and packages for the purpose of selling, or using them for business, after hearing the opinions of the Health Science Council:

- (i) apparatus, or containers and packages prescribed in the preceding Article;
 - (ii) apparatus, or containers and packages that do not conform to the standards established pursuant to the provisions of paragraph (1) of the following Article; and
 - (iii) apparatus, or containers and packages that violate the provisions of paragraph (3) of the following Article.
- (2) When the Minister of Health, Labour and Welfare intends to make a prohibition under the provisions of the preceding paragraph, the Minister must consult with the heads of the relevant administrative organs in advance.
- (3) The provisions of Article 9, paragraphs (3) and (4) apply mutatis mutandis to cases in which a prohibition under the provisions of paragraph (1) has been made. In such a case, the term "food or additives" in paragraph (3) of that Article is deemed to be replaced with "apparatus, or containers and packages".

Article 18 (1) The Prime Minister may establish standards for apparatus, or containers and packages or their raw materials to be sold or used for business, or establish the criteria for the manufacturing method of apparatus, or containers and packages, after hearing the opinions of the Food Sanitation Standards Council.

- (2) When the standards or criteria have been established pursuant to the provisions of the preceding paragraph, the apparatus, or containers and packages that do not conform to the standards must not be sold, manufactured or imported for the purpose of selling, or used for business, raw materials that do not conform to the standards must not be used, and the apparatus, or containers and packages must not be manufactured by a method that does not conform to the criteria.
- (3) Substances (excluding substances generated by chemical change of substances) which are raw materials of materials specified by Cabinet Order taking into consideration the impact of the elution or seepage of the components into food must not be used for apparatus, or containers and packages, when the quantity permitted to be contained in the apparatus, or containers and packages manufactured, or the quantity permitted to be eluted or seep into food from apparatus, or containers and packages manufactured

using those substances is not specified in the standards referred to in paragraph (1) of the Article; provided, however, that this does not apply if the apparatus, or containers and packages, are processed so that the substances does not have the risk of eluting or seeping into food at a quantity exceeding the quantity specified by the Prime Minister as unlikely to harm human health after hearing the opinions of the Food Sanitation Standards Council (excluding the case in which the substance is used for the part of the apparatus, or containers and packages which come into contact with food).

Chapter IV Labeling and Advertising

- Article 19 (1) The Prime Minister may establish necessary criteria for the labeling of apparatus, or containers and packages for which standards or criteria have been established pursuant to the provisions of paragraph (1) of the preceding Article, from the viewpoint of accurately conveying necessary information on public health concerning apparatus, or containers and packages to general consumers, after hearing the opinions of the Consumer Commission.
- (2) Apparatus, or containers and packages for which the criteria for labeling have been established pursuant to the provisions of the preceding paragraph must not be sold, displayed for the purpose of selling, or used for business, if they do not have a labeling that conforms to the criteria.
- (3) Criteria for the labeling of food and additives intended for sale is to be governed by the provisions of the Food Labeling Act (Act No. 70 of 2013).

Article 20 False or exaggerated labeling or advertising that is likely to cause harm to public health may not be used for food, additives, apparatus, or containers and packages.

Chapter V Japan's Specifications and Standards for Food Additives

Article 21 The Prime Minister is to prepare Japan's Specifications and Standards for Food Additives and list the criteria and standards for the additives for which the criteria and standards have been established pursuant to the provisions of Article 13, paragraph (1), and additives for which the criteria have been established pursuant to the provisions of Article 4, paragraph (1) of the Food Labeling Act.

Chapter VI Monitoring and Guidance

Article 21-2 The national government and prefectures, etc. must work together in cooperation with each other to ensure that the monitoring or guidance

concerning food sanitation (referred to below as "monitoring and guidance") will be comprehensively and promptly conducted, in order to prevent persons poisoned by food, additives, apparatus, or containers and packages or persons suspected of being poisoned by them (referred to below as "persons poisoned by food, etc.") from spreading or increasing across wide areas, and prevent violations of this Act, or orders or dispositions based on this Act, concerning food, additives, apparatus, or containers and packages that are distributed over wide areas.

Article 21-3 (1) The Minister of Health, Labour and Welfare may establish a wide-area cooperation council consisting of the national government, prefectures, etc., and other relevant organizations pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare (referred to as "the council" below in this Article and Article 66), in order to ensure the development of a coordination and cooperation system in implementing monitoring and guidance.

- (2) When the council finds it necessary, the council may add persons other than the members of the council who are persons found to be necessary by the council and prefectures, etc. as members.
- (3) The members of the council must respect the results of discussions concerning the matters agreed upon at the council meetings.
- (4) Beyond what is provided for in the preceding three paragraphs, the matters necessary for operating the council are decided by the council.

Article 22 (1) The Minister of Health, Labour and Welfare and the Prime Minister are to establish guidelines concerning the monitoring and guidance to be implemented by the national government and prefectures, etc. (referred to below as the "guidelines").

- (2) The guidelines are to specify the following matters:
 - (i) basic direction on the implementation of monitoring and guidance;
 - (ii) matters concerning items for which monitoring and guidance should be intensively implemented;
 - (iii) matters concerning the system for implementing monitoring and guidance;
 - (iv) matters concerning ensuring of coordination and cooperation between the national government, prefectures, etc., and other relevant organizations in implementing monitoring and guidance; and
 - (v) other important matters concerning the implementation of monitoring and guidance.
- (3) When the Minister of Health, Labour and Welfare and the Prime Minister have established or amended the guidelines, they must publicize that fact and notify prefectural governors, etc. of that fact without delay.

- Article 23 (1) Each fiscal year, the Minister of Health, Labour and Welfare is to establish a plan on the monitoring and guidance to be implemented by the national government concerning the following fiscal year's import of food, additives, apparatus, and containers and packages (referred to below as the "imported food monitoring and guidance plan"), based on the guidelines.
- (2) The imported food monitoring and guidance plan is to specify the following matters:
- (i) matters concerning items for which monitoring and guidance should be intensively implemented, in view of the circumstances at the productions site and other circumstances;
 - (ii) matters concerning guidance of the implementation of voluntary sanitation management for a business operator engaged in import; and
 - (iii) other necessary matters for implementing monitoring and guidance.
- (3) When the Minister of Health, Labour and Welfare has established or amended the imported food monitoring and guidance plan, the Minister is to publicize that fact without delay.
- (4) The Minister of Health, Labour and Welfare is to publicize the implementation status of the imported food monitoring and guidance plan.

- Article 24 (1) Each fiscal year, the prefectural governor, etc. must establish a plan concerning the following fiscal year's monitoring and guidance to be implemented by that prefecture, etc. (referred to below as "prefectural plan for monitoring and guidance of food sanitation"), based on the guidelines.
- (2) A prefectural plan for monitoring and guidance of food sanitation is to specify the following matters:
- (i) matters concerning items for which monitoring and guidance should be intensively implemented;
 - (ii) matters concerning guidance on the implementation of voluntary sanitation management for food business operators;
 - (iii) matters concerning the ensuring of coordination and cooperation with the national government, prefectures, etc., and other relevant organizations in implementing monitoring and guidance; and
 - (iv) other necessary matters for implementing monitoring and guidance.
- (3) A prefectural plan for monitoring and guidance of food sanitation must be established by taking into account the situation of establishment of facilities by food business operators in the areas of that prefecture, etc., the status of occurrence of food sanitation hazards, and other actual circumstances of the regions.
- (4) When a prefectural governor, etc. has established or amended the prefectural plan for monitoring and guidance of food sanitation, the prefectural governor,

etc. must publicize that fact and report that fact to the Minister of Health, Labour and Welfare and the Prime Minister, without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare and Cabinet Office Order.

- (5) The prefectural governor, etc. must publicize the implementation status of the prefectural plan for monitoring and guidance of food sanitation pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare and Cabinet Office Order.

Chapter VII Inspections

Article 25 (1) Food or additives for which standards have been established pursuant to the provisions of Article 13, paragraph (1), or apparatus, or containers and packages for which standards have been established pursuant to the provisions of Article 18, paragraph (1), which are specified by Cabinet Order, must not be sold, displayed for the purpose of selling, or used for business, unless they have undergone an inspection by the Minister of Health, Labour and Welfare, a prefectural governor, or a registered conformity assessment body, in accordance with the classification specified by Cabinet Order and are attached with the labeling specified by Order of the Ministry of Health, Labour and Welfare certifying that they have passed the inspection.

- (2) A person who intends to undergo an inspection conducted by the Minister of Health, Labour and Welfare or a registered conformity assessment body under the provisions of the preceding paragraph must pay a fee specified by the Minister in consideration of the actual costs required for the inspections, and must pay a fee specified by the registered conformity assessment body by obtaining approval from the Minister in consideration of the actual costs required for the inspection for the inspection conducted by a registered conformity assessment body .

- (3) The fees referred to in the preceding paragraph to be paid by a person who intends to undergo an inspection by the Minister of Health, Labour and Welfare will be the national treasury's income and those to be paid by a person who intends to undergo an inspection by a registered conformity assessment body will be the registered conformity assessment body's income.

- (4) Beyond what is provided for in the preceding three paragraphs, the necessary matters for the inspection referred to in paragraph (1) and the measures to be taken after passing the inspection are specified by Cabinet Order.

- (5) A request for examination may not be made for the results of the inspection referred to in paragraph (1).

Article 26 (1) When a prefectural governor discovers food, additives, apparatus,

or containers and packages stated in the following items, and finds that the food, additives, apparatus, or containers and packages that the person produced or processed are likely to continue to fall under those stated in the following items in view of the capability, etc. for conducting inspections of the person who produced or processed them and necessary for preventing occurrence of food sanitation hazards, the prefectural governor may order that the person should undergo an inspection by the prefectural governor or a registered conformity assessment body on the food, additives, apparatus, or containers and packages, in accordance with the requirements and procedures specified by Cabinet Order:

- (i) food or additives stated in Article 6, item (ii) or (iii);
 - (ii) food or additives that do not conform to the standards established pursuant to the provisions of Article 13, paragraph (1);
 - (iii) food for which additives are used in a method that does not conform to the criteria established pursuant to the provisions of Article 13, paragraph (1);
 - (iv) food prescribed in Article 13, paragraph (3);
 - (v) apparatus, or containers and packages prescribed in Article 16;
 - (vi) apparatus, or containers and packages that do not conform to standards established pursuant to the provisions of Article 18, paragraph (1); and
 - (vii) apparatus, or containers and packages violating Article 18, paragraph (3).
- (2) When the Minister of Health, Labour and Welfare finds it necessary for preventing the occurrence of food sanitation hazards, the Minister may order a person who imports food, additives, apparatus, or containers and packages that are the same type as those produced or processed by a person who has produced or processed food, additives, apparatus, or containers and packages stated in each item of the preceding paragraph or food prescribed in Article 12 to undergo an inspection conducted by the Minister or a registered conformity assessment body on the food, additives, apparatus, or containers and packages.
- (3) When the Minister of Health, Labour and Welfare finds it necessary for preventing the occurrence of food sanitation hazards, the Minister may order a person who imports food, additives, apparatus, or containers and packages that are found to be likely to fall under food, additives, apparatus, or containers and packages stated in each item of paragraph (1) or food prescribed in Article 12, in view of circumstances at production sites and other circumstances to undergo an inspection conducted by the Minister or a registered conformity assessment body on the food, additives, apparatus, or containers and packages.
- (4) A person who has received the order referred to in the preceding three paragraphs must not sell the food, additives, apparatus, or containers and packages, display them for the purpose of selling, or use them for business until after the person has undergone the inspection and has received the notice of the results of the inspection.

- (5) The notice referred to in the preceding paragraph which is given by a registered conformity assessment body is to be given through the prefectural governor or the Minister of Health, Labour and Welfare who has ordered that the person should undergo the inspection.
- (6) A person who intends to undergo an inspection conducted by the Minister of Health, Labour and Welfare or a registered conformity assessment organ under the provisions of paragraphs (1) through (3), must pay a fee specified by the Minister in consideration of the actual costs of the inspections for an inspection conducted by the Minister, and must pay a fee specified by the registered conformity assessment body by obtaining an approval from the Minister in consideration of the actual costs of the inspections for an inspection conducted by a registered conformity assessment body.
- (7) The provisions of paragraphs (3) through (5) of the preceding Article apply *mutatis mutandis* to inspections referred to in paragraphs (1) through (3).

Article 27 A person who intends to import food, additives, apparatus, or containers and packages for the purpose of selling or to use for business must notify the Minister of Health, Labour and Welfare each time they import the articles pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- Article 28 (1) When the Minister of Health, Labour and Welfare, the Prime Minister, or a prefectural governor, etc. finds it necessary, they may request a business operator or other relevant persons to make the necessary report, have their officials conduct an inspection of the place of business, office, warehouse, and other places, inspect food, additives, apparatus, or containers and packages to be used for selling or used for business, business facilities, books and documents, and other objects, or have the officials collect and remove food, additives, apparatus, or containers and packages to be used for selling or used for business, to the extent necessary for using them for testing, without compensation for the food, additives, apparatus, or containers or packages.
- (2) When having officials conduct on-site inspection, or collect and remove objects pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare, the Prime Minister, or the prefectural governor, etc. must have the officials carry their identification card, and, present it when requested by the relevant persons.
 - (3) The authority under the provisions of paragraph (1) must not be construed as having been granted for the purpose of a criminal investigation.
 - (4) The Minister of Health, Labour and Welfare, the Prime Minister, or a prefectural governor, etc. may entrust the affairs concerning the testing of food, additives, apparatus, or containers and packages that have been collected and

removed pursuant to the provisions of paragraph (1) to a registered conformity assessment body.

- Article 29 (1) The national government and prefectures must establish necessary facilities for inspections to have a registered conformity assessment body conduct the affairs concerning the inspections referred to in Article 25, paragraph (1) or Article 26, paragraphs (1) through (3) (referred to below as "product inspections") and the testing of food, additives, apparatus, or containers and packages that have been collected and removed pursuant to the provisions of paragraph (1) of the preceding Article.
- (2) Cities with public health centers and special wards must establish necessary facilities for inspections to have a registered conformity assessment body conduct the affairs concerning the testing of food, additives, apparatus, or containers and packages that have been collected and removed pursuant to the provisions of paragraph (1) of the preceding Article.
- (3) The necessary matters for food sanitation inspection facilities of prefectures, etc. are specified by Cabinet Order.

- Article 30 (1) The Minister of Health, Labour and Welfare, the Prime Minister, or a prefectural governor, etc. is to appoint food sanitation inspectors from among their officials to have those officials enforce the authority prescribed in Article 28, paragraph (1) and perform the duties of providing guidance on food sanitation.
- (2) A prefectural governor, etc. must have food sanitation inspectors they have appointed implement monitoring and guidance pursuant to the provisions of the prefectural plan for monitoring and guidance of food sanitation.
- (3) The Prime Minister is to have food sanitation inspectors appointed by the Prime Minister implement monitoring and guidance related to the labeling or advertising of food, additives, apparatus, and containers and packages, in accordance with the guidelines.
- (4) The Minister of Health, Labour and Welfare is to have food sanitation inspectors appointed by the Minister of Health, Labour and Welfare implement monitoring and guidance related to the import of food, additives, apparatus, and containers and packages, as provided for in the imported food monitoring and guidance plan.
- (5) Beyond what is provided for in the preceding paragraphs, the qualifications of food sanitation inspectors and other necessary matters concerning food sanitation inspectors are specified by Cabinet Order.

Chapter VIII Registered Conformity Assessment Bodies

Article 31 A person who seeks to obtain registration as a registered conformity assessment body must pay a fee specified by Cabinet Order in consideration of the actual costs of inspections and apply for registration with the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Article 32 A corporation falling under any of the following items may not obtain registration as a registered conformity assessment body:

- (i) a corporation or an officer engaged in its business has violated this Act or a disposition based on this Act, has been sentenced to a fine or severer punishment, and two years have not passed since they finished serving the sentence or ceased to be subject to the sentence;
- (ii) a corporation that has had its registration revoked pursuant to the provisions of Article 43, and two years have not passed since the date of the revocation; or
- (iii) a corporation for which a person who was an officer engaged in the business of the corporation related to the revocation of registration under the provisions of Article 43 within 30 days before the date of the revocation, and two years have not passed since the date of the revocation, is an officer engaged in its business.

Article 33 (1) When a person who has applied for registration pursuant to the provisions of Article 31 (referred to as an "applicant for registration" below in this paragraph) satisfies all of the following requirements, the Minister of Health, Labour and Welfare must register that person. In such a case, the necessary procedures for registration are specified by Order of the Ministry of Health, Labour and Welfare.

- (i) applicant for registration possesses the machines, equipment, and other facilities respectively listed in column 2 of the Appended Table for each type of product inspection listed in column 1 of that Table, and, for which product inspections are conducted by a person who has the knowledge and experience that satisfy the conditions listed in column 3 of that Table, and the number of those persons exceeds the number listed in column 4 of that Table;
- (ii) measures to ensure the credibility of product inspections stated in the following sub-items have been taken:
 - (a) a full-time administrator is appointed for each type of product inspection at a department that conducts inspections;
 - (b) documents on management of operation of product inspections and securing of precision of product inspections have been prepared;
 - (c) a specialized department is established for managing the operation of product inspections and securing precision of product inspections, in

- accordance with what is stated in the documents stated in sub-item (b);
- (iii) applicant for registration does not fall under any of the following sub-items as a person controlled by a business person that sells, or manufactures, imports, processes, or displays for the purpose of selling, or uses for business (referred to as a "business operator subject to inspections" below in this item and Article 39, paragraph (2)) food, additives, apparatus, or containers and packages for which product inspections must be undertaken pursuant to the provisions of Article 25, paragraph (1) or Article 26, paragraphs (1) through (3):
- (a) if an applicant for registration is a stock company, a business operator subject to inspections is its parent corporation (meaning a parent corporation prescribed in Article 879, paragraph (1) of the Companies Act (Act No. 86 of 2005));
 - (b) the proportion of officers or employees of a business operator subject to inspections (including persons who were officers or employees of a business operator subject to inspections in the past two years) account for more than half of the officers of an applicant for registration (for a membership company (meaning a membership company prescribed in Article 575, paragraph (1) of the Companies Act), employees that execute its business);
 - (c) officers who have the right to represent the applicant for registration are officers or employees of a business operator subject to inspections (including those who were officers or employees of a business operator subject to inspections in the past two years).
- (2) Registration is made by entering the following matters in the register:
- (i) the date of registration and registration number;
 - (ii) the name of the registered conformity assessment body, the name of its representative, and the location of its principal office;
 - (iii) the type of product inspections that the registered conformity assessment body conducts; and
 - (iv) the name and the location of the office in which the registered conformity assessment body conducts product inspections.

Article 34 (1) Unless registration of a registered conformity assessment body is renewed at the end of each period of not less than three years which is specified by Cabinet Order, the registration ceases to be effective upon the expiration of the period.

(2) The provisions of Article 31 through the preceding Article apply mutatis mutandis to the renewal of registration referred to in the preceding paragraph.

Article 35 (1) A registered conformity assessment body must conduct product inspections without delay, when requested to conduct a product inspection,

excluding cases in which there are legitimate grounds not to do so.

- (2) A registered conformity assessment body must conduct product inspections in a fair manner, and by a method that conforms to the technical criteria specified by Order of the Ministry of Health, Labour and Welfare.

Article 36 (1) When a registered conformity assessment body intends to newly establish or abolish an office in which it conducts product inspections, or change the location of the office, it must notify the Minister of Health, Labour and Welfare of that fact by no later than one month before the day of the establishment, abolition, or change.

- (2) When there has been any change to the matters stated in Article 33, paragraph (2), items (ii) and (iv) (limited to the part related to the name of the office), the registered conformity assessment body must notify the Minister of Health, Labour and Welfare of that fact without delay, and when it intends to change the matters stated in item (iii) of that paragraph, it must notify the Minister of that fact by no later than one month before the day of the change.

Article 37 (1) A registered conformity assessment body must establish rules concerning the operation of product inspections (referred to below as "operational rules") and obtain an approval from the Minister of Health, Labour and Welfare before commencing the operation of product inspections. The same applies when the registered conformity assessment body intends to change the operational rules.

- (2) Operational rules must specify the method of conducting product inspections, fees concerning product inspections, and other matters specified by Order of the Minister of Health, Labour and Welfare.
- (3) When the Minister of Health, Labour and Welfare finds that the operational rules for which the Minister has granted approval referred to in paragraph (1) have become inappropriate for conducting product inspections in a fair manner, the Minister may order the registered conformity assessment body to change the operational rules.

Article 38 A registered conformity assessment body must not suspend the operation of product inspections in whole or in part or abolish the operation of product inspections, without obtaining the approval of the Minister of Health, Labour and Welfare.

Article 39 (1) A registered conformity assessment body must prepare an inventory of property, balance sheet, and profit and loss statement, or income and expenditure account statement, and business report (including the electronic or magnetic record (meaning a record created in electronic form,

magnetic form, or any other form that cannot be perceived by the human senses which is to be used for information processing by computers; the same applies below in this Article) when electronic or magnetic records are prepared in lieu of those documents; referred to as "financial statements, etc." in the following paragraph and Article 89) for the business year within three months after the end of each business year, and keep them at the office for five years.

(2) A business operator subject to inspections and other interested persons may make the following requests at any time within the business hours of a registered conformity assessment body; provided, however, that when making a request referred to in item (ii) or (iv), they must pay fees specified by the registered conformity assessment body.

(i) when financial statements, etc. are prepared as documents, a request to inspect or copy the documents;

(ii) a request for a transcript or an extract of the documents referred to in the preceding item;

(iii) when financial statements, etc. are prepared as electronic or magnetic records, a request to inspect or copy the media that displays the matters recorded on the electronic or magnetic records by the means specified by Order of the Ministry of Health, Labour and Welfare;

(iv) a request for provision of the matters recorded on the electronic or magnetic records referred to in the preceding item by electronic or magnetic means specified by Order of the Ministry of Health, Labour and Welfare, or a request for delivery of the documents stating the matters.

Article 40 (1) Officers or employees of a registered conformity assessment body or persons who formerly held those positions must not divulge any secret concerning the operation of product inspections, or affairs entrusted to them pursuant to the provisions of Article 28, paragraph (4) (referred to as "entrusted affairs" in the following paragraph), which they have learned.

(2) Officers or employees of a registered conformity assessment body who are engaged in the operation of product inspections or entrusted affairs are deemed to be officials engaged in public services under laws and regulations in applying the Penal Code (Act No. 45 of 1907) and other penal provisions.

Article 41 When the Minister of Health, Labour and Welfare finds that a registered conformity assessment body no longer satisfies any of the items of Article 33, paragraph (1), the Minister may order the registered conformity assessment body to take necessary measures in order to satisfy those provisions.

Article 42 When the Minister of Health, Labour and Welfare finds that a

registered conformity assessment body has violated the provisions of Article 35, or that product inspections conducted by a registered conformity assessment body, labeling under the provisions of Article 25, paragraph (1), or the statement in the notice under the provisions of Article 26, paragraph (4) is not appropriate, the Minister may order that the registered conformity assessment body should conduct product inspections or take necessary measures for improving the method of product inspections or other operational methods.

Article 43 When a registered conformity assessment body falls under any of the following items, the Minister of Health, Labour and Welfare may revoke the registration of the registered conformity assessment organ, or order the suspension of the operation of product inspections in whole or in part, by specifying a period:

- (i) when a registered conformity assessment body has violated the provisions of this Chapter;
- (ii) when a registered conformity assessment body has come to fall under Article 32, item (i) or (iii);
- (iii) when a registered conformity assessment body has conducted product inspections without following the operational rules that obtained the approval referred to in Article 37, paragraph (1);
- (iv) when a registered conformity assessment body has violated an order under the provisions of Article 37, paragraph (3) or the preceding two Articles;
- (v) when a registered conformity assessment body has rejected a request under the provisions of each item of Article 39, paragraph (2) without legitimate grounds; or
- (vi) when a registered conformity assessment body has obtained registration referred to in Article 33, paragraph (1) by wrongful means.

Article 44 A registered conformity assessment body must keep books, enter the matters concerning product inspections specified by Order of the Ministry of Health, Labour and Welfare in the books, and preserve them, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Article 45 In any of the following cases, the Minister of Health, Labour and Welfare must issue public notice of those matters in an Official Gazette:

- (i) when the Minister has granted the registration referred to in Article 33, paragraph (1);
- (ii) when registration of a registered conformity assessment body has ceased to be effective pursuant to the provisions of Article 34, paragraph (1);
- (iii) when a notification under the provisions of Article 36, paragraph (1) or (2) has been given;

- (iv) when the Minister has granted the approval referred to in Article 38;
- (v) when the Minister has revoked the registration or ordered the suspension of product inspections, pursuant to the provisions of Article 43.

Article 46 (1) A person other than a registered conformity assessment body must not use labeling, advertising, or conduct other acts that may cause people to misunderstand the operation the person conducts to be product inspection.

(2) The Minister of Health, Labour and Welfare may order a person other than a registered conformity assessment body that they should take measures so as not to cause people to misunderstand the operation the person conducts to be product inspection.

Article 47 (1) The Minister of Health, Labour and Welfare may have a registered conformity assessment body make a report on its operation or accounting situation, or have their officials enter the office or place of business of a registered conformity assessment body to inspect the status of operations or books, documents, and other objects, or question the relevant persons, to the extent necessary for the enforcement of this Act.

(2) The provisions of Article 28, paragraphs (2) and (3) apply mutatis mutandis to the case referred to in the preceding paragraph.

Chapter IX Business

Article 48 (1) A business operator that produces or processes dairy products, additives specified by the Prime Minister pursuant to the provisions of Article 12, or other food or additives that require sanitary consideration in particular in the process of production or processing, which are specified by Cabinet Order, must have a full-time food sanitation supervisor for each facility to supervise the production or processing in a sanitary manner; provided, however, that this does not apply to facilities which the business operator personally supervises the facility as a food sanitation supervisor.

(2) If a business operator conducts production or processing business that require to have a full-time food sanitation supervisor pursuant to the provisions of the preceding paragraph at two or more facilities, and those facilities are adjacent to each other, it is sufficient to have one food sanitation supervisor for those two or more facilities, notwithstanding the provisions of that paragraph.

(3) A food sanitation supervisor must supervise persons who are engaged in the production or processing of food or additives at the facility to prevent violations of this Act, or orders or dispositions based on this Act concerning the food or additives that the food sanitation supervisor supervises.

(4) Beyond what is provided for in the preceding paragraph, a food sanitation

supervisor must pay necessary attention to sanitation management method at the facility and other matters concerning food sanitation, in order to prevent violations of this Act or orders or dispositions based on this Act and prevent food sanitation hazards concerning the food or additives the food sanitation supervisor manages at the facility, and express necessary opinions to a business operator.

- (5) When a food sanitation supervisor has been placed at a facility, a business operator must respect the opinions of the food sanitation supervisor expressed under the provisions of the preceding paragraph.
- (6) Only persons falling under any of the following items may become a food sanitation supervisor:
 - (i) a physician, dentist, pharmacist, or veterinarian;
 - (ii) a person who has graduated from a university under the School Education Act (Act No. 26 of 1947), a university under the former University Order (Imperial Order No. 388 of 1918), or a technical college under the former Technical College Order (Imperial Order No. 61 of 1903) after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, or agricultural chemistry (including a person who has completed the course and has completed the first-semester course of a professional and vocational university under that Act);
 - (iii) a person who has completed the prescribed course at a training institute for food sanitation supervisors that has obtained registration from a prefectural governor;
 - (iv) a person who has graduated from a high school or secondary education school under the School Education Act or a secondary school under the former Secondary School Order (Imperial Order No. 36 of 1943), or a person who is found to have equal or higher scholastic ability than those persons pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare and has been engaged in sanitation management of production or processing of food or additives for three years or more at a production business or processing business for which full-time food sanitation supervisors are required to be placed pursuant to the provisions of paragraph (1), and, has completed the training session that have obtained the registration from a prefectural governor.
- (7) A person who possesses the qualifications of a food sanitation supervisor because the person falls under item (iv) of the preceding paragraph may become a food sanitation supervisor only at a facility for the same type of production business or processing business as the business for which the person has been engaged in sanitation management work for three years or more.
- (8) When a business operator prescribed in paragraph (1) has placed a food

sanitation supervisor or has become a food sanitation supervisor themselves at their facility, they must notify the prefectural governor that has jurisdiction over the locality of the facility of the name of the food sanitation supervisor or the fact that the business operator themselves have become a food sanitation supervisor and other matters specified by Order of the Ministry of Health, Labour and Welfare within 15 days. The same applies when the business operator has changed the food sanitation supervisor.

Article 49 Necessary matters concerning registration of training facilities referred to in paragraph (6), item (iii) of the preceding Article or registration of training sessions referred to in item (iv) of that paragraph are specified by Cabinet Order, and the subjects to be taken and other necessary matters concerning courses at training facilities referred to in item (iii) of that paragraph and courses for training sessions referred to in item (iv) of that paragraph are specified by Order of the Ministry of Health, Labour and Welfare.

Article 50 (1) The Minister of Health, Labour and Welfare may establish the necessary criteria concerning measures to prevent toxic or harmful substances from getting mixed into the food or additives in the process of the production or processing of food or additives.

(2) When criteria have been established pursuant to the provisions of the preceding paragraph, a business operator (excluding poultry slaughterers prescribed in Article 6, paragraph (1) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act) must comply with the criteria.

Article 51 (1) The Minister of Health, Labour and Welfare is to establish criteria for the following matters related to the sanitary management of facilities for business (excluding business that manufacture apparatus, or containers and packages and businesses of poultry slaughtering defined in Article 2, item (v) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (referred to as "poultry slaughtering businesses" in Article 54 and Article 57, paragraph (1))) and other necessary measures for public health (referred to as "measures necessary for public health" below in this Article") under Order of the Ministry of Health, Labour and Welfare:

- (i) matters concerning the maintenance of cleanliness and extermination of rats and insects of the interior and exterior of the facilities, and other general sanitation management;
- (ii) matters concerning initiatives to control processes that are particularly important for preventing food sanitation hazards (for a small scale business operator (excluding a business operator that manufactures apparatus, or

- containers and packages, and a poultry slaughterer prescribed in Article 6, paragraph (1) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act; the same applies in the following paragraph) and other business operators specified by Cabinet Order, initiatives in accordance with the characteristics of the food handled by the business operator).
- (2) A business operator must establish the necessary measures for public health in compliance with the criteria established pursuant to the provisions of the preceding paragraph and pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and comply with those measures.
- (3) The prefectural governor, etc. may establish necessary provisions on necessary measures for public health by Prefectural or Municipal Ordinance, provided that the provisions do not violate the criteria established pursuant to the provisions of paragraph (1).

Article 52 (1) The Minister of Health, Labour and Welfare is to establish criteria for the following matters related to the sanitary management of facilities for business that manufactures apparatus, or containers and packages, and other necessary measures for public health (referred to as "measures necessary for public health" below in this Article) under Order of the Ministry of Health, Labour and Welfare:

- (i) matters concerning the maintenance of the cleanliness and other general sanitation management of the interior and exterior of the facilities;
- (ii) matters concerning measures to appropriately manage manufacturing necessary for preventing occurrence of food sanitation hazards.
- (2) A business operator that manufactures apparatus, or containers and packages must take necessary measures for public health in compliance with the criteria established pursuant to the provisions of the preceding paragraph (for a business operator that manufactures apparatus, or containers and packages made only from raw materials of materials other than those specified by Cabinet Order prescribed in Article 18, paragraph (3), limited to the matters stated in item (i) of the preceding paragraph).
- (3) The prefectural governor, etc. may establish necessary provisions on necessary measures for public health by Prefectural or Municipal Ordinance, provided that the provisions do not violate the criteria established pursuant to the provisions of paragraph (1).

Article 53 (1) A person who sells, or manufactures or imports for the purpose of selling, apparatus, or containers and packages made from raw materials of materials specified by Cabinet Order prescribed in Article 18, paragraph (3), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, must explain that the apparatus, or containers and packages the

person handles falls under either of the following items to the other party to the sale:

- (i) for the raw materials of materials specified by Cabinet Order prescribed in Article 18, paragraph (3), the apparatus, containers or packages have been manufactured by using only raw materials that conform to the standards established pursuant to the provisions of paragraph (1) of that Article; or
 - (ii) the apparatus, or containers and packages have undergone processing prescribed in the proviso to Article 18, paragraph (3).
- (2) When a person who sells, or produces or imports for the purpose of selling, raw materials of apparatus, or containers and packages and made from materials specified by Cabinet Order prescribed in Article 18, paragraph (3) receives a request from a person who manufactures apparatus, or containers and packages using those raw materials for confirmation that the raw materials conform to the standards established pursuant to the provisions of paragraph (1) of that Article, they must endeavor to provide necessary explanations pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Article 54 Prefectures must establish criteria necessary from the viewpoint of public health for facilities of the business that have a significant impact on public health (excluding poultry slaughtering businesses) and are specified by Cabinet Order by Prefectural Ordinance, taking into consideration the criteria specified by Order of the Ministry of Health, Labour and Welfare.

Article 55 (1) A person who seeks to conduct a business prescribed in the preceding Article must obtain a license from the prefectural governor pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) In the case referred to in the preceding paragraph, the prefectural governor must grant a license when the prefectural governor finds that the business facilities conform to the criteria under the provisions of the preceding Article; provided, however, that the prefectural governor may not grant the license referred to in that paragraph when the person who seeks to conduct the business prescribed in the preceding Article falls under any of the following items:

- (i) a person who has been punished for violating this Act or a disposition based on this Act, and two years have not passed since the person finished serving the sentence or ceased to be subject to the sentence;
- (ii) a person who has had their approval revoked pursuant to the provisions of Articles 59 through 61, and for whom two years have not passed since the date of the revocation; or
- (iii) a corporation that has a person falling under any of the preceding two

- items among the officers in charge of its business.
- (3) A prefectural governor may attach necessary conditions such as a valid period of not less than five years to the approval referred to in paragraph (1).

Article 56 (1) When a person who has obtained the approval referred to in paragraph (1) of the preceding Article (referred to as an "approved business operator" below in this Article) has transferred their business, or an inheritance, a merger, or a split (limited to one that has the approved business operator succeed to the business) for an approved business operator has been implemented, a person who has been transferred the business, or an heir (if there are two or more heirs, and an heir that is to succeed to the business has been selected by the consent of all the heirs, that heir), a corporation surviving the merger, a corporation established by the merger, or a corporation succeeding to the business by the split is to succeed to the status of the approved business operator.

- (2) A person who has succeeded to the status of the approved business operator pursuant to the provisions of the preceding paragraph must notify the prefectural governor to that effect without delay, by attaching a document proving that fact.

Article 57 (1) A person who seeks to conduct business (excluding business prescribed in Article 54, a business that has a little impact on public health and is specified by Cabinet Order, and a poultry slaughtering business) must notify a prefectural governor of the name and the location of their business office and other matters specified by Order of the Ministry of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare in advance.

- (2) The provisions of the preceding Article apply mutatis mutandis to a person who has made a notification under the provisions of the preceding paragraph. In such a case, the terms "a person who has obtained the approval referred to in paragraph (1) of the preceding Article" and "an approved business operator" in paragraph (1) of that Article are deemed to be replaced with "a person who has made a notification under the provisions of paragraph (1) of the following Article" and "a notifying business operator", respectively, and the term "an approved business operator" in paragraph (2) of that Article is deemed to be replaced with "a notifying business operator".

Article 58 (1) When a business operator falls under either of the following items and recalls food or additives they have collected, produced, imported, processed or sold, or apparatus, or containers and packages they have manufactured, imported, or sold (excluding cases in which the recall is made by receiving an

order under the provisions of paragraph (1) or (2) of the following Article and cases specified by Order of the Ministry of Health, Labour and Welfare and Cabinet Office Order as those unlikely to cause food sanitation hazards), they must notify a prefectural governor of the fact that they have commenced the recall and the status of the recall, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare and Cabinet Office Order, without delay.

- (i) when the business operator violates or is likely to violate referred in the provisions of Article 6, Articles 10 through 12, Article 13, paragraph (2) or (3), Article 16, Article 18, paragraph (2) or (3), or Article 20; or
 - (ii) when the business operator violates or is likely to violate a prohibition under the provisions of Article 9, paragraph (1) or Article 17, paragraph (1).
- (2) When a notification under the provisions of the preceding paragraph has been filed, a prefectural governor must report the matters notified to the Minister of Health, Labour and Welfare or the Prime Minister pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare or Cabinet Office Order.

Article 59 (1) When a business operator violates the provisions of Article 6, Articles 10 through 12, Article 13, paragraph (2) or (3), Article 16 or Article 18, paragraph (2) or (3), or violates a prohibition under the provisions of Article 9, paragraph (1) or Article 17, paragraph (1), the Minister of Health, Labour and Welfare or a prefectural governor may order the business operator or the officials of the Ministry or the prefecture to dispose of the food, additives, apparatus, or containers and packages, or order the business operator to take other necessary measures to eliminate the food sanitation hazards.

- (2) When a business operator has violated the provisions of Article 20, the Prime Minister or a prefectural governor may order the business operator or the officials of the Ministry or the prefecture to dispose of the food, additives, apparatus, or containers and packages, or order the business operator to take other necessary measures to eliminate the food sanitation hazards caused by the false or exaggerated labeling or advertising.

Article 60 (1) When a business operator violates the provisions of Article 6, Article 8, paragraph (1), Articles 10 through 12, Article 13, paragraph (2) or (3), Article 16, Article 18, paragraph (2) or (3), Article 19, paragraph (2), Article 20, Article 25, paragraph (1), Article 26, paragraph (4), Article 48, paragraph (1), Article 50, paragraph (2), Article 51, paragraph (2), Article 52, paragraph (2) or Article 53, paragraph (1), violates a prohibition under the provisions of Article 7, paragraphs (1) through (3), Article 9, paragraph (1) or Article 17, paragraph (1), has come to fall under Article 55, paragraph (2), item (i) or (iii), or violates the conditions under the provisions of paragraph (3) of that Article, a

prefectural governor may revoke the approval referred to in paragraph (1) of that Article, prohibit the business in whole or in part, or suspend the business by specifying a period.

- (2) When a business operator (limited to a person or corporation that is engaged in import of food, additives, apparatus, or containers and packages) violates the provisions of Article 6, Article 8, paragraph (1), Article 10, paragraph (2), Article 11, Article 12, Article 13, paragraph (2) or (3), Article 16, Article 18, paragraph (2) or (3), Article 26, paragraph (4), Article 50, paragraph (2), Article 51, paragraph (2), Article 52, paragraph (2) or Article 53, paragraph (1), or violates a prohibition under the provisions of Article 7, paragraphs (1) to (3), Article 9, paragraph (1) or Article 17, paragraph (1), the Minister of Health, Labour and Welfare may prohibit the business in whole or in part, or suspend the business by specifying a period.

Article 61 When a business operator violates a criteria under the provisions of Article 54 for their business facilities, a prefectural governor may order the business operator to develop and improve the facilities, revoke the approval referred to in Article 55, paragraph (1), prohibit the business in whole or in part, or suspend the business by specifying a period.

Chapter X Miscellaneous Provisions

Article 62 The national treasury is to bear half of the following expenses of prefectures or cities with public health centers, pursuant to the provisions of Cabinet Order:

- (i) expenses required for removal under the provisions of Article 28, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3));
- (ii) expenses required for placing food sanitation inspectors under the provisions of Article 30, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3));
- (iii) expenses required for the approval of business under the provisions of Article 55, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraph (1));
- (iv) expenses required for disposal under the provisions of Article 59 (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3));
- (v) expenses required for autopsies of corpses under the provisions of Article 64, paragraph (1) or (2) (including as applied mutatis mutandis pursuant to Article 68, paragraph (1)); and
- (vi) expenses required for lawsuits concerning the enforcement of this Act and cost for compensation to be paid as a result of the lawsuits.

Article 63 (1) A physician who has diagnosed a patient of food poisoning, etc., or has examined the corpse of a patient of food poisoning must immediately notify the director of the nearest public health center to that effect.

(2) When the director of a public health center has received a notification referred to in the preceding paragraph, or finds that patients with food poisoning, etc. have been found, the director must promptly make a report to a prefectural governor, etc., and conduct an investigation, pursuant to the provisions of Cabinet Order.

(3) When a prefectural governor, etc. has received a report from the director of a public health center pursuant to the provisions of the preceding paragraph, and finds that the number of patients with food poisoning, etc. who have been found is higher than the number specified by Order of the Ministry of Health, Labour and Welfare, it is likely that such a situation will occur, or in other cases specified by Order of the Ministry of Health, Labour and Welfare, the prefectural governor, etc. must immediately make a report to the Minister of Health, Labour and Welfare.

(4) When the director of public a health center has conducted an investigation under the provisions of paragraph (2), the director must make a report to a prefectural governor, etc. pursuant to the provisions of Cabinet Order.

(5) When a prefectural governor, etc. has received a report under the provisions of the preceding paragraph, the prefectural governor, etc. must make a report to the Minister of Health, Labour and Welfare, pursuant to the provisions of Cabinet Order.

Article 64 (1) When a prefectural governor, etc. finds it necessary for investigating the cause of death, the prefectural governor, etc. may have the corpse of a person who has died of a disease that was or is suspected to have been caused by food, additives, apparatus, or containers and packages be autopsied with the consent of the bereaved family.

(2) In the case referred to in the preceding paragraph, when the cause of death cannot be determined without performing an autopsy on the corpse and as a result of not determining the cause, it is likely that serious public sanitation hazards will occur, the prefectural governor, etc. may perform an autopsy on the corpse even without obtaining the consent of the bereaved family.

(3) The provisions of the preceding two paragraphs must not preclude compulsory dispositions under the provisions concerning criminal proceedings to be made.

(4) When performing an autopsy on a corpse pursuant to the provisions of paragraph (1) or (2), care must be taken not to lose respect for the deceased.

Article 65 If the number of patients with food poisoning, etc. who have been

confirmed is higher than the number specified by Order of the Ministry of Health, Labour and Welfare, it is likely that such a situation will occur, or patients with food poisoning, etc. have been found over a wide area or are likely to spread over a wide area, and there is an urgency to prevent the occurrence of food sanitation hazards, the Minister of Health, Labour and Welfare may request prefectural governors, etc. to investigate the causes of food poisoning and report the investigation results, by specifying a time limit.

Article 66 In the case prescribed in the preceding Article, when the Minister of Health, Labour and Welfare finds it necessary, the Minister must hold a council meeting, share necessary information on the investigation of the causes of food poisoning and the results of the investigation, aim at closer cooperation among the relevant organizations, and endeavor to conduct discussions on necessary measures to prevent patients with food poisoning, etc. to be found over a wide area, or their increase.

Article 67 (1) A prefecture, etc. is to endeavor to provide necessary advice, guidance, and other assistance to food business operators, in order to prevent the occurrence of food poisoning and improve food sanitation in the region.

(2) A prefecture, etc. may appoint a food sanitation promoter from among the persons who have public reputation, and have enthusiasm, knowledge and experience for improving food sanitation, in order to promote voluntary activities by food business operators concerning the improvement of food sanitation.

(3) A food sanitation promoter is to cooperate in the policy measures of prefectures, etc., respond to requests for consultation from food business operators, and give advice to them concerning sanitation management method of facilities for restaurant business and other matters concerning food sanitation.

Article 68 (1) The provisions of Article 6, Article 9, Article 12, Article 13, paragraphs (1) and (2), Articles 16 through 20 (excluding Article 18, paragraph (3)), Articles 25 through 61 (excluding Article 51, Article 52, paragraph (1), item (ii) and paragraph (2), and Article 53), and Articles 63 through 65 apply *mutatis mutandis* to toys designated by the Minister of Health, Labour and Welfare and the Prime Minister as those likely to harm the health of infants when they touch the toys. In such a case, the term "Additives (excluding natural flavoring agents and things that have been generally served for human consumption, and are used as additives)" in Article 12 is deemed to be replaced with "Chemically synthesized compounds intended to be used as additives for toys (meaning substances obtained by causing a chemical reaction other than a

decomposition reaction to elements or compounds by chemical means)".

- (2) The provisions of Article 6, and Article 13, paragraphs (1) and (2) apply mutatis mutandis to detergents used for washing vegetables, fruits, or tableware.
- (3) The provisions of Articles 15 through 18, Article 25, paragraph (1), Articles 28 through 30, Article 51, Article 54, Article 57, and Articles 59 through 61 apply mutatis mutandis to cases in which food is continuously provided to a large number of persons or unspecified persons at schools, hospitals, or other facilities.

Article 69 In order to prevent the occurrence of food sanitation hazards, the Minister of Health, Labour and Welfare, the Prime Minister, and a prefectural governor are to endeavor to publicize the name, etc. of the person who has violated this Act or a disposition based on this Act and disclose the circumstances of the food sanitation hazard.

Article 70 (1) When the Minister of Health, Labour and Welfare intends to conduct the following acts, the Minister is to publicize the purpose, content, and other necessary matters and broadly seek the opinions of the public; provided, however, that this does not apply if there is an urgency to prevent the occurrence of food sanitation hazards and there is no time to broadly seek the opinions of the public in advance:

- (i) to specify cases that are unlikely to harm human health prescribed in the proviso to Article 6, item (ii) (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (2));
 - (ii) to prohibit the sales pursuant to the provisions of Article 7, paragraphs (1) through (3), or revoke the prohibition in whole or in part pursuant to the provisions of paragraph (4) of that Article;
 - (iii) to enact, amend, or repeal Order of the Ministry of Health, Labour and Welfare referred to in Article 10, paragraph (1), Article 51, paragraph (1), Article 52, paragraph (1), or Article 54;
 - (iv) to establish or amend the imported food monitoring and guidance plan prescribed in Article 23, paragraph (1); and
 - (v) to establish the criteria prescribed in Article 50, paragraph (1).
- (2) When the Prime Minister intends to conduct the following acts, the Prime Minister is to publicize the purpose, content, and other necessary matters and broadly seek the opinions of the public; provided, however, that this does not apply if there is an urgency to prevent the occurrence of food sanitation hazards and there is no time to broadly seek the opinions of the public in advance:
- (i) to specify cases that are unlikely to harm human health prescribed in

Article 12;

- (ii) to establish the criteria or standards prescribed in Article 13, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (2));
 - (iii) to specify substances that are clearly unlikely to harm human health, or the quantity that is unlikely to harm human health, prescribed in Article 13, paragraph (3);
 - (iv) to establish the criteria or standards prescribed in Article 18, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3));
 - (v) to specify the quantity that is unlikely to harm human health prescribed in the proviso to Article 18, paragraph (3); and
 - (vi) to establish the criteria for labeling prescribed in Article 19, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)).
- (3) When a prefectural governor, etc. intends to establish or change the prefectural plans for the monitoring and guidance of food sanitation prescribed in Article 24, paragraph (1), the prefectural governor, etc. must publicize the purpose, content, and other necessary matters, and broadly seek the opinions of the public.
- (4) In the case referred to in the proviso to paragraph (1) or the proviso to paragraph (2), the Minister of Health, Labour and Welfare or the Prime Minister is to broadly seek the opinions of the public without delay, after the fact.
- (5) The provisions of paragraph (1) and the preceding paragraph apply *mutatis mutandis* when the Minister of Health, Labour and Welfare and the Prime Minister intend to designate a designated ingredient, etc. and to establish or change the guidelines pursuant to the provisions of Article 8, paragraph (1).

Article 71 In order to reflect the people's or the residents' opinions in the policy measures concerning food sanitation and promote the exchange of information and opinions between relevant persons, the Minister of Health, Labour and Welfare, the Prime Minister, and the prefectural governor, etc. must publicize the implementation status of the policy measures, and broadly seek the opinions of the people or the residents concerning the policy measures.

Article 72 (1) When the Minister of Health, Labour and Welfare intends to conduct the acts stated in the items of Article 70, paragraph (1), the Minister must consult with the Prime Minister in advance.

(2) When the Prime Minister intends to conduct the acts stated in the items of Article 70, paragraph (2), the Prime Minister must consult with the Minister of

Health, Labour and Welfare in advance.

- (3) When the Minister of Health, Labour and Welfare finds it necessary, the Minister may request the Prime Minister to conduct the acts stated in the items of Article 70, paragraph (2).
- (4) When the Prime Minister finds it necessary, the Prime Minister may request the Minister of Health, Labour and Welfare to conduct the acts stated in the items of Article 70, paragraph (1).

Article 73 The Minister of Health, Labour and Welfare and the Prime Minister are to endeavor to ensure close cooperation with each other through the exchange of necessary information, such as reports under the provisions of Article 8, paragraph (2) and Article 63, paragraph (5), in order to prevent the occurrence of sanitation hazards resulting from eating and drinking.

Article 74 Deleted

Article 75 Deleted

Article 76 The term "prefectural governor" in Article 48, paragraph (8), Article 55, Article 56, paragraph (2) (including as applied mutatis mutandis pursuant to Article 57, paragraph (2) following the deemed replacement of terms), Article 57, paragraph (1), Article 58, Article 59, Article 60, paragraph (1), Article 61, and Article 69 is deemed to be replaced with "mayor" for cities with public health centers and "ward mayor" for special wards; provided, however, that this does not apply to dispositions on business specified by Cabinet Order which are specified by Cabinet Order.

Article 77 Beyond what is provided for in the main clause of the preceding Article, affairs specified by Cabinet Order as those to be handled by prefectures in this Act are to be handled by designated cities or core cities (referred to below as "designated cities, etc.") in designated cities referred to in Article 252-19, paragraph (1) of the Local Autonomy Act (Act No. 67 of 1947) (referred to below as "designated cities") and core cities referred to in Article 252-22, paragraph (1) of the same Act (referred to below as "core cities"), pursuant to the provisions of Cabinet Order. In such a case, the provisions of this Act concerning prefectures apply to designated cities, etc. as the provisions concerning designated cities, etc.

Article 78 (1) A person who is dissatisfied with the ruling on request for examination of a disposition (limited to a disposition related to type 1 statutory entrusted functions defined in Article 2, paragraph (9), item (i) of the Local

Autonomy Act (referred to as "type 1 statutory entrusted functions" in the following paragraph and the following Article)) made by the head of a local government (excluding prefectures; the same applies in the following paragraph) pursuant to the provisions of this Act, may make a request for re-examination to the Minister of Health, Labour and Welfare (for a disposition under the provisions of Article 59, paragraph (2) (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3), the Prime Minister); the same applies in the following paragraph).

- (2) When the head of a local government delegates the authority to make dispositions related to type 1 statutory entrusted functions among the affairs to be handled by them pursuant to the provisions of this Act to an official positioned as their subsidiary body or to the head of an administrative organ under their control, and a ruling on a request for re-examination which is referred to in Article 255-2, paragraph (2) of the Local Autonomy Act against a disposition taken by the official or head of the administrative organ based on the authority delegated has been made, a person who is dissatisfied with the ruling may make a request for further re-examination to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 252-17-4, paragraphs (5) through (7) of that Act.

Article 79 (1) The affairs that are to be handled by prefectures pursuant to the provisions of Article 25, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3)), Article 26, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraph (1)), Article 28, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 30, paragraph (2) (excluding the part related to monitoring and guidance incidental to the approval of conducting business (limited to business specified by Cabinet Order by taking into consideration the status of distribution of food or additives) prescribed in Article 54, and including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3)), Article 59 (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3)), Article 63 (including as applied mutatis mutandis pursuant to Article 68, paragraph (1)), and Article 64, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraph (1)) are deemed to be type 1 statutory entrusted functions.

- (2) The affairs that are to be handled by cities with public health centers or special wards pursuant to the provisions of Article 28, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3)), Article 30, paragraph (2) (excluding the part related to monitoring and guidance incidental to the approval of conducting business (limited to business specified by Cabinet Order by taking into consideration the status of

distribution of food or additives) prescribed in Article 54, and including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)), Article 59 (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)), Article 63 (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)), and Article 64, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)) are to be type 1 statutory entrusted functions.

- Article 80 (1) The authority of the Minister of Health, Labour and Welfare prescribed in this Act may be delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) The authority delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph may be delegated to the head of a Regional Branch Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) The Prime Minister is to delegate the authority under this Act (excluding the authority specified by Cabinet Order) to the Commissioner of the Consumer Affairs Agency.

Chapter XI Penal Provisions

- Article 81 (1) A person falling under any of the following items is punished by imprisonment for a period not exceeding three years or a fine not exceeding three million yen:
- (i) a person who violates the provisions of Article 6 (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (2)), Article 10, paragraph (1), or Article 12 (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1));
 - (ii) a person who violates the prohibition under the provisions of Article 7, paragraphs (1) through (3);
 - (iii) a business operator that disobeys an order issued by the Minister of Health, Labour and Welfare or a prefectural governor (when the terms are deemed to be replaced pursuant to the provisions of Article 76, a mayor or a ward mayor; the same applies below in this item) under the provisions of Article 59, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)) or an order issued by the Prime Minister or a prefectural governor under the provisions of Article 59, paragraph (2) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)) (including persons who furnish food prescribed in Article 68,

- paragraph (3)), or a person who conducts business in violation of a disposition under the provisions of Article 60 (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)).
- (2) A person who has committed a crime referred to in the preceding paragraph may be punished by both imprisonment and a fine depending on the circumstances.

Article 82 (1) A person who violates the provisions of Article 13, paragraph (2) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (2)) or paragraph (3), Article 16 (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)), Article 19, paragraph (2) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)), Article 20 (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)), or Article 55, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)) is punished by imprisonment for a period not exceeding two years or a fine not exceeding two million yen.

(2) A person who has committed a crime referred to in the preceding paragraph may be punished by both imprisonment and a fine depending on the circumstances.

Article 83 A person falling under any of the following items is punished by imprisonment for a period not exceeding one year or a fine not exceeding one million yen:

- (i) a person who violates the provisions of Article 10, paragraph (2), Article 11, Article 18, paragraph (2) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)) or paragraph (3), Article 25, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)), Article 26, paragraph (4) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)), and Article 63, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1));
- (ii) a person who violates the prohibition under the provisions of Article 9, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)) or Article 17, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3));
- (iii) a person who divulges any secret they have learned in the course of duty in violation of the provisions of Article 40, paragraph (1);
- (iv) a person who violates the criteria under the provisions of Article 54 (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)) or violates the conditions under the provisions of Article 55, paragraph (3) (including as applied *mutatis mutandis* pursuant to Article 68,

- paragraph (1)); or
- (v) a business operator that disobeys an order issued by a prefectural governor (when the terms are deemed to be replaced pursuant to the provisions of Article 76, a mayor or a ward mayor) under the provisions of Article 61 (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)) (including persons who furnish food prescribed in that paragraph), or a person who conducts business in violation of a disposition under the provisions of Article 61 (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)).

Article 84 An officer or employee of a registered conformity assessment body who has violated an order of suspension of business under the provisions of Article 43 is punished by imprisonment for a period not exceeding one year, or a fine not exceeding one million yen.

Article 85 A person falling under any of the following items is punished by a fine not exceeding 500 thousand yen:

- (i) a person who has refused, obstructed or evaded an on-site inspection or collection and removal by an official under the provisions of Article 28, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3));
- (ii) a person who has not made a report under the provisions of Article 28, paragraph (1) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3)) or has made a false report;
- (iii) a person who has not made a notification under the provisions of Article 27, Article 48, paragraph (8) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1) for both cases), Article 57, paragraph (1), or Article 58, paragraph (1), or has made a false notification; or
- (iv) a person who violates an order under the provisions of Article 46, paragraph (2).

Article 86 When a violation stated in any of the following items has been committed, the officer or the employee of a registered conformity assessment body who has committed the violation is punished by a fine not exceeding 500 thousand yen:

- (i) when they have abolished all the operations for product inspections without obtaining the approval referred to in Article 38;
- (ii) when they have failed to state the matters prescribed in Article 44, have made a false statement, or have failed to preserve books, in violation of that Article;
- (iii) when they have failed to make a report under the provisions of Article 47,

- paragraph (1) or have made a false report;
- (iv) when they have refused, obstructed, or evaded inspections under the provisions of Article 47, paragraph (1), have not given answers to questions under the provisions of that paragraph, or have given false answers.

Article 87 When a food sanitation supervisor has neglected their duties under the provisions of Article 48, paragraph (3), and there have been acts falling under violations referred to in Articles 81 through 83 concerning food or additives related to their supervision at the facility, the food sanitation supervisor is punished by a fine prescribed in the respective Articles depending on the manner of the acts; provided, however, that this does not apply when the food sanitation supervisor is the person who has committed the acts.

Article 88 When a representative of a corporation, an agent, an employee or any other worker of a corporation or a person has committed an act in violation of the provisions stated in the following items in relation to the business of the corporation or the person, in addition to the offender being punished, the corporation is punished by a fine prescribed in each of those items, and the person is punished by a fine referred to in the respective Articles; provided, however, that this does not apply when the person is to be punished by a fine as a food sanitation supervisor pursuant to the provisions of the preceding Article:

- (i) the provisions of Article 81 or Article 82 (limited to the part related to the provisions of Article 13, paragraph (2) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (2)) or paragraph (3), Article 19, paragraph (2) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)), and Article 20 (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1))): a fine not exceeding 100 million yen; and
- (ii) the provisions of Article 82 (excluding the part related to the provisions of Article 13, paragraph (2) (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (2)) or paragraph (3), Article 19, paragraph (2) (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1)), and Article 20 (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1))), Article 83, or Article 85: a fine referred to in the respective Articles.

Article 89 A person who has not kept financial statements in violation of the provisions of Article 39, paragraph (1), has not entered the matters that should be entered in financial statements, has made a false statement in them, or has refused a request under the provisions of each item of paragraph (2) of that

Article without legitimate grounds, is punished by a civil fine not exceeding 200 thousand yen.

Appended Table (Re: Article 33)

Physicochemical inspections	<p>(i) Centrifugal separator</p> <p>(ii) Water purifying apparatus</p> <p>(iii) Deep freezer</p> <p>(iv) Homogenizer</p> <p>(v) Gas chromatograph</p> <p>(vi) Gas chromatograph mass spectrometer (limited to those which conduct inspections of agricultural chemicals remaining in food defined in Article 2, paragraph (1) of the Agricultural Chemicals Regulation Act)</p>	<p>A person who falls under any of the following items:</p> <p>(i) a person who has graduated from a university (excluding a junior college) under the School Education Act, a university under the former University Order, or a technical college under the former Technical College Order after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, agricultural chemistry, or applied chemistry, or an equivalent course, and has experience of being engaged in the operation of physicochemical inspections for one year or more;</p>	Four persons
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	<p>(vii) Atomic absorption photometer</p> <p>(viii) High performance liquid chromatograph</p>	<p>(ii) a person who has graduated from a junior college or a college of technology under the School Education Act after completing a course in industrial chemistry or an equivalent course , and has experience of being engaged in the operation of physicochemical inspections for three years or more;</p> <p>(iii) a person who has equal or greater knowledge and experience than those stated in the preceding two items.</p>	
Bacteriological inspections	<p>(i) Centrifugal separator</p> <p>(ii) Water purifying apparatus</p> <p>(iii) Deep freezer</p> <p>(iv) Homogenizer</p> <p>(v) Dry heat sterilizer</p>	<p>A person who falls under any of the following items:</p> <p>(i) a person who has graduated from a university (excluding a junior college) under the School Education Act, a</p>	Four persons

	(vi) Optical microscope	university under the former University Order, or a technical college under the former Technical College Order after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, agricultural chemistry, or biology, or an equivalent course , and has experience of being engaged in the operation of bacteriological inspections for one year or more;	
	(vii) Autoclave	(ii) a person who has graduated from a junior college or a college of technology under the School Education Act after completing a course in biology or an equivalent course , and has experience of being engaged in the operation of bacteriological inspections for three years or more;	

	(viii) Incubator	(iii) a person who has equal or greater knowledge and experience than those stated in the preceding two items.	
Inspections using animals	<p>1. Centrifugal separator</p> <p>2. Water purifying apparatus</p>	<p>A person who falls under any of the following items:</p> <p>(i) a person who has graduated from a university (excluding a junior college) under the School Education Act, a university under the former University Order, or a technical college under the former Technical College Order after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, agricultural chemistry, or biology, or an equivalent course , and has experience of being engaged in the operation of inspections using animals for one year or more;</p>	Three persons

	3. Deep freezer	(ii) a person who has graduated from a junior college or a college of technology under the School Education Act after completing a course in biology or an equivalent course , and has experience of being engaged in the operation of inspections using animals for three years or more;	
	4. Homogenizer	(iii) a person who has equal or greater knowledge and experience than those stated in the preceding two items.	