

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, to ensure food safety and thereby to protect citizens' 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) (hereinafter referred to as "cities with health centers") and special wards must take the necessary measures to disseminate the correct knowledge concerning food sanitation through educational and PR activities, conduct the collection, compilation, analysis, and provision of information on food sanitation, promote research on food sanitation, enhance inspection capabilities concerning food sanitation, and foster human resources to be engaged in the improvement of food sanitation and enhance their capabilities.

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

(3) The national government is to develop a system for conducting the collection, compilation, analysis, and provision of information on food sanitation, carrying out research, and making inspections on food sanitation with regard to

imported food, additives, apparatus, and containers and packaging, and take the measures necessary to ensure international coalition. At the same time, the national government is to provide prefectures, cities with health centers and special wards (hereinafter referred to as "prefectures, etc.") with the technical assistance necessary for them to pursue their responsibilities as set forth in the preceding two paragraphs.

Article 3 (1) A food business operator (meaning a person or corporation who is engaged in collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives, or producing, importing, or selling apparatus, or containers and packaging, or a person or corporation who continuously provides food to many and unspecified persons at schools, hospitals or other facilities; the same applies hereinafter), on their own responsibility, must endeavor to ensure the safety of the food, additives, apparatus, or containers and packaging which they collect, produce, import, process, cook, store, transport, sell, provide to many and unspecified persons, or use in business (hereinafter referred to as "food for sale, etc."), and for that purpose, they must endeavor to obtain the knowledge and skills necessary to ensure the safety of food for sale, etc., ensure the safety of raw materials of food for sale, etc., conduct voluntary inspections of food for sale, etc., and take other necessary measures.

(2) A food business operator must endeavor to make a record of any necessary information such as the name of the person who has sold food for sale, etc. or raw materials thereof to the food business operator and retain 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 take any necessary measures appropriately and promptly, such as the provision of the record prescribed in the preceding paragraph to the national government or prefectures, etc. and the disposal of the food for sale, etc. which caused the food sanitation hazards.

Article 4 (1) The term "food" as used in this Act means all food and drinks; provided, however, that this term does not include pharmaceutical products, quasi-pharmaceutical products or regenerative medicine products specified by 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 which are used by being added, mixed or infiltrated into food or by other methods 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 thereof which are used for flavoring food.

- (4) The term "apparatus" as used in this Act means tableware, kitchen utensils, and other machines, equipment, and other articles which are used for collecting, producing, processing, cooking, storing, transporting, displaying, delivering, or consuming food or additives and which come into direct contact with food or additives; provided, however, that this term does not include machines, equipment, and other articles used for harvesting food in agriculture and fisheries.
- (5) The term "containers and packaging" as used in this Act means articles which contain or wrap food or additives and are presented "as is" when delivering food or additives.
- (6) The term "food sanitation" as used in this Act means sanitation concerning eating and drinking, with regard to food, additives, apparatus, and containers and packaging.
- (7) The term "business" as used in this Act means the act of collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives, or the act of producing, importing, or selling apparatus, or containers and packaging, in the course of trade; provided, however, that the term does not include the business of harvesting food in agriculture and fisheries.
- (8) The term "a business" as used in this Act means a person or corporation that is engaged in business.
- (9) The term "a registered conformity assessment body" as used in this Act means a corporation that has obtained 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 Food or additives which are meant to be sold (including supplying other than selling them to many and unspecified persons; the same applies hereinafter) must be collected, produced, processed, used, cooked, stored, transported, displayed and delivered in a clean and sanitary manner.

Article 6 The following food and additives must not be sold (including cases of being supplied but not being sold to many and unspecified persons; the same applies hereinafter), or collected, produced, imported, processed, used, cooked, stored, or displayed for the purpose of sale:

- (i) those which are rotten or have deteriorated, or are immature; provided, however, that this does not apply to those which are unlikely to cause harm to human health in general and are recognized as edible;

- (ii) those which contain or bear toxic or harmful substances or are suspected to contain or bear such substances; provided, however, that this does not apply when the Minister of Health, Labour and Welfare specifies that the substances are unlikely to cause harm to human health;
- (iii) those which are contaminated with pathogens or are suspected to be so, and which are likely to cause harm to human health;
- (iv) those which are likely to cause harm to human health due to contamination or the addition of foreign substances or on other grounds.

Article 7 (1) When things which have not generally been served for human consumption and have not been proven to be unlikely to cause harm to human health or things including those things have newly come to be sold or are going to be sold as food, the Minister of Health, Labour and Welfare may prohibit the sales of those things as food, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards.

(2) Regarding things which have generally been served for human consumption but are served in a manner significantly different from the norm, the Minister of Health, Labour and Welfare may prohibit the sale of those things as food, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when there is no evidence to prove that those things are unlikely to cause harm to human health and the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards.

(3) In the case of serious harm to human health which is suspected to have been caused by food, and when it is suspected, from the conditions of the harm, that the food includes things which have not generally been served for human consumption and which are likely to cause the harm, the Minister of Health, Labour and Welfare may prohibit the sale of such food, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards.

(4) When the Minister of Health, Labour and Welfare has prohibited the sale under the preceding three paragraphs, and finds that there is no likelihood to cause food sanitation hazards resulting from things or food pertaining to the prohibition, based on an application from an interested person concerning the prohibition, or as required, pursuant to Ministry of Health, Labour and Welfare Order, the Minister of Health, Labour and Welfare is to rescind the prohibition, in whole or in part, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

(5) When the Minister of Health, Labour and Welfare has prohibited the sales under paragraphs (1) to (3), or has rescinded the prohibition, in whole or in

part, under the preceding paragraph, the Minister of Health, Labour and Welfare is to issue public notice in the Official Gazette.

Article 8 (1) A business that handles food containing any ingredient or material which requires special attention from the viewpoint of preventing food sanitation hazards and which has been designated by the Minister of Health, Labour and Welfare by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council (referred to as a "designated ingredient, etc." in paragraph (3) and Article 70, paragraph (1)) (hereinafter in this paragraph referred to as "food containing designated ingredient, etc."), upon obtaining information that any food containing designated ingredient, etc. handled by the business causes or may cause harm to human health, must notify the relevant prefectural governor, the city mayor of the relevant city with health centers or the ward mayor of the relevant special ward (hereinafter referred to as the "prefectural governor, etc.") of that information without delay pursuant to Ministry of Health, Labour and Welfare Order.

(2) When there has been a notification under the preceding paragraph, 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 monitor harm to human health suspected of being caused by the ingestion of a designated ingredient, etc., and when requested by the relevant prefectural governor, etc. for cooperation necessary in conducting investigation on harm to human health suspected of being caused by the ingestion of a designated ingredient, etc. in order to prevent food sanitation hazards, must endeavor to respond to the request and provide information on the harm or other necessary cooperation.

Article 9 (1) Regarding specific food or additives which are collected, produced, processed, cooked, or stored in a specific country or region, or which are collected, produced, processed, cooked, or stored by a specific person, when, as a result of inspections under Article 26, paragraphs (1) to (3), or Article 28, paragraph (1), a considerable number of food or additives falling under the following items are found, or it is found that food or additives falling under the following items are likely to be included to a considerable extent, judging from the conditions of food sanitation management at the production site or on other grounds specified by Ministry of Health, Labour and Welfare Order, and the Minister of Health, Labour and Welfare finds it particularly necessary to prevent food sanitation hazards resulting from that specific food or additives, considering the level of the likelihood to cause harm to human health and other matters specified by Ministry of Health, Labour and Welfare Order, the

Minister of Health, Labour and Welfare may prohibit the sales of the relevant specific food or additives, or the collection, production, import, processing, use, or cooking of that specific food or additives for the purpose of sale, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council:

- (i) food or additives listed in each item of Article 6;
 - (ii) food prescribed in Article 12;
 - (iii) food or additives which do not conform to the standards established pursuant to the provisions of Article 13, paragraph (1);
 - (iv) food in which additives are used by methods that do not conform to the criteria established pursuant to the provisions of Article 13, paragraph (1);
 - (v) food prescribed in Article 13, paragraph (3).
- (2) When the Minister of Health, Labour and Welfare intends to issue a prohibition under the preceding paragraph, the Minister of Health, Labour and Welfare must consult with the heads of the relevant administrative organs in advance.
- (3) When the Minister of Health, Labour and Welfare has issued a prohibition under paragraph (1), and finds that there is no likelihood to cause food sanitation hazards resulting from specific food or additives pertaining to the prohibition, based on an application from an interested person concerning the prohibition, or as required, pursuant to Ministry of Health, Labour and Welfare Order, the Minister of Health, Labour and Welfare is to rescind the prohibition, in whole or in part, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.
- (4) When the Minister of Health, Labour and Welfare has issued a prohibition under paragraph (1), or has issued a rescission of prohibition, in whole or in part under the preceding paragraph, the Minister of Health, Labour and Welfare is to issue public notice in the Official Gazette.

Article 10 (1) The meat, bones, milk, organs, and blood of livestock (meaning livestock prescribed in Article 3, paragraph (1) of the Slaughterhouse Act (Act No. 114 of 1953) and others specified by Ministry of Health, Labour and Welfare Order; the same applies hereinafter) which have or are suspected to have any of the diseases listed in item (i) or item (iii), have any of the abnormalities listed in item (i) or item (iii), or have died, or the meat, bones, and organs of poultry (meaning poultry prescribed in Article 2, item (i) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Act No. 70 of 1990) and others specified by Ministry of Health, Labour and Welfare Order; the same applies hereinafter) which have or are suspected to have any of the diseases listed in item (ii) or item (iii), have any of the disorders listed in item (ii) or item (iii), or have died, must not be sold as food, or be collected, processed, used, cooked, stored, or displayed as food for the purpose of sale,

except for cases specified by Ministry of Health, Labour and Welfare Order; provided, however, that this does not apply to the meat, bones, and organs of dead livestock or poultry which the ministry's officials find as unlikely to cause harm to human health and as edible.

- (i) diseases or abnormalities listed in each item of Article 14, paragraph (6) of the Slaughterhouse Act;
 - (ii) diseases or abnormalities listed in each item of Article 15, paragraph (4) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act;
 - (iii) diseases or abnormalities other than those listed in the preceding two items which are specified by Ministry of Health, Labour and Welfare Order.
- (2) The meat, milk and organs of livestock, and, the meat and organs of poultry, and, products thereof specified by Ministry of Health, Labour and Welfare Order (hereinafter referred to as "livestock meat, etc." in this paragraph) must not be imported as food for the purpose of sale, unless they have certificates or their copies attached which have been issued by a governmental organization of an exporting country, and which certify that they are not the meat, milk or organs of livestock, or, the meat or organs of poultry, or, products thereof which have or are suspected to have any of the diseases listed in each item of the preceding paragraph, have any of the abnormalities listed in each item of the same paragraph, or have died, and which contain other matters specified by Ministry of Health, Labour and Welfare Order (hereinafter referred to as "matters regarding sanitation" in this paragraph); provided, however, that this does not apply to livestock meat, etc. imported from countries specified by Ministry of Health, Labour and Welfare Order, for which matters regarding sanitation concerning the livestock meat, etc. have been sent from a governmental organization of those countries via a telecommunications line to a computer (with an input-output device) used by the Ministry of Health, Labour and Welfare and have been recorded in a file on the computer.

Article 11 (1) The food and additives specified by Ministry of Health, Labour and Welfare Order as requiring measures to control particularly important processes to be taken in order to prevent food sanitation hazards must not be imported for the purpose of sale, unless they have been produced or processed in the countries or regions, or facilities specified by the Minister of Health, Labour and Welfare as actually taking those measures.

- (2) The food and additives specified by Ministry of Health, Labour and Welfare Order as requiring certification of the conditions of food sanitation management at the production site in order to check that they do not fall under any of the food and additives listed in the items of Article 6 and to check other matters specified by Ministry of Health, Labour and Welfare Order must not be imported for the purpose of sale, unless they have certificates or copies thereof

attached which have been issued by a governmental organization of an exporting country and which contain the relevant matters.

Article 12 Additives (excluding natural flavoring agents and things that have generally been served for human consumption, and are used as additives) and preparations and food containing additives must not be sold, or be produced, imported, processed, used, stored, or displayed for the purpose of sale, except for cases that the Minister of Health, Labour and Welfare specifies as unlikely to cause harm to human health by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

Article 13 (1) From the viewpoint of public health, the Minister of Health, Labour and Welfare may establish the criteria for the methods of producing, processing, using, cooking, or preserving food or additives to be served for the purpose of sale, or may establish standards for the ingredients of food or additives to be served for the purpose of sale, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation 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 methods that do not conform to such criteria; food or additives that do not conform to such criteria must not be sold or imported; and food or additives that do not conform to such standards must not be produced, imported, processed, used, cooked, preserved, or sold.

(3) Food in which substances that are the ingredients of agricultural chemicals (meaning agricultural chemicals prescribed in Article 2, paragraph (1) of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948), hereinafter 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 feed for the purpose of usage specified by Ministry of Agriculture, Forestry and Fisheries Order based on Article 2, paragraph (3) of the same Act, and pharmaceutical products that are prescribed 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 produced by chemical change of those substances and excluding substances that the Minister of Health, Labour and Welfare specifies as clearly unlikely to cause harm to human health) remain in a quantity exceeding the quantity that the Minister of Health, Labour and Welfare specifies as unlikely to cause harm to human health by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, must not be produced, imported, processed, used, cooked, preserved,

for the purpose of sale, or sold; provided, however, that this does not apply when standards concerning the ingredients of food under paragraph (1) have been established with regard to the residual limit of those substances in the food.

Article 14 When the Minister of Health, Labour and Welfare establishes a limit on the amount of substances (including substances produced by the chemical change of those substances) that are the ingredients of agricultural chemicals, feed additives prescribed in Article 2, paragraph (3) of the Act on Safety Assurance and Quality Improvement of Feed, and pharmaceutical products that are prescribed 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 only for animals (hereinafter referred to as "agricultural chemicals, etc." in this Article) that remain in food, as standards concerning the ingredients of food set forth in paragraph (1) of the preceding Article, when the Minister of Health, Labour and Welfare designates the scope of edible meat, milk and other products of the target animals (meaning the target animals prescribed in Article 14, paragraph (2), item (iii) (b) of the same Act after replacing the relevant terms pursuant to the provisions of Article 83, paragraph (1) of the same Act) for which regenerative medicine products that are prescribed in Article 2, paragraph (9) of the same Act and are to be used only for animals (hereinafter referred to as "animal regenerative medicine products" in this Article) have been used, or when the Minister of Health, Labour and Welfare otherwise finds it necessary, the Minister of Health, Labour and Welfare may request the Minister of Agriculture, Forestry and Fisheries to provide data concerning the ingredients of the agricultural chemicals, etc. or concerning the component cells, transgenes and other materials specified by Ministry of Health, Labour and Welfare Order of the animal regenerative medicine products, or to provide other necessary cooperation.

Chapter III Apparatus, and Containers and Packaging

Article 15 Apparatus, and containers and packaging used in conducting business must be clean and sanitary.

Article 16 Apparatus, or containers and packaging which contains or bears toxic or harmful substances and is likely to cause harm to human health, or apparatus, or containers and packaging which comes into contact with food or additives and has a harmful effect on them and which is likely to cause harm to human health must not be sold, produced or imported for the purpose of sale,

or used in business.

Article 17 (1) Regarding specific apparatus, or containers and packaging which are produced in a specific country or region, or are produced by a specific person, when, as a result of inspections under Article 26, paragraphs (1) to (3), or Article 28, paragraph (1), a considerable number of apparatus, or containers and packaging falling under the following items are found, or it is found that apparatus, or containers and packaging falling under the following items are likely to be included to a considerable extent, judging from the conditions of food sanitation management at the production site or on other grounds specified by Ministry of Health, Labour and Welfare Order, and the Minister of Health, Labour and Welfare finds it particularly necessary to prevent food sanitation hazards resulting from that specific apparatus, or containers and packaging, considering the level of the likelihood to cause harm to human health and other matters specified by Ministry of Health, Labour and Welfare Order, the Minister of Health, Labour and Welfare may prohibit the sales of the relevant specific apparatus, or containers and packaging, the production or import of the relevant specific apparatus, or containers and packaging for the purpose of sale, or the use of that specific apparatus, or containers and packaging in business, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council:

- (i) apparatus, or containers and packaging prescribed in the preceding Article;
 - (ii) apparatus, or containers and packaging which do not conform to the standards established pursuant to the provisions of paragraph (1) of the following Article.
 - (iii) apparatus, or containers and packaging that violate paragraph (3) of the following Article.
- (2) When the Minister of Health, Labour and Welfare intends to issue a prohibition under the preceding paragraph, the Minister of Health, Labour and Welfare 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 where a prohibition under paragraph (1) has been issued. In this case, the term "food or additives" in paragraph (3) of the same Article is deemed to be replaced with "apparatus, or containers and packaging."

Article 18 (1) From the viewpoint of public health, the Minister of Health, Labour and Welfare may establish standards for apparatus, or containers and packaging, or the raw materials thereof to be served for the purpose of sale or to be used in business, or may establish the criteria for the production methods thereof, by hearing the opinions of the Pharmaceutical Affairs and Food

Sanitation Council.

- (2) When the standards or criteria have been established pursuant to the provisions of the preceding paragraph, the apparatus, or containers and packaging that does not conform to the standards must not be sold, produced or imported for the purpose of sale, or used in business; raw materials that do not conform to the standards must not be used; and the apparatus, or containers and packaging must not be produced by methods that do not conform to the criteria.
- (3) Substances (excluding substances generated by chemical change of the substances) as raw materials of materials specified by Cabinet Order by taking into consideration the impact on public health of the elution or seeping out of their components into food must not be used for apparatus, or containers and packaging, where the quantity allowed to be contained in the apparatus, or containers and packaging produced using the substances or the quantity allowed to be eluted or seep out into food from the apparatus, or containers and packaging produced using the substances is not specified in the standards established pursuant to paragraph (1) of the same Article; provided, however, that this does not apply when apparatus, or containers and packaging is processed so that those substances are unlikely to be eluted or seep out into food at levels exceeding the quantity specified by the Minister of Health, Labour and Welfare as unlikely to cause harm to human health by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council (excluding the case where those substances are used in the part of the apparatus, or containers and packaging that comes into contact with food).

Chapter IV Labeling and Advertising

- Article 19 (1) From the viewpoint of accurately communicating to general consumers information on apparatus, or containers and packaging that is necessary for public health, the Prime Minister may establish necessary criteria for the labeling of apparatus, or containers and packaging for which standards or criteria have been established pursuant to the provisions of paragraph (1) of the preceding Article, by hearing the opinions of the Consumer Commission.
- (2) Apparatus, or containers and packaging 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 sale, or used in business, without labeling that conforms to the criteria.
 - (3) Criteria for the labeling of food and additives for the purpose of sale is subject to the Food Labeling Act (Act No. 70 of 2013).

Article 20 False or exaggerated labeling or advertising, which is likely to cause harm to public health regarding food, additives, apparatus, or containers and packaging, must not be used.

Chapter V Japan's Specifications and Standards for Food Additives

Article 21 Regarding 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, the Minister of Health, Labour and Welfare and the Prime Minister are to compile the Japan's Specifications and Standards for Food Additives that contains the relevant criteria and standards.

Chapter VI Monitoring and Guidance

Article 21-2 The national government and prefectures, etc. must work together in coordination with each other to ensure that their monitoring or guidance related to food sanitation (hereinafter referred to as "monitoring and guidance") is to be implemented comprehensively and promptly, in order to prevent persons who have been or are suspected to have been poisoned due to food, additives, apparatus, or containers and packaging (hereinafter referred to as "persons poisoned by food, etc.") from spreading or increasing across wide areas, and to prevent any violations of this Act or orders or dispositions based on this Act with regard to food, additives, apparatus, or containers and packaging that are widely distributed.

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 Ministry of Health, Labour and Welfare Order (hereinafter referred to as "council" in this Article and Article 66), in order to ensure the development of a system for coordination and cooperation in the implementation of monitoring and guidance.

- (2) The council may include as its members, prefectures, etc. other than the member prefecture, etc. of the council and other persons deemed necessary by the council, when the council finds it necessary.
- (3) The members of the council must respect the results of discussions concerning the matters agreed upon at the council meetings.
- (4) In addition to what are provided for in the preceding three paragraphs, the matters necessary for operating the council are specified 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. (hereinafter referred to as the "guidelines").

(2) The guidelines are to define the following matters:

- (i) basic directions concerning the implementation of monitoring and guidance;
- (ii) matters concerning items for which monitoring and guidance should be implemented intensively;
- (iii) matters concerning a system for implementing monitoring and guidance;
- (iv) matters concerning the ensuring of coordination and cooperation between the national government, prefectures, etc. and other relevant organizations in implementing monitoring and guidance.
- (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 revised the guidelines, they must make this public and notify prefectural governors, etc. to that effect without delay.

Article 23 (1) The Minister of Health, Labour and Welfare is to establish a plan concerning the monitoring and guidance to be implemented by the national government regarding the following fiscal year's import of food, additives, apparatus, and containers and packaging (hereinafter referred to as the "imported food monitoring and guidance plan") each fiscal year, based on the guidelines.

(2) The imported food monitoring and guidance plan is to define the following matters:

- (i) matters concerning items for which monitoring and guidance should be implemented intensively, judging from circumstances at the productions sites and other circumstances;
- (ii) matters concerning guidance on the implementation of voluntary sanitation management for a business engaged in import;
- (iii) other matters required for implementing monitoring and guidance.

(3) When the Minister of Health, Labour and Welfare has established or revised the imported food monitoring and guidance plan, the Minister of Health, Labour and Welfare is to make this public without delay.

(4) The Minister of Health, Labour and Welfare is to make the implementation status of the imported food monitoring and guidance plan public.

Article 24 (1) The prefectural governor, etc. must establish plans concerning the following fiscal year's monitoring and guidance to be implemented by that

- prefecture, etc. (hereinafter referred to as "prefectural plans for the monitoring of and guidance on food sanitation") each fiscal year, based on the guidelines.
- (2) Prefectural plans for the monitoring of and guidance on food sanitation are to define the following matters:
- (i) matters concerning items for which monitoring and guidance should be implemented intensively;
 - (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 and other relevant organizations including other prefectures, etc. in implementing monitoring and guidance;
 - (iv) other matters required for implementing monitoring and guidance.
- (3) Prefectural plans for the monitoring of and guidance on food sanitation must be established by taking into consideration the situation of establishing facilities by food business operators in areas of that prefecture, etc., actual conditions of food sanitation hazards, and other circumstances of the areas.
- (4) When the prefectural governor, etc. has established or revised prefectural plans for the monitoring of and guidance on food sanitation, the prefectural governor, etc. must make this public and report this to the Minister of Health, Labour and Welfare and the Prime Minister, without delay, pursuant to Ministry of Health, Labour and Welfare Order and Cabinet Office Order.
- (5) The prefectural governor, etc. must make the implementation status of prefectural plans for the monitoring of and guidance on food sanitation public, pursuant to Ministry of Health, Labour and Welfare Order and Cabinet Office Order.

Chapter VII Inspections

- Article 25 (1) Food or additives specified by Cabinet Order for which standards have been established pursuant to the provisions of Article 13, paragraph (1), or apparatus, or containers and packaging specified by Cabinet Order for which standards have been established pursuant to the provisions of Article 18, paragraph (1) must not be sold, displayed for the purpose of sale, or used in business, unless they have the labeling specified by Ministry of Health, Labour and Welfare Order attached which certifies that they have undergone inspections 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 have passed the inspections.
- (2) A person who intends to undergo inspections by the Minister of Health, Labour and Welfare pursuant to the provisions of the preceding paragraph must pay a fee specified by the Minister of Health, Labour and Welfare in

consideration of the actual costs of the inspections, and a person who intends to undergo inspections by a registered conformity assessment body pursuant to the provisions of the preceding paragraph must pay a fee specified by the registered conformity assessment body by obtaining approval from the Minister of Health, Labour and Welfare in consideration of the actual costs of the inspections.

- (3) The fee set forth in the preceding paragraph which has been paid by a person who intends to undergo inspections by the Minister of Health, Labour and Welfare is deemed to be income of the Treasury and the fee set forth in the preceding paragraph which has been paid by a person who intends to undergo inspections by a registered conformity assessment body is deemed to be income of the registered conformity assessment body.
- (4) In addition to what are provided for in the preceding three paragraphs, the matters necessary for inspections set forth in paragraph (1) and the measures to be taken after having passed the inspections are specified by Cabinet Order.
- (5) No request for examination may be made against the results of the inspections set forth in paragraph (1).

- Article 26 (1) When a prefectural governor has found food, additives, apparatus, or containers and packaging listed in the following items, and finds, in light of the capabilities, etc. for conducting inspections of the person who produced or processed them, that the food, additives, apparatus, or containers and packaging which the person produced or processed are likely to continue to fall under those listed in the following items and finds it necessary to prevent food sanitation hazards, the prefectural governor may, following requirements and procedures specified by Cabinet Order, order the person to undergo inspections by the prefectural governor or a registered conformity assessment body regarding the relevant food, additives, apparatus, or containers and packaging:
- (i) food or additives listed in Article 6, item (ii) or item (iii);
 - (ii) food or additives which do not conform to standards established pursuant to the provisions of Article 13, paragraph (1);
 - (iii) food for which additives are used in methods that do 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 packaging prescribed in Article 16;
 - (vi) apparatus, or containers and packaging which do not conform to standards established pursuant to the provisions of Article 18, paragraph (1);
 - (vii) apparatus, or containers and packaging violating Article 18, paragraph (3).
- (2) When the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards, the Minister of Health, Labour and Welfare may order a person who imports food, additives, apparatus, or containers and

packaging of the same type as those produced or processed by a person who has produced or processed food, additives, apparatus, or containers and packaging listed in each item of the preceding paragraph or food prescribed in Article 12 to undergo inspections by the Minister of Health, Labour and Welfare or a registered conformity assessment body regarding the relevant food, additives, apparatus, or containers and packaging.

- (3) When the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards, the Minister of Health, Labour and Welfare may order a person who imports food, additives, apparatus, or containers and packaging which are found as likely to fall under those listed in each item of paragraph (1) or food prescribed in Article 12, judging from circumstances at production sites and other circumstances, to undergo inspections by the Minister of Health, Labour and Welfare or a registered conformity assessment body regarding the relevant food, additives, apparatus, or containers and packaging.
- (4) A person who has received the order under the preceding three paragraphs must not sell the relevant food, additives, apparatus, or containers and packaging, display them for the purpose of sale, or use them in business until the person undergoes the relevant inspections and receives notice of the results thereof.
- (5) The notice set forth in the preceding paragraph which is to be made by a registered conformity assessment body is to be made through the prefectural governor or the Minister of Health, Labour and Welfare who has ordered the person to undergo the relevant inspections.
- (6) A person who intends to undergo inspections by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraphs (1) to (3) must pay a fee specified by the Minister of Health, Labour and Welfare in consideration of the actual costs of the inspections, and a person who intends to undergo inspections by a registered conformity assessment body pursuant to the provisions of paragraphs (1) to (3) must pay a fee specified by the registered conformity assessment body by obtaining approval from the Minister of Health, Labour and Welfare in consideration of the actual costs of the inspections.
- (7) The provisions of paragraphs (3) to (5) of the preceding Article apply *mutatis mutandis* to inspections set forth in paragraphs (1) to (3).

Article 27 A person who intends to import food, additives, apparatus, or containers and packaging for the purpose of sale or to use in business must make a notification to the Minister of Health, Labour and Welfare on a case-by-case basis, pursuant to Ministry of Health, Labour and Welfare Order.

Article 28 (1) The Minister of Health, Labour and Welfare, the Prime Minister, or the prefectural governor, etc., when they find it necessary, may request a business or other relevant persons to submit the necessary report, or have their officials visit places of business, offices, warehouses, and other locations, inspect food, additives, apparatus, or containers and packaging to be served for the purpose of sale or to be used in business, business facilities, books and documents, and other objects, or have them remove, without compensation, food, additives, apparatus, or containers and packaging to be served for the purpose of sale or to be used in business, within the limit necessary for using them for the purpose of testing.

(2) The Minister of Health, Labour and Welfare, the Prime Minister, or the prefectural governor, etc., when having their officials conduct on-site inspections, or remove objects pursuant to the provisions of the preceding paragraph, must have them carry their identification and produce it at the request of the relevant persons.

(3) The authority prescribed in 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 the prefectural governor, etc. may entrust affairs concerning the testing of food, additives, apparatus, or containers and packaging that have been removed pursuant to the provisions of paragraph (1) to a registered conformity assessment body.

Article 29 (1) The national government and prefectures must set up necessary facilities for inspections where inspections under Article 25, paragraph (1) or Article 26, paragraphs (1) to (3) (hereinafter referred to as "product inspections") and affairs concerning the testing of food, additives, apparatus, or containers and packaging that have been removed pursuant to the provisions of paragraph (1) of the preceding Article are to be carried out.

(2) Cities with health centers and special wards must set up necessary facilities for inspections where affairs concerning the testing of food, additives, apparatus, or containers and packaging that have been removed pursuant to the provisions of paragraph (1) of the preceding Article are to be carried out.

(3) The matters necessary 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 the prefectural governor, etc. are to appoint food sanitation inspectors from among their officials to have them enforce the authority thereof prescribed in Article 28, paragraph (1) and perform the duties of guidance on food sanitation.

(2) The prefectural governor, etc. must have food sanitation inspectors appointed

- by the prefectural governor, etc. implement monitoring and guidance, pursuant to the prefectural plans for the monitoring of and guidance on food sanitation.
- (3) The Prime Minister, pursuant to the guidelines, is to have food sanitation inspectors appointed by the Prime Minister implement monitoring and guidance pertaining to the labeling or advertising of food, additives, apparatus, and containers and packaging.
- (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 pertaining to the import of food, additives, apparatus, and containers and packaging, pursuant to the imported food monitoring and guidance plan.
- (5) In addition to what is provided for in each of the preceding paragraphs, the qualifications of food sanitation inspectors and other matters necessary for food sanitation inspectors are specified by Cabinet Order.

Chapter VIII Registered Conformity Assessment Bodies

Article 31 A person who intends 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 Ministry of Health, Labour and Welfare Order.

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

- (i) a corporation that has been sentenced to a fine or severer punishment for violation of this Act or any disposition based on this Act, or whose officer in charge of its business has been sentenced to a fine or severer punishment for violation of this Act or any disposition based on this Act, and two years have not passed since it finished serving the sentence or ceased to be subject to the sentence;
- (ii) a corporation that has had its registration rescinded pursuant to the provisions of Article 43, and two years have not passed since the date of the rescission;
- (iii) a corporation whose business is to be conducted by an officer who has been an officer in charge of the business of the corporation pertaining to the rescission of registration under Article 43 within 30 days prior to the date of the rescission, and two years have not passed since the date of the rescission.

Article 33 (1) When a person who has applied for registration under Article 31 (hereinafter referred to as an "applicant for registration" in this paragraph)

conforms to all the following requirements listed below, the Minister of Health, Labour and Welfare must register that person. In this case, the procedures necessary for the registration are specified by Ministry of Health, Labour and Welfare Order.

- (i) a person is to possess the machines, equipment, and other facilities listed in column 2 of the Appended Table respectively for each type of product inspection listed in column 1 of the same Table and product inspections are to be conducted by a person who has the knowledge and experience that conform to the conditions listed in column 3 of the same Table, and the number of those persons is to exceed the number listed in column 4 of the same Table;
- (ii) measures to ensure the credibility of product inspections listed below are taken:
 - (a) full-time supervisors are appointed for each type of product inspection at departments conducting inspections;
 - (b) documents concerning management of the operation and securing accuracy of product inspections are prepared;
 - (c) a specialized department is established for managing the operation and ensuring accuracy of product inspections in accordance with what is stated in the documents listed in (b);
- (iii) an applicant for registration does not fall under any of the following subitems as a person controlled by a business that sells food, additives, apparatus, or containers and packaging for which product inspections under Article 25, paragraph (1) or Article 26, paragraphs (1) to (3) must be undertaken, or who produces, imports, processes, or displays such articles for the purpose of sale, or uses them in business (hereinafter referred to as "a business subject to inspections" in this item and in Article 39, paragraph (2)):
 - (a) if an applicant for registration is a stock company, a business subject to inspections is its parent corporation (meaning parent corporations prescribed in Article 879, paragraph (1) of the Companies Act (Act No. 86 of 2005));
 - (b) more than half of the officers of an applicant for registration (in the case of a partnership corporation (meaning partnership corporations prescribed in Article 575, paragraph (1) of the Companies Act), employees in charge of its business) are officers or employees of a business subject to inspections (including those who have been officers or employees of a business subject to inspections in the past two years);
 - (c) representative officers of an applicant for registration are officers or employees of a business subject to inspections (including those who have been officers or employees of a business subject to inspections in the past two years).

- (2) Registration is made by entering the following information in the registry:
- (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 main office;
 - (iii) the types of product inspections which the registered conformity assessment body conducts;
 - (iv) the name and the location of the office where the registered conformity assessment body conducts product inspections.

Article 34 (1) Registration as a registered conformity assessment body, unless it is renewed at an interval of not less than three years as specified by Cabinet Order, ceases to be effective upon the expiration of the period.

- (2) The provisions of Article 31 to the preceding Article apply *mutatis mutandis* to the renewal of registration set forth 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, except for cases where 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 Ministry of Health, Labour and Welfare Order.

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

- (2) A registered conformity assessment body, when there has been any change to the information listed in Article 33, paragraph (2), items (ii) and (iv) (limited to the parts pertaining to the name of the office), must notify the Minister of Health, Labour and Welfare to that effect without delay, and, when intending to change the information listed in item (iii) of the same paragraph, must notify the Minister of Health, Labour and Welfare to that effect no later than one month before the day the change is scheduled.

Article 37 (1) A registered conformity assessment body must establish rules concerning the operation of product inspections (hereinafter referred to as "operational rules") and apply for approval from the Minister of Health, Labour and Welfare prior to the initiation of the operation of product inspections. The same applies when it intends to change the rules.

- (2) Operational rules must define methods for conducting product inspections,

fees concerning product inspections, and other matters specified by Minister of Health, Labour and Welfare Order.

- (3) When the Minister of Health, Labour and Welfare finds that operational rules for which the Minister of Health, Labour and Welfare has granted approval under paragraph (1) have become inappropriate for conducting product inspections in a fair manner, the Minister of Health, Labour and Welfare may order the registered conformity assessment body to change the operational rules.

Article 38 A registered conformity assessment body must not suspend, in whole or in part, the operation of product inspections nor abolish the operation of product inspections without obtaining the approval of the Minister of Health, Labour and Welfare.

Article 39 (1) Within three months after the end of each business year, a registered conformity assessment body must prepare an inventory of property, balance sheet, profit and loss statement or income and expenditure account statement, and business report for the business year (including an electronic or magnetic record (meaning a record used in computerized information processing which is created in electronic form, magnetic form, or any other form that cannot be perceived by the human senses; hereinafter the same applies in this Article) when electronic or magnetic records are prepared instead of those paper documents; referred to as "financial statements, etc." in the following paragraph and Article 89), and maintain them at the office for five years thereafter.

- (2) A business subject to inspections and any other interested person may make the following requests at any time within the business hours of a registered conformity assessment body. However, when making a request set forth in item (ii) or item (iv), they must pay fees specified by the registered conformity assessment body.

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

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

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

(iv) a request for provision of the matters recorded on the electronic or magnetic records set forth in the preceding item in electronic or magnetic means specified by Ministry of Health, Labour and Welfare Order, or a

request for delivery of the written documents stating the matters.

Article 40 (1) Officers, employees of a registered conformity assessment body or those who formerly held such positions must not disclose secrets which have come to their knowledge concerning the operation of product inspections or the affairs entrusted to them pursuant to the provisions of Article 28, paragraph (4) (referred to as "entrusted affairs" in the following paragraph).

(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 duties by laws and regulations in applying the penal provisions prescribed by the Penal Code (Act No. 45 of 1907) or other laws and regulations.

Article 41 When the Minister of Health, Labour and Welfare finds that a registered conformity assessment body has ceased to conform to any of the items of Article 33, paragraph (1), the Minister of Health, Labour and Welfare may order the registered conformity assessment body to take necessary measures to ensure conformity to these 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 by a registered conformity assessment body, labeling under Article 25, paragraph (1), or what are stated in the notice under Article 26, paragraph (4) are not appropriate, the Minister of Health, Labour and Welfare may order the registered conformity assessment body to conduct product inspections or take necessary measures to improve its methods of product inspections or other operational methods.

Article 43 The Minister of Health, Labour and Welfare, when a registered conformity assessment body falls under any of the following items, may rescind the registration thereof, or order the suspension of the operation of product inspections, in whole or in part, for a specified 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 item (iii);
- (iii) when a registered conformity assessment body has conducted product inspections without following the operational rules approved under Article 37, paragraph (1);
- (iv) when a registered conformity assessment body has violated an order under Article 37, paragraph (3) or the preceding two Articles;

- (v) when a registered conformity assessment body has rejected a request under each item of Article 39, paragraph (2), without legitimate grounds;
- (vi) when a registered conformity assessment body has obtained registration under Article 33, paragraph (1), by wrongful means.

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

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

- (i) when the Minister of Health, Labour and Welfare has granted registration under 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 there has been a notification under Article 36, paragraph (1) or paragraph (2);
- (iv) when the Minister of Health, Labour and Welfare has granted approval under Article 38;
- (v) when the Minister of Health, Labour and Welfare has rescinded 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 or advertising or conduct any other acts which may cause people to mistake the operation the person conducts for a product inspection.

(2) The Minister of Health, Labour and Welfare may order a person other than a registered conformity assessment body to take measures not to cause people to mistake the operation the person conducts for a 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 financial situation, or have the ministry's officials visit offices or places of business of a registered conformity assessment body to inspect its operational situation or books, documents and other objects, or question 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 cases set forth in the preceding paragraph.

Chapter IX Business

- Article 48 (1) A business that produces or processes dairy products, additives specified by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 12, or other food or additives requiring special consideration with regard to sanitation in the process of production or processing and which are specified by Cabinet Order must place a full-time food sanitation supervisor in each facility to have the food sanitation supervisor manage the production or processing in a sanitary manner; provided, however, that this does not apply to facilities which the business itself manages as a food sanitation supervisor.
- (2) If a business conducts production or processing business for which full-time food sanitation supervisors are required under the preceding paragraph at two or more facilities, and those facilities are adjacent to each other, one food sanitation supervisor is sufficient for those two or more facilities, notwithstanding the provisions of the preceding paragraph.
- (3) A food sanitation supervisor must supervise persons who are engaged in the production or processing of food or additives at the facility so that there should be no violations pertaining to this Act nor orders or dispositions based on this Act with regard to the food or additives the food sanitation supervisor manages.
- (4) In addition to what is provided for in the preceding paragraph, a food sanitation supervisor must take necessary care and express necessary opinions to the business with regard to sanitation management methods at the facility and other matters concerning food sanitation, in order to prevent any violations pertaining to this Act or orders or dispositions based on this Act and prevent food sanitation hazards, with regard to the food or additives the food sanitation supervisor manages at the facility.
- (5) When a food sanitation supervisor has been placed at a facility, a business must respect the opinions the food sanitation supervisor expresses pursuant to the provisions of the preceding paragraph.
- (6) No person other than those 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 old University Order (Imperial Order No. 388 of 1918) or a vocational training school under the old Vocational Training School 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 that course and has completed the first semester course of a professional university under the same 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 old Secondary School Order (Imperial Order No. 36 of 1943) or a person who is deemed to have equal or higher academic ability than the above-mentioned persons pursuant to Ministry of Health, Labour and Welfare Order and who has been engaged in sanitation management of production or processing of food or additives for three years or more at production or processing business for which full-time food sanitation supervisors are required under paragraph (1), and has completed the course for training sessions that have obtained registration from a prefectural governor.
- (7) A person who possesses the qualifications of a food sanitation supervisor because the person fall under item (iv) of the preceding paragraph may become a food sanitation supervisor only at a facility for the same type of production or processing business as the one where the person has been engaged in sanitation management work for three years or more.
- (8) When a business prescribed in paragraph (1) has placed a food sanitation supervisor at its facility or has become a food sanitation supervisor itself, it must notify the name of the food sanitation supervisor or the fact that the business itself has become a food sanitation supervisor and other matters specified by Ministry of Health, Labour and Welfare Order to the prefectural governor of the location of the facility within 15 days. The same applies when the business has changed the food sanitation supervisor.

Article 49 Necessary matters concerning registration of training institutes under paragraph (6), item (iii) of the preceding Article or training sessions under item (iv) of the same paragraph are specified by Cabinet Order, and subjects and other necessary matters concerning courses at training institutes under item (iii) of the same paragraph and courses for training sessions under item (iv) of the same paragraph are specified by Ministry of Health, Labour and Welfare Order.

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 food or additives in the process of the production or processing of the food or additives.

(2) When criteria have been established pursuant to the provisions of the preceding paragraph, a business (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 pertaining to the sanitary management of facilities for businesses (excluding businesses producing apparatus, or containers and packaging and businesses of poultry slaughtering prescribed 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 pertaining to other measures necessary for public health (hereinafter referred to as "measures necessary for public health in the Article") under Ministry of Health, Labour and Welfare Order:

- (i) matters concerning the maintenance of cleanliness of the interior and exterior of the facilities, and extermination of rats and insects, and other general sanitation management;
 - (ii) matters concerning measures to control processes that are particularly important to prevent food sanitation hazards (in the case of a small business (excluding a business that produces apparatus, or containers and packaging 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 any other business specified by Cabinet Order, measures appropriate for the characteristics of the food handled by the business).
- (2) A business must establish and comply with measures necessary for public health in accordance with the criteria established pursuant to the provisions of the preceding paragraph and pursuant to Ministry of Health, Labour and Welfare Order.
- (3) The prefectural governor, etc., by Prefectural or Municipal Ordinance, may establish necessary provisions concerning measures necessary for public health, provided that the provisions are not in violation of 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 pertaining to the sanitary management of facilities for business that produces equipment, or containers and packaging, and other measures necessary for public health (hereinafter referred to as "measures necessary for public health" in this Article) under Ministry of Health, Labour and Welfare Order:

- (i) matters concerning the maintenance of the cleanliness of the interior and exterior of such facilities and other general sanitation management;
- (ii) matters concerning measures to appropriately manage production necessary to prevent food sanitation hazards.

- (2) A business that produces apparatus, or containers and packaging must take measures necessary for public health in accordance with the criteria established pursuant to the provisions of the preceding paragraph (in the case of a business that produces apparatus, or containers and packaging made only of raw materials of materials other than those specified by Cabinet Order as prescribed in Article 18, paragraph (3), limited to the matters listed in item (i) of the preceding paragraph).
- (3) The prefectural governor, etc., by Prefectural or Municipal Ordinance, may establish necessary provisions concerning measures necessary for public health, provided that the provisions are not in violation of the criteria established pursuant to the provisions of paragraph (1).

Article 53 (1) A person who sells, or produces or imports for the purpose of sale, apparatus, or containers and packaging made from raw materials of materials specified by Cabinet Order as prescribed in Article 18, paragraph (3), pursuant to Ministry of Health, Labour and Welfare Order, must explain to the counterparty of the sales of the apparatus, or containers and packaging the person handles that the relevant apparatus, or containers and packaging the person handles falls under either of the following items:

- (i) with regard to raw materials of materials specified by Cabinet Order as prescribed in Article 18, paragraph (3), the apparatus, containers or packaging has been made using only raw materials that conform to the standards established pursuant to the provisions of paragraph (1) of the same Article; or
 - (ii) the apparatus, or containers and packaging has been processed as prescribed in the proviso of Article 18, paragraph (3).
- (2) A person who sells, or produces or imports for the purpose of sale, raw materials that are used for apparatus, or containers and packaging and that are those of materials specified by Cabinet Order as prescribed in Article 18, paragraph (3), must endeavor to provide necessary explanations pursuant to Ministry of Health, Labour and Welfare Order, upon receipt of a request by a person who produces apparatus, or containers and packaging using the raw materials to confirm that the raw materials conform to the standards established pursuant to the provisions of paragraph (1) of the same Article.

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

- Article 55 (1) A person who intends to conduct businesses prescribed in the preceding Article must obtain approval from the prefectural governor pursuant to Ministry of Health, Labour and Welfare Order.
- (2) In the case set forth in the preceding paragraph, the prefectural governor must grant approval when the prefectural governor finds that the business facilities conform to the criteria under the preceding Article; provided, however, that the prefectural governor may not grant approval when the person who intends to conduct businesses prescribed in the preceding Article falls under any of the following items:
- (i) a person who has been punished for violation of this Act or any 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 the person's approval rescinded pursuant to the provisions of Articles 59 to 61, and two years have not passed since the date of the rescission;
 - (iii) a corporation that has persons falling under any of the preceding two items among the officers in charge of its business.
- (3) A prefectural governor may attach the necessary conditions such as a valid period of not less than five years to the approval set forth in paragraph (1).

- Article 56 (1) When there has been an inheritance, merger, or split related to a person who has obtained the approval set forth in paragraph (1) of the preceding Article (hereinafter referred to as an "approved business" in this Article) (limited to an inheritance, merger, or split for succeeding to the relevant business), an heir (when there are two or more heirs and one particular heir has been selected as the successor of the business by consent of all the heirs, the selected heir), a corporation surviving the merger, a corporation established by the merger, or a corporation succeeding to the relevant business by the split is to succeed to the status of an approved business.
- (2) A person who has succeeded to the status of the approved business pursuant to the provisions of the preceding paragraph must notify the prefectural governor to that effect without delay, by attaching a document proving the fact.

- Article 57 (1) A person who intends to conduct business (excluding businesses prescribed in Article 54, those which have a minor impact on public health and are specified by Cabinet Order, and poultry slaughtering businesses) must notify the relevant prefectural governor in advance of the name and the location of the person's business office and other matters specified by Ministry of Health, Labour and Welfare Order, pursuant to Ministry of Health, Labour

and Welfare Order.

- (2) The provisions of the preceding Article apply mutatis mutandis to persons who have made a notification pursuant to the provisions of the preceding paragraph. In this case, the terms "person who has obtained the approval set forth in paragraph (1) of the preceding Article" and "approved business" in paragraph (1) of the same Article are deemed to be replaced with "person who has made a notification pursuant to the provisions of paragraph (1) of the following Article" and "notifying business", respectively; and the term "approved business" in paragraph (2) of the same Article is deemed to be replaced with "notifying business."

Article 58 (1) When a business falls under any of the following items and recalls any food or additives collected, produced, imported, processed or sold by the business, or any apparatus, or containers and packaging produced, imported or sold by the business (excluding cases where the recall is made due to an order under paragraph (1) or (2) of the following Article and cases specified by Ministry of Health, Labour and Welfare Order and Cabinet Office Order as unlikely to cause food sanitation hazards), the business must notify the relevant prefectural governor of the fact that it has initiated the recall and the status of the recall, without delay, pursuant to Ministry of Health, Labour and Welfare Order and Cabinet Office Order.

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

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

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

Article 60 (1) When a business has violated any of the provisions of Article 6, Article 8, paragraph (1), Articles 10 to 12, Article 13, paragraph (2) or paragraph (3), Article 16, Article 18, paragraph (2) or paragraph (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), when a business has violated any prohibition under Article 7, paragraphs (1) to (3), Article 9, paragraph (1) or Article 17, paragraph (1), when a business has come to fall under any of Article 55, paragraph (2), item (i) or item (iii), or when a business has violated any conditions prescribed under paragraph (3) of the same Article, a prefectural governor may rescind the approval under paragraph (1) of the same Article, prohibit the business in whole or in part, or suspend the business for a specified period.

(2) When a business (limited to a person or corporation who imports food, additives, apparatus, or containers and packaging) has violated any of the provisions of Article 6, Article 8, paragraph (1), Article 10, paragraph (2), Article 11, Article 12, Article 13, paragraph (2) or paragraph (3), Article 16, Article 18, paragraph (2) or paragraph (3), Article 26, paragraph (4), Article 50, paragraph (2), Article 51, paragraph (2), Article 52, paragraph (2) or Article 53, paragraph (1), or when a business has violated any prohibition under 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 for a specified period.

Article 61 When a business has violated any criteria under Article 54 with regard to the business's business facilities, a prefectural governor may order the business to develop and improve the facilities, rescind the approval under Article 55, paragraph (1), prohibit the business in whole or in part, or suspend the business for a specified period.

Chapter X Miscellaneous Provisions

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

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

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

(2) When the director of a health center has received a notification set forth in the preceding paragraph or in other cases where the director finds that there have been persons poisoned by food, etc., the director must promptly make a report to the prefectural governor, etc. and conduct an investigation, pursuant to Cabinet Order.

(3) When the prefectural governor, etc. has received a report from the director of a health center pursuant to the provisions of the preceding paragraph, and when there have been or are likely to be more persons poisoned by food, etc. than those specified by Ministry of Health, Labour and Welfare Order, or in other cases specified by Ministry of Health, Labour and Welfare Order, the prefectural governor, etc. must immediately make a report to the Minister of Health, Labour and Welfare.

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

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

Article 64 (1) The prefectural governor, etc., when they find it necessary to investigate the cause of death, may submit 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 packaging to be autopsied with the consent of the bereaved family.

- (2) In the case set forth in the preceding paragraph, when the cause of death cannot be determined without performing an autopsy on a corpse and as a result, it is likely to result in serious public sanitation hazards, the prefectural governor, etc. may submit the corpse to be autopsied after notifying the bereaved family, even without obtaining the consent thereof.
- (3) The provisions of the preceding two paragraphs must not preclude compulsory dispositions under the Rules of Criminal Procedure.
- (4) When autopsying a corpse pursuant to the provisions of paragraph (1) or paragraph (2), care must be taken to pay respect to the deceased.

Article 65 If there have been or are likely to be more persons poisoned by food, etc. than those specified by Ministry of Health, Labour and Welfare Order, or if persons poisoned by food, etc. have come into existence or are likely to spread across wide areas, and there is an urgency to prevent 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, within a fixed 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 of Health, Labour and Welfare must hold a council meeting, share necessary information on the investigation of the causes of food poisoning and the results thereof, promote closer cooperation among the relevant organizations, and endeavor to conduct discussions on measures necessary to prevent persons poisoned by food, etc. from increasing or spreading across wide areas.

Article 67 (1) The prefectures, etc. are to endeavor to provide necessary advice, guidance and other assistance to food business operators in order to prevent food poisoning and improve food sanitation in the region.

- (2) The prefectures, etc. may appoint a food sanitation promotion leader from among those who have the public's trust, and who have enthusiasm, knowledge and experience for the improvement of food sanitation, in order to promote voluntary activities by food business operators concerning the improvement of food sanitation.
- (3) A food sanitation promotion leader is to cooperate in the measures set by prefectures, etc., provide consultation for food business operators, and perform other activities such as giving advice to them, with regard to sanitation management methods for facilities for restaurant businesses 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 to 20 (excluding Article 18, paragraph (3)), Articles 25 to 61 (excluding Article 51, Article 52, paragraph (1), item (ii) and paragraph (2), and Article 53), and Articles 63 to 65 apply mutatis mutandis to toys designated by the Minister of Health, Labour and Welfare as those likely to harm the health of infants when they touch them. In this case, the term "Additives (excluding natural flavoring agents and things that have generally been served for human consumption and are used as additives)" in Article 12 is deemed to be replaced with "Chemically synthesized compounds (meaning substances obtained by causing a chemical reaction other than a decomposition reaction to elements or compounds by chemical means) intended to be used as additives for toys."

(2) The provisions of Article 6, and Article 13, paragraphs (1) and (2) apply mutatis mutandis to cleaning agents used for cleaning vegetables, fruits, or tableware.

(3) The provisions of Articles 15 to 18, Article 25, paragraph (1), Articles 28 to 30, Article 51, Articles 54, Article 57 and Articles 59 to 61 apply mutatis mutandis to cases where food is continuously provided to many and unspecified persons at schools, hospitals or other facilities.

Article 69 In order to prevent food sanitation hazards, the Minister of Health, Labour and Welfare, the Prime Minister and a prefectural governor are to endeavor to clarify the situation of food sanitation hazards by making the name, etc. of a person who has violated this Act or any disposition based on this Act public.

Article 70 (1) When the Minister of Health, Labour and Welfare intends to specify cases that are unlikely to cause harm to human health prescribed in the proviso of Article 6, item (ii) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (2)), intends to prohibit the sales under Article 7, paragraphs (1) to (3) or rescind the prohibition in whole or in part under paragraph (4) of the same Article, intends to designate a designated ingredient, etc. pursuant to the provisions of Article 8, paragraph (1), intends to establish, revise, or abolish the Ministry of Health, Labour and Welfare Order set forth in Article 10, paragraph (1), intends to specify cases that are unlikely to cause harm to human health prescribed in Article 12, intends to establish the criteria or standards prescribed in Article 13, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (2)), intends to specify substances that are clearly unlikely to cause harm to human health or the quantity that is unlikely to cause harm to human health prescribed in Article

13, paragraph (3), intends to establish the criteria or standards prescribed in Article 18, paragraph (1) (including as applied *mutatis mutandis* under Article 68, paragraphs (1) and (3)), intends to specify the quantity that is unlikely to cause harm to human health prescribed in the proviso of Article 18, paragraph (3), intends to establish or revise the imported food monitoring and guidance plan prescribed in Article 23, paragraph (1), intends to establish the criteria prescribed in Article 50, paragraph (1), or intends to establish, revise, or abolish the Ministry of Health, Labour and Welfare Order set forth in Article 51, paragraph (1), Article 52, paragraph (1) or Article 54, the Minister of Health, Labour and Welfare is to make the purpose, contents, and other necessary matters public to broadly seek the opinions of the public; provided, however, that this does not apply if there is an urgency to prevent food sanitation hazards and there is no time to broadly seek the opinions of the public in advance.

- (2) When the prefectural governor, etc. intends to establish or revise the prefectural plans for the monitoring of and guidance on food sanitation prescribed in Article 24, paragraph (1), the prefectural governor, etc. must make the purpose, contents, and other necessary matters public to broadly seek the opinions of the public.
- (3) In the case set forth in the proviso of paragraph (1), the Minister of Health, Labour and Welfare is to broadly seek the opinions of the public without delay, after the fact.
- (4) The provisions of paragraph (1) and the preceding paragraph apply *mutatis mutandis* when the Prime Minister intends to establish the criteria for labeling prescribed in Article 19, paragraph (1) (including as applied *mutatis mutandis* under Article 68, paragraph (1)) and when the Minister of Health, Labour and Welfare and the Prime Minister intend to establish or revise the guidelines.

Article 71 In order to reflect citizens' or residents' opinions in the 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 make the implementation status of the measures public, and broadly seek the opinions of the citizens or residents on the measures.

Article 72 (1) In the case prescribed in the main clause of Article 70, paragraph (1), the Minister of Health, Labour and Welfare must consult with the Prime Minister in advance.

- (2) When the Prime Minister intends to establish the criteria for labeling prescribed in Article 19, paragraph (1) (including as applied *mutatis mutandis* under Article 68, paragraph (1)), the Prime Minister must consult with the

Minister of Health, Labour and Welfare in advance.

(3) When the Minister of Health, Labour and Welfare has established the criteria or standards prescribed in Article 18, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or Article 13, paragraph (1) as applied mutatis mutandis under Article 68, paragraph (1) or (2), or when the Minister of Health, Labour and Welfare finds it necessary, the Minister of Health, Labour and Welfare may request the Prime Minister to establish the criteria for labeling prescribed in Article 19, paragraph (1) (including as applied mutatis mutandis under Article 68, 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, such as the exchange of necessary information, in order to prevent 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 by replacing the terms under Article 57, paragraph (2)), Article 57, paragraph (1), Article 58, Article 59, Article 60, paragraph (1), Article 61 and Article 69 is replaced with "city mayor" for cities with health centers and "ward mayor" for special wards; provided, however, that this does not apply to any disposition specified by Cabinet Order concerning businesses specified by Cabinet Order.

Article 77 In addition to what is provided for in the main clause of the preceding Article, affairs which are specified as those to be handled by prefectures in this Act and are specified by Cabinet Order are to be handled, in designated cities set forth in Article 252-19, paragraph (1) of the Local Autonomy Act (Act No. 67 of 1947) (hereinafter referred to as "designated cities") and in core cities set forth in Article 252-22, paragraph (1) of the same Act (hereinafter referred to as "core cities"), by designated cities or core cities (hereinafter referred to as "designated cities, etc."), pursuant to Cabinet Order. In this 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 concerning a request for examination on a disposition (limited to a disposition pertaining to type 1 statutory entrusted functions prescribed 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 public entity (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 (the Prime Minister in cases involving a disposition under Article 59, paragraph (2) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)); the same applies in the following paragraph).

- (2) If the head of a local public entity has delegated the authority to make dispositions pertaining to type 1 statutory entrusted functions among the affairs to be handled by the head pursuant to the provisions of this Act to an official serving as the head's subsidiary body or to the head of an administrative organ under the control of the head, and a ruling is made on a request for re-examination made under Article 255-2, paragraph (2) of the Local Autonomy Act against a disposition made by the official or head of the administrative organ with the authority delegated, a person who is dissatisfied with the ruling may make a request for further examination to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 252-17-4, paragraphs (5) to (7) of the same Act.

Article 79 (1) Affairs that are to be handled by prefectures pursuant to the provisions of Article 25, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 26, paragraph (1) (including as applied mutatis mutandis under 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 pertaining to monitoring and guidance incidental to the approval of conducting business (limited to businesses 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 under Article 68, paragraphs (1) and (3)), Article 59 (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 63 (including as applied mutatis mutandis under Article 68, paragraph (1)), and Article 64, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraph (1)) are deemed to be type 1 statutory entrusted functions.

- (2) Affairs that are to be handled by cities with health centers or special wards, pursuant to the provisions of Article 28, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 30, paragraph (2) (excluding the part pertaining to monitoring and guidance incidental to the approval of conducting business (limited to businesses 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 under Article 68, paragraphs (1) and (3)), Article 59 (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 63 (including as applied mutatis mutandis under Article 68, paragraph (1)), and Article 64, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraph (1)) are deemed to be type 1 statutory entrusted functions.

Article 80 (1) The authority of the Minister of Health, Labour and Welfare specified by this Act may be delegated to the Director-Generals of the Regional Bureaus of Health and Welfare, pursuant to Ministry of Health, Labour and Welfare Order.

(2) The authority delegated to the Director-Generals of the Regional Bureaus of Health and Welfare pursuant to the provisions of the preceding paragraph may be delegated to the head of the Regional Branch of Health and Welfare, pursuant to Ministry of Health, Labour and Welfare Order.

(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 has violated the provisions of Article 6 (including as applied mutatis mutandis under Article 68, paragraphs (1) and (2)), Article 10, paragraph (1), or Article 12 (including as applied mutatis mutandis under Article 68, paragraph (1));

(ii) a person who has violated the prohibition under Article 7, paragraphs (1) to (3);

(iii) a business that has not obeyed an order issued by the Minister of Health, Labour and Welfare or a prefectural governor (a city mayor or ward mayor when replacing the terms pursuant to the provisions of Article 76; hereinafter the same applies in this item) pursuant to the provisions of Article 59, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or an order issued by the Prime Minister or a prefectural governor pursuant to the provisions of Article 59, paragraph (2) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)) (including those who provide food prescribed in Article 68, paragraph (3)), or a person who has conducted business in violation of a

disposition under Article 60 (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)).

- (2) A person who has committed any of the crimes set forth in the preceding paragraph may be cumulatively punished by both imprisonment and a fine depending on the circumstances.

Article 82 (1) A person who has violated the provisions of Article 13, paragraph (2) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (2)) or paragraph (3), Article 16 (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 19, paragraph (2) (including as applied mutatis mutandis under Article 68, paragraph (1)), Article 20 (including as applied mutatis mutandis under Article 68, paragraph (1)), or Article 55, paragraph (1) (including as applied mutatis mutandis under 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 any of the crimes set forth in the preceding paragraph may be cumulatively 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 has violated the provisions of Article 10, paragraph (2), Article 11, Article 18, paragraph (2) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or paragraph (3), Article 25, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 26, paragraph (4) (including as applied mutatis mutandis under Article 68, paragraph (1)), and Article 63, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraph (1));
- (ii) a person who has violated the prohibition under Article 9, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraph (1)) or Article 17, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3));
- (iii) a person who has disclosed secrets they learned in the course of their duties in violation of Article 40, paragraph (1);
- (iv) a person who has violated the criteria under Article 54 (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or who has violated the conditions under Article 55, paragraph (3) (including as applied mutatis mutandis under Article 68, paragraph (1));
- (v) a business that has not obeyed an order issued by a prefectural governor (a city mayor or ward mayor when replacing the terms pursuant to the

provisions of Article 76) pursuant to the provisions of Article 61 (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)) (including those who provide food prescribed in the same paragraph), or a person who has conducted business in violation of a disposition under Article 61 (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)).

Article 84 Officers or employees of a registered conformity assessment body who have violated an order of suspension of business under Article 43 are 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 on-site inspections or removal by officials under Article 28, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3));
- (ii) a person who has not made a report under Article 28, paragraph (1) (including as applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or who has made a false report;
- (iii) a person who has not made a notification under Article 27, Article 48, paragraph (8) (both including as applied mutatis mutandis under Article 68, paragraph (1)), Article 57, paragraph (1) or Article 58, paragraph (1), or who has made a false notification;
- (iv) a person who has violated an order under Article 46, paragraph (2).

Article 86 Officers or employees of a registered conformity assessment body who have committed any of the following violations are punished by a fine not exceeding 500 thousand yen:

- (i) when a registered conformity assessment body has abolished all operations for product inspections without obtaining approval under Article 38;
- (ii) when a registered conformity assessment body has not stated matters prescribed in Article 44, has made a false statement, or has failed to retain books, in violation of the same Article;
- (iii) when a registered conformity assessment body has not made a report under Article 47, paragraph (1) or has made a false report;
- (iv) when a registered conformity assessment body has refused, obstructed or evaded inspections under Article 47, paragraph (1), has not given answers to questions under the same paragraph, or has given false answers.

Article 87 When a food sanitation supervisor has neglected their duties under

Article 48, paragraph (3), and there have been acts falling under violations set forth in Articles 81 to 83 with regard to food or additives pertaining to their supervision at the relevant facility, the food sanitation supervisor is punished by a fine as prescribed in the respective Articles in accordance with the manner of those 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 person, in connection with the business of the corporation or person, has committed an act in violation of the provisions listed in the following items, not only the offender is punished but also the corporation is punished by a fine prescribed in the relevant respective items or the individual is punished by a fine prescribed in the respective Articles; provided, however, that this does not apply when the individual is to be punished by a fine as a food sanitation supervisor pursuant to the provisions of the preceding Article:

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

Article 89 A person who has not maintained financial statements in violation of Article 39, paragraph (1), has not stated matters that should be stated in financial statements, has made a false statement, or has refused a request under each item of Article 39, paragraph (2) without legitimate grounds is punished by a civil fine not exceeding 200 thousand yen.

Appended Table (Re: Article 33)

| | | | |
|-----------------------------|--------------------------|--|------|
| Physicochemical inspections | 1. Centrifugal separator | A person who falls under any of the following items: | Four |
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| 2. Water purifying apparatus | (i) a person who has graduated from a university (excluding a junior college) under the School Education Act, a university under the old University Order, or a vocational training school under the old Vocational Training School Order after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, agricultural chemistry, or applied chemistry, or a course relevant to these, and has experience of being engaged in the operation of physicochemical inspections for one year or more; |
| 3. Deep freezer | (ii) a person who has graduated from a junior college or a vocational high school under the School Education Act after completing a course in industrial chemistry or a course relevant to this, and has experience of being engaged in the operation of physicochemical inspections for three years or more; |
| 4. Homogenizer | (iii) a person who has equal or greater knowledge and experience than those listed in the preceding two items. |
| 5. Gas chromatograph 6. Gas chromatograph mass spectrometer (limited to those which conduct inspections of agricultural chemicals remaining in food that are prescribed in Article 2, paragraph (1) of the Agricultural Chemicals Regulation Act) | |

| | | | |
|-----------------------------|--|--|-------|
| | <p>7. Atomic absorption photometer</p> <p>8. High performance liquid chromatograph</p> | | |
| Bacteriological inspections | <p>1. Centrifugal separator</p> <p>2. Water purifying apparatus</p> <p>3. Deep freezer</p> <p>4. Homogenizer</p> <p>5. Dry heat sterilizer</p> <p>6. Optical microscope</p> <p>7. Autoclave</p> <p>8. Incubator</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 old University Order, or a vocational training school under the old Vocational Training School Order after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, agricultural chemistry, or biology, or a course relevant to these, and has experience of being engaged in the operation of bacteriological inspections for one year or more;</p> <p>(ii) a person who has graduated from a junior college or a vocational high school under the School Education Act after completing a course in biology or a course relevant to this, and has experience of being engaged in the operation of bacteriological inspections for three years or more;</p> <p>(iii) a person who has equal or greater knowledge and experience than those listed in the preceding two items.</p> | Four |
| Inspections using animals | <p>1. Centrifugal separator</p> | <p>A person who falls under any of the following items:</p> | Three |

